SYNOPSIS

Name of Sponsor/Company: Theravance, Inc.		
Name of Finished Product: Telavancin for Injection		
Name of Active Substance: Telavancin		

Title of Study:
A Phase 3, Randomized, Double-blind, Parallel-group, Multinational Trial of Intravenous Telavancin Versus Vancomycin for Treatment of Hospital-acquired Pneumonia with a Focus on Patients with Infections Due to Methicillin-resistant *Staphylococcus aureus*

Investigators: See Appendix 6

Study Centers: Total number of centers, 250; see Appendix 6

Publications: See Appendix 12

Period Studied:		**Phase of Development:**
Date of first enrollment	23 January 2005	Phase 3
Date last visit completed	02 May 2007	

Objectives:

The primary objective of this study was to compare the efficacy and safety of telavancin with vancomycin in the treatment of adults with Gram-positive hospital-acquired pneumonia (HAP) with an emphasis on patients with infections due to methicillin-resistant *Staphylococcus aureus* (MRSA).

A key secondary objective of this study was to pool the data from this study with those from a second study of identical design (Study 0015) and to assess the superiority of telavancin to vancomycin in patients with MRSA infections.

Methodology:

This was a randomized, double-blind, active-controlled, parallel-group, multicenter, multinational trial. Patients with Gram-positive HAP (primarily due to MRSA) were randomized to receive either telavancin 10 mg/kg IV q 24 hours or vancomycin 1 g IV q 12 hours.

Since the study was designed to enroll patients with Gram-positive HAP, especially patients with infection due to MRSA, vancomycin was the chosen comparator agent. For patients infected with MSSA, the investigators had the option of using an antistaphylococcal penicillin as the comparator agent. For patients with suspected or proven polymicrobial infections involving Gram-negative and/or anaerobic bacteria in addition to the Gram-positive organisms for which study medication was used, aztreonam and/or metronidazole therapy, respectively, was to be added. Piperacillin-tazobactam was to be administered for Gram-negative coverage **only** if aztreonam was not appropriate due to an unacceptable level of resistance among Gram-negative bacteria. However, as piperacillin-tazobactam has activity against MSSA and *S. pneumoniae,* patients with those organisms and no MRSA, who required more than 24 hours of treatment with one of these medications, were not be enrolled. For such patients already enrolled, wherever possible, the piperacillin-tazobactam was to be discontinued or changed to aztreonam as soon as possible. Finally, therapy with metronidazole was to be considered unnecessary if piperacillin-tazobactam was administered, as this agent also has activity against anaerobic bacteria. The Original Protocol had allowed imipenem for Gram-negative coverage as well as aztreonam and/or metronidazole therapy; however, imipenem was removed as a treatment option in Protocol Amendment 1.

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Since the use of concomitant Gram-negative therapy was left to the Investigators' discretion, an assessment of the adequacy of Gram-negative coverage was made by the study medical monitors for patients with Gram-negative pathogens only or mixed Gram-positive and Gram-negative baseline pathogens, following study completion. This determination was made while the monitors were blinded to study treatment assignment and outcome. Gram-negative therapy was considered adequate if concomitant antibiotic(s) with in vitro activity covering all Gram-negative pathogens isolated at Baseline was administered from Study Day 1 through end of therapy (EOT). Patients were considered to have received inadequate therapy if (a) they never received antibiotic(s) with in vitro activity covering all Gram-negative pathogens isolated at Baseline (i.e., never received adequate therapy) or (b) they did not receive concomitant antibiotic(s) with in vitro activity covering all Gram-negative pathogens isolated at Baseline until Study Day 3 or later (i.e., inadequate initial therapy). For purposes of these determinations, in the absence of in vitro susceptibility data, a concomitant antibiotic with known Gram-negative activity was deemed active against the baseline Gram-negative pathogen unless the antibiotic was known to routinely not have activity against the baseline pathogen. Patients with no baseline pathogens were considered to have received inadequate Gram-negative therapy if they (a) never received at least one antibiotic with known Gram-negative activity (i.e., never received adequate therapy) or (b) did not receive at least one antibiotic with known Gram-negative activity until Study Day 3 or later (i.e., inadequate initial therapy).

Baseline evaluations were performed within 24 hours prior to treatment start and included pertinent medical history, vital signs, an assessment of the clinical signs and symptoms of pneumonia (i.e., body temperature [oral, tympanic, or rectal], respiratory rate, sputum characterization, cough characterization, and assessment of pleuritic chest pain), Glasgow coma score, a chest x-ray or computed tomography (CT) scan for evaluation of radiographic lung infiltrates, oxygenation status (strongly encouraged, but only required for patients who were ventilated and/or had an existing arterial line), clinical laboratory tests, coagulation testing (at selected sites for patients who had blood collected for pharmacokinetic [PK] evaluation), and three sequential 12-lead electrocardiograms (ECGs). The components of the Acute Physiology and Chronic Health Evaluation (APACHE II) were also collected.

A pulmonary specimen or sputum for Gram-stain and culture and two independent blood specimens were also obtained at Baseline. These specimens were to be processed as soon as possible after collection, or they were to be refrigerated. All organisms isolated by the local laboratory were to be subcultured and sent to a central microbiology laboratory for identification of genus and species and MIC testing, in accordance with Clinical and Laboratory Standards Institute (CLSI) guidelines. A baseline pathogen was defined as an organism known to cause pneumonia identified from the baseline respiratory cultures from sputum, endotracheal aspirate (ETA), blind bronchial suctioning (BBS), bronchoalveolar lavage (BAL), mini-BAL, or protected specimen brush (PSB). A sputum or endotracheal suction sample was considered adequate if it had >25 polymorphonuclear leukocytes and <10 squamous epithelial cells per field at 100× magnification (low-power, 10× objective). If baseline respiratory cultures did not identify a respiratory pathogen (or if baseline respiratory cultures were not available), then an organism known to cause pneumonia that was identified from baseline blood cultures was considered a baseline pathogen.

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The calendar day of first study medication administration was designated as Day 1; subsequent calendar days were Days 2, 3, etc. During the study treatment phase, blinded study medication infusions were administered daily per protocol. Patients were evaluated daily for the occurrence of treatment-emergent adverse events (TEAEs). Additional daily procedures included an assessment of the clinical signs and symptoms of pneumonia, blood cultures if the baseline blood cultures were positive (or if negative, the investigator suspected a bloodstream infection after treatment initiation), and documentation of study medication administration and all concomitant medications. Clinical laboratory tests were collected and three sequential 12-lead ECGs were performed on each of Study Days 4, 7, 10, 14, 17, and 21 (each within a window of ±1 day). If the QTc interval was >500 msec, an ECG was to be repeated in 15 minutes; if a second QTc measurement was also >500 msec, study medication was to be discontinued. On Study Day 4 only (±1-day window), coagulation testing and pharmacokinetic (PK) sampling were conducted (only at selected sites) and a pulmonary specimen or sputum for Gram stain and culture was obtained (only if clinically indicated); and on Study Days 4 and 7, a chest x-ray or CT scan was performed. Oxygenation status as measured by arterial blood gas was strongly encouraged on Study Days 4 and 7, but was required only for patients who were ventilated and/or had an existing arterial line.

For all patients, posttreatment visits included an End-of-therapy (EOT) Visit (conducted no later than 3 days after the last dose of study medication) and a Follow-up Visit (conducted within 7 to 14 days after the last dose of study medication). Both the EOT and Follow-up Visit procedures included an assessment of adverse events, documentation of all concomitant medications, and clinical laboratory tests. In addition, both the EOT and Follow-up Visit evaluation procedures included an assessment of the clinical signs and symptoms of pneumonia, and a pulmonary specimen or sputum for Gram stain and culture (only if clinically indicated). At the EOT Visit only, a chest x-ray or CT scan was performed, as well as collection of three 12-lead ECGs. Oxygenation status was strongly encouraged, but was required only for patients who were ventilated and/or had an existing arterial line.

Upon a patient's termination of study medication (i.e., at the EOT Visit), the Investigator was to assess the patient's clinical response at EOT as cure, failure, or indeterminate, defined as follows:

- Failure:
  At least one of the following:
  - Persistence or progression of signs and symptoms of pneumonia that still require antibiotic therapy
  - Termination of study medication due to "lack of efficacy" and initiation within 2 calendar days of therapy with a potentially effective antistaphylococcal medication
  - Death on or after Study Day 3 attributable to primary infection
- Cure: Signs and symptoms of pneumonia improved to the point that no further antibiotics for pneumonia were required, and baseline radiographic findings improved or did not progress.
- Indeterminate: Inability to determine outcome (for example, Gram-positive antibiotic coverage no longer required but Gram-negative antibiotic coverage continuing at EOT)

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For all patients randomized into the study, a Follow-up Visit was to be conducted 7 to 14 days after the last dose of study medication. However, for the specific case of patients in whom study medication was discontinued but other antibiotics were given to treat pneumonia due to Gram-negative organisms only, the Follow-up Visit was to be conducted 7 to 14 days after the last dose of ALL antibiotics administered to treat the pneumonia (per Protocol Amendment 1; Section 6.8.1). A blinded Test-of-cure (TOC) assessment was conducted at the Follow up Visit only for those patients who were evaluated as a clinical cure or indeterminate at the EOT Visit. For purposes of analysis, a Clinical Response of failure at EOT was extrapolated to the TOC evaluation. The blinded evaluation of clinical response was considered adequate to minimize bias, and after discussions with FDA at the End-of-Phase 2 meeting, it was decided that an independent clinical events committee in these studies was not necessary. The investigator was to assess the patient's clinical response at TOC as cure, failure, or indeterminate as defined below:

- Failure:

  At least one of the following:

  - Relapsed pneumonia with the same Gram-positive organism after termination of study medication
  - Death after the end of study medication therapy attributable to primary infection (i.e., pneumonia)

- Cure:

  - Signs and symptoms of pneumonia resolved, and
  - Baseline radiographic findings improved or did not progress (see below).

- Indeterminate: Inability to determine outcome

A second posttreatment chest x-ray or computed tomography (CT) scan was not required for the Follow-up Visit since the assessments were only made for patients who had an EOT assessment of cure or indeterminate (had already demonstrated resolution/nonprogression of radiographic findings and of signs and symptoms). Because clearance of pneumonia as documented by chest radiographs may be slower (weeks to months after treatment) than other, more clinically relevant markers (signs and symptoms), the TOC assessment focused on these measures.

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Number of Patients (Planned and Analyzed):
Randomization resulted in a population that was well balanced between treatment groups according to whether patients were enrolled under the Original Protocol or under Protocol Amendment 1. The majority of all patients were enrolled and treated under Protocol Amendment 1.

Randomization Summary – All Randomized Patients

	Number of Patients by Randomized Treatment Group		
	Telavancin 10 mg/kg (N=386)	**Vancomycin (N=385)**	**Overall (N=771)**
Randomized	386	385	771
Randomized but Not Treated	9	5	14
Received Study Medication	377	380	757
Enrolled Under Original Protocol	60	55	115
Enrolled Under Protocol Amendment 1	317	325	642

Source: 0019 CSR, Table 7-1

The table below summarizes the number of patients included in each analysis population by treatment group.

	Telavancin 10 mg/kg	**Vancomycin**
	Number (%) of Patients [1]	
Randomized	386	385
Safety (As-treated)	379	378
Efficacy Populations (As-randomized)		
All Treated (AT)	377 (100%)	380 (100%)
Modified All-treated (MAT)	303 (80%)	282 (74%)
Clinically Evaluable (CE)	171 (45%)	170 (45%)
Microbiologically Evaluable (ME)	135 (36%)	124 (33%)
ME as Percent of CE	79%	73%

[1] Percentages are calculated relative to the number of patients treated (AT)
AT – all patients who received at least one dose of study medication.
MAT – those AT patients who had a respiratory pathogen isolated at Baseline.
CE – those AT patients whose adherence to the protocol made it reasonable to infer that their clinical response reflected the effect of the study medication
ME – those CE patients who had at least one Gram-positive pathogen that was associated with pneumonia
Source: 0019 CSR, Table 8-1

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Diagnosis and Main Criteria for Inclusion:

The study was designed to enroll patients with any Gram-positive HAP. However, an objective of the study was to assess the effectiveness of telavancin compared with vancomycin against infections due to MRSA. Therefore, it was strongly recommended that patients considered for enrollment had at least one of the following risk factors for MRSA infection:

- Hospitalization within previous 6 months
- Antibiotic treatment (especially fluoroquinolones) within prior 3 months
- ≥1 chronic illness (especially diabetes)
- Prior infection with MRSA
- Admission from a nursing home or a long term care facility
- Surgical procedure during current hospital stay
- Residence in an area known to have a high prevalence of community-acquired MRSA

Inclusion

To be eligible for inclusion in this study, patients were required to meet the following criteria:

- Males and females ≥18 years of age
- Clinical signs and symptoms consistent with pneumonia acquired after at least 48 hours of continuous stay in an inpatient acute or chronic care facility or acquired within 7 days after being discharged from a hospitalization of ≥3 days duration. At least two of the following signs and symptoms must have been present:
  - Cough
  - Purulent sputum or other deep respiratory specimen
  - Auscultatory findings of pneumonia
  - Dyspnea, tachypnea, or hypoxemia
  - Identification of an organism consistent with a respiratory pathogen isolated from cultures of respiratory tract, sputum, or blood samples

AND, at least two of the following must also have been present:

  - Fever (>38°C) or hypothermia (rectal/core temperature <35°C)
  - Respiratory rate >30 breaths/min
  - Pulse rate ≥120 beats/min
  - Altered mental status
  - Need for mechanical ventilation
  - Elevated total peripheral WBC count >10,000 cells/mm^3, >15% immature neutrophils (band forms) regardless of total peripheral WBC count, or leukopenia with total WBC count <4500 cells/mm^3
- A chest radiograph with findings consistent with a diagnosis of pneumonia (new or progressive infiltrates, consolidation, or pleural effusion) within 48 hours prior to randomization in the study
- Availability of appropriate respiratory or sputum specimens for Gram stain and culture, and venous access for IV dosing
- Willing to have received IV therapy for the duration of treatment
- Informed consent was to be obtained for participation in this study as defined by the local Institutional Review Board/Independent Ethics Committee (IRB/IEC)

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Exclusion

Patients were to be excluded from this study if they met any of the following criteria:

- Received more than 24 hours of potentially effective systemic (intravenous [IV], intramuscular [IM], or by mouth [PO]) antibiotic therapy for Gram-positive pneumonia immediately prior to randomization, (unless documented to have not responded to at least 3 days of treatment or if the isolated pathogen for the current pneumonia was resistant in vitro to previous treatment; per Amendment No. 1). Patients with renal impairment who had received one or more doses of vancomycin during the last week prior to enrollment were to contact the Study Physician Helpline to determine eligibility.
- Respiratory tract specimens or sputum with only Gram-negative bacteria seen on Gram stain or culture
- Known infection with methicillin-susceptible *Staphylococcus aureus* (MSSA) or *Streptococcus pneumoniae* that required more than 24 hours of concomitant study medication therapy with an antibiotic for Gram-negative coverage that has activity versus MSSA or *S. pneumoniae* (e.g., piperacillin-tazobactam)
- Known or suspected pulmonary disease that precluded evaluation of therapeutic response (e.g., granulomatous diseases, lung cancer, or another malignancy metastatic to the lungs); cystic fibrosis or active tuberculosis
- Known or suspected *Legionella pneumophila* pneumonia
- Known or suspected infection with an organism that was not susceptible to medications permitted by the protocol
- Documented or suspected meningitis, endocarditis, or osteomyelitis
- Refractory shock (per Amendment No. 1), defined as supine systolic blood pressure <90 mm Hg for >2 hours with evidence of hypoperfusion or requirement for high-dose sympathomimetic agents (dopamine ≥10 µg/kg/min or norepinephrine ≥0.1 µg/kg/min)
- Baseline QTc >500 msec, congenital long QT syndrome, uncompensated heart failure, or abnormal K+ or Mg++ blood levels that could not be corrected (per Amendment No. 1)
- Severely neutropenic (absolute neutrophil count <500/mm^3) or anticipated to develop severe neutropenia during the study treatment period due to prior or planned chemotherapy, or had human immunodeficiency virus (HIV) with CD4 count <100/mm^3 during the last 6 months
- Requirement for concomitant administration of intravenous Sporanox® (itraconazole), Vfend® (voriconazole), Geodon® (ziprasidone), or any other medication containing a cyclodextrin solubilizer, per Amendment No. 1
- Female patients of childbearing potential if they were pregnant, nursing, or unable to use a highly effective method of birth control during the study and for at least one complete menstrual cycle (per Amendment No. 1) following the last dose of study medication. A negative serum pregnancy result must have been documented prior to treatment. A highly effective method of birth control was defined as one that results in a low failure rate (i.e., <1% per year) when used consistently and correctly, such as implants, injectables, combined oral contraceptives, some intrauterine devices (IUDs), sexual abstinence, or a vasectomized partner.

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- Male patients must have agreed to use medically acceptable birth control for at least 3 months following the last dose of study medication. A vasectomy or a condom used with a spermicide was a medically acceptable birth control method for males.
- Prior enrollment in a clinical trial of telavancin
- Known hypersensitivity to, or intolerance of, study medications or their formulation excipients
- Treatment with another investigational medication within 30 days of study entry
- Patients unlikely to survive at least 7 days due to underlying illness
- Patients unlikely to comply with the study procedures or to return for scheduled post-treatment evaluations
- Any other condition that in the opinion of an investigator, would confound or interfere with evaluation of safety or efficacy of the investigational medication, or prevent compliance with the study Protocol

Test Product, Dose and Mode of Administration, Batch Number:
Telavancin, 10 mg/kg body weight, in 5% dextrose injection USP (D5W), 5% glucose injection USP (G5W), or normal saline; 100-250 mL IV over 60 minutes
Lot Numbers: 2213-10-645043, -645048, -645066, -812062, -829580, -829581, -829583

Duration of Treatment:
The Investigator was to determine the total duration of study therapy, as clinically indicated. The minimum duration of study therapy was to be 7 days and the maximum allowable duration of study therapy was to be 21 days. Study medication was to be administered in a double-blind manner and dummy infusions were to be used to mask the difference in dosing intervals. Required monitoring and dosage adjustments for telavancin and vancomycin were to be managed by study personnel not responsible for clinical assessment of the patients, as described in a Blinding Plan prepared by each investigative site. Patients were to be treated with IV therapy throughout and were not to be switched to oral therapy. When appropriate and necessary to complete study therapy, patients were to be discharged but were to continue to receive IV study medication on an outpatient basis.

