SPRYCEL

(active substance: dasatinib,
marketing authorisation numbers: EU/1/06/363/001-015)

Study CA 180-035

Submission according to § 42b AMG

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1) SYNOPSIS

A Randomized, Two-arm, Multicenter, Open-label Phase III Study of BMS-354825 Administered Orally at a Dose of 70 mg Twice Daily or 140 mg Once Daily in Subjects with Chronic Myeloid Leukemia in Accelerated Phase or in Myeloid or Lymphoid Blast Phase or with Philadelphia Chromosome Positive Acute Lymphoblastic Leukemia who are Resistant or Intolerant to Imatinib Mesylate

Study Initiation Date: 03-Jun-2005
Study Completion Date: 24-Mar-2008 (LPLV for the primary analysis)
08-Jul-2011 (for Addendum 01)
30-Jun-2013 (for Addendum 02)
Report Date: 14-Oct-2013

STATEMENT ON SIGNIFICANT CHANGES MADE SUBSEQUENTLY TO THE TRIAL PROTOCOL THAT ARE NOT COVERED IN THE REPORT ABOVE -

- **there are no changes that are not covered in the synopsis**

2) LIST OF INVESTIGATIONAL SITES that enrolled patients

Name of Sponsor/Company: Bristol-Myers Squibb	Individual Study Table Referring to the Dossier	*(For National Authority Use Only)*
Name of Finished Product: Sprycel		
Name of Active Ingredient: Dasatinib		

SYNOPSIS

Clinical Study Report for CA180035

TITLE OF STUDY: A Randomized, Two-arm, Multicenter, Open-label Phase III Study of BMS-354825 Administered Orally at a Dose of 70 mg Twice Daily or 140 mg Once Daily in Subjects with Chronic Myeloid Leukemia in Accelerated Phase or in Myeloid or Lymphoid Blast Phase or with Philadelphia Chromosome Positive Acute Lymphoblastic Leukemia who are Resistant or Intolerant to Imatinib Mesylate

INVESTIGATORS/STUDY CENTERS: 129 principal investigators/638 subjects were enrolled at 130 sites (129 unique sites - sites 136 and 137 in South Africa are the same): 65 in Europe (includes Russia), 35 in North America (US and Canada), 9 in South America, 10 in Asia, 6 in Australia, and 5 in South Africa.

PUBLICATIONS:
Kantarjian HM, Ottmann O, Pasquini R, Goh YT, Kim DW, Van Tornout J, et al. Dasatinib (SPRYCEL) 140 mg once daily (QD) vs 70 mg twice daily (BID) in patients (pts) with advanced phase chronic myeloid leukemia (ABP-CML) or Ph(+) ALL who are resistant or intolerant to imatinib (im): results of the CA180035 study. Blood 2006;108:224a (Abstract 746).

STUDY PERIOD: Study Initiation Date: 3-Jun-2005 **CLINICAL PHASE:** 3

Study Completion Date: 24-Mar-2008 (LPLV).

OBJECTIVES: The primary objective of this study was to compare the efficacy of dasatinib when administered to subjects at 140 mg once daily (QD) relative to dasatinib administered at 70 mg twice daily (BID) in overall population.

The main secondary objective was to estimate the difference in major hematologic response (MaHR) rates between treatment groups (QD vs BID) by disease phase and imatinib status. Other secondary objectives were: 1) to estimate the rates of MaHR, overall hematologic response (OHR), and major cytogenetic response (MCyR) by treatment group, disease phase, and imatinib status; 2) to assess time to and duration of MaHR by treatment group, disease phase, and imatinib status; 3) to assess progression-free and overall survival by treatment group, disease phase, and imatinib status; 4) to assess the safety of dasatinib, in particular the incidence of adverse events (AEs), the number of dose reductions, interruptions, and treatment discontinuations for toxicity by treatment group; 5) to collect population pharmacokinetic (PK) data; 6) to describe the spectrum of mutations at baseline and at time of progressive disease; 7) to explore the roles of BCR-ABL mRNA expression and point mutations in the BCR-ABL gene as predictors or surrogates of responses.

METHODOLOGY: This was a randomized 2-arm multicenter, open-label Phase 3 study of dasatinib for subjects with accelerated phase CML, blast phase CML, or Ph+ ALL, either resistant or intolerant to imatinib. Subjects were stratified by disease status (accelerated phase CML, myeloid blast phase CML, and

lymphoid blast phase CML, or Ph+ ALL) and imatinib status (resistant or intolerant). Subjects were randomized within each strata to receive dasatinib at a dose of 70 mg BID or 140 mg QD. Treatment continued until progression of disease or development of intolerable toxicity. All subjects were followed for a minimum of 30 days after the last dose of study therapy or until recovery from all toxic effects. Subsequent follow-up visits were to occur at least every 4 weeks until all study-related toxicities returned to baseline levels (or ≤ Grade 1), stabilized, or were deemed irreversible. Follow-up observations for survival analysis were done every 3 months until subject's death or lost to follow-up.

NUMBER OF SUBJECTS (Planned and Analyzed): A total of 638 subjects were enrolled, 611 were randomized (478 imatinib-resistant and 133 imatinib-intolerant subjects), and 609 received at least 1 dose of dasatinib. Data cutoff date was 05-May-2008.