Reference Therapy, Dose and Mode of Administration, Batch Number:
Vancomycin (1 gm IV) was dosed according to the manufacturer's package insert, and commercial supplies were used. The vancomycin regimen was to be monitored and dosage adjusted on the basis of weight and/or renal function, following the institutional policy at each investigative site, by personnel who were not blinded to study treatment. In a similar manner, the dosage of telavancin was to be adjusted in patients with moderate to severe renal insufficiency by unblinded personnel, as follows:

Creatinine Clearance (mL/min)	Telavancin Dosage
30-50	7.5 mg/kg q 24 hr
<30	10 mg/kg q 48 hr
Hemodialysis	10 mg/kg q 48 hr (supplemental telavancin not required following dialysis)

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Criteria for Evaluation:

Efficacy
The primary efficacy endpoint was the Clinical Response determined by the Investigator at the TOC evaluation.

The following were assessed as secondary or tertiary efficacy endpoints:
- By-pathogen microbiological response at TOC
- By-patient microbiological response at TOC
- Clinical response at EOT
- Duration of treatment with study medication
- All-cause mortality
- Time to resolution of fever (defined as the first day of the earliest 2-day period during all temperatures were ≤38°C)
- change from Baseline in parameters of disease progression such as temperature, respiratory rate, chest radiographic findings
- Potential superinfection

Safety

Safety was assessed by monitoring for TEAEs and by assessing changes from Baseline in clinical laboratory test results (chemistry, hematology, and urinalysis) and 12-lead ECGs.

Statistical Methods:
Analysis Populations

Four analysis populations were defined for efficacy-related summaries. These four populations were not mutually exclusive; a patient could belong to more than one population. In all four populations, patients were associated with the treatment group assigned by the randomization:
- All-treated (AT): All patients who received any amount of study medication
- Modified All-treated (MAT): Patients in the AT Population who also had a baseline pathogen identified, defined as an organism known to cause pneumonia identified from baseline respiratory cultures from sputum, ETA, BBS, BAL, mini-BAL, or PSB
- Clinically Evaluable (CE): Patients in the AT Population whose adherence to protocol expectations made it reasonable to infer that his/her clinical outcome reflected the effect of study medication
- Microbiologically Evaluable (ME): Patients in the CE Population who also had a Gram-positive baseline respiratory pathogen, as defined above for the MAT Population

Efficacy
The primary efficacy analysis was an evaluation of telavancin's clinical noninferiority to vancomycin, with respect to Clinical Response at the TOC assessment, employing a prospectively determined noninferiority margin (the "Δ") of 20% and a post hoc noninferiority margin of 14% (see 0019 CSR, Section 8.4.2.5 for a complete description of the methods used to calculate and justify the post hoc noninferiority margin) meaning that noninferiority will be declared if the lower bound of the 95% CI for the difference in cure rates (telavancin - vancomycin) exceeds -Δ. In this analysis, the CE and AT analysis populations were considered co-primary.

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Secondary efficacy variables included by-patient and by-pathogen microbiological response at TOC, as well as clinical response, by-patient and by-pathogen microbiological response at EOT, and all-cause mortality.

Safety

Adverse events were tabulated and summarized according to the Medical Dictionary for Regulatory Activities (MedDRA, Version 6.1). Continuous laboratory measurements were displayed using summary statistics (mean, median, etc.) by treatment group and visit. Observed values and changes from Baseline were summarized. Continuous laboratory measurements were also summarized in terms of values relative to laboratory normal ranges (i.e., high, normal, low) in a pre- to post-treatment shift table (e.g., normal → high) at each visit. In addition, the number (%) of patients in each treatment group who exhibited a potentially clinically significant (PCS) laboratory change, as defined by prospectively identified criteria, was summarized.

For QTc interval (Fridericia [primary analysis; QTcF] and Bazett [QTcB] corrections) and QT, the triplicate measurements at each nominal assessment time were averaged to obtain a single analysis value for each assessment time. On-treatment average change and on-treatment maximum changes were summarized using summary statistics (mean, median, etc.), and were statistically tested for within- and between-group significance. In addition, for QTc interval, on-treatment maximum values and on-treatment maximum change were summarized by the number/percent of patients with maximum values ≤450, >450 to ≤480, >480 to ≤500, and >500 msec, and by the number/percent of patients with maximum increases ≤30, >30 to ≤60, and >60 msec.

Additionally, TEAEs in the Cardiac Disorder System Order Class (SOC) were summarized for patients with extreme QTcF changes (i.e., >60 msec maximum increase from Baseline or >500 msec maximum value).

Other ECG parameters and morphology were also assessed in a similar manner but with different criteria for outliers depending on the parameter. These data, however, will be summarized across studies in the Integrated Summary of Safety.

Summary – Results:

In both the AT and CE Populations, treatment groups were generally similar with regard to key baseline and demographic characteristics. There were more patients in the telavancin group than in the vancomycin group that had acute lung injury (5% vs. 3%); however, there were more patients in the vancomycin group than in the telavancin group who were on vasopressors (12% vs. 6%). The observed signs and symptoms and chest radiographs were consistent with a diagnosis of HAP. Approximately one-third of patients had radiographic evidence of pleural effusion and more than half exhibited multilobar infiltrates. Approximately 30% of patients met the definition of having ventilator-associated pneumonia (VAP), i.e., development of pneumonia after being ventilated for >48 hours.

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Key Demographic and Baseline Characteristics – AT Population

	Telavancin 10 mg/kg (N=377)	Vancomycin (N=380)	p-value*
Age (years)			
Mean±SD	61 ±17.8	62 ±18.0	0.667
>=65 YEARS	195 (52%)	196 (52%)	1.000
>=75 YEARS	99 (26%)	109 (29%)	0.465
Sex (n)			
FEMALE	125 (33%)	124 (33%)	0.938
Race (n)			
WHITE	248 (66%)	254 (67%)	0.191
BLACK, OF AFRICAN HERITAGE	15 (4%)	6 (2%)	
ASIAN	81 (21%)	91 (24%)	
OTHER (including multiple race)	33 (9%)	29 (8%)	
Medical History			
Diabetes	85 (23%)	77 (20%)	0.479
Congestive Heart Failure	59 (16%)	63 (17%)	0.767
COPD	87 (23%)	88 (23%)	1.000
Chronic Renal Failure	11 (3%)	17 (4%)	0.336
Shock	15 (4%)	18 (5%)	0.722
ARDS	9 (2%)	10 (3%)	1.000
Acute Lung Injury (but not ARDS)	18 (5%)	13 (3%)	0.365
ICU			
ICU at Baseline	207 (55%)	224 (59%)	0.272
Vasopressors/Inotropics [1]			
Use of Vasopressors/Inotropics	24 (6%)	45 (12%)	0.011
Baseline Renal Status			
Creatinine Clearance <= 50 mL/min	109 (29%)	105 (28%)	0.747
Acute Renal Failure	30 (8%)	29 (8%)	0.893
Hemodialysis	3 (<1%)	5 (1%)	0.725
APACHE II [3]			
Mean±SD	15 ±5.9	16 ±6.3	0.058
Type of Pneumonia			
VAP	113 (30%)	111 (29%)	0.873
Late VAP (>=4 Days on Ventilation at Diagnosis)	98 (26%)	90 (24%)	0.501
PaO2/FiO2 (Mean±SD)	254 ±170.4	257 ±144.9	0.342
NVAHAP	264 (70%)	269 (71%)	0.873

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Key Demographic and Baseline Characteristics – AT Population (Cont'd)

	Telavancin 10 mg/kg (N=377)	Vancomycin (N=380)	p-value*
Sign of Pneumonia			
Fever (temp >38°C)	292 (77%)	301 (79%)	0.597
WBC >10,000/mm³ [4]	194 (62%)	208 (63%)	0.745
Purulent Secretions	345 (92%)	361 (95%)	0.060
Heart Rate >120/min	61 (16%)	65 (17%)	0.770
Respiratory Rate >30/min	98 (26%)	109 (29%)	0.416
SIRS [2]	312 (83%)	321 (84%)	0.556
Radiological Characteristics			
Multilobar Involvement	235 (62%)	231 (61%)	0.709
Pleural Effusion	112 (30%)	112 (29%)	1.000
Prior Antibiotic Use (>24 Hrs Prior to Enrollment)			
Used Prior Antibiotic (>24 Hrs)	210 (56%)	218 (57%)	0.660
Pathogen Resistant to Prior Antibiotic Therapy	58 (15%)	61 (16%)	1.000
Failed Prior Antibiotic Therapy for HAP	127 (34%)	125 (33%)	0.556
Pneumonia Occurred Despite Prior Antibiotics	97 (26%)	98 (26%)	0.846

* Fisher's exact test for character variables; 2-sided Wilcoxon test for continuous variables.
[1] Use of dopamine, norepinephrine, dobutamine, epinephrine, or phenylephrine.
[2] SIRS: patients present with two or more of the following crtieria -
1. temperature >38C or <36C, 2. heart rate >90beats/minute,
3. respiration >20/min or PaCO2 <32mmHG, 4. leukocyte count >12,000/mm3,
<4,000/mm3, or >10% immature (band) cells
[3] Components with missing value were converted to 0.
[4] Denominator includes only patients with a baseline WBC result.
Output file: h19_t_basechar_at_01.rtf
Source: Dataset(s): ADDEMOG Program: \SCE\LOCAL\SANDBOX_2789951\Biostat\td-6424\hap\0019\csr\programs\t_basechar.sas Run Date: 27OCT08/15:39 by wabanadmin on NET_ASRV SASv9.1

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In both treatment groups and in both the MAT and the ME Populations, ≥73% of patients were infected with Gram-positive pathogens isolated from the respiratory tract. The most frequent Baseline isolate was *S. aureus*, of which approximately 60% were MRSA. In the MAT Population, 7% of patients in the telavancin group and 9% of patients in the vancomycin group were bacteremic at Baseline. Nearly one third of patients had mixed infections (Gram-positive/Gram-negative) isolated from the respiratory tract. The majority of pathogens recovered from the blood of patients at Baseline were Gram-positive, of which MRSA and MSSA were the most prevalent.

Baseline Gram-positive Pathogens – MAT Population

	Telavancin 10 mg/kg	**Vancomycin**
Baseline Gram-Positive Pathogens	220 (73%)	205 (73%)
S. aureus (All)	199 (66%)	178 (63%)
MRSA	117 (39%)	117 (41%)
MSSA	83 (27%)	63 (22%)
Strep pneumoniae	14 (5%)	23 (8%)
Enterococcus faecalis	10 (3%)	13 (5%)
Enterococcus faecium	3 (< 1%)	1 (< 1%)

Source: 0019 CSR, Table 8-16

Efficacy: A summary of key efficacy endpoint results is provided in the following table.

Summary of Key Efficacy Parameters at Test-of-Cure

Efficacy Parameter	**Analysis Population**	**Telavancin 10 mg/kg**	**Vancomycin**	**Diff (95% CI) [1]**
		Number (%) of Patients		
Clinical Cure Rate	AT	227/377 (60.2%)	228/380 (60.0%)	0.2% (-6.8% , 7.2%)
	CE	139/171 (81.3%)	138/170 (81.2%)	0.1% (-8.2% , 8.4%)
Clinical Cure Rates for Patients with Single Gram-positive Pathogen Only	ME	71/82 (86.6%)	59 / 77 (76.6%)	10.0% (-2.0%, 22.0%)
MRSA	ME	30 / 38 (78.9%)	32 / 46 (69.6%)	9.4%(-9.7%^ , 27.2%)^
MSSA	ME	31 / 34 (91.2%)	16 / 19 (84.2%)	7.0%(-11.7%^,27.6%)^
Clinical Cure Rate by Pathogen				
Staphylococcus aureus	ME	91 / 121 (75.2%)	80 / 105 (76.2%)	-1.0% (-12.2%, 10.2%)
MRSA	ME	47 / 69 (68.1%)	52 / 70 (74.3%)	-6.2% (-21.2%, 8.9%)
MSSA	ME	44 / 52 (84.6%)	29 / 37 (78.4%)	6.2% (-10.1%, 23.0%)^
By-Patient Microbiologic Eradication Rate	MAT	186/303 (61.4%)	167/282 (59.2%)	2.2% (-5.8%, 10.1%)
	ME	103/135 (76.3%)	96/124 (77.4%)	-1.1% (-11.4% , 9.2%)

[1] Difference (telavancin – vancomycin); two-sided 95% CI
^ = Confidence interval uses Agresti-Caffo adjustment.
Source: 0019 CSR; Table 8-32, Table 8-36, Table 8-39, Table 8-40, Supporting Table 131

SYNOPSIS (CONT'D)

Name of Sponsor/Company: Theravance, Inc.		
Name of Finished Product: Telavancin for Injection		
Name of Active Substance: Telavancin		

Telavancin was demonstrated to be clinically noninferior to vancomycin using the prespecified noninferiority margin of 20%. Telavancin was also demonstrated to be clinically noninferior to vancomycin based on the post hoc noninferiority margin for clinical response, as evidenced by the lower bound of the 95% CI around the difference (telavancin - vancomycin) in cure rates being greater than -14% in the AT and CE Populations. In fact, the lower bound of the 95% CI around the difference between treatments in cure rates exceeded -10% and the 95% CI also included zero for the primary efficacy parameter (clinical response at TOC) in both of the co-primary analysis populations. In sensitivity analyses of the AT and CE Population that considered all deaths as clinical failures, telavancin was also demonstrated to be clinically noninferior to vancomycin based on the post hoc noninferiority margin for clinical response as evidenced by the lower bound of the 95% CI around the difference (telavancin - vancomycin) in cure rates being greater than --14%.

For patients in the ME Population who had a single Gram-positive pathogen and no Gram-negative pathogens isolated at Baseline, cure rates were numerically higher in the telavancin group compared with the vancomycin group (86.6% vs. 76.6%). The 95% CI around the treatment difference included zero. In patients who had only MRSA or only MSSA, clinical cure rates were numerically higher in the telavancin group compared with the vancomycin group (78.9% vs. 69.6% and 91.2% vs. 84.2%, respectively). For these patients, the 95% CI around the treatment difference included zero. In patients with mixed Gram-positive and Gram-negative pathogens at Baseline, cure rates were numerically lower in the telavancin group compared with the vancomycin group (62.5% vs. 77.5%) and the 95% CI around the treatment difference included zero. The lower cure rates in patients with mixed infections in the telavancin group was mostly due to higher rates of inappropriate Gram-negative coverage (11 vs. 3), prior treatment failures (9 vs. 0), and multi-resistant infections including *P. aeruginosa* and *A. calcoaceticus* (14 vs. 2) in the telavancin group compared with the vancomycin group.

For patients in the ME Population, the most common pathogen isolated at Baseline (without regard to whether patients had one or multiple baseline pathogens) was *S. aureus*, and clinical cure rates against this pathogen were similar in both treatment groups. Cure rates were also evaluated by methicillin susceptibility of the *S. aureus* isolated at Baseline. In patients with MSSA, the clinical cure rate was numerically higher in the telavancin group than in the vancomycin group; whereas in patients with MRSA, the clinical cure rate was numerically higher in the vancomycin group than in the telavancin group. It should be noted, however, that cure rates in patients with MRSA as the only pathogen at Baseline were numerically higher in the telavancin group compared with the vancomycin group, and therefore the result for all MRSA (with or without other pathogens) may be confounded by the presence of other pathogens.

Microbiological eradication rates in the MAT and ME Populations were similar to the clinical cure rates in these populations.

All-cause mortality for the AT Population, evaluated as a secondary efficacy endpoint, is summarized in the following table. The percentage of AT patients who died of any cause during or after study medication was 18.3% in the telavancin group compared with the 20.8% in the vancomycin group. The percentage of deaths was similar between treatment groups for patients who died during treatment and for patients who died anytime during treatment or within 28 days after last study medication. For both time periods, the 95% CI around the treatment difference (telavancin – vancomycin) in death rates included zero.

SYNOPSIS (CONT'D)

Name of Sponsor/Company: Theravance, Inc.		
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Name of Active Substance: Telavancin		

All-cause Mortality – AT Population

	Telavancin 10 mg/kg (N=377)	Vancomycin (N=380)	Difference (95% CI) [1]
Deaths while receiving study medication			
Within-treatment mortality	43 (11.4%)	36 (9.5%)	1.9% (-2.4% , 6.3%)
Deaths during or after study medication			
During or after treatment mortality	69 (18.3%)	79 (20.8%)	-2.5% (-8.1% , 3.2%)

[1] Difference in mortality rates (telavancin - vancomycin); two sided 95% CI on the difference.
^= Confidence interval uses Agresti-Caffo adjustment.
Source: 0019 CSR, Table 8-43

Results of secondary endpoints including time to defervescence, changes in clinical signs and symptoms, changes in oxygenation status, EOT chest radiograph findings, and duration of therapy support the effectiveness of telavancin in treating patients with HAP.

There was no evidence of decreased susceptibility to either telavancin or vancomycin during the study, i.e., there were no organisms recovered from either EOT or TOC cultures that had more than a two fold increase in telavancin or vancomycin MIC.

Efficacy results were analyzed for the subgroup of patients who had VAP, defined as the development of pneumonia after being ventilated for >48 hours. For the AT and CE Populations, clinical cure rates were comparable between treatment groups.

Safety: A summary of key safety parameters is provided in the following table:

Summary of Treatment-emergent Adverse Events - Safety Population, Study 0019

	Telavancin 10 mg/kg N=379	Vancomycin N=378
No. (%) of Patients with at Least 1 AE	295 (78%)	296 (78%)
No. (%) of Deaths	70 (18%)	78 (21%)
No. (%) of Patients with Any Serious AEs	107 (28%)	109 (29%)
No. (%) of Patients Who Discontinued Study Drug or Study Due to AEs	27 (7%)	23 (6%)

Source: 0019 CSR, Table 9-2

Safety

- A total of 379 patients were treated with telavancin and 378 patients were treated with vancomycin in this study.
- Median duration of therapy was comparable between the two treatment groups (9 days).
- Overall, 81% of patients received the protocol-recommended 7 to 21 days of study medication, and the proportions were similar between the two treatment groups.