Number of Treated Subjects by Disease Type and Schedule							
Accelerated N = 316		Myeloid Blast N = 148		Lymphoid Blast N = 61		Ph+ ALL N = 84	
QD N = 157	BID N = 159	QD N = 74	BID N = 74	QD N = 33	BID N = 28	QD N = 40	BID N = 44

DIAGNOSIS AND MAIN CRITERIA FOR INCLUSION: Subjects ≥ 18 years of age with accelerated phase CML, myeloid blast phase CML, lymphoid blast phase CML, or Ph+ ALL and a primary or acquired hematologic resistance to imatinib or intolerance to imatinib were included.

TEST PRODUCT, DOSE AND MODE OF ADMINISTRATION, DURATION OF TREATMENT, BATCH NUMBERS: Dasatinib was administered orally at a starting dose of 140 mg QD or 70 mg BID; treatment was to continue until progression of disease or development of intolerable toxicity or subject's decision to withdraw. Batch numbers were: 20 mg tablets - 4L77202; 5A04130/4M4311Z; 5A04132/4M4312Z; 5A04134/4M4313Z; 5C06213/5C4301Z; 5C06214/5C4302Z; 5E01515/5D4305Z; 5E01517; 5E01519/5D4333Z; 5E01522; 5E01523; 5E01524/5C4330Z; 5E01527/5D4306Z; 5E01529/5C4329Z; 5E01533. 50 mg tablets - 4L77205; 5A10548; 5A10549/5A4307Z; 5A10557/5A4308Z; 5C05064/5B4305Z; 5C05065/5B4307Z; 5C08599/5B4306Z; 5C08601/5B4308Z; 5C08609/5B4310Z; 5H01128/5G4303Z.

REFERENCE THERAPY, DOSE AND MODE OF ADMINISTRATION, DURATION OF TREATMENT, BATCH NUMBERS: Gleevec 400 mg tablets - Batch number was 4M67208.

CRITERIA FOR EVALUATION:

Efficacy: The primary objective was a comparison of efficacy (non-inferiority) between the QD and BID schedules. The primary efficacy endpoint was the rate of MaHR. Secondary endpoints included rates of OHR and MCyR, the difference of MaHR between QD and BID groups, time to and duration of MaHR, progression-free survival and overall survival.**Safety:** Toxic effects were assessed continuously. Assessment of safety was based on medical review of AEs, clinical laboratory tests, and electrocardiograms (ECGs). On-study AEs were graded by severity according to the NCI Common Terminology Criteria for Adverse Events (CTCAE), version 3.0. The investigator AE terms were coded and grouped by preferred term and system organ class using the MedDRA dictionary, version 9.0 and were summarized by any grade, Grade 3 to 4, and Grade 5.

STATISTICAL CONSIDERATIONS:

Demographic and baseline characteristics were tabulated by group (QD vs BID), disease phase, and imatinib status using descriptive statistics. The primary objective of this study was to compare the efficacy

of dasatinib when administered to subjects at 140 mg QD relative to dasatinib administered at 70 mg BID in the overall population. The QD schedule was considered similar (non-inferior) to the BID schedule if the lower bound of the 2-sided 95% asymptotic confidence interval of the difference in major hematologic response rates (MaHRR QD minus MaHRR BID) was ≥ -12%. The main secondary objective was to estimate the difference in MaHR between QD and BID groups by disease phase and imatinib status. Two-sided exact 95% confidence intervals of the differences were provided based on the method proposed by Agresti and Min.

Response rates (MaHR, OHR, and MCyR) were provided by group, disease phase, and imatinib status. Two-sided exact 95% CIs were provided based on the method proposed by Clopper and Pearson. The distribution of the progression-free and overall survival and time to and duration of MaHR and MCyR were estimated using the Kaplan-Meier product limit method. The median of the distribution was provided along with its 95% CI.

All analyses of efficacy were performed using the dosing schedule as randomized. Two sensitivity analyses were performed for the primary objective. The first sensitivity analysis used the method of DerSimonian and Laird, assuming a fixed effects model, which adjusts the estimate of rate of MaHR differences for the stratification factors (imatinib status and disease type) as randomized. Adjusted estimates of rate of MaHR differences and associated 2-sided 95% CI were computed. The second sensitivity analysis was a per-protocol analysis, which provides estimates of the rate of MaHR difference and associated 95% CI for subject's who did not have a significant protocol deviation with the exception of the subjects whose only significant protocol deviation was switch in assigned treatment group (N=5). As a secondary analysis, MaHR and OHR rates and difference between groups of MaHR and OHR rates, were estimated based on the dataset of randomized subjects.

Safety analyses included the frequency of assessment of AEs, serious adverse events (SAEs), deaths, AEs leading to discontinuation, and laboratory abnormalities. Toxicity rates, using the worst CTC Grade per subject, for selected ≥ Grade 3 drug-related AEs (eg, fluid retention, pleural/pericardial effusion, myelosuppression, and dose reduction due to toxicity) were compared between the 2 groups using the Fisher exact test. All analyses were presented for all treated subjects.

SUMMARY OF RESULTS:

Disposition, Demographics, and Other Pertinent Baseline Characteristics:

Of the 638 enrolled subjects, 611 were randomized and 609 received at least 1 dose of dasatinib. Of the 609 treated subjects, 128 subjects remain on study as of 05-May-2008 and 481 discontinued study treatment (243 subjects in the QD group and 238 subjects in the BID group).