SYNOPSIS (CONT'D)

Name of Sponsor/Company: Theravance, Inc.		
Name of Finished Product: Telavancin for Injection		
Name of Active Substance: Telavancin		

- The proportions of patients who experienced at least one TEAE were comparable in the telavancin (78%) and vancomycin groups (78%).
- The majority of patients who experienced at least one adverse event experienced mild or moderate events.
- Severe adverse events occurred in 32% of telavancin-treated and 30% of vancomycin-treated patients.
- Common adverse events (occurring in >5% of patients) occurred at a similar frequency in both treatment groups. Among telavancin-treated patients, the most common events were constipation (10%), diarrhea (10%), anemia (9%), hypokalemia (8%), hypotension (7%), and hypertension (6%). Among vancomycin-treated patients, the most common adverse events were hypokalemia (10%), diarrhea (10%), anemia (10%), constipation (9%), and hypotension (7%).
- A total of 177 patients who participated in the study died: 148 patients (70 in the telavancin group and 78 in the vancomycin group) died within the predefined data collection window and 29 patients (17 in the telavancin group and 12 in the vancomycin group) died outside the data collection window.
- The within-window mortality rate was lower in the telavancin group (18.5%) than the vancomycin group (20.6%). However, the difference between treatment groups was not statistically significant.
- Of the 148 patients who died within the data capture window, 79 patients died while receiving study medication: 44 (12%) patients in the telavancin group and 35 (9%) patients in the vancomycin group. The remainder of the deaths occurred after EOT: 26 (7%) patients in the telavancin group and 43 (11%) patients in the vancomycin group.
- More patients in the vancomycin group died after EOT (43/378, 11.4%) compared with the telavancin group (26/379, 6.9%). When examined according to the timing of the TEAE that led to death, equal proportions of patients in both treatment groups experienced a TEAE prior to EOT that led to death. More patients in the vancomycin group experienced a TEAE after EOT that led to death (33 patients) compared with patients in the telavancin group (17 patients).
- The only event with an outcome of death that occurred with a difference in frequencies between the treatment groups of more than 1% was multi-organ failure (3% telavancin, 1% vancomycin), which was attributed to more severely injured and septic patients at Baseline in the telavancin group, coupled with more patients in the telavancin group with mixed infections who did not receive appropriate antibiotic coverage for the Gram-negative pathogens.
- The individual TEAEs with an outcome of death that occurred at a 1% difference between treatment groups and were higher in the telavancin group than the vancomycin group were septic shock (13 [3%] telavancin-treated patients and 9 [2%] vancomycin-treated patients) and multi-organ failure (11 [3%] telavancin-treated patients and 4 [1%] vancomycin-treated patients).
- The individual TEAEs with an outcome of death that occurred at a ≥1% incidence in the vancomycin group than the telavancin group were cardiac failure congestive (0% telavancin, 2% vancomycin), respiratory failure (2% telavancin and 3% vancomycin) and pneumonia (<1% telavancin and 2% vancomycin).

SYNOPSIS (CONT'D)

Name of Sponsor/Company: Theravance, Inc.		
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- There was one cardiac death attributed by the Investigator to study medication in the telavancin group, but this patient had a long history of severe heart disease and also experienced atrial fibrillation 3 days before study medication administration. Only a single dose of study medication was administered.
- Three renal events led to death: two in the telavancin group, considered by the Investigator to be not related to study medication versus one in the vancomycin group, which was considered by the Investigator to be possibly/probably related to study medication. However, all three patients received prior or concomitant medications known to be nephrotoxic.
- Serious adverse events were reported for 28% of patients in the telavancin group and 29% of patients in the vancomycin group.
- Five patients (1%) in the telavancin group and 10 patients (3%) in the vancomycin group experienced an SAE considered by the Investigator to be possibly/probably related to study medication.
- In both the telavancin and vancomycin groups, 9 patients (2%) experienced an SAE associated with renal dysfunction. In all cases the patients had significant comorbidities and/or were receiving potentially nephrotoxic concomitant medications.
- There were more patients with an SAE of multi-organ failure in the telavancin group (13 patients, 3%) than in the vancomycin group (6 patients, 2%). Of these patients, 11 patients in the telavancin group and 4 in the vancomycin group died within the analysis window. Based on case-by-case reviews, the difference between treatment groups in the incidence rate of SAEs of multi-organ failure may be attributed to more severely injured and septic patients in the telavancin group at Baseline, coupled with more telavancin patients with mixed infections who did not receive appropriate antibiotic coverage for the Gram-negative pathogens.
- There were more cases of pulmonary embolism (PE) in the telavancin group (six patients, 2%) than in the vancomycin group (one patient, <1%). All of the SAEs of pulmonary embolism were judged by the Investigator to be unrelated to study medication as there were clear risk factors for PE in each case that likely contributed to the event.
- Rates of discontinuation of study medication for adverse events were similar between the two treatment groups (27 patients [7%] in the telavancin group and 23 patients [6%] in the vancomycin group), as were the rates for the most common adverse events leading to discontinuation: QTc prolongation (3 patients [<1%] in the telavancin group and 2 patients [<1%] in the vancomycin group) and renal adverse events, i.e., renal failure acute, renal impairment, and blood creatinine increased, (4 patients [1%] in the telavancin group and 4 patients [1%] in the vancomycin group).
- The only clinically meaningful changes in mean values from Baseline in hematologic parameters were decreases in neutrophils and white blood cell counts, which indicate response of the baseline infection to treatment.
- Potentially clinically significant changes in serum creatinine (value ≥133 µmol/L and at least 50% greater than Baseline) occurred in 12% of telavancin-treated and 9% of vancomycin-treated patients for patients with normal values at Baseline and in 20% of telavancin-treated and 8% of vancomycin-treated patients with abnormal values at Baseline.

SYNOPSIS (CONT'D)

Name of Sponsor/Company: Theravance, Inc.		
Name of Finished Product: Telavancin for Injection		
Name of Active Substance: Telavancin		

- Potentially clinically significant increases in ALT (to at least three times the upper limit of normal and at least 50 U/L above Baseline) occurred in 6% patients in the telavancin group and 8% of patients in the vancomycin group. Similar increases in AST occurred in 7% and 5% of patients in the two treatment groups, respectively.
- Concurrence of both liver injury (i.e., increased serum alanine aminotransferase or aspartate aminotransferase levels) and reduced liver function (increased total serum bilirubin levels), i.e., Hy's Law, did not occur in any patient.
- Incidence of cardiac TEAEs occurred more often in the vancomycin group (19%) than the telavancin group (16%).
- The proportions of patients with postdrug maximum mean QTcF interval greater than 500 msec were comparable between treatment groups (2% in each group). These patients had either pre-existing cardiac conditions at Baseline and/or abnormal baseline ECG findings.
    - A total of 21 (7%) telavancin-treated patients and 21 (7%) of vancomycin-treated patients experienced a maximum change in QTcF interval greater than 60 msec during the study. Six patients in the telavancin group and four patients in the vancomycin group with a post-drug change in QTcF interval greater than 60 msec also had a QTcF interval >500 msec during the study.
    - Five telavancin-treated patients with a maximum QTcF value >500 msec or a maximum increase from Baseline in QTcF >60 msec had seven cardiac TEAEs, two of which were SAEs in one patient (atrial fibrillation [verbatim term: high frequency atrial fibrillation] and cardiac arrest) and two of which occurred in another patient (myocardial ischemia and QTc prolongation).
    - One telavancin-treated patient had a maximum change in QTc interval of 246.7 msec that was associated with myocardial ischemia.
    - Seven vancomycin-treated patients with a maximum QTcF value >500 msec or a maximum increase from Baseline in QTcF >60 msec had a total of nine cardiac TEAEs, one of which was an SAE, which resulted in death (cardiac failure).
    - None of these patients meeting extreme ECG criteria experienced arrhythmias attributable to prolonged QTcF interval.

SYNOPSIS (CONT'D)

Name of Sponsor/Company: Theravance, Inc.		
Name of Finished Product: Telavancin for Injection		
Name of Active Substance: Telavancin		

Overall Conclusion:

In Study 0019, telavancin at a dose of 10 mg/kg administered once daily as a 1-hour intravenous infusion (or a reduced dose in patients with moderate or severe renal insufficiency) was shown to be non-inferior to vancomycin in the treatment of adult patients with HAP, including infections caused by *Staphylococcus aureus* (methicillin-susceptible or methicillin-resistant) and *Streptococcus pneumoniae*. The safety profile of telavancin was compatible with the treatment of seriously ill adult patients with HAP.

Date of Report:
23 December 2008

SUMMARY OF CHANGES

THERAVANCE, INC. PROTOCOL 0019, AMENDMENT 1

Original Protocol Date: 10 August 2004

Amendment 1 Date: 28 September 2005

SUMMARY AND RATIONALE

Herein is a summary of the important revisions incorporated into Protocol 0019 Amendment 1, dated 28 September 2005.

1. The medical monitor has changed from Dr. Barriere to Dr. Friedland and the Co-principal Investigator has changed from Dr. Fowler to Dr. Rubenstein.

2. Data regarding the Phase 2 complicated skin and skin structure infections has been removed as this is now covered in the Investigator's Brochure in more detail (Section 2.2).

3. Imipenem for Gram-negative coverage has been removed as a treatment option. Aztreonam is still the preferred antibiotic for Gram-negative coverage. Piperacillin/tazobactam remains an alternative antibiotic for those sites with a high rate of aztreonam resistance (Sections 2.3.1, 4.1, 5.3, 6.3, and original 8.5). This change was made to reduce the number of allowed drugs in the treatment comparisons. In addition, recent in vitro studies performed at Theravance have indicated potential synergy between imipenem and vancomycin as well as imipenem and telavancin. Removing imipenem will reduce the bias in the study results due to the potential synergy.

4. Exclusion criterion #1: Prior antibiotic use within the previous 24 hours has been clarified. Only antibiotics that are potentially effective against Gram-positive hospital-acquired pneumonia (HAP) cannot be administered for more than 24 hours prior to randomization. In addition, treatment failure has been defined as failure to respond to at least 3 days of therapy (Section 5.3).

5. Exclusion criterion #8: Sustained shock has been revised to "refractory shock", which allows the use of low-dose sympathomimetics. Due to changes in medical practice,

it was impractical to exclude the use of any sympathomimetics in this patient population (Section 5.3).

6. Exclusion criterion #9: Uncorrected abnormal K+ or Mg++ blood levels has been changed to abnormal K+ or Mg++ blood levels that cannot be corrected. This allows enrollment of those patients who are able to respond to K+ or Mg++ replacement therapy (Section 5.3).

7. Exclusion criterion #11: Geodon (ziprasidone) therapy is added to the exclusion list as it is also formulated with cyclodextrin (Sections 5.3 and original 8.5.2).

8. Exclusion criterion #12a: The time period for effective birth control following completion of study medication has been redefined from one month to one complete menstrual cycle (Section 5.3).

9. The instructions for reconstitution of telavancin for injection 250 mg have been revised to specify addition of **23 mL** of 5% Dextrose Injection USP (D5W) to each vial, rather than 24 mL, to account for changes in the drug product manufacturing. The final concentration remains 10 mg of telavancin per mL of reconstituted solution. In addition, telavancin may be reconstituted with normal saline or 5% Glucose Injection (G5W) (Section 6.1). Further, telavancin can also be administered in normal saline infusion bags (Sections 6.2 and 6.5).

10. The telavancin stability information has been updated to reflect data from recently completed stability studies indicating that telavancin in reconstituted vials and infusion bags is stable for 72 hours under refrigeration (2-8 °C). Once removed from refrigeration, telavancin in reconstituted vials and infusion bags must be used within 48 hours (Section 6.1).

11. It has been made clearer that patients with methicillin-sensitive *S. aureus* pneumonia may be treated with an antistaphylococcal penicillin instead of vancomycin (Section 6.2).

12. Statements regarding the use of cover sleeves for the study medication infusion bags has been removed. The appearances of dilute solutions of telavancin,

vancomycin, and antistaphylococcal penicillins are indistinguishable (Sections 6.5 and 6.7).

13. An instruction that local laboratory values will be used to estimate initial creatinine clearance has been added. Central laboratory data will not be available before administration of the first dose of study medication (Section 6.6).

14. An instruction to call the Physician Helpline for patients requiring continuous renal replacement has been added as this method of dialysis/filtration requires a dosage adjustment of telavancin (Section 6.6).

15. The 12-hour duration between study medication infusions has been clarified. It is permissible to administer two active doses of telavancin in less than 24 hours if necessary. All active doses of telavancin or vancomycin should be separated by at least 8 hours. This will allow flexibility for sites to administer study medications within a reasonable time window (Section 6.7).

16. The requirement for arterial blood gas measurements has been revised. They are strongly encouraged; however, they are only required for patients who are ventilated or who have existing arterial lines (Section 7.1).

17. The magnification for assessment of sputum or endotracheal aspiration specimens has been corrected to 100X (low power field, 10X objective) (Section 7.1).

18. Central laboratory testing has been clarified and an appendix with the list of lab tests has been added.

19. The definitions for clinical response at End-of-Therapy (Section 7.1.6.1 in original protocol) have been more clearly defined. Failure requires continuation of antibiotic therapy while cure requires that no further antibiotics are needed.

20. Instructions regarding the Follow-up visit and Test-of-Cure evaluation have been revised to provide for a Follow-up visit for all patient during which the Test-of-Cure evaluation will be conducted for those patients whose clinical response assessment at End-of-Therapy was determined to be either “Cure” or “Indeterminate” (Section 7.1.6 in original protocol).

21. The definitions for clinical response at Test-of-Cure (Section 7.1.7.1 in original protocol) have been more clearly defined. Indeterminate has been added as a possible outcome. Relapsed infection requires isolation of the same Gram-positive organism.

22. The pharmacokinetic timepoints have been revised to provide better data for the population PK analysis (Section 7.1.8 in original protocol).

23. Pharmacoeconomic objectives and analyses have been added (Sections 7.1.10, 11.2.5, and 11.5.5 in amended protocol).

24. An instruction that investigative sites should use their local laboratories for patient eligibility and for urgent patient management decisions has been added because results from the central laboratory (except for alert and panic values) may not be available for 24-48 hours after specimen collection (Section 8.1).

25. Management of study patients whose pretreatment cultures are subsequently found to grow only Gram-negative organisms has been revised. If these patients still require Gram-positive coverage, they are to remain on study medication and in the study. However, if these patients do not require any further Gram-positive therapy, they are to have study drug discontinued and an End-of-Therapy visit is to be completed. The Follow-up visit (including Test-of-Cure assessment) must be completed 7 to 14 days after **ALL** antibiotics are stopped instead of after only stopping study medication (Sections 8.2 and 9, and addition of Appendix 5).

26. Patients with persistent *S. aureus* infections are to remain on study medication for as long as the study protocol allows (i.e., up to 3 weeks). This may make it possible to still assess clinical response of the pneumonia in the all-treated population. However, if these patients are found to have deep-seated infections, they will not be part of the clinically evaluable population (Removal of Section 8.3 in original protocol and changes to Section 9).

27. Patient discontinuation criteria have been modified to allow for a more complete assessment of clinical outcomes in the All-Treated population (Section 9). These changes have been discussed in Items 25 and 26.

28. As described in Item 25 above, the Follow-up visit must occur 7-14 days after stopping study medication, except for those patients with only Gram-negative organisms cultured from respiratory specimens, where the Follow-up visit must occur 7-14 days after stopping all antibiotics. This allows for a clinical outcome for all patients in the all-treated population (Section 9).

29. Reporting of worsening of hospital-acquired pneumonia as a serious adverse event to the sponsor is not necessary unless it results in death. Worsening of the infection will be captured in the clinical assessment of the infection (Section 10.2).

30. The definition of the clinically evaluable analysis population has been edited to be consistent with other changes in the amendment (Section 11.3).

31. The primary analyses in both the individual study analysis (Section 11.5.3.1) and the pooled-study analysis (Section 11.5.3.6.3) have been made more explicit. In the individual study, the primary analysis will evaluate telavancin's non-inferiority to vancomycin. In the two-study (Protocol 0015 and 0019) pooled analyses, the primary analysis will evaluate telavancin's superiority to vancomycin in the subset of subjects with MRSA pneumonia at baseline.

32. The primary analysis population for the pooled-study MRSA superiority analysis will be the all-treated population, not the clinically evaluable population as indicated in original protocol (Section 11.5.3.6.3). The change has been made because an all-treated population is more appropriate for evaluating superiority than is a 'per-protocol' population. The power calculation for the MRSA superiority analysis has also been updated to reflect the larger size of the all-treated population (Section 11.6).