The age of the study population ranged from 15 to 84 years with an overall mean age of 52.3 years and a median age of 55.0 years. The 2 groups were balanced for age, gender, and race. Subjects in the 2 groups had the same length of initial CML (58 months median time for both). Subjects were extensively pretreated in both treatment groups.

All randomized subjects in this study had received prior imatinib treatment and were either resistant (N=477) or intolerant (N=132) to imatinib. The majority of imatinib-resistant subjects in the QD and BID groups had acquired resistance (63% and 62%, respectively). A similar number of subjects in the QD group vs the BID group had primary resistance to imatinib (14% and 16%, respectively). The intolerant subjects were equally distributed at baseline between the QD and BID groups (22% and 21%, respectively). A small difference was reported among the 2 groups in hematologic response to imatinib therapy; more subjects in the QD group vs the BID group reported a CCyR (24% vs 22%) and minimal cytogenetic response (11% vs 6%) to imatinib therapy.

Efficacy Results: Efficacy results pooled over all the disease phases demonstrated the non-inferiority of the QD schedule of treatment to the BID schedule. In randomized subjects, hematologic responses were similar between the 2 groups with a MaHR of 51% in the QD group and 50% in the BID group. The difference in

MaHR rate between the QD and BID groups was 0.8% (95% CI: -7.1% - 8.7%). The non-inferiority of the QD schedule to the BID schedule was also supported by two specified sensitivity analyses. In the analysis adjusted by stratification factors, the difference in MaHR rate was 0.7% (95% CI: -6.5% - 8.0%) and in the per-protocol analysis, the difference in MaHR rate was 2.1% (95% CI: -6.1% - 10.2%).

The median time to MaHR was 1.9 months in both groups. Among subjects who achieved a MaHR, the median duration of response was similar in the QD group vs the BID group (21.2 months vs 24.7 months, respectively). Overall, of the 155 subjects with MaHR in the QD group, 73 progressed. In the BID group, 60 of the 152 subjects with MaHR progressed. When evaluated within each disease phase, the number of subjects who progressed was similar between the QD and BID groups in subjects.

Efficacy results pooled over all the disease phases as well as individual disease phase showed little difference between the QD and BID groups in MCyR (42% vs 41%, respectively) with a difference in rate of -0.2% (95% CI: -7.6% - 8.0%). The time to MCyR was 1.9 months in both groups.

Among subjects who achieved a MCyR, the median duration of response was shorter in the QD group vs the BID group (13.1 months vs 22.2 months, respectively). Of the 127 subjects with MCyR in the QD group, 65 progressed. In the BID group, 53 of the 126 subjects with MCyR progressed.

Progression-free survival (PFS) was similar between the 2 treatment groups. The median length of PFS was 7.6 months in the QD group vs 10.4 months in the BID group with a QD/BID hazard ratio of 1.07 (95% CI: 0.88 - 1.32). Assessment of PFS by disease phase showed little difference between the QD and BID groups.

Safety Results:

Of the 609 treated subjects, 321 subjects died. Of the 321 deaths, 126 subjects died within 30 days of last dose of study therapy. The number of deaths reported within 30 days of treatment was similar between the QD and BID groups (QD: 65 subjects and BID: 61 subjects). Nearly half of these deaths were due to disease progression in both the groups (QD: 35 subjects and BID: 25 subjects). A clear difference between the two groups was observed in deaths within 30 days of last dose of study therapy due to cardiovascular disease and infection; 2 subjects in QD group compared to 7 subjects in the BID group died from cardiovascular disease, 11 subjects in the QD group compared to 18 subjects in the BID group died from infection. Death from fatal bleeding was similar between the QD and BID groups with 8 subjects and 6 subjects, respectively.

Adverse events that led to discontinuation of study therapy were similar in the QD group (N=97; 32%) and the BID group (N=95; 31%). Drug-related AEs that led to discontinuation of study therapy were similar in the QD group (N=41; 14%) and the BID group (N=50; 16%). A difference was however noted among the 2 groups in drug-related pleural effusion events that led to discontinuation of study therapy; 6 (2%) subjects in the QD group and 14 (5%) subjects in the BID group.

Specific analyses were performed on fluid retention events as AEs of special interest. Table 1 summaries these AEs by group in all treated subjects pooled across disease phase. Pleural effusion was reported in fewer subjects in the QD group compared with the BID group (24% vs 36%) (p=0.001). In both groups, the majority of pleural effusions were drug-related. The number of subjects with drug-related other fluid-related events (including generalized edema, pulmonary edema, CHF/cardiac dysfunction, and pericardial effusion) was lower in the QD group (5%) compared to BID group (13%).

Table 1: Adverse Events of Special Interest by Relationship Pooled Across Disease Phase; Treated Subjects

	Number (%) of Subjects			
	QD N = 304		BID N = 305	
	Any Relationship	Related	Any Relationship	Related
Fluid Retention	128 (42)	97 (32)	153 (50)	130 (43)
Pleural Effusion	72 (24)	60 (20)	109 (36)	99 (33)
Superficial Edema	77 (25)	46 (15)	79 (26)	57 (19)
Other Fluid Related	25 (8)	15 (5)	59 (19)	41 (13)
CHF/Cardiac Dysfunction	8 (3)	3 (1)	12 (4)	6 (2)
Pulmonary Edema	7 (2)	4 (1)	13 (4)	8 (3)
Pericardial Effusion	6 (2)	5 (2)	22 (7)	17 (6)
Generalized Edema	7 (2)	5 (2)	16 (5)	10 (3)
Pulmonary Hypertension	1 (< 1)	0	5 (2)	4 (1)
Ascites	1 (< 1)	0	4 (1)	3 (1)