33. Grammatical modifications have been made throughout the protocol for the sake of clarity and consistency.

Site Investigators and Institutional Review Boards/Ethics Committees

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Argentina	01006	Hospital General de Agudos Dr. Cosme Argerich Almirante Brown 240 Buenos Aires, C1155ADP Argentina	Comite de Etica en Investigacion Clinica “Dr. Virgilio Foglia” Tucuman 335-7° “D“ (C1049AAG) Buenos Aires Argentina IRB Chair: Barclay, Carlos A. Comite de Docencia e Investigacion Hospital General de Agudos Dr. Cosme Argerich Av. Almirante Brown 240 C1155ADP Buenos Aires Argentina IRB Chair: Napoli, Eduardo Comite de Bioetica Hospital General de Agudos Dr. Cosme Argerich Av. Almirante Brown 240 C1155ADP Buenos Aires, Argentina IRB Chair: Bertorello. Andres	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Argentina	01007	Hospital de Infecciosas Francisco Javier Muniz Uspallata 2272 (C1282AEN) Ciudad de Buenos Aires Argentina	Comite de Etica en Investigacion Clinica “Dr. Virgilio Foglia” Tucuman 335-7 “D” (C1049AAG) Buenos Aires Argentina IRB Chair: Barclay, Carlos A. Comite Hospitalario de Bioetica Hospital F.J. Muniz Uspallata 2272 (C1282AEN) Buenos Aires Argentina IRB Chair: Saul, Pablo Comite de Docencia e Investigacion Hospital F. J. Muniz Uspallata 2272 (C1282AEN) Buenos Aires Argentina IRB Chair: Waisman, Jaime Luis	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Argentina	01016	Sanatorio San Jose Sanchez de Bustamante 1674 (C1425DHU) Ciudad de Buenos Aires Argentina	Comite de Etica en Investigacion Clinica “Dr. Virgilio Foglia” Tucuman 335-7° “D“ (C1049AAG) Buenos Aires Argentina IRB Chair: Barclay, Carlos A. Comite de Docencia e Investigacion Sanatorio San Jose Sanchez de Bustamante 1674 (C1425DHU) Buenos Aires Argentina IRB Chair: Da Ponte, Pablo	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Argentina	01017	Hospital Aleman Av. Pueyrredon 1640 (C1118AAT) Ciudad de Buenos Aires Argentina	Comite de Etica en Investigacion Clinica “Dr. Virgilio Foglia” Tucuman 335-7° “D“ (C1049AAG) Buenos Aires Argentina IRB Chair: Barclay, Carlos A. Departamento de Docencia e Investigacion Hospital Aleman Av. Pueyrredon 1640 (1118) Ciudad de Buenos Aires Argentina IRB Chair: Seoane, Martin IRB Chair: Saidon, Patricia IRB Chair: Yahia, Julio Comité de Bioetica Medica Av. Pueyrredon 1640 (1118) Buenos Aires Argentina IRB Chair: Reyero, Silvia	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Argentina	01018	Sanatorio Allende Hipolito Yrigoyen 384 (5000) Cordoba Argentina	Comite de Etica en Investigacion Clinica “Dr. Virgilio Foglia” Tucuman 335-7° “D“ (C1049AAG) Buenos Aires Argentina IRB Chair: Barclay Carlos A. Comite Institucional de Etica de Investigacion en Salud del Sanatorio Allende Hipolito Yrigoyen 384 (5000) Cordoba Argentina IRB Chair: Allende, Del Sanatorio	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Argentina	01019	Hospital de Clinicas Jose de San Martin Universidad de Buenos Aires Facultad de Medicina Av. Cordoba 2351 7° (C1120AAR) Ciudad de Buenos Aires Argentina	Comite de Etica en Investigacion Clinica “Dr. Virgilio Foglia” Tucuman 335-7° “D“ (C1049AAG) Buenos Aires Argentina IRB Chair: Barclay, Carlos A. Comite de Etica del Hospital de Clinicas Av. Cordoba 2351 (C1120AAR) Buenos Aires Argentina IRB Chair: Gherardi, Carlos Direccion de Docencia e Investigacion Av. Cordoba 2351 (C1120AAR) Buenos Aires Argentina IRB Chair: De San Martin, Jose	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Argentina	01021	Hospital Privado Centro Medico de Cordoba Naciones Unidas 346 (5016) Cordoba Argentina	Comite de Etica en Investigacion Clinica “Dr. Virgilio Foglia” Tucuman 335-7° “D“ (C1049AAG) Buenos Aires Argentina IRB Chair: Barclay, Carlos A. Hospital Privado Centro Medico de Cordoba Departamento de Docencia e Investigacion Comite De Revision Interna Av. Naciones Unidas 346 Parque Velez Sarfield (5016) Cordoba Argentina IRB Chair: Kahn, Adrian (Coordinator)	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Argentina	01022	Hospital Privado de la Comunidad Cordoba 4545 (7600) Mar del Plata Buenos Aires Argentina	Comite de Etica en Investigacion Clinica “Dr. Virgilio Foglia” Tucuman 335-7° “D“ (C1049AAG) Buenos Aires Argentina IRB Chair: Barclay, Carlos A. Fundacion Medica de Mar del Plata Departmento de Docencia e Investigacion Cordoba 4545 (7600) Mar del Plata Buenos Aires Argentina IRB Chair: Pinna, Diego	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Argentina	01026	Instituto de Oncologia Angel H Roffo Av. San Martin 5481 (C1417DTB) Ciudad de Buenos Aires Argentina	Comite de Etica en Investigacion Clinica “Dr. Virgilio Foglia” Tucuman 335-7° “D“ (C1049AAG) Buenos Aires Argentina IRB Chair: Barclay, Carlos A. Comite de Etica del Instituto A. Roffo Av. San Martin 5481 (C1417DTB) Buenos Aires Argentina IRB Chair: Kirchuck, Ricardo I. Comite de Docencia e Investigacion Instituto A. Roffo Av. San Martin 5481 (C1417DTB) Ciudad de Buenos Aires Argentina IRB Chair: Kirchuck, Ricardo I.	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Argentina	01029	Hospital General de Agudos Carlos G. Durand Av. Diaz Velez 5044 (C1405DCR) Ciudad de Buenos Aires Argentina	Comite de Etica en Investigacion Clinica “Dr. Virgilio Foglia” Tucuman 335-7° “D“ (C1049AAG) Buenos Aires Argentina IRB Chair: Barclay, Carlos A. Comite de Etica Hospital General de Agudos Carlos G. Durand Av. Diaz Velez 5044 (C1405DCR) Buenos Aires Argentina IRB Chair: Dalamon, Ricardo Sergio Comité de Dodencia e Investigacion Hospital General de Agudos Carlos G. Durand Av. Diaz Velez 5044 (C1405DCR) Buenos Aires Argentina IRB Chair: Dalamon, Ricardo Sergio	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Australia	02015	Western Hospital Department of Intensive Care Gordon Street Footscray VIC 3011 Australia	Melbourne Health Human Research Ethics Committee Charles Connibere Building The Royal Melbourne Hospital Flemington Road Parkville VIC 3052 Australia IRB Chair: Colman, PG	CV
Australia	02016	Eastern Clinical Research Unit Level 4, Clive Ward Centre 16 Arnold Street Box Hill VIC 3128 Australia	Eastern Health Research and Ethics Committee Level 2, Clive Ward Centre 16 Arnold Street Box Hill VIC 3128 Australia IRB Chair: Eastern Health Ethics Committee does not disclose any names of their members due to confidentiality (NTF)	CV
Australia	02017	The Queen Elizabeth Hospital Level 1 Department of Intensive Care Medicine 28 Woodville Road Woodville SA 5011 Australia	Human Research Ethics Committee Level 4 The Queen Elizabeth Hospital Department of Intensive Care Medicine 28 Woodville Road Woodville SA 5011 Australia IRB Chair: Matthew, Timothy	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Australia	02019	Blacktown Hospital Department of Intensive Care Medicine Blacktown Road Blacktown NSW 2148 Australia	Sydney West Area Health Service (Westmead Campus) Human Research Ethics Committee Research Office, Clinical Sciences Westmead Hospital Campus Westmead NSW 2145 Australia IRB Chair: Smith, Howard	CV
Australia	02023	Westmead Hospital Intensive Care Unit Hawkesbury Road Westmead NSW 2145 Australia	Sydney West Area Health Service (Westmead Campus) Human Research Ethics Committee Research Office, Clinical Sciences Westmead Hospital Campus Westmead NSW 2145 Australia IRB Chair: Smith, Howard	CV
Australia	02026	Intensive Care Unit The Bendigo Hospital Bendigo Health Lucan Street Bendigo VIC 3550 Australia	Bendigo Health Human Research Ethics Committee PO Box 126 Bendigo VIC 3552 Australia IRB Chair: Disler, Peter	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Australia	02027	Hornsby Ku-ring-gai Hospital Intensive Care Unit Palmerston Rd Hornsby NSW 2077 Australia	Human Research Ethics Committee Research Office, Level 4, Vindin House Royal North Shore Hospital Pacific Hwy St. Leonards NSW 2065 Australia IRB Chair: Arquiza, Melizza Linda (Ethics Officer)	CV
Australia	02028	Intensive Care Unit The Canberra Hosptial Yamba Drive Garran ACT 2605 Australia	ACT Health and Community Care Human Research Ethics Committee 11 Moore Street Canberra, ACT 2601 Australia IRB Chair: AM Grant, Elizabeth	CV
Australia	02029	Intensive Care Unit Monash Medical Centre 246 Clayton Road Clayton VIC 3168 Australia	Southern Health Human Research Ethics Committee 246 Clayton Road Clayton VIC 3168 Australia IRB Chair: Briggs, William	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Australia	02030	St. Vincent's Hospital Intensive Care Services 390 Victoria Street Darlinghurst NSW 2010 NO 1572 Australia	Human Research Ethics Committee Level 6, de Lacy Bldg. Victoria Street Darlinghurst, 2010 NSW Australia IRB Chair: Brien, Jo-Anne	CV
Brazil	05000	Hospital do Servidor Publico Estadual Rua Pedro de Toledo, 1800 Sao Paulo – SP – CEP: 04039-020 Brazil	Comite de Etica em Pesquisa Instituto de Assistencia Medica ao Servidor Publico Estadual Av. Ibirapuera , 981 - 6° andar – sl. 605 Sao Paulo – SP – CEP: 04029-000 Brazil IRB Chair: Moraes de Andrade, Ana Maria	CV
Brazil	05003	Irmandade da Santa Casa de Misericordia de Porto Alegre Rua Prof. Annes Dias, 285 Pavilhao Pereira Filho – UTI 2nd andar Porto Alegre – RS - 90020-090 Brazil	Comite de Etica em Pesquisa – CEP/ISCMPA Rua Prof. Annes Dias, 285 Porto Alegre – Rio Grande do Sul CEP 90020-090 Brazil IRB Chair: Teloken, Claudio (Coordinator)	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Brazil	05005	Hospital Professor Edmundo Vasconcelos Rua Borges Lagoa, 1450 Vila Clementino Sao Paulo – SP – CEP: 04038-905 Brazil	Comite de Etica em Pesquisa do Hospital Professor Edmundo Vaconcelos Rua Borges Lagoa, 1450 CEP: 04038-905 Sao Paulo – SP Brazil IRB Chair: Perroni, Valdete Gomes Coelho	CV
Brazil	05006	Hospital Guilherme Alvaro Rua Oswaldo Cruz, 197 Santos – SP – CEP: 11045-904 Brazil	Comite de Etica em Pesquisa do Hospital Guilherme Alvaro Rua Oswaldo Cruz, 197 - Boqueirao Santos – SP – CEP: 11045-904 Brazil IRB Chair: Heilbrun, Erico Paulo (Coordinator)	CV
Brazil	05010	Hospital Estadual Mario Covas Av. Pereira Barreto, s/n Santo Andre, SP – CEP: 09190-610 Brazil	Comite de Etica em Pesquisa da Faculdade de Medicina do ABC Av. Principe de Gales, 821 Santo Andre, SP – CEP: 09060-650 Brazil IRB Chair: Fiss, Elie	CV
Brazil	05011	Instituto Dante Pazzanese de Cardiologia Av. Dr. Dante Pazzanese, 500. Sao Paulo – SP – CEP: 04012-180 Brazil	Comite de Ethica em Pesquisa do Instituto Dante Pazzanese de Cardiologia Av. Dr. Dante Pazzanese, 500. Ibirapuera Sao Paulo – SP – CEP: 04012-180 Brazil IRB Chair: Farsky, Pedro Silvio	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Bulgaria	44000	Multifunctional Hospital for Active Treatment and Emergency Medicine (MHATEM) “N.I. Pirogov” Anesthesiology and Intensive Care Clinic 21, Totleben Blvd 1606 Sophia Bulgaria	Local Ethics Committee Multifunctional Hospital for Active Treatment and Emergency Medicine (MHATEM) “N.I. Pirogov” 21, Totleben Blvd 1606 Sophia Bulgaria IRB Chair: Pomoranski, Ivan	CV
Bulgaria	44001	Multifunctional Hospital for Active Treatment and Emergency Medicine (MHATEM) “N.I. Pirogov” Section of Burns and Plastic Surgery 21, Totleben Blvd 1606 Sophia Bulgaria	Local Ethics Committee Multifunctional Hospital for Active Treatment and Emergency Medicine (MHATEM) “N.I. Pirogov” 21, Totleben Blvd 1606 Sophia Bulgaria IRB Chair: Pomoranski, Ivan	CV
Bulgaria	44003	University Multifunctional Hospital for Active Treatment “Sv. Anna” Clinic of Anesthesiology and Intensive Care 1, “Dimitar Mollov” Str. 1709 Sofia Bulgaria	Local Ethics Committee University Multifunctional Hospital for Active Treatment “Sv. Anna” Clinic of Anesthesiology and Intensive Care 1, “Dimitar Mollov” Str. 1709 Sofia Bulgaria IRB Chair: Petkov, N.	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Bulgaria	44004	Multifunctional Hospital for Active Treatment “Prof Kirkovich” Intensive Care Unit 0, “Stoletov” Blvd. 6003 Stara Zagora Bulgaria	Local Ethics Committee Multifunctional Hospital for Active Treatment “Prof Kirkovich” 0, “Stoletov” Blvd, 6003 Stara Zagora Bulgaria IRB Chair: Dr. Radieva	CV
Bulgaria	44005	University Multifunctional Hospital for Active Treatment Anesthesiology and Intensive Care Unit 11, “Armeiska” Str. 6003 Stara Zagora Bulgaria	Local Ethics Committee University Multifunctional Hospital for Active Treatment 11, “Armeiska” Str. 6003 Stara Zagora Bulgaria IRB Chair: Yovtchev, Y.	CV
Bulgaria	44006	Regional Hospital for Pulmonary Diseases First Pulmonology Department 1, “Aleia Lilia” Str. 7002 Rousse Bulgaria	Local Ethics Committee Regional Hospital for Pulmonary Diseases, First Pulmonology Department 1, “Aleia Lilia” Str. 7002 Rousse Bulgaria IRB Chair: Dr. Getov	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Bulgaria	44008	University Multifunctional Hospital for Active Treatment (UMHAT) “Sv. Marina” Anesthesiology and Intensive Care Medicine Clinic 1, “Hristo Smirnenski” Str. 9010 Varna Bulgaria	Local Ethics Committee University Multifunctional Hospital for Active Treatment (UMHAT) “Sv. Marina” 1, “Hristo Smirnenski” Str. 9010 Varna, Bulgaria IRB Chair: Kotsev, Iskren	CV
Bulgaria	44009	University Multifunctional Hospital for Active Treatment “Sv. Georgi” Anesthesiology and Intensive Care Unit 15A, “Vassil Aprilov” Str. 4000 Plovdiv Bulgaria	Local Ethics Committee University Multifunctional Hospital for Active Treatment “Sv. Georgi” 15A, “Vassil Aprilov” Str. 4000 Plovdiv Bulgaria IRB Chair: Pehlivanov, Blagovest	CV
Bulgaria	44010	Specialized Hospital for Active Treatment of Pneumo-Phtysiatric Diseases 64, “General Gurko” Str. 8000 Bourgas Bulgaria	Local Ethics Committee Specialized Hospital for Active Treatment of Pneumo-Phtysiatric Diseases 64, “General Gurko” Str. 8000 Bourgas Bulgaria IRB Chair: Kichukova, Stanka	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Canada	06005	Hospital 5415 boul de l'Assomption Montreal, Quebec H1T 2M4	Maisonneuve Rosemont Hospital Ethic Board 5415 boul de l'Assomption Montreal, Quebec H1T 2M4 IRB Chair: Savignac, Mme Paule	CV
Canada	06011	University of Calgary Foothills Medical Center AGW5, Infection Prevention and Control 1403 29th Street N.W. Calgary, Alberta Canada T2N 2T9	University of Calgary Conjoint Health Research Ethics Board Office of Medical Bioethics Heritage Medical Research Bldg, Room 93 3330 Hospital Dr. N.W. Calgary, Alberta Canada T2N 4N1 IRB Chair: Godlovitch, Glenys	CV
Canada	06017	Royal Columbian Hospital Intensive Care Unit 330 East Columbia Street New Westminster, British Columbia V3L 3W7	Fraser Health Research Ethics Board #300-10334 152A Street Surrey, BC Canada V3R 7P8 IRB Chair: Foulkes, Marc R.	CV
Canada	06019	Vancouver General Hospital, Division of Infectious Diseases Heather Pavillion East, D452-2733 Heather Street Vancouver, British Columbia Canada V5Z 3J5	University of British Columbia Clinical Research Ethics Board Research Pavillion, Room 210-828 West 10th Avenue Vancouver, British Columbia Canada V5Z 1L8 IRB Chair: Loewen, Peter	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Canada	06024	University of Calgary Foothills Medical Center AGW5, Infection Prevention and Control 1403 29th Street N.W. Calgary, Alberta Canada T2N 2T9	University of Calgary Conjoint Health Research Ethics Board Office of Medical Bioethics Heritage Medical Research Bldg, Room 93 3330 Hospital Dr. N.W. Calgary, Alberta Canada T2N 4N1 IRB Chair: Godlovitch, Glenys	CV
Canada	06025	Intensivist, Department of General Internal Medicine Kingston General Hospital 76 Stuart St., Angada 4 Kingston, Ontario K7L 2V7	Queen's University Health Services & Affiliated Teaching Hospitals Human Research Ethics Board Office of Research Services Fleming Hall – Room 301 Kingston, Ontario K7L 2N6 IRB Chair: Clark, Albert	CV
Canada	06028	Brandon Regional Health Center 150 McTavish Avenue East Brandon MB Canada R7A 2B3	Brandon Regional Health Authority Ethics Committee Brandon Regional Health Center 150 McTavish Avenue East Brandon, Manitoba Canada R7A 2B3 IRB Chair: Wilson, Charles	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Canada	06031	University of Calgary Foothills Medical Center AGW5, Infection Prevention and Control 1403 29th Street N.W. Calgary, Alberta Canada T2N 2T9	University of Calgary Conjoint Health Research Ethics Board Office of Medical Bioethics Heritage Medical Research Bldg, Room 93 3330 Hospital Dr. N.W. Calgary, Alberta Canada T2N 4N1 IRB Chair: Godlovitch, Glenys	CV
Chile	07003	Hospital Dr. Hernan Henriquez Aravena Manuel Montt 115 Temuco Chile	Comite de Etica-Cientifico Servicio de Salud Araucania Sur General Mackenna 51 Temuco Chile IRB Chair: Osses, Hardy Muller (Secretary)	CV
Chile	07004	Hospital de Carabineros Simon Bolivar 2200 Santiago Chile	Comite de Etica-Cientifica - Servicio de Salud Metropolitano Oriente Av Salvador 364, Providencia Santiago Chile IRB Chair: Vacarezza, Ricardo	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Chile	07008	Clinica Davila Recoleta 464 Santiago de Chile Chile	Comite de Etica de la Investigacion Organismo asesor de Direccion Del Servicio de Salud Metropolitano Norte CEI-SSMN Maruri 272 Santiago Chile IRB Chair: N/A Comite Etica Clinica Davila Recoleta 464 Santiago Chile IRB Chair: N/A	CV
Chile	07010	Hospital del Salvador Av. Salvador 364, Providencia Santiago Chile	Comite de Etica-Cientifico - Servicio de Salud Metropolitano Oriente Av. Salvador 364, Providencia Santiago Chile IRB Chair: Vacarezza, Ricardo (Secretary)	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
China	08000	Intensive Care Unit of Emergency Department Beijing Anzhen Hospital of the capital university of medical sciences An Zhen Li, An Ding Men Wai Chao Yang District Beijing, 100029 P.R. China	Ethics Committee of the First Affiliated Hospital, Sun Yat-Sen University 58 Zhongshan Road 2 Guangzhou 510080 Guangdong Province P.R. China IRB Chair: Wang, Shenming Ethics Committee of Beijing Anzhen Hospital of the capital university of medical sciences An Zhen Li, An Ding Men Wai Chao Yang District Beijing, 100029 P.R. China IRB Chair: N/A	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
China	08001	Department of Respiratory Medicine The Second Affiliated Hospital of Medical College, Zhejiang University 88, Jiefang Road Hangzhou, 310009 Zhejiang Province P.R. China	Ethics Committee of the First Affiliated Hospital, Sun Yat-Sen University 58 Zhongshan Road 2 Guangzhou 510080 Guangdong Province P.R. China IRB Chair: Wang, Shenming Ethics Committee of The Second Affiliated Hospital of Medical College, Zhejiang University 88 Jiefang Road Hangzhou 310009 Zhejiang Province P.R. China IRB Chair: N/A	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
China	08002	Pulmonary and Critical Care Division The First Affiliated Hospital of People's Liberation Army General Hospital No. 51, Fucheng Road Hai Dian District Beijing, 100037 P.R. China	Ethics Committee of the First Affiliated Hospital, Sun Yat-Sen University 58 Zhongshan Road 2 Guangzhou 510080 Guangdong Province P.R. China IRB Chair: Wang, Shenming Ethics Committee of The First Affilated Hospital of People's Liberation Army General Hospital No. 51 Fucheng Road Hai Dian District Beijing, 100037 P.R. China IRB Chair: N/A	CV
China	08003	Department of Respiratory Medicine The First Affiliated Hospital of Sun Yat-Sen University 58, Zhongshan Road 2 Guangzhou, 510080 Guangdong Province P.R. China	Ethics Committee of the First Affiliated Hospital, Sun Yat-Sen University 58 Zhongshan Road 2 Guangzhou 510080 Guangdong Province P.R. China IRB Chair: Wang, Shenming	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
China	08004	Department of Respiratory Medicine Nanjing General Hospital of Nanjing Military Command 305, East Zhongshan Road Nanjing, 210002 Jiangsu Province P.R. China	Ethics Committee of The First Affiliated Hospital, Sun Yat-Sen University 58 Zhongshan Road 2 Guangzhou 510080 Guangdong Province P.R. China IRB Chair: Wang, Shenming Ethics Committee of Nanjing General Hospital of Nanjing Military Command 305 East Zhongshan Road Nanjing 210002 Jiangsu Province P.R. China IRB Chair: N/A	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
China	08005	Department of Infectious Disease The First Affiliated Hospital of Medical College, Zhejiang University 79 Qingchun Road Hangzhou 310003 Zhejiang Province P.R. China	Ethics Committee of the First Affiliated Hospital, Sun Yat-Sen University 58 Zhongshan Road 2 Guangzhou 510080 Guangdong Province P.R. China IRB Chair: Wang, Shenming Ethics Committee of The First Affiliated Hospital of Medical College, Zhejiang University 79 Qingchun Road Hangzhou 310003 Zhejiang Province P.R. China IRB Chair: N/A	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
China	08006	Department of Respiratory Medicine The Third Affiliated Hospital of Sun Yat-Sen University Gang Ding, Shi Pai Guangzhou, 510060 Guangdong Province P.R. China	Ethics Committee of the First Affiliated Hospital Sun Yat-Sen University 58 Zhongshan Road 2 Guangzhou 510080 Guangdong Province P.R. China IRB Chair: Wang, Shenming Ethics Committee of The Third Affiliated Hospital of Sun Yat-Sen University Gang Ding, Shi Pai Guangzhou, 510060 Guangdong Province P.R. China IRB Chair: N/A	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
China	08007	Department of Respiratory Medicine The First Affiliated Hospital of Nanjing Medical University 300 Guangzhou Road Nanjing 210029 Jiangsu Province P.R. China	Ethics Committee of the First Affiliated Hospital, Sun Yat-Sen University 58 Zhongshan Road 2 Guangzhou 510080 Guangdong Province P.R. China IRB Chair: Wang, Shenming Ethics Committee of The First Affiliated Hospital of Nanjing Medical University 300 Guangzhou Road Nanjing 210029 Jiangsu Province P.R. China IRB Chair: N/A	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
China	08008	The Institute of Infectious Diseases The Second Hospital of Tianjin Medical University No. 23 Ping Jiang Dao, He Xi District Tianjin, 300211 P. R. China	Ethics Committee of The First Affiliated Hospital. Sun Yat-Sen University 58 Zhongshan Road 2 Guangzhou 510080 Guangdong Province P.R. China IRB Chair: Wang, Shenming Ethics Committee of The Second Hospital of Tianjin Medical University No.23 Ping Jiang Dao, He Xi District Tianjin, 30021 1 P.R. China IRB Chair: N/A	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
China	08009	Department of Respiratory Medicine Shanghai Jiao Tong University Affiliated First People's Hospital 85 Wujin Road Shanghai, 200080 P.R. China	Ethics Committee of the First Affiliated Hospital, Sun Yat-Sen University 58 Zhongshan Road 2 Guangzhou 510080 Guangdong Province P.R. China IRB Chair: Wang, Shenming E. C. Shanghai Jiao Tong University Affiliated First People's Hospital 85 Wujin Road Shanghai, 200080 P.R. China IRB Chair: N/A	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
China	08010	Department of Respiratory Medicine Nanjing Drum Tower Hospital 321 Zhongshan Road Nanjing 210008 Jiangsu Province P.R. China	Ethics Committee of Nanjing Drum Tower Hospital 58 Zhongshan Road 2 Guangzhou 510080 Guangdong Province P.R. China IRB Chair: N/A Ethics Committee of Nanjing Drum Tower Hospital 321 Zhongshan Road Nanjing 210008 Jiangsu Province P.R. China IRB Chair: N/A	CV
China	08011	37# Guo Xue Xiang, Chengdu, Sichuan China	IRB of West China Hospital 37# Guo Xue Xiang Chengdu, Sichuan China IRB Chair: N/A	CV
China	08012	He Xitong Zi Po Road Chang Sha City China	The Ethics Committee of The Third Xiang Ya Hospital He Xitong Zi Po Road Chang Sha City China IRB Chair: N/A	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
China	08013	No.180 Feng Lin Road, Xu Hui District Shanghai P.R. China 200032	Ethics Committee of Zhongshan Hospital, Fudan University No.180 Feng Lin Road, Xu Hui District Shanghai P.R.China 200032 IRB Chair: N/A	CV
China	08014	No. 1095 Jie Fang Road Wu Han City China	The Ethics Committee of Tong Ji Hospital of Tong Ji Medical College of Hua Zhong University of Science & Technology No.1095 Jie Fang Road Wu Han City China IRB Chair: N/A	CV
China	08015	No. 174 Changhai Road Shanghai P.R. China, 200433	Ethics Committee of Shanghai Changhai Hospital No.174 Changhai Road Shanghai P.R., China 200433 IRB Chair: N/A	CV
China	08016	Respiratory Department of Hainan Provincial People's Hospital Xiuhua Road 19, Xiuying District Haikou China, 570311	The IRB of Hainan Provincial People's Hospital Xiuhua Road 19, Xiuying District Haikou China, 570311 IRB Chair: N/A	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
China	08018	No. 3 Qing Chun Road East Hangzhou, Zhejiang Province P.R. China, 310016	Ethics Committee of Sir Run Run Shaw Hospital No. 3 Qing Chun Road East Hangzhou, Zhejiang Province P.R. China, 310016 IRB Chair: N/A	CV
China	08019	The First Affiliated Hospital of China Medical University No.155 Nanjing Bei Road, Heping Area Shenyang, Liaoning China	The First Affiliated Hospital of China Medical University No.155 Nanjing Bei Road, Heping Area Shenyang, Liaoning China IRB Chair: N/A	CV
China	08020	No. 8, Xi Shen Ku Road, Xi Cheng Area Beijing China	IRB of The First Affiliated Hospital of Peking University No. 8, Xi Shen Ku Road, Xi Cheng Area Beijing China IRB Chair: N/A	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
China	08021	Respiratory Department General Hospital of Shenyang Military Region No. 83 Wen Hua Road Shen He District Shenyang, 110016 P.R. China	Ethics Committee of the First Affiliated Hospital, Sun Yat-Sen University 58 Zhongshan Road 2 Guangzhou 510080 Guangdong Province P.R. China IRB Chair: N/A Ethics Committee of General Hospital of Shenyang Military Region No. 83 Wen Hua Road Shen He District Shenyang, 110016 P.R. China IRB Chair: N/A	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
China	08022	Respiratory Department XiJing Hospital of The 4th Military Medical University No. 15, Chang Le Xi Road Xin Cheng District Xian, 710032 P.R. China	Ethics Committee of the First Affiliated Hospital, Sun Yat-Sen University 58 Zhongshan Road 2 Guangzhou 510080 Guangdong Province P.R. China IRB Chair: Wang, Shenming Ethics Committee of Xijing Hospital of The 4th Military Medical University No. 15, Chang Le Xi Road Xian, 710032 P.R. China IRB Chair: N/A	CV
China	08023	Department of Infectious Disease Peking Union Medical College Hospital No. 1 Shuaifuyuan Wangfujing, Dongcheng Area Beijing China	Peking Union Medical College Hospital Ethics Committee No. 1 Shuaifuyuan Wangfujing, Dongcheng Area Beijing China IRB Chair: N/A	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Croatia	09005	Clinical Hospital Centre Zagreb Kispaticeva 12 10000 Zagreb Croatia	Drug Committee of Clinical Hospital Centre Zagreb Kispaticeva 12, 10000 Zagreb Croatia IRB Chair: Buljevic, Bruno Central Ethics Committee of Republic of Croatia Ksaver 200a, 10000 Zagreb Croatia IRB Chair: Ljubicic, Neven Ministry of Health and Social Welfare of Republic of Croatia Ksaver 200a 10000 Zagreb Croatia IRB Chair: Vrhovac, Bozidar	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Croatia	09007	University Hospital for Infectious Diseases Mirogojska 8 10000 Zagreb Croatia	Local Ethics Committee of University Hospital for Infectious Diseases “Dr. Fran Mihaljevic” Mirogojska 8, 10000 Zagreb Croatia IRB Chair: Himbele, Josip Drug Committee of University Hospital for Infectious Diseases “Dr. Fran Mihaljevic” Mirogojska 8, 10000 Zagreb Croatia IRB Chair: Himbele, Josip Central Ethics Committee of Republic of Croatia Ksaver 200a, 10000 Zagreb Croatia IRB Chair: Ljubicic, Neven Ministry of Health and Social Welfare of Republic of Croatia Ksaver 200a 10000 Zagreb Croatia IRB Chair: Vrhovac, Bozidar	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Croatia	09009	Clinical Hospital Centre Zagreb Kispaticeva 12 10000 Zagreb Croatia	Drug Committee of Clinical Hospital Centre Zagreb Kispaticeva 12 10000 Zagreb Croatia IRB Chair: Buljevic, Bruno Central Ethics Committee of Republic of Croatia Ksaver 200a, 10000 Zagreb, Croatia IRB Chair: Ljubicic, Neven Ministry of Health and Social Welfare of Republic of Croatia Ksaver 200a 10000 Zagreb Croatia IRB Chair: Vrhovac, Bozidar	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Czech Republic	10011	Hospital Vítkovice Pneumology Department Zaluzanskeho 1192/15 703 84 Ostrava-Vitkovice Czech Republic	Multicentric Ethics Committee at the Teaching Hospital Praha Motol V uvalu 84 150 06 Praha 5 IRB Chair: Regula, Jaroslaw Ethics Committee at the Hospital Vitkovice Zaluzanskeho 1192/15 703 84 Ostrava-Vitkovice IRB Chair: Cizek, Vladimir	CV
Czech Republic	10012	Regional Hospital Tabor Pneumology Department Trida Kapitana Jarose 2000 390 03 Tabor Czech Republic	Multicentric Ethics Committee at the Teaching Hospital Praha Motol V uvalu 84 150 06 Praha 5 IRB Chair: Regula, Jaroslaw Ethics Committee at the Regional Hospital Tabor, Trida Kapitana Jarose 2000 390 03 Tabor IRB Chair: Klenha, Kamil	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Czech Republic	10013	Teaching Hospital Hradec Kralove Medical ICU, Department of Gerontology Sokolska 581 500 05 Hradec Kralove 5 Czech Republic	Multicentric Ethics Committee at the Teaching Hospital Praha Motol V uvalu 84 150 06 Praha 5 IRB Chair: Regula, Jaroslaw Ethics Committee at the Teaching Hospital Hradec Kralove Sokolska 581 500 05 Hradec Kralove 5 IRB Chair: Vortel, Jiri	CV
Estonia	11001	East-Tallinn Central Hospital Surgery Clinic, Intensive Care Department 18 Ravi Str. Tallinn 10138 Estonia	Tallinn Medical Research Ethics Committee/ National Institute for Health Development Hiiu 42 Tallinn 11619 Estonia IRB Chair: Kahn, H.	CV
Estonia	11003	North Estonia Regional Hospital Anaesthesiology & Intensive Care Clinic 19 Sutiste Str. Tallinn 13419 Estonia	Tallinn Medical Research Ethics Committee/ National Institute for Health Development Hiiu 42 Tallinn 11619 Estonia IRB Chair: Kahn, H.	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
France	12008	Hopital Jean Verdier Service d'Anesthesie Reanimation Avenue du 14 juillet 93143 Bondy, Cedex France	C.C.P.P.R.B. – Paris-Broussais-HEGP 96, rue Didot 75014 Paris France IRB Chair: Herve, Christian (President)	CV
France	12009	Hopital Europeen Georges Pompidou Service de Reanimation Medicale 20-40, rue Leblanc 75908 Paris Cedex 15 France	C.C.P.P.R.B. – Paris-Broussais-HEGP 96, Rue Didot 75014 Paris France IRB Chair: Herve, Christian (President)	CV
France	12010	Centre Hospitalier du pays d'Aix Service de reanimation polyvalente Ave de Tamaris 13100 Aix –en – Provence France	C.C.P.P.R.B. – Paris-Broussais-HEGP 96, Rue Didot 75014 Paris France IRB Chair: Herve, Christian (President)	CV
France	12015	CHU Bichat – Claude Bernard Service de Reanimation Chirurgicale 46, Rue Henri Huchard 75018 Paris France	C.C.P.P.R.B. – Paris-Broussais-HEGP 96, rue Didot 75014 Paris France IRB Chair: Herve, Christian (President)	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
France	12020	Centre Hospitalier Intercommunal De Bigorre Service De Pneumologie Bd Marechal de Lattre de Tassigny 65000 Tarbes Cedex 13 France	C.C.P.P.R.B. – Paris-Broussais-HEGP 96, Rue Didot 75014 Paris France IRB Chair: Herve, Christian (President)	CV
France	12021	CHU Sud Unite' de Reanimation Medicale - Service de Nephrologie Avenue Rene Laennec 80054 Amiens Cedex 1 France	C.C.P.P.R.B. – Paris-Broussais-HEGP 96, Rue Didot 75014 Paris France IRB Chair: Herve, Christian (President)	CV
France	12030	CHU Hotel Dieu department d'anesthesie reanimation 1, Place du Parvis Notre Dame 75004 Paris France	C.C.P.P.R.B. – Paris-Broussais-HEGP 96, rue Didot 75014 Paris France IRB Chair: Herve, Christian (President)	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Georgia	47000	Tbilisi State Medical University based on AIDS & Clinical Immunology Research Center of National Antiseptic Center 16. Al. Kazbegi Ave. 0160 Tbliisi Georgia	Local Ethics Committee of Ltd I. Javakhishvili Tbilisi State University Clinic 60, D Agmashenebeli Ave Tbilisi, Georgia IRB Chair: Antadze, A.	CV
Georgia	47001	Tbilisi State Medical University based on AIDS & Clinical Immunology Research Center of National Antiseptic Center 16. Al. Kazbegi Ave. 0160 Tbliisi Georgia	Local Ethics Committee of Tbilisi State Medical University of Institute of Postgraduate Medical Education and Continuous Professional Development 29, Chavchavadze Ave. 0179 Tbilisi Georgia IRB Chair: Antadze, A.	CV
Georgia	47002	Legal Entity of Public Low "N. Kipshidze Central Clinical Hospital" of Tbilisi State Medical University 29 Vaja Pshavela Ave. 0160 Tbilisi Georgia	Local Ethics Committee of Legal Entity of Public Low "N. Kipshidze Central Clinical Hospital" of Tbilisi State Medical University 29 Vaja Pshavela Ave. 0160 Tbilisi Georgia IRB Chair: Akhmiteli, T.	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Georgia	47003	Fund “Georgian Patriarchate Therapy Clinic “Upovartatvis” and its fund of development” based on Tbilisi #1 Hospital of Clinic’s Association, 9 Tsinandali Street 0144 Tbilisi Georgia	Local Ethics Committee of Union Clinical City-First Hospital 9 Tsinandali Street 0144 Tbilisi Georgia IRB Chair: Germanishvili, Z.	CV
Georgia	47004	JSC Academic O. Gudushauri National Medical Centre 18/20 Lubliana Street 0159 Tbilisi Georgia	Local Ethics Committee of JSC Academic O. Gudushauri National Medical Centre 18/20 Lubliana Street Tbilisi Georgia IRB Chair: Abesadze, Archil	CV