CONCLUSIONS:

Efficacy

- Dasatinib was efficacious in both schedules with the QD group displaying non-inferior MaHR rates compared with the BID group. Consistent with the results observed in the overall population, when analyzed by each disease phase (accelerated, myeloid and lymphoid blast phase and Ph+ ALL), the MaHR rates were similar in the two treatment groups
- MaHR and MCyR were durable; median durations were similar in the QD group and the BID group, both in the overall population as well as in individual disease phases

Safety

- Both dose schedules were tolerable in subjects in the overall population. This result was consistently observed in individual disease phases as well
- The QD schedule was associated with fewer dose reductions and interruptions vs the BID schedule
- Fewer subjects in the QD group than in the BID group reported fluid retention-related AEs of all grades, including pleural effusion, pulmonary edema, pericardial effusion, and CHF

Overall

- The 140 mg QD schedule represents the optimal risk/benefit ratio and is the recommended dose in advanced phase CML (accelerated, myeloid and lymphoid blast phase) and Ph+ ALL subjects

DATE OF REPORT: 18-Jul-2008

Name of Sponsor/Company: Bristol-Myers Squibb	Individual Study Table Referring to the Dossier	*(For National Authority Use Only)*
Name of Finished Product: Sprycel		
Name of Active Ingredient: Dasatinib		

SYNOPSIS

Addendum No. 1 Clinical Study Report for Study CA180035

TITLE OF STUDY: A Randomized, Two-arm, Multicenter, Open-label Phase III Study of BMS-354825 Administered Orally at a Dose of 70 mg Twice Daily or 140 mg Once Daily in Subjects with Chronic Myeloid Leukemia in Accelerated Phase or in Myeloid or Lymphoid Blast Phase or with Philadelphia Chromosome Positive Acute Lymphoblastic Leukemia who are Resistant or Intolerant to Imatinib Mesylate

INVESTIGATORS/STUDY CENTERS: 129 principal investigators participated in the study. 638 subjects were enrolled at 130 sites (129 unique sites - sites 136 and 137 in South Africa were the same): 65 in Europe (includes Russia), 35 in North America (United States and Canada), 9 in South America, 10 in Asia, 6 in Australia, and 5 in South Africa.

PUBLICATIONS:

Kantarjian H, Cortes J, Kim DW, et al. Phase 3 study of dasatinib 140 mg once daily versus 70 mg twice daily in patients with chronic myeloid leukemia in accelerated phase resistant or intolerant to imatinib: 15-month median follow-up. Blood. 2009;113:6322-6329.

Lilly MB, Ottmann OG, Shah NP, et al. Dasatinib 140 mg once daily versus 70 mg twice daily in patients with Ph-positive acute lymphoblastic leukemia who failed imatinib: Results from a phase 3 study. Am J Hematol. 2010; 85:164-170.

STUDY PERIOD: Study Initiation Date: 03-Jun-2005 **CLINICAL PHASE:** 3

Data cutoff date for Addendum 01: 08-Jul-2011

INRODUCTION: Previous clinical study reports (CSRs) included analyses with 6 months and 2 years of follow-up in subjects with accelerated phase chronic myeloid leukemia (CML), blast phase CML, or with Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) either resistant or intolerant to imatinib treated with dasatinib on either a once daily (QD) or a twice daily (BID) schedule. The current report presents long-term safety and efficacy results with 5 years of follow-up in subjects treated with dasatinib on either a QD or BID schedule.

OBJECTIVES: The protocol-specified objectives analyzed in this report were to:

- Estimate the rates of hematologic response and major hematologic response (MaHR) by disease phase
- Assess duration of MaHR by dosing group and disease phase
- Assess progression-free survival (PFS) and overall survival (OS) by dosing group and disease phase

- Assess the safety of dasatinib, in particular the incidence of AEs of special interest and treatment discontinuations for toxicity by dosing group
- Describe the spectrum of mutations at baseline and at time of progressive disease

METHODOLOGY: This was a randomized, 2-arm, multicenter, open-label Phase 3 study of dasatinib for subjects with accelerated phase CML, blast phase CML, or with Ph+ ALL either resistant or intolerant to imatinib. Subjects were stratified by disease status (accelerated phase CML, myeloid blast phase CML, and lymphoid blast phase CML, or Ph+ ALL) and imatinib status (resistant or intolerant). Subjects were randomized within each strata to receive dasatinib at a dose of 70-mg BID or 140-mg QD.

Amendment 3 allowed subjects on a BID dosing schedule to switch to a QD dosing schedule.

NUMBER OF SUBJECTS (Planned and Analyzed): 638 subjects were enrolled, 611 were randomized (478 imatinib-resistant and 133 imatinib-intolerant subjects), and 609 received at least 1 dose of dasatinib. Data cutoff for this CSR addendum was 08-Jul-2011.

DIAGNOSIS AND MAIN CRITERIA FOR INCLUSION: Subjects ≥ 18 years of age with accelerated phase CML, blast phase CML (myeloid and lymphoid phase), or Ph+ ALL and a primary or acquired hematologic resistance to imatinib or intolerance to imatinib were included.