Germany	13009	Vivantes Auguste-Viktoria- Klinikum Klinik fur Innere Medizin Gastroenterologie und Infektiologie Rubensstr. 125 D-12157 Berlin, Germany	Landesamt fur Gesundheit und Soziales Geschaftsstelle der Ethikkommission des Landes Berlin Sachsische Str. 28 D-10707 Berlin Germany IRB Chair: Hidebrandt, Lecturer	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Germany	13014	Medizinische Hochschule Hannover Abteilung fur Pneumologie Carl-Neuberg-Str. 1 D-30625 Hannover Germany	Landesamt fur Gesundheit und Soziales Geschaftsstelle der Ethikkommission des Landes Berlin Sachsische Str. 28 D-10707 Berlin Germany IRB Chair: Hidebrandt, Lecturer Ehtik-Kommission der Medizinischen Hochschule Hannover Carl-Neuberg-Str. 1 D-30625 Hannover Germany IRB Chair: N/A	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Germany	13015	Universitatsklinikum Rostock Klinik und Poliklinik fur Innere Medizin Abteilung fur Pneumologie Ernst-Heydemann–Str. 6 18057 Rostock Germany	Landesamt fur Gesundheit und Soziales Geschaftsstelle der Ethikkommission des Landes Berlin Sachsische Str. 28 10707 Berlin Germany IRB Chair: Hidebrandt, Lecturer Arztekammer Mecklenburg-Vorpommern Ethikkommission August-Bebel-Str. 9A 18055 Rostock Germany IRB Chair: N/A	CV
Greece	14000	. University Hospital of Patra 26500 Rio – Patra	Scientific Council University Hospital of Patra Red Cross General Hospital of Athens 1 Erithrou Stavrou and Athanasaki Street 115 26 Athens Greece IRB Chair: Vagenakis, Apostolos	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Greece	14001	Special Infections Unit "Tzaneion" General Hospital of Pireaus Afentouli 1Tzanni and Street 185 36 Pireaus Greece	Administrative Board “Tzaneion” General Hospital of Piraeus Afentouli 1 and Tzanni Street 185 36 Pireaus Greece IRB Chair: Karamanoli, D.	CV
Greece	14005	3rd Department of Internal Medicine and Special Infections Unit Red Cross General Hospital of Athens 1 Erithrou Stavrou and Athanasaki Street 115 26 Athens Greece	Scientific Council Red Cross General Hospital of Athens 1 Erithrou Stavrou and Athanasaki Street 115 26 Athens Greece IRB Chair: Vagenakis, Apostolos	CV
Greece	14007	Department of Respiratory and Critical Care Medicine General Hospital of Chest Diseases "Sotiria" 152 Mesogion Avenue, Athens 115 27 Greece	Scientific Council General Hospital of Chest Diseases "Sotiria" 152 Mesogion Avenue, Athens 115 27 Greece IRB Chair: Anagnostopoulou, Ourania	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Greece	14009	ICU and Clinic of Chest Diseases “KAT: General Hospital 2 Nikis Street Kifissia 14561 Athens Greece	“KAT: General Hospital 2 Nikis Street Kifissia 14561 Athens Greece Red Cross General Hospital of Athens 1 Erithrou Stavrou and Athanasaki Street 115 26 Athens Greece IRB Chair:	CV
Greece	14012	Intensive Care Unit 251 Airforce General Hospital 3 P. Kanellopoulou Street Athens, 115 25 Greece	Scientific Committee 251 Airforce General Hospital 3 P. Kanellopoulou Street Athens, 115 25 Greece IRB Chair: Vagenakis, Apostolos	CV
Greece	14014	Intensive Care Unit General Hospital of Lamia Terma Papasiopoulou Street Lamia 35100 Greece	Scientific Council General Hospital of Lamia Terrna Papasiopoulou Street Lamia 35100 Greece IRB Chair: Vagenakis, Apostolos	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Israel	18002	Internal Medicine Ward F E. Wolfson Medical Center Holon 58100 Israel	E. Wolfson Medical Center Helsinki Committee E. Wolfson Medical Center Holon 58100 Israel IRB Chair: Knovel, Bolsalev	CV
Israel	18004	Infectious Diseases Unit Sheba Medical Center Tel Hashomer 52621 Israel	Sheba Medical Center Helsinki Committee Sheba Medical Center Tel Hashomer 52621 Israel IRB Chair: Chair is not identified on Membership List	CV
Israel	18005	Infectious Disease Unit Assaf Harofeh Medical Center Zerifin 70300 Israel	Assaf Harofeh Medical Center Helsinki Committee Assaf Harofeh Medical Center Zerifin 70300 Israel IRB Chair: Eliraz, A.	CV
Israel	18006	Internal Medicine Ward B Barzilai Medical Center Ashkelon 78306 Israel	Barzilai Medical Center Helsinki Committee Barzilai Medical Center Ashkelon 78306 Israel IRB Chair: Reisin, L.	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Israel	18008	Internal Medicine Ward D Kaplan Medical Center Rehovot 76100 Israel	Kaplan Medical Center Helsinki Committee Kaplan Medical Center Rehovot 76100 Israel IRB Chair: Eliraz, A.	CV
Israel	18012	General Intensive Care Unit Western Galilee Hospital - Nahariya Nahariya 22100 Israel	Western Galilee Hospital Helsinki Committee Western Galilee Hospital - Nahariya Nahariya 22100 Israel IRB Chair: N/A	CV
Israel	18013	Infectious Diseases Unit Rambam Medical Center Haifa 31096 Israel	Rambam Medical Center Helsinki Committee Rambam Medical Center Haifa 31096 Israel IRB Chair: Barnet, Moshe	CV
Korea	20002	80, Guro-dong, Guro-gu Seoul 152-703, Korea	IRB of Korea University Guro Hospital 80, Guro-dong, Guro-gu Seoul 152-703, Korea IRB Chair: N/A	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Korea	20009	Pusan National University Hospital 10 Ami-dong 1-ga, Seo-gu, Busan Korea Formerly: Pusan National University Hospital 10 Ami-dong 1-ga, Seo-gu, Busan Korea	IRB of Pusan National University Hospital 10, Ami-dong 1-ga, Seo-gu Busan Korea IRB Chair: N/A	CV CV
Korea	20010	Korea University Anam Hospita 126-1 Anam-dong 5-ga, Seongbuk-gu Seoul 136-705, Korea	IRB of Korea University Anam Hospital, 126-1, Anam-dong 5-ga, Seongbuk-gu Seoul 136-705, Korea IRB Chair: N/A	CV
Korea	20011	Respiratory and Allergic Division Department of Internal Medicine Yeungnam University Medical Center 317-1 Daemyeong-dong, Nam-gu Daegu 705-305, Korea	IRB of Yeungnam University Medical Center 317-1 Daemyeong-dong, Nam-gu Daegu 705-305, Korea IRB Chair: N/A	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Korea	20012	San 5 Woncheon-dong, Yeongtong-gu Suwon-si Gyeonggi-do Korea	IRB of Ajou University Hospital San 5, Woncheon-dong, Yeongtong-gu Suwon-si Gyeonggi-do Korea IRB Chair: N/A	CV
Korea	20013	Division of Infectious Diseases, Department of Internal Medicine Ewha Womans University College of Medicine Ewha Womans University Mokdong Hospital 911-1, Mok-dong, Yangcheon-gu Seoul, (#158-710) Korea	The Intitutional Review Board Ewha Womans University Mokdong Hospital 911-1, Mok-dong, Yangcheon-gu Seoul, (#158-710) Korea IRB Chair: N/A	CV
Korea	20014	The Catholic University of Korea. Kangnam St. Mary's Hospilal. 505. Banpo-dong. Seocho-gu, Seoul Korea	IRB of Kangnam St. Mary's Hospital 505, Banpo-dong, Seocho-gu Seoul Korea IRB Chair: N/A	CV
Korea	20015	Wonju Christian Hospital 162, Ilsan-dong Wonju, Kangwon-do Korea	IRB of Wonju Christian Hospital 162, Ilsan-dong Wonju, Kangwon-do Korea IRB Chair: N/A	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Korea	20016	Ulsan University Hospital, 290-3, Jeonha-dong, Dong-gu Ulsan, (#682-714) Korea	The Institutional Review Board Ulsan University Hospital, 290-3 Jeonha-dong, Dong-gu Ulsan, (#682-714) Korea IRB Chair: N/A	CV
Korea	20017	Division of Infectious Diseases Department of Internal Medicine Gil Medical Center, Gachon Medical School 1198, Kuwol-dong, Namdong-gu Incheon, (#405-760) Korea	The Institutional Review Board Gil Medical Center, Gachon Medical School 1198, Kuwol-dong, Namdong-gu Incheon, (#405-760) Korea IRB Chair: N/A	CV
Korea	20018	Division of Infectious Diseases Department of Internal Medicine Severance Hospital, Yonsei University College of Medicine 134, Sinchon-dong, Seodaemun-gu Seoul, (#120-752) Korea	The Institutional Review Board Severance Hospital, Yonsei University College of Medicine 134, Sinchon-dong, Seodaemun-gu Seoul, (#120-752) Korea IRB Chair: N/A	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Korea	20019	KyungHee University Medical Center 1, Hoeki-dong, Dongdaemun-gu Seoul, (#130-702) Korea	The Institutional Review Board KyungHee University Medical Center 1, Hoeki-dong, Dongdaemun-gu, Seoul, (#130-702) Korea IRB Chair: N/A	CV
Latvia	21003	Riga Hospital Nr. 1 Bruninieku 5 Latvia	State Agency of Medicines Latvia Riga. Jersikas 15 Central Ethics Committee 11 Novembra Krastmala 29 Riga LV-1050 Latvija IRB Chair: Porftis, Nilss	CV
Latvia	21004	Daugavpils Regional Hospital Vasarnicu 20 Latvia	State Agency of Medicines Latvia Riga. Jersikas 15 Central Ethics Committee 11 Novembra krastmala 29, Riga LV-1050 Latvija IRB Chair: Porftis, Nilss	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Lebanon	48000	Division of Pulmonary and Critical Care American University of Beirut Medical Center Riad El Solh Beirut 1107 2020 Lebanon	The Institutional Review Board Faculty of Medicine American University of Beirut Riad El Solh Beirut 1107 2020 Lebanon IRB Chair: Salti, Ibrahim	CV
Lebanon	48001	Pulmonary Service St. George University Hospital Achrafieh 1100 2807 Lebanon	Medical Ethics Committee St. George University Hospital Achrafieh 1100 2807 Lebanon IRB Chair: Tohme, Souheil	CV
Lebanon	48002	Pulmonary and Critical Care Department Hotel Dieu de France University Hospital Alfred Naccache Ave Achrafieh Lebanon	Ethics Committee Hotel Dieu de France University Hospital Alfred Naccache Ave Achrafieh Lebanon IRB Chair: Halaby, Georges	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Lithuania	22004	Vilnius University Hospital Santariskiu Clinics Santariskiu 2 LT08661 Vilnius, Lithuania	Lithuanian Bioethics Committee Vilniaus str. 33-230 LT-1119 Vilnius, Lithuania IRB Chair: Gefenas, Eugenijus State Medicine Control Agency Traku str. 14 LT-01132 Vilnius Lithuania IRB Chair: Jankunas, Rimas	CV
Lithuania	22005	Klaipeda District Hospital S. Neries str. 3g LT-92231 Klaipeda Lithuania	Lithuanian Bioethics Committee Vilniaus str. 33-230 LT-1119 Vilnius Lithuania IRB Chair: Gefenas, Eugenijus State Medicine Control Agency Traku str. 14, LT-01132 Vilnius, Lithuania IRB Chair: Jankunas, Rimas	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Lithuania	22006	Klaipeda Hospital Liepojos str. 41 LT-92288 Klaipeda Lithuania	Lithuanian Bioethics Committee Vilniaus str. 33-230 LT-1119 Vilnius Lithuania IRB Chair: Gefenas, Eugenijus State Medicine Control Agency Traku str. 14, LT-01132 Vilnius, Lithuania IRB Chair: Jankunas, Rimas	CV
Mexico	40000	Hospital Central Dr. Ignacio Morones Prieto Avenida Venustiano Carranza No. 2395, Zona Universitaria, 78240, San Luis Potosi San Luis Potosi Mexico	Comite de Etica del Hospital Central Dr. Ignacio Morones Prieto Avenida Venustiano Carranza No. 2395, Zona Universitaria 78240, San Luis Potosi, San Luis Potosi Mexico IRB Chair: Arocha, Nicolas Perez (President)	CV
Mexico	40001	Hospital Civil “Fray Antonio Alcalde” Calle Hosptial No. 278 S.H. 44100, Guadalajara Jalisco Mexico	Comite de Etica del Hospital Civil “Fray Antonio Alcalde” Calle Hospital No. 278 S.H. 44100, Guadalajara Jalisco Mexico IRB Chair: Alvarez, Jaime Agustin Gonzalez (President)	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Mexico	40002	Hospital General Dr. Aurelio Valdivieso Calzada Porfirio Diaz 400 Colonia Reforma 68050, Oaxaca Oaxaca Mexico Formerly: Hospital General Dr. Aurelio Valdivieso Calzada Porfirio Diaz 400 Colonia Reforma 68050, Oaxaca Oaxaca Mexico	Comite de Etica del Hospital General Dr. Aurelio Valdivieso Calzada Porfirio Diaz 400 Colonia Reforma 68050, Oaxaca Oaxaca Mexico IRB Chair: Franco, Miguel Angel Reyes (President)	CV CV
Mexico	40004	Hospital San Jose TEC de Monterrey Morones Prieto #3000 Pte., Colonia Los Doctores 64710, Monterrey Neuvo Leon Mexico	Comite de Etica Hospital San Jose TEC de Monterrey Morones Prieto #3000 Pte., Colonia Los Doctores 64710, Monterrey Neuvo Leon Mexico IRB Chair: Escoboza, Jose Rafael Borbolla	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Mexico	40006	Hospital Central Universitario de Chihuahua Rosales 3302, Colonia Obrera 31350, Chihuahua Chihuahua Mexico	Comite de Etica del Hospital Central Universitario de Chihuahua Rosales 3302, Colonia Obrera 31350, Chihuahua Chihuahua, Mexico IRB Chair: Oiivas, A. Maria Del Rosario Vazquez (President)	CV
Mexico	40008	Hospital Medica Sur Puente de Piedra No. 150 Col. Toriello Guerra C.P. 14050 Del Tlalpan Mexico D.F Mexico	Comite de Investigacion para Estudios es Humanos Puente de Piedra # 150. Toriello Guerra. Tlalpan C.P. 14050. Mexico D.F. IRB Chair: Mendez-Sanchez, Nahum (President)	CV
Mexico	40009	Unidad de Prevencion Diagnostico y Educacion S.C Luis Donaldo Colosio # 208 Int 107 C.P 20129 Aguascalientes Aguascalientes	Comite de Ensenanza, Investigacion, Capacitacion Etica y Admision del Centenario Hospital Miguel Hidalgo Galeana Sur 465, Col Obraje CP 20230 Aguascalientes Ags. IRB Chair: Reyes, Carlos A. Dominguez (Secretary)	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Philippines	42000	UP-Philippines General Hospital Taft Avenue Manila Philippines	Research Implementation Development Office, UP-Philippines General Hospital Taft Avenue Manila Philippines IRB Chair: N/A	CV
Philippines	42002	Veterans Memorial Medical Center North Avenue, Diliman Quezon City Philippines	Research and Ethics Committee, Veterans Memorial Medical Center North Avenue, Diliman Quezon City Philippines IRB Chair: Barrenechea, Emerita A.	CV
Philippines	42003	Medical Staff Office Lung Center of the Philippines Quezon Avenue Quezon City Manila Philippines	Ethics Review Committee Lung Center of the Philippines Quezon Avenue Quezon City Manila Philippines IRB Chair: N/A	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Philippines	42004	St. Luke's Medical Center E. Rodriguez Sr. Avenue Quezon City Philippines	Ethics Review Board St. Luke's Medical Center E. Rodriguez Sr. Avenue Quezon City Philippines IRB Chair: N/A	CV
Philippines	42005	Makati Medical Center Amorsolo Street Legaspi Village Makati City Philippines	Makati Medical Center - Institutional Review Board Amorsolo Street Legaspi Village Makati City Philippines IRB Chair: N/A	CV
Philippines	42006	Manila Doctors Hospital United Nations Avenue Manila Philippines	Research & Ethics Committee Manila Doctors Hospital 667United Nations Avenue Manila Philippines IRB Chair: Cuayo-Juico, Cynthia	CV
Philippines	42007	Quirino Memorial Medical Center Medical Private Clinic Katipunan Road Corner P. Tuazon Avenue 1109 Quezon City Philippines	Institutional Review Board Quirino Memorial Medical Center Katipunan Road Corner P. Tuazon Avenue 1109 Quezon City Philippines IRB Chair: N/A	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Poland	25014	Oddzial Intensywej Terapii I Anestezjolgii Wojewodzki Szpital Specialistyczny im.Stefana Kardynala Wyszynskiego Samodzielny Publiczny Zaklad Opieki Zdrowotnej Al. Krasnicka 100 20-718 Lublin Poland	Komisja Bioetyczna przy CMKP ul. Marymoncka 99 01-813 Warszawa Poland IRB Chair: Regula, Jaroslaw Komisja Bioetyczna Lubelskiej Isby Lekarskiej ul. Chmielna 4 20-079 Lublin Poland	CV
Poland	25018	Oddzial Kliniczny Anestezjologii i Intensywnej Terapii Samodzielny Publiczny Zaklad Opieki Zdrowotnej Uniwersytecki Szpital Kliniczny Nr 1 im. Norberta Barlickiego Uniwersytetu Medycznego w Lodziul. Kopcinskiego 22 90-153 Lodz Poland	Komisja Bioetyczna przy Centrum Medycznym Ksztlacenia Podyplomowego Warszawa ul. Marymoncka 99-103 IRB Chair: Regula, Jaroslaw Uczelniana Komisja Etyki Badan Naukowych Al. Kosciuszki 4 80-419 Lodz Poland IRB Chair: N/A	CV
Poland	25019	Klinika Anestezjologii i Intensywnej Terapii Samodzielny Publiczny Szpital Kliniczny im. W. Orlowskiego ul. Czemiakowska 231 00-416 Warszawa Poland	Komisja Bioetyczn przy CMKP ul. Marymoncka 99 01-813 Warszawa Poland IRB Chair: Regula, Jaroslaw	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Poland	25020	Klinika Anestezjologii i Intensywnej Terapii Centralny Szpital Kliniczny MSWiA ul. Woloska 137 02-507 Warszawa Polska	Komisja Bioetyczna przy Centrum Medycznym Ksztalcenia Podyplomowego ul. Marymoncka 99/103 Warszawa Polska IRB Chair: Regula, Jaroslaw Komisja Etyczna Nadzoru Nad Badaniami na Ludziach Centralnego Szpitalia Klinicznego MSWiA ul. Woloska 137 02-507 Warszawa Poland	CV
Poland	25023	I Oddzial Chorob Pluc Krakowski Szpital Specjalistyczny im. Jana Pawla II Ul. Pradnicka 80 31-202 Krakow Poland	Komisja Bioetyczna CMKP Ul. Marymoncka 99 01-813 Warszawa Poland IRB Chair: Regula, Jaroslaw Komisja Bioetyczna przy Okregowej Izbie Lekarskiej ul.Krupnicza 11a 31-123 Krakow Poland	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Poland	25024	III Oddzial Chorob Wewnetrznych Szpital Specjalistyczny im. S. Zeromskiego Samodzielny Publiczny Zaklad Opieki Zdrowotnej w Krakowie Os. Na Skarpie 66 31-913 Krakow Poland	Komisja Bioetyczna CMKP ul. Marymoncka 99 01-813 Warszawa Poland IRB Chair: Regula, Jaroslaw Komisja Bioetyczna przy Okregowej Izbie Lekarskiej ul.Krupnicza 11a 31-123 Krakow Poland	CV
Poland	25028	Samodzielny Publiczny Szpital Kliniczny Nr 2 im. H. Swiecickiego A.M. Oddzial Klinizny Anestezjologii, Intensywnej Terapii i Leczenia Bolu ul. Przybyszewskiego 49 60-355 Poznan Poland	Komisja Bioetyczna przy Centrum Medycznym Ksztalcenia Podyplomowego ul. Marymoncka 99/103 01-813 Warszawa Poland IRB Chair: Regula, Jaroslaw	CV
Poland	25029	Oddzial Kliniczny Kliniki Chirurgii Ogolnej I Gastroenterologicznej SPZOZ Szpitala Uniwersyteckiego w Krakowie ul. Kopernika 40 31-501 Krakow Poland	Komisja Bioetyczna CMKP Ul. Marymoncka 99 01-813 Warszawa Poland IRB Chair: Regula, Jaroslaw	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Poland	25030	Klinika Ane3sterzjologii I Intensywnej Terapii Samodzielny Publiczny Szpital Kliniczny Nr 1 P.A.M. w Szczecinie Ul. Unii Lubelskiej 1 71-252 Szczecin Poland	Komisja Bioetyczna przy Centrum Medycznym Ksztalcenia Podyplomowego ul. Marymoncka 99/103 01-813 Warszawa IRB Chair: Regula, Jaroslaw	CV
Poland	25031	Oddzial Kliniczny Anestezjologii I Intensywnej Terapii Katedry Anestezjologii, Intensywnej Terapii I Medycyny Ratunkowej Slaskiej Adademii Medycznej Wojewodzki Szpital Specjalisty Nr 5 im Sw. Barbary Plac Medykow 1 41-200 Sosnowiec Poland	Komisja Bioetyczna przy Centrum Medycznym Ksztalcenia Podyplomowego ul. Marymoncka 99/103 01-813 Warszawa IRB Chair: Regula, Jaroslaw	CV
Portugal	26000	Hospital Sao Sebastiao Unidade de Cuidados Intermedios Rua. Dr. Candido Pinho 4520-211 Santa Maria da Feira Portugal	Comissao de Etica para a Investigacao Clinica (CEIC) Parque de Saude de Lisboa – Avenida do Brasil, 53 1749-004 Lisboa – Portugal IRB Chair: Veloso, Antonio Jose De Barros	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Portugal	26007	Hospital de Santa Marta Sevico de Pneumologia Rua Santa Marta 1150-291- Lisboa Portugal	Comissao de Etica para a Investigacao Clinica (CEIC) Parque de Saude de Lisboa – Avenida do Brasil, 53 1749-004 Lisboa – Portugal IRB Chair: Veloso, Antonio Jose De Barros	CV
Portugal	26008	Hospital Distrital de Faro Unidade de Cuidadow Intensivos Rua Leao Penedo 8000-386 Faro Portugal	Comissao de Etica para a Investigacao Clinica (CEIC) Parque de Saude de Lisboa – Avenida do Brasil, 53 1749-004 Lisboa – Portugal IRB Chair: Veloso, Antonio Jose De Barros	CV
Romania	43000	Clinical Hospital of Pneumoftiziology 30 Dr I Cihac Street 700115 Lasi Romania	National Ethics Committee 48 Aviator Sanatescu St., Sector 1 011478 Bucharest Romania IRB Chair: Litarczek, George (President)	CV
Romania	43002	Clinical Emergency County Hospital Craiova, 1 Tabaci St., Surgery Dept. no. 3, 3rd floor, 200642 Craiova Romania	National Ethics Committee 48 Aviator Sanatescu St., Sector 1 011478 Bucharest Romania IRB Chair: Litarczek, George (President)	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Romania	43004	Clinical Emergency Hospital “Sf. Pantelimon” 340 Pantelimon Ave., 2nd sector 021659 Bucharest Romania	National Ethics Committee 48 Aviator Sanatescu St., Sector 1 011478 Bucharest Romania IRB Chair: Litarczek, George (President)	CV
Romania	43005	Clinical County Hospital No 1 Timisoara, ICU Dept. 156 I. Bulbuca Street 300736 Timisoara Romania	National Ethics Committee 48 Aviator Sanatescu St., Sector 1 011478 Bucharest Romania IRB Chair: Litarczek, George (President)	CV
Russia	27015	Municipal Health Care Institution Municipal Clinical Hospital #13 1/1, Velozavodskaya str. Moscow, 115280 Russia	Ethics Committee at the Federal Body of Medicines Quality Contol 8,,Petrovsky Blvd., bld. 3 Moscow, 127051 Russia IRB Chair: Semeshkina, O.B. Local Ethics Committee of Municipal Health Care Institution Municipal Clinial Hospital #13 1/1, Velozavodskaya str.. Moscow, 115280 Russia IRB Chair: Semeshkina, O.B.	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Russia	27016	Municipal Health Care Institution of Moscow Municipal Clinical Hospital #11 of Health Department of Moscow 6, Dvintsev str. 127018, Moscow Russia	Ethics Committee at the Federal Body of Medicines Quality Contol 8,,Petrovsky Blvd., bld. 3 Moscow, 127051 Russia IRB Chair: Semeshkina, O.B. Ethics Committee at Roszdravnadzor 4, Slavyanskaya Sq., bld. 1 109074 Moscow Russian Federation IRB Chair: Vyalkov. A.I. Local Ethics Committee of Municipal Health Care Institution of Moscow Municipal Clinical Hospital #11 of Health Department of Moscow 6, Dvintsev Street, 127018, Moscow Russia IRB Chair: Seltsovsky, A.P.	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Russia	27018	Central Clinical & Diagnostic Federal State Institution “National Medical Surgery Center named after N.I. Pirogov” under Federal Agency for Health Care & Social Development 70, Nizhnyaya Pervomayskaya 105203 Moscow Russia	Ethics Committee at the Federal Body of Medicines Quality Control 8, Petrovsky Blvd., bld. 3 Moscow 127051 Russia IRB Chair: Komarov, F.I. Ethics Committee at Roszdravnadzor 4, Slavyanskaya Sq., bld. 1 109074 Moscow Russian Federation IRB Chair: Vyalkov. A.I. Local Ethics Committee of the Central Clincal & Diagnostics Federal State Institution “National Medicine & Surgery Center named after N.I. Pirogov” under Federal Agency for Health Care & Social Development 70, Nizhnyaya Pervomayskaya 105203 Moscow Russia IRB Chair: Novic, Andrey Arkadievich	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Russia	27019	State Institution “Scientific Research Institute of Clinical & Experimental Lymphology of RAMS, Siberian Branch” based on Fund of development and specific medical aid “Sanitary Medical unit-168” 2, Timakov str., 630117 Novosibirsk, Russia 2, Arbuzov str., 630117 Novosibirsk Russia	Ethics Committee at the Federal Body of Medicines Quality Control 8, Petrovsky Blvd., bld. 3 Moscow 127051 Russia IRB Chair: Komarov, F.I. Ethics Committee at Roszdravnadzor 4, Slavyanskaya Sq., bld. 1 109074 Moscow Russian Federation IRB Chair: Vyalkov. A.I. Local Ethics Committee of State Institution “Scientific Research Institute of Clinical & Experimental Lymphology of RAMS, Siberian Branch 2, Timakov str. 630117 Novosibirsk Russia IRB Chair: Letyagina, E.A.	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Russia	27020	Municipal Health Care Institution “Municipal Clinical Hospital #2” 21, Polzunov str. Novosibirsk, 630051 Russia	Ethics Committee at the Federal Body of Medicines Quality Control 8, Petrovsky Blvd., bld. 3 Moscow 127051 Russia IRB Chair: Komarov, F.I. Ethics Committee at Roszdravnadzor 4, Slavyanskaya Sq., bld. 1 109074 Moscow Russian Federation IRB Chair: Vyalkov. A.I. Local Ethics Committee of Municipal Health Care Instiurion “Municipal Clinical Hospital #2” 21, Polzunov str. Novosibirsk, 630051 Russia IRB Chair: Klimchuk, T.V.	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Russia	27021	Federal State Institution Novosibirsk Scientific Research Institute of Blood Circulation Pathology named after academician E.N. Meshalkin 15, Rechkunovskaya str. 630055 Novosibirsk Russia	Ethics Committee at the Federal Body of Medicines Quality Control 8, Petrovsky Blvd., bld. 3 Moscow 127051 Russia IRB Chair: Komarov, F.I. Local Ethics Committee of Ferderal State Institution Novosibirsk Scientific Research Institute of Blood Circulation Pathology named after academician E.N. Meshalkin 15, Rechkunovskaya str. 630055 Novosibirsk Russia IRB Chair: Nikolayevich, Lomivorotov Vladimir	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Russia	27022	Saint-Petersburg State Medical Institution “Municipal Hospital #26” 2, Kostyushko str. Saint Petersburg 196247 Russia	Ethics Committee at the Federal Body of Medicines Quality Control 8, Petrovsky Blvd., bld. 3 Moscow 127051 Russia IRB Chair: Komarov, F.I. Ethics Committee at Roszdravnadzor 4, Slavyanskaya Sq., bld. 1 109074 Moscow Russian Federation IRB Chair: Vyalkov. A.I. Local Ethics Committee of the Saint-Petersburg State Medical Institution “Municipal Hospital #26” 2, Kostyushko str. Saint Petersburg 196247 Russia IRB Chair: Petrovich, Konstantin	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Russia	27025	Municipal Health Care Institution Clinical Hospital of Emergency Care named after N.V. Solovyev 11, Zagorodny Sad str. 150003, Yaroslavi Russia	Ethics Committee at the Federal Body of Medicines Quality Control 8, Petrovsky Blvd., bld. 3 Moscow 127051 Russia IRB Chair: Komarov, F.I. Local Ethics Committee of Municipal Health Care Institution Clinical Hospital of Emergency Care named after N.V. Solovyev 11, Zagorodny Sad str. 150003, Yaroslavi Russia IRB Chair: Berezin, V.N. (Chief)	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Russia	27026	State Medical Institution of Moscow "Clinical Hospital #7" 4, Kolomensky proezd. Moscow 115446 Russia	Ethics Committee at the Federal Body of Medicines Quality Control 8, Petrovsky Blvd., bld. 3 Moscow 127051 Russia IRB Chair: Komarov, F.I. Ethics Committee at Roszdravnadzor 4, Slavyanskaya Sq., bld. 1 109074 Moscow Russian Federation IRB Chair: Vyalkov. A.I. Local Ethics Committee of the State Medical Institution of Moscow "Clinical Hospital #7" 4, Kolomensky proezd. Moscow 115446 Russia IRB Chair: N/A	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Russia	27027	Moscow State Institution of Public Health “Municipal Clinical Hospital #53” 26, Trofimova Street 115432, Moscow Russia	Ethics Committee at the Federal Body of Medicines Quality Control 8, Petrovsky Blvd., bld. 3 Moscow 127051 Russia IRB Chair: Komarov, F.I. Ethics Committee at Roszdravnadzor 4, Slavyanskaya Sq., bld. 1 109074 Moscow Russian Federation IRB Chair: Vyalkov. A.I.	CV
Serbia	50000	Clinic for Pulmonary Diseases and TBC “Knez Selo” ZP 18204 Gornji Metejevac 18 000 Nis Serbia	Medicines and Medical Devices Agency of Serbia Vojvode Stepe 458 11152 Belgrade IRB Chair: N/A Ethics Committee Clinic for Pulmonary Diseases and TBC “Knez Selo” ZP 18204 Gornji Metejevac 18 000 Nis Serbia IRB Chair: Zivkovic, Miroslava	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Serbia	50001	Beogradska bb Clincal Center Kragujevac 34 000 Kragujevac Serbia	Ethics Committee Clincal Center Kragujevac Zmaj Jovina 30 34 000 Kragujevac Serbia IRB Chair: Jankovic, Slobodan Medicines and Medical Devices Agency of Serbia Vojvode Stepe 458 11152 Belgrade IRB Chair: N/A	CV
Serbia	50002	Institute for Lung Diseases and TBC Visegradska 26/20 11000 Belgrade Serbia	Ethics Committee Clinical Center Serbia Pasterova 2 11000 Belgrade Serbia IRB Chair: Milasinovic, Goran (Vice-President)	CV
Serbia	50003	Clinical Hospital Center “Bezanijska Kosa” Autoput BB, 11070 Belgrade, Serbia	Ethics Committee Clinical Hospital Center “Bezanijska Kosa” Autoput BB, 11070 Belgrade, Serbia IRB Chair: Vukotic, Dusan (President)	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Slovakia	29001	Oddelenie anesteziologie Slovensky ustav srdcovych a cievnych chorob, Pod Krasnou horkou 1 833 46 Bratislava Slovak Republic	Eticka komisia Slovensky ustav srdcovych a cievnych chorob Pod Krasnou horkou 1 833 46 Bratislava Slovak Republic IRB Chair: Janekova, Etela	CV
Slovakia	29002	II. Oddelenie tuberkulozy a respiracnyh chorob Specializovana nemocnica sv. Svorada ZOBOR, n.o. Klastorska 134 949 88 NITRA-ZOBOR Slovak Republic	Eticka komisia Specializovana nemocnica sv. Svorada ZOBOR, n.o. Klastorska 134 949 88 NITRA-ZOBOR Slovak Republic IRB Chair: Matula, Bohumil (President)	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Slovakia	29005	Teaching Hospital Nitra 2nd Internal Medicine Clinic, Dept. of Internal Medicine & Clinical Pharmacology Spitalska 6 950 01 Nitra Slovak Republic	Ethics Committee of Teaching Hospital Nitra Spitalska 56 950 01 Nitra Slovak Republic IRB Chair: Murgas, Miroslav Multicentre Ethics Committee Teaching Hospital & Policlinic of akad. L. Derer's Limbova 5 833 05 Bratislava Slovak Republic IRB Chair: N/A	CV
Slovenia	51000	University Clinic of Respiratory and Allergic Diseases Golnik Golnik 38 4204 Golnik Slovenia	The National Medical Ethics Committee University Medical Centre Ljubjana Zaloska 7 1525 Ljubljana Slovenia IRB Chair: Trontelj, Joze (President)	CV
Slovenia	51001	Department of Respiratory and Allergic Desiases General and Teaching Hospital Celje Oblakova 6, 3000 Celje Slovenia	The National Medical Ethics Committee University Medical Centre Ljubjana Zaloska 7 1525 Ljubljana Slovenia IRB Chair: Trontelj, Joze (President)	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
South Africa	30001	Medi-Clinic Hospital Block, Room 1 Lower Ground Floor Blomfontein 9301 South Africa	South African Medical Association Research Ethics Committee Block F Castle Walk Corporate Park Nossob Street Erasmuskloof Ext 3 Pretoria 0153 South Africa IRB Chair: N/A	CV
South Africa	30002	East Rand Clinical Research Centre Corner of Trichardt and North Rand Roads Boksburg 1462 South Africa	South African Medical Association Research Ethics Committee Block F Castle Walk Corporate Park Nossob Street Erasmuskloof Ext 3 Pretoria 0153 South Africa IRB Chair: N/A	CV
South Africa	30007	Sr. Stephanie O'Keefe Medical Centre Little Company of Mary Hospital Groenkloof Pretoria 0181 South Africa	South African Medical Association Research Ethics Committee Block F Castle Walk Corporate Park Nossob Street Erasmuskloof Ext 2 Pretoria 0153 South Africa IRB Chair: N/A	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
South Africa	30912	Department of Surgery, Pretoria Academic Hospital Room 71143, Level H7 Voortrekker Road Pretoria 0001 South Africa	Faculty of Health Sciences Research Ethics Committee University of Pretoria Soutpansberg Road MRC – Building, Room 2-19 Pretoria Gauteng South Africa IRB Chair: Snyman, J.R.	CV
South Africa	30913	Park Medical Center 19 Rhodes Street Witbank 1035 South Africa	South African Medical Association Research Ethics Committee Block F Castle Walk Corporate Park Nossob Street Erasmuskloof Ext 3 Pretoria 0153 South Africa IRB Chair: N/A	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Spain	31014	Hospital General Universitario de Valencia Avda. Tres Cruces, s/n 46014 Valencia Spain	Comite Etico Regional de la Comunidad de Madrid Unidad de Bioetica P° Recoletos, 14-7 planta 28001 Madrid Spain IRB Chair: Martinez, Jesus Inigo (Secretary) Comite Etico de Investigacion Clinica Hospital General Universitario de Valencia Avda. Tres Cruces, s/n 46014 Valencia Spain IRB Chair: N/A	CV
Spain	31016	Hospital Ramon y Cajal Ctra. De Colmenar, Km 9,1 28034 Madrid Spain	Comite Etico Regional de la Comunidad de Madrid Unidad de Bioetica P Recoletos, 14-7 planta 28001 Madrid Spain IRB Chair: Martinez, Jesus Inigo (Secretary) Comite Etico de Investigacion Clinica Hospital Ramon y Cajal Ctra. De Colmenar, Km 9,1 28034 Madrid Spain IRB Chair: N/A	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Spain	31018	Hospital Juan Canalejo Xubias de Arriba, 84 15006 La Coruna Spain	Comite Etico Regional de la Comunidad de Madrid Unidad de Bioetica P Recoletos, 14-7 planta 28001 Madrid Spain IRB Chair: Martinez, Jesus Inigo (Secretary) Comite Etico Investigacion Clinica de Galicia (SERGAS) Division de Farmacia y Productos Sanitarios Conselleria de Sanidade c/ San Lazaro, s/n 15703 Santiago de Compostela Spain IRB Chair: N/A	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Spain	31019	Avda. Reyes Catolicos, 2 28040 Madrid Spain	Comite Etico Regional de la Comunidad de Madrid Unidad de Bioetica P Recoletos, 14-7 planta 28001 Madrid Spain IRB Chair: Martinez, Jesus Inigo (Secretary) Comite Etico de Investigacion Clinica Fundacion Jimeniz Diaz Avda. Reyes Catolicos, 2 28040 Madrid Spain IRB Chair: N/A	CV
Spain	31020	Fundacion Hospital de Alcorcon Budapest, s/n 28922 Alcorcon (Madrid) Spain	Comite Etico Regional de la Comunidad de Madrid Unidad de Bioteca P Recoletos, 14-7 planta 28001 Madrid Spain IRB Board: Martinez, Jesus Inigo (Secretary) Comite Etico Investigacion Clinica Fundacion Hospital Alcorcon c/Budapest, s/n 28922 Alcorcon (Madrid) Spain IRB Chair: N/A	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Spain	31022	Complejo Universitario de Ourense C/Ramon Puga, 53 32005 Ourense Spain	Comite Etico Regional de la Comunidad de Madrid Unidad de Bioteca P Recoletos, 14-7 planta 28001 Madrid Spain IRB Board: Martinez, Jesus Inigo (Secretary) Comite Etico Investigacion Clinica de Galicia (SERGAS) Division de Farmacia y Productos Sanitarios Conselleria de Sanidade C/ San Lazaro, s/n 15703 Santiago de Compostela Spain IRB Chair: N/A	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Spain	31024	Hospital Universitario Miguel Servet Paseo Isabel La Catolica, 1-3 50009 Zaragoza Spain	Comite Etico Regional de la Comunidad de Madrid Unidad de Bioteca P Recoletos, 14-7 planta 28001 Madrid Spain IRB Board: Martinez, Jesus Inigo (Secretary) Comite Etico de Investigacion Clinica de Aragon Avda. Gomez Laguna, 25; planta 3 50009 Zaragoza Spain IRB Board: N/A	CV