TEST PRODUCT, DOSE AND MODE OF ADMINISTRATION, DURATION OF TREATMENT: Dasatinib was administered orally at a starting dose of 140-mg QD or 70-mg BID. Amendment 3 to the protocol allowed subjects on the BID dosing schedule to switch to the QD dosing schedule. Treatment was to continue until progression of disease, development of intolerable toxicity, or subject's decision to withdraw.

REFERENCE THERAPY, DOSE AND MODE OF ADMINISTRATION, DURATION OF TREATMENT, BATCH NUMBERS: Not applicable.

CRITERIA FOR EVALUATION:

Efficacy: The primary objective was a comparison of efficacy (non-inferiority) between the QD and BID groups. Efficacy endpoints included MaHR, PFS, and OS. **Safety:** On-study AEs were graded by severity according to the National Cancer Institute's (NCI) Common Terminology Criteria for Adverse Events (CTCAE), version 3.0.

STATISTICAL CONSIDERATIONS:

In this addendum, hematologic response rates, PFS, OS, and duration of MaHR are provided. The distribution of PFS and OS and the duration of MaHR are estimated using the Kaplan-Meier product limit method. The median of the distribution was provided along with its 95% confidence interval (CI). Sensitivity analyses of PFS and duration of MaHR were performed by censoring subjects whose progression was reported in the follow-up phase of the study at their last on-study assessment date. All analyses of efficacy were performed using the assigned dose schedule at randomization (following the intent-to-treat [ITT] principle). Amendment 3 to the protocol allowed subjects to switch from the BID dosing schedule to the QD dosing schedule; therefore, the results presented in this addendum must be interpreted with caution.

Safety analyses included the frequency of AEs, SAEs, deaths, AEs leading to discontinuation, and laboratory abnormalities. Toxicity rates, using the worst CTCAE grade per subject, for selected AEs of special interest (eg, fluid retention, pleural/pericardial effusion, and myelosuppression) were compared between the 2 dose groups using the Fisher exact test. All analyses were presented for all treated subjects.

SUMMARY OF RESULTS:

Disposition, Demographics, and Other Pertinent Baseline Characteristics:

A total of 638 subjects were enrolled, 611 subjects were randomized, and 609 subjects received treatment. As of the data cutoff, 42/609 (6.9%) treated subjects were still on treatment (Table 1). Demographic and baseline characteristics, as described in the 2-year CSR, are summarized in Table 2.

Table 1: Subject Disposition; Enrolled Subjects by Treatment Schedule

	Enrolled Subjects (N = 638)	
	QD	**BID**
All Randomized, n (%)	306 (100.0)	305 (100.0)
Never Treated, n (%)	1 (0.3)	1 (0.3)
Treated, n (%)	305 (99.7)	304 (99.7)
As Treated	304 (100.0)	305 (100.0)
On Treatment	27 (8.9)	15 (4.9)
Off Treatment	277 (91.1)	290 (95.1)
Adverse event unrelated to study drug	23 (7.6)	22 (7.2)
Disease progression	140 (46.1)	121 (39.7)
Investigator request	7 (2.3)	9 (3.0)
Other	34 (11.2)	48 (15.7)
Study drug toxicity	61 (20.1)	77 (25.2)
Subject request	12 (3.9)	13 (4.3)

Table 2: Demographic and Disease Characteristics; Randomized Subjects

	Randomized Subjects (N = 611)	
	QD (N = 306)	**BID (N = 305)**
Disease, n (%)		
Accelerated Phase CML	158 (51.6)	159 (52.1)
Blast Phase CML		
Myeloid	75 (24.5)	74 (24.3)
Lymphoid	33 (10.8)	28 (9.2)
Ph+ ALL	40 (13.1)	44 (14.4)
Age		
N	306	304
Mean age (SD)	51.7 (14.9)	52.8 (15.2)
Range	16-81	15-84
Gender, n (%)		
Male	173 (56.5)	171 (56.1)
Female	133 (43.5)	134 (43.9)
Race, n (%)		
White	235 (76.8)	236 (77.4)
Black/African American	17 (5.6)	18 (5.9)
Asian	38 (12.4)	38 (12.5)
Other	13 (4.2)	9 (3.0)
Not reported	3 (1.0)	3 (1.0)

Efficacy Results:

All analyses of efficacy were performed using datasets from the as-randomized subject population (ie, following the ITT principle). Among the subjects still on study after the 2-year CSR, 54/57 (94.7%) originally randomized to the QD dose group remained on QD dosing whereas 29/57 (50.9%) subjects originally randomized to the BID dose group had switched to the QD dosing by the last recorded dose. Because switching from the BID to QD dosing schedule was allowed, the results presented in this addendum to the CSR should be interpreted with caution.

The median duration of therapy for the overall population was comparable for the QD (6 months) and BID (6.2 months) groups. With 5 years of follow-up, dasatinib administered as 140-mg QD had a similar efficacy profile as the original approved dose of 70-mg BID, which is consistent with data previously reported with 6 months and 2 years of follow-up. The MaHR (complete hematologic response [CHR] or no evidence for leukemia [NEL]) for the overall population was 51% for the QD group and 50% for the BID group, which was unchanged from the 2-year CSR. Among subjects achieving a MaHR, 64% in the QD group and 58% in the BID group progressed. The median duration of response remained unchanged from the previous 2-year CSR at 21.1 months (95% CI: 14,4 - 30.7) in the QD group and 24.7 months (95% CI: 19.5 - 35.6) in the BID group. The estimated 5-year MaHR rates in the QD and BID groups for the overall population were 32.4% and 26.3%, respectively.