Spain	31025	Hospital Universitario de Salamanca Paseo de San Vicente, 182 37007 Salamanca Spain	Comite Etico Regional de la Comunidad de Madrid Unidad de Bioteca P Recoletos, 14-7 planta 28001 Madrid Spain IRB Board: Martinez, Jesus Inigo (Secretary) Comite Etico de Investigacion Clinica Hospital Universitario de Salamanca Paseo de San Vicente, 182 37007 Salamanca Spain IRB Chair: N/A	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Spain	31026	Hospital General Universitario Gregorio Maranon C/ Dr. Esquerdo, 46 28007 Madrid Spain	Comite Etico Regional de la Comunidad de Madrid Unidad de Bioteca P Recoletos, 14-7 planta 28001 Madrid Spain IRB Board: Martinez, Jesus Inigo (Secretary) Comite Etico de Investigacion Clinica Hospital General Universitario Gregorio Maranon C/ Dr. Esquerdo, 46 28007 Madrid Spain IRB Chair: N/A	CV
Spain	31027	Hospital General de Yague Servicio de Medicina Intensiva Avda. Del Cid 96 s/n 09005 Burgos	Ethic Committee of Clinical Research Regional de Madrid C/ Aduana, 29 3º Planta 28013 Madrid IRB Chair: Martinez, Jesus Inigo	CV
Spain	31028	Hospital General de Segovia Unidad de Cuidados Intensivos Hospital Base Carretera Ávila s/n 40001 Segovia	Ethic Committee of Clinical Research Regional de Madrid C/ Aduana, 29 3º Planta 28013 Madrid IRB Chair: Martinez, Jesus Inigo	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Spain	31029	Hospital Clinico San Carlos Unidad de Cuidados Intensivos Planta 2, Norte C/ Profesor Martin Lagos s/n 28040 Madrid	Ethic Committee of Clinical Research Regional de Madrid C/ Aduana, 29 3º Planta 28013 Madrid IRB Chair: Martinez, Jesus Inigo	CV
Spain	31030	Hospital del Mar Unidad de Cuidados Intensivos Passeif maritim 25-29 08003 Barcelona	Ethic Committee of Clinical Research Regional de Madrid C/ Aduana, 29 3º Planta 28013 Madrid IRB Chair: Martinez, Jesus Inigo	CV
Spain	31031	Hospital U. Marques de Valdecilla Servico de Enfermedades Infecciosas Avda. Valdecilla, 25 39008 Santander	Ethic Committee of Clinical Research Regional de Madrid C/ Aduana, 29 3º Planta 28013 Madrid IRB Chair: Martinez, Jesus Inigo	CV
Thailand	34001	Department of Anesthesiology Faculty of Medicine Siriraj Hospital 2 Prannok Road Bangkoknoi, Bangkok 10700 Thailand	Ethics Committee Faculty of Medicine Siriraj Hospital Mahidol University 2 Prannok Road Bangkoknoi, Bangkok 10700 Thailand IRB Chair: Nimmannit, Sumalee	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Thailand	34002	Department of Medicine Faculty of Medicine, Khon Kaen University 123 Mitraphab Road Muang, Khon Kaen 40002 Thailand	The Khon Kaen University Ethics Committee for Human Research 123 Mitraphab Road, Dean office 6th Floor Faculty of Medicine, Khon Kaen University 123 Mitraphab Road Muang, Khon Kaen 40002 Thailand IRB Chair: Srinakarin, Jiraporn	CV
Thailand	34003	Department of Medicine Rajvithee Hospital Phayathai Road Rajthevee, Bangkok 10400 Thailand	The Ethical Review Committee for Research in Human Subjects Ministry of Public Health Tiwanon Road, Muang Nonthaburi 11000 Thailand IRB Chair: Banchuin, Chatri	CV
Thailand	34005	Pulmonary & Critical Care Unit Department of Internal Medicine, Faculty of Medicine Chiang Mai University Muang, Chiang Mai 50200 Thailand	Research Ethics Committee Faculty of Medicine Chiang Mai University 110 Intavaroros Road Muang, Chiang Mai 50200 Thailand IRB Chair: Klunklin, Kumpol	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Thailand	34006	Department of Medicine, Bamrasnaradura Institute Tiwanon Road, Nonthaburi 11000 Thailand	Institutional Review Board of Bamrasnaradura Infectious Diseases Institute 126 Tiwanon Road Nothaburi 11000 Thailand IRB Chair: Sunthornkachit, Rujanee The Ethical Review Committee for Research in Human Subjects Ministry of Public Health Tiwanon Road, Muang Nonthaburi 11000 Thailand IRB Chair: Banchuin, Chatri	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Ukraine	36000	Kyiv Medical Academy of Post-Graduate Education, Department of Medical Genetics 9, Dorogozhytska Str. 04112, Kyiv Ukraine Institute of Tuberculosis & Pulmonology named after F.G. Yanovsky AMS of Ukraine Department of Asthma & Evidentiary Medicine 10, Amosova Str. 03680, Kyiv Ukraine	Ethics Committee of State Pharmacological Centre of Ministry of Health of Ukraine 7, Grushevsky str. 01021, Kyiv Ukraine IRB Chair: Chumak, V.T.	CV
Ukraine	36001	Kyiv Municipal Clinical Hospital #3 26, Petra Zaporozhtsa str. 02125, Kyiv Ukraine National Medical University, Department of Therapy of Stomatology Faculty 13, T. Shevchenko blvd. 01601, Kyiv Ukraine	Central Ethics Committee of Health Ministry of Ukraine 5, Narodnogo Opolchennya str. Kyiv, 03680 Ukraine IRB Chair: Chumak, V.T.	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Ukraine	36002	Central Military Clinical Hospital of the Ministry of Defense of Ukraine 18 Gospitalna str. 01133, Kyiv Ukraine Institute of Tuberculosis & Pulmonology named after F.G. Yanovsky of AMS of Ukraine, Department of Methods of Treatment of Non-specific Lung Diseases 10, Amosova Str. 03680, Kyiv Ukraine	Central Ethics Committee of Health Ministry of Ukraine 5, Narodnogo Opolchennya str. Kyiv, 03680 Ukraine IRB Chair: Chumak, V.T.	CV
Ukraine	36003	Departmental Clinical Hospital of the South-Western Railway 9, Povitroflotsky Ave., 03049, Kyiv Ukraine National Medical University, Department of Propedeutics of Internal Medicine 13, T. Shevchenko blvd. 01601, Kyiv Ukraine	Central Ethics Committee of Health Ministry of Ukraine 5, Narodnogo Opolchennya str. Kyiv, 03680 Ukraine IRB Chair: Chumak, V.T.	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Ukraine	36004	Donetsk Regional Clinical Hospital 14 llicha Ave. 83099, Donetsk Ukraine Donetsk State Medical University, Department of Internal Diseases #1, 16, Ilicha Ave. 83003, Donetsk Ukraine	Central Ethics Committee of Health Ministry of Ukraine 5, Narodnogo Opolchennya str. Kyiv, 03680 Ukraine IRB Chair: Chumak, V.T.	CV
Ukraine	36005	Institute of Tuberculosis & Pulmonology named after F.G. Yanovsky of AMS of Ukraine Department of Diagnositcs, Therapy & Clinical Pharmacology of Lung Diseases 10, Amosova Str. 03680, Kyiv Ukraine	Ethics Committee of State Pharmacological Centre of Ministry of Health of Ukraine 7, Grushevsky str. 01021, Kyiv Ukraine IRB Chair: Chumak, V.T.	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
Ukraine	36006	Institute of Tuberculosis & Pulmonology named after F.G. Yanovsky of AMS of Ukraine Department of Pulmonology 10, Amosova Str. 03680, Kyiv Ukraine	Central Ethics Committee of Health Ministry of Ukraine 5, Narodnogo Opolchennya str. Kyiv, 03680 Ukraine IRB Chair: Chumak, V.T.	CV
Ukraine	36007	Kyiv City Tuberculosis Hospital #1 Department of Differential Diagnostics of Respiratory Diseases 121/3, Kharkivske shose 02091, Kyiv Ukraine	Central Ethics Committee of Health Ministry of Ukraine 5, Narodnogo Opolchennya str. Kyiv, 03680 Ukraine IRB Chair: Chumak, V.T.	CV
USA	38051	Syracuse VA Medical Center 800 Irving Ave. Syracuse, NY 13210	Human Studies Subcommittee Syracuse VA Medical Center 800 Irving Ave. Syracuse, NY 13210 IRB Chair: Lantinga, Larry J.	CV
USA	38052	University of Alabama at Birmingham 1900 University Blvd. 229 Tinsley Harrison Towers Birmingham, AL 35294-0006	WIRB 3535 Seventh Avenue SW Olympia, WA 98502-5010 Or: PO Box 12029 Olympia, WA 98508-2029 IRB Chair: Schultz, Theodore D.	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
USA	38053	1653 West Congress Parkway Suite 297 Jelke Chicago, IL 60612	Office of Research Affairs Rush University Medical Center 1750 West Congress Parkway PB II Suite 439 Chicago, IL 60612 IRB Chair: Korenblit, Alan	CV
USA	38055	Section Head Critical Care Anesthesiology Department of Anesthesiology Wake Forest University School of Medicine Medical Center Boulevard Winston-Salem, NC 27157-1009	The Institutional Review Board Cheryl C. Byers, Director Wake Forest University Health Sciences Medical Center Boulevard Winston-Salem, NC 27157 IRB Board: Harper, Margaret	CV
USA	38062	The University of Texas Health Center at Tyler 11937 US HWY 271 Tyler, TX 75708	Institutional Review Board The University of Texas Health Center at Tyler 11937 US HWY 271 Tyler, TX 75708 IRB Chair: N/A	CV
USA	38065	Denver Health Medical Center Department of Surgery MC0206 777 Bannock Street Denver, CO 80204	Colorado Multiple Institutional Review Board (COMIRB) 120101 E.Colfax Avenue Rm #2353 Campus Box F-490 Aurora, CO 80045 IRB Chair: Easterday, Kenneth	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
USA	38067	Duke University Medical Center Box 31012 Durham, NC 27710	Duke University Health System IRB 2400 Pratt Street, 9th Floor Box 2991 Durham, NC 27705 IRB Chair: Farmer, Joseph	CV
USA	38069	Lowcountry Infectious Diseases, P.A. 1938 Charlie Hall Blvd. Charleston, SC 29414	Trident Medical Center 9330 Medical Plaza Drive Charleston, SC 29406 IRB Chair: Foster, Rick	CV
USA	38078	One Guthrie Square Sayre, PA 18840	Guthrie Healthcare System Institutional Review Board One Guthrie Square Sayre, PA 18840 IRB Chair: Lee, Ferrol J.	CV
USA	38084	Staten Island University Hospital 475 Seaview Avenue Staten Island, NY 10305	Biomedical Research Alliance of New York, LLC Institutional Review Board 225 Community Drive, Suite 100 Great Neck, NY 11021 IRB Chair: Krasinski, Keith	CV
USA	38085	407 West Fourth Street Rolla, MO 65401	Phelps County Regional Medical Center – IRB 1000 West Tenth Street Rolla, MO 65401 IRB Chair: Landgraf, Chelsea	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
USA	38086	Dedicated Clinical Research 10474 W. Thunderbird Blvd., Suite 200 Sun City, AZ 85351	Sun Health Institutional Review Board 10515 W. Santa Fe Drive Sun City, AZ 85351 IRB Chair: Gurin, Joanne B	CV
USA	38092	Regional Infectious Diseases – Infusion Center 830 West High Street, Suite 255 Lima, OH 45801	Joint IRB of St. Rita's Medical Center and SCCI 730 W. Market Street Lima, OH 45801 IRB Chair: Lehman, Ronda IRB of Lima Memorial Hospital 1001 Bellefontaine Avenue Lima, OH 45804 IRB Chair: N/A	CV
USA	38095	North Florida / South Georgia Veterans Health System 619 South Marion Avenue Building 38, Room 233 Lake City, FL 32025	University of Florida Health Center Institutional Review Board P.O. Box 100173 Gainesville, FL 32610-0173 IRB Chair: Iafrate, Peter R.	CV
USA	38096	Division of Pulmonary & Critical Care Medicine Temple University School of Medicine 3401 North Broad Street Room 777, Parkinson Pavilion Philadelphia, PA 19140	Temple University Institutional Review Board Temple University Health Sciences Center 3400 North Broad Street (509-00) Philadelphia, PA 19140 IRB Chair: Jacobs, Michael	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
USA	38097	Infectious Disease Specialists of Atlanta 2665 North Decatur Road Suite 330 Decatur, Georgia 30033	DeKalb Medical Center IRB 2701 North Decatur Road Decatur, Georgia 30033 IRB Chair: Weissman, Joseph D.	CV
USA	38098	University of California Irvine Medical Center 101 City Drive South Orange, CA 92868	Office of Research Administration University of California, Irvine 300 University Tower Irvine, CA 92697-7600 IRB Chair: UCI does not release membership list	CV
USA	38108	Regional Infectious Diseases Infusion Center 830 West High Street, Suite 255 Lima, OH 45801	Joint IRB of St. Rita's Medical Center and SCCI 730 W. Market Street Lima, OH 45801 IRB Chair: Lehman, Ronda (co-Chair) IRB of Lima Memorial Hospital 1001 Bellefontaine Avenue Lima, OH 45804 IRB Chair: N/A	CV
USA	38111	Department of Infectious Disease St. John's Pavilliion, 1st Floor 301 North Eighth Street Spingfield, IL 62701	Fox Commercial Institutional Review Board 326 North Seventh Street, Ste. 218 Springfield, IL 62701 IRB Chair: Robinson, Kathy	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
USA	38137	The Metro Foundation 500 East Ogden Avenue, Suite C Hinsdale, IL 60521	Our Lady of Resurrection Medical Center Institutional Review Board 5645 West Addison Street Chicago, IL 60634 IRB Chair: Amir-Mokri, Ebrahim	CV
USA	38147	Microbiology Lab 508 Fulton Street Durham, NC 27705	Durham VAMC 508 Fulton Street Durham, NC 27705 IRB Chair: Whited, John D.	CV
USA	38151	Monmouth Medical Center 300 Second Avenue SH 214 Long Branch, NJ 07740	Monmouth Medical Center IRB Department of Medical Affairs 300 Second Avenue Stanley 223 Long Branch, NJ 07740 IRB Chair: Zinterhofer, Louis	CV
USA	38159	Division of Medical Education 101 East Wood Street Spartanburg, SC 29303	SRMC Institutional Review Board 101 East Wood Street Spartanburg, SC 29303 IRB Chair: Mistr, Ernest	CV
USA	38219	Southeastern Lung Care 1380 Milstead Avenue Conyers, GA 30012 NO 1572	WIRB 3535 Seventh Avenue SW Olympia, WA 98502-5010 IRB Chair: Schultz, Theodore D.	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
USA	38220	Nebraska-Western Iowa Health Care System 4101 Woolworth Avenue (111D) Omaha, NE 68105	Research Services Nebraska-Western Iowa Health Care System 4101 Woolworth Avenue (111D) Omaha, NE 68105 IRB Chair: Romberger, Debra	**CV**
USA	38222	Akron General Medical Center 400 Wabash Avenue Akron, OH 44307	Akron General Medical Center Institutional Review Board 400 Wabash Avenue Akron, OH 44307 IRB Chair: Gardner, William G.	CV
USA	38249	Miami Jewish Horne & Hospital for the Aged 5200 NE 2nd Avenue Miami, FL 33137	WIRB 3535 Seventh Avenue SW Olympia, WA 98502-5010 IRB Chair: Schultz, Theodore D.	CV
USA	38252	Brevard Pulmonary Specialist, P.A. 103 Longwood Avenue Rockledge, FL 32955	Wuesthoff Health Systems 110 Longwood Avenue, MS #4 Rockledge, FL 32956-5002 IRB Chair: Sprawls, Duff	CV
USA	38263	Infectious Disease Specialists, PC 500 West Broadway, Suite 370 Missoula, MT 59802	Joint Investigation Review Board 500 West Broadway Missoula, MT 59802 IRB Chair: Tahta, Stephen	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
USA	38313	Memorial Hospital of Rhode Island 111 Brewster Street Pawtucket, RI 02860	Committee for the Use of Human Subjects in Research Memorial Hospital of Rhode Island 111 Brewster Street Pawtucket, RI 02860 IRB Chair: Stefanec, Tihomir	CV
USA	38319	Edward Hospital & Health Services 801 South Washington Street Naperville, IL 60540	Institutional Review Board Edward Hospital & Health Services 801 South Washington Street Naperville, IL 60540 IRB Chair: Jacobsen, Karen	CV
USA	38325	Henry Ford Hospital 2799 W. Grand Blvd., CFP 126 Detroit, MI 48202	Henry Ford Hospital Institutional Review Board 2799 W. Grand Blvd. Detroit, MI 48202 IRB Chair: Roehrs, Timothy	CV
USA	38340	ECMC Department of Surgery 462 Grider Street Buffalo, NY 14215	Health Sciences Institutional Review Board University at Buffalo 150 Parker Hall Buffalo, NY 14214-8004 IRB Chair: Spaulding, Monica B.	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
USA	38341	Maricopa Medical Center 2601 E. Roosevelt Street Phoenix, AZ 85008	Maricopa Integrated Health System Institutional Review Board 2601 E. Roosevelt Street Phoenix, AZ 85008 IRB Chair: Drachman, David	CV
USA	38343	Genesee Lung Associates 1513 South Center Road Burton, MI 48509	Genesys Regional Medical Center Institutional Review Board One Genesys Parkway Grand Blanc, MI 48439 IRB Chair: Vogel, Mark	CV
USA	38346	6932 Williams Rd., Suite 1600 Niagara Falls, NY 14304	WIRB 3535 Seventh Avenue SW Olympia, WA 98502-5010 IRB Chair: Schultz, Theodore D.	CV
USA	38357	200 Medical Center Drive, Suite 2M Hazard, KY 41701	Appalachian Regional Healthcare, Inc. Institutional Review Board System Center – Hazard 100 Airport Gardens Road Hazard, KY 41701 IRB Chair: McGuire, Russ	CV
USA	38358	Gonzalez, J. Mario, MD, PA 6550 Fannin Street, Suite 2317 Houston, TX 77030	The Methodist Hospital Research Institute Institutional Review Board 6565 Fannin Street, STB1-14 Houston, TX 77030 IRB Chair: Miller, Susan	CV

Country	Study Site No.	Investigator	Institutional Review Board/Ethics Committee	Credentials
USA	38409	Erie County Medical Center 462 Grider Street Buffalo, NY 14215	University at Buffalo The State University of New York Health Sciences Institutional Review Board 150 Parker Hall Buffalo, NY 14214-8004 IRB Chair: Spaulding, Monica	CV
USA	38413	Bergan Mercy Medical Building 7710 Mercy Road, Suite 428 Omaha, NE 68124	WIRB 3535 Seventh Avenue SW Olympia, WA 98502-5010 IRB Chair: Schultz, Theodore D.	CV
USA	38417	Internal Medicine Pulmonary & Critical Care Associates, PC 4101 W. Conejos Place, Ste. 200 Denver, CO 80204	St. Anthony Hospitals Institutional Review Board 4231 W.16th Avenue Denver, CO 80204 IRB Chair: Offner, Patrick	CV
USA	38419	Alegent Health Immanuel Medical Center 6901 North 72nd Street Omaha, NE 68122	WIRB 3535 Seventh Avenue SW Olympia, WA 98502-5010 IRB Chair: Schultz, Theodore D.	CV