The median PFS for the overall population was 7.8 months in the QD group and 10.4 months in the BID group with a QD/BID hazard ratio of 1.04 (95% CI of 0.87-1.25). With 5 years of follow-up, 77% in the 140-mg QD group and 71% in the 70-mg BID group progressed. The estimated 5-year PFS rates were also similar in the QD and BID groups for the overall population (16.9% vs 15.9%, respectively). The reasons for progression in the overall population remain similar between the 2 treatment groups.

The median length of OS for the overall population was 17.7 months and 22.4 months in the QD and BID groups, respectively. The QD/BID hazard ratio was 1.17 (95% CI: 0.96-1.43) with the CI crossing the reference point indicating a lack of a measurable difference. This lack of measurable difference was also noted in all the disease subsets with 5 years of follow-up. The estimated 5-year OS rates in the QD and BID groups for the overall population were 28.8% and 36.1%, respectively.

As of the data cutoff date, 42 subjects continued on therapy.

Safety Results:

The safety profile for the overall population was similar between the 140-mg QD group and the 70-mg BID group; however, as previously reported at the time of the 2-year CSR, fluid retention AEs continued to occur at a lower frequency in the 140-mg QD group compared with the 70-mg BID group.

With 5 years of follow-up, 384 (63%) subjects died. The most common cause of death in both dose groups was disease progression: 119/304 (39.1%) subjects in the QD group and 102/305 (33.4%) subjects in the BID group. Drug-related SAEs were reported in 134/304 (44.1%) subjects in the QD group and in 144/305 (47.2%) subjects in the BID group. An identical number of subjects (114) in each dose group reported severe (grade 3 to grade 5) drug-related SAEs (QD: 37.5% and BID: 37.4%).

Drug-related AEs leading to discontinuation were reported in 58/304 (19.1%) subjects in the QD group and in 67/305 (22%) subjects in the BID group. Fewer events of pleural effusion led to subject discontinuations in the QD group (N=15, 4.9%) than in the BID group (N=25, 8.2%).

As previously reported, fluid-retention related AEs were monitored safety events of special interest. Table 3 summarizes these AEs by group in all treated subjects pooled across disease phase. With 5 years of follow-up, the majority of pleural effusions were drug-related. Drug-related pleural effusion (any grade) was reported in fewer subjects in the QD group compared with the BID group (24% vs 36%). The difference in the rate of pleural effusions between the 2 groups remained statistically significant (P=0.003) in favor of the 140-mg QD dose group. The number of subjects with other types of fluid retention AEs (any grade and including generalized edema, pulmonary edema, CHF/cardiac dysfunction, pericardial effusion,

pulmonary hypertension, and ascites) was greater in the BID group (14%) compared with the QD group (6%).

Table 3: Drug-related Fluid Retention AEs of Special Interest, Any Grade, by CSR Period Pooled Across Disease Phase; Treated Subjects

	Number of Subjects (%)	
	QD N=304	**BID N=305**
Fluid Retention	107 (35)	137 (45)
Pleural Effusion	72 (24)	110 (36)
Superficial Edema	47 (16)	61 (20)
Other Fluid Related	18 (6)	43 (14)
CHF/Cardiac Dysfunction	3 (1)	5 (2)
Pulmonary Edema	4 (1)	8 (3)
Pericardial Effusion	6 (2)	17 (6)
Generalized Edema	6 (2)	12 (4)
Pulmonary Hypertension	1 (<1)	5 (2)
Ascites	0	4 (1)

CONCLUSIONS:

Exposure

- Among the subjects receiving treatment after 2 years, the majority continued on a QD dosing schedule with a large proportion of subjects on the BID schedule switching to QD

Efficacy

- Dasatinib was efficacious in both schedules with the QD group continuing to demonstrate non-inferiority based on MaHR rates. The MaHR rates remained unchanged from the prior 2-year CSR. Consistent with the results observed in the overall population and when analyzed by each disease phase, the MaHR rates were similar in the QD and BID groups
- MaHR remained durable with median durations similar in the QD and BID groups in both the overall population as well as in the individual disease phases
- The median PFS and OS in the QD group remained non-inferior to the BID group based on associated hazard rations for the overall population as well as the different disease phases
- Estimated 5-year PFS rates were similar in the QD and BID groups for the overall population (16.9% and 15.9%, respectively). Estimated 5-year OS rates in the QD and BID groups for the overall population were 28.8% and 36.1%, respectively
- Three mutations were observed to have persisted or developed in subjects who discontinued dasatinib for loss of response: V299L, T315I, and F317L

Safety

- With 5 years of follow-up, the number of subjects in the QD group with fluid retention AEs (all grades) continued to be lower compared with the BID group. The difference in the rate of pleural effusion between the 2 groups remains statistically significant (P=0.003) in favor of the QD dose group

Overall

- After 5 years of follow-up, dasatinib, administered as 140-mg QD continues to be associated with a non-inferior efficacy profile and an improved safety profile when compared with dasatinib administered at the original approved dose of 70-mg BID

DATE OF REPORT: 20-Dec-2011

SYNOPSIS

Addendum 02 Clinical Study Report for Study CA180035

TITLE OF STUDY: A Randomized, Two-Arm, Multicenter, Open-label Phase III Study of BMS-354825 Administered Orally at a Dose of 70 mg Twice Daily or 140 mg Once Daily in Subjects with Chronic Myeloid Leukemia in Accelerated Phase or in Myeloid or Lymphoid Blast Phase or with Philadelphia Chromosome Positive Acute Lymphoblastic Leukemia who are Resistant or Intolerant to Imatinib Mesylate

PURPOSE: CA180035 was a randomized study designed to compare the efficacy of dasatinib when administered at 140 mg once daily (QD) relative to dasatinib administered at 70 mg twice daily (BID) in imatinib resistant or intolerant subjects with accelerated phase chronic myelogenous leukemia (CML), blast phase CML (myeloid and lymphoid), or Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL).

Previous clinical study reports (CSRs) included efficacy and safety analyses with 6 months, 2 years, and 5 years of follow-up data. At the time of the 5-year data cutoff, 42 (7%) subjects were still on-treatment.

After the 5-year data cutoff, the duration of the study was extended for 2 additional years (7 years total) for subjects who continued to have clinical benefit and no feasible alternate access to dasatinib, but the requirement to follow patients for survival and to collect other efficacy data was removed from the protocol for the remainder of the study. During the additional 2 years, safety data continued to be collected for as much as up to 7 years of study treatment at which time the study was closed.

The purpose of this Addendum 02 CSR is to provide a final and cumulative safety summary of all subjects who had received at least 1 dose of study treatment up to 7 years, including long-term safety results for the subjects remaining on-treatment after the 5-year data cutoff. Data presented in this CSR synopsis report are not intended to evaluate effectiveness for the proposed indications.

NUMBER OF SUBJECTS: 638 subjects were enrolled, 611 were randomized (478 imatinib-resistant and 133 imatinib-intolerant subjects), and 609 received at least 1 dose of dasatinib.

DISPOSITION, DEMOGRAPHICS AND OTHER PERTINENT BASELINE CHARACTERISTICS:

As of the end-of-study visit (30-Jun-2013), no subjects remain on study treatment (Table 1). Demographic and baseline characteristics are summarized in Table 2.

Table 1: Subject Disposition; Enrolled Subjects by Treatment Schedule

	Enrolled Subjects (N = 638)	
	QD	**BID**
All Randomized, n (%)	306 (100.0)	305 (100.0)
Never Treated, n (%)	1 (0.3)	1 (0.3)
Treated, n (%)	305 (99.7)	304 (99.7)
As Treated[a]	304 (100.0)	305 (100.0)
On Treatment	0	1 (0.3)[b]
Off Treatment	304 (100.0)	304 (99.7)
Adverse event unrelated to study drug	23 (7.6)	22 (7.2)
Disease progression	141 (46.4)	122 (40.0)
Investigator request	8 (2.6)	9 (3.0)
Other	59 (19.4)	58 (19.0)
Study drug toxicity	62 (20.4)	80 (26.2)
Subject request	11 (3.6)	13 (4.3)

[a] One subject (CA180035-76-35152) randomized to the QD group received BID instead of the QD at the start of the study in error; therefore, the number of subjects off treatment are based on the number of subjects as treated.

[b] As of 30-Jun-2013, no subjects remain on study treatment. One subject (CA180035-140 35061) in the BID group was recorded in error as being on-treatment because the end-of-study case report form (CRF) was lost when the site withdrew from study participation; the date of last dose recorded for this subject was 29-Mar-2008.

Table 2: Baseline Demographic and Disease Characteristics; Randomized Subjects

	Randomized Subjects (N = 611)	
	QD (N = 306)	**BID (N = 305)**
Disease, n (%)		
Accelerated Phase CML	158 (51.6)	159 (52.1)
Blast Phase CML		
Myeloid	75 (24.5)	74 (24.3)
Lymphoid	33 (10.8)	28 (9.2)
Ph+ ALL	40 (13.1)	44 (14.4)
Age		
N	306	304
Mean age (SD)	51.7 (14.9)	52.8 (15.2)
Range	16-81	15-84
Gender, n (%)		
Male	173 (56.5)	171 (56.1)
Female	133 (43.5)	134 (43.9)
Race, n (%)		
White	235 (76.8)	236 (77.4)
Black/African American	17 (5.6)	18 (5.9)
Asian	38 (12.4)	38 (12.5)
Other	13 (4.2)	9 (3.0)
Not reported	3 (1.0)	3 (1.0)

SUMMARY OF SAFETY RESULTS:

The safety profile for the overall population was similar between the 140-mg QD group and the 70-mg BID group; however, as previously reported, fluid retention adverse events (AEs) continued to occur at a lower frequency in the 140-mg QD group compared with the 70-mg BID group (Table 3).

Table 3: Summary of Safety; Treated Subjects

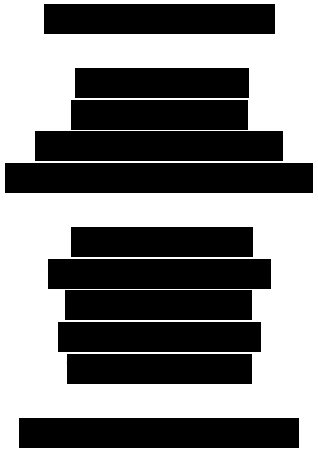
	Number of Subjects (%)	
	QD N=304	**BID N=305**
Deaths	203 (66.8)	186 (61.0)
All AEs	299 (98.4)	303 (99.3)
All SAEs	228 (75.0)	236 (77.4)
AEs Leading to Discontinuation	118 (38.8)	114 (37.4)
Drug-related Fluid Retention	109 (35.9)	137 (44.9)
Pleural Effusion	72 (23.7)	110 (36.1)
Superficial Edema	47 (15.5)	61 (20.0)
Other Fluid Related	21 (6.9)	44 (14.4)
CHF/Cardiac Dysfunction	4 (1.3)	5 (1.6)
Pulmonary Edema	4 (1.3)	8 (2.6)
Pericardial Effusion	6 (2.0)	17 (5.6)
Generalized Edema	6 (2.0)	12 (3.9)
Pulmonary Hypertension	3 (1.0)	6 (2.0)
Ascites	0	4 (1.3)

CONCLUSIONS:

The safety results for subjects treated with dasatinib for up to 7 years were consistent with the known safety profile of dasatinib. These results show that dasatinib is safe and tolerable with long-term exposure.

- With up to 7 years of treatment, the number of subjects in the QD group with fluid retention related-AEs (all grades) continued to be lower compared with the BID group. The difference in the rate of pleural effusion between the 2 groups remains statistically significant (P=0.003) in favor of the QD dose group.
- Among the 42 subjects continuing treatment after the 5-year follow-up, no new safety signals were identified.
- With up to 7 years of study duration, dasatinib, administered as 140-mg QD continues to be associated with an improved safety profile when compared with dasatinib administered at the original approved dose of 70-mg BID.

DATE OF REPORT: 14-Oct-2013

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
001	[redacted]	The Univ. Of Texas - MD Anderson Cancer Ctr. (Office) Dept. Of Leukemia, Room Fc4.2026 1515 Holcombe Blvd., Unit 428 Houston, TX 77030 United States Of America The Univ. Of Texas - MD Anderson Cancer Ctr. (Prev. Office) 1515 Holcombe Blvd. Box 428 Houston, TX 77030-4009 United States Of America Univ. Of Texas Md Anderson Cancer Ctr. (Prev. Office) 1515 Holcombe Blvd Houston, TX 77030-4009 United States Of America The Univ. Of Texas - MD Anderson Cancer Ctr. (Pt. Treat.) 1515 Holcombe Blvd. / 1400 Holcombe Blvd. Houston, TX 77030-4009 United States Of America		36

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
	[redacted]	The Univ. Of Texas - MD Anderson Cancer Ctr. (Prev. Pt. Treat.) 1515 Holcombe Blvd. Houston, TX 77030-4009 United States Of America Univ. Of Texas Md Anderson Cancer Ctr. (Prev. Pt. Treat.) 1515 Holcombe Blvd Houston, TX 77030-4009 United States Of America		
002	[redacted]	Ucla Dept. Of Med. (Office) Division Of Hematology/Oncology 10833 Le Conte Ave., 42-121 Chs Los Angeles, CA 90095 United States Of America Ucla School Of Med. (Prev. Office) 11-934 Factor Bldg. Los Angeles, CA 90095 United States Of America Paquette, Ronald (Prev. Office) 42-121 Chs Bldg. 10833 Le Conte Ave Los Angeles, CA 90095 United States Of America	[redacted]	11

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
	[redacted]	Paquette, Ronald (Prev. Office) 42-121 Chs Bldg. Los Angeles, CA 90095 United States Of America Ucla Oncology Clin. (Pt. Treat.) 200 Med. Plaza Ste. 120 Los Angeles, CA 90095 United States Of America Ucla Ronald Reagan Med. Ctr. (Pt. Treat.) 757 Westwood Plaza Los Angeles, CA 90095 United States Of America Ucla Med. Ctr. (Prev. Pt. Treat.) Bowyer Oncology Ctr. 200 Med. Plaza Ste. 120 Los Angeles, CA 90095 United States Of America Drug Shipment: (Prev. Pt. Treat.) Investigational Pharmacist Drug Information Services 650 Charles E. Young Dr. Los Angeles, CA 90095 United States Of America		

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
	[redacted]	Ucla Med. Ctr. (Prev. Pt. Treat.) Oncology Ctr. 200 Med. Plaza Ste. 120 Los Angeles, CA 90095 United States Of America Drug Shipment: (Prev. Pt. Treat.) Drug Information Services William Reeve 650 Charles E. Young Dr. Los Angeles, CA 90095 United States Of America Drug Shipment: (Prev. Pt. Treat.) Ki-Jung Sung-Thay Drug Information Services 650 Charles E. Young Dr. Los Angeles, CA 90095 United States Of America For Supplies: (Prev. Pt. Treat.) 924 Westwood Blvd Ste. 200 Attention: Lynn Tihopu Los Angeles, CA 90024 United States Of America		

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
	[redacted]	Ucla Dept. Of Med. (Prev. Pt. Treat.) Clin. Res. Ctr. 27-066 Chs 650 Charles E. Young Dr. Los Angeles, CA 90095 United States Of America Drug Shipment: (Prev. Pt. Treat.) Ronald Reagan Ucla Med. 662 Gayley Ave. Room B504a Los Angeles, CA 90095 United States Of America		
005	[redacted]	Washington Univ. School Of Med. (Office) Division Of Bone Marrow Transplantation & Leukemia 660 South Euclid Ave., Box 8007 St. Louis, MO 63110-1093 United States Of America Washington Univ. School Of Med. (Pt. Treat.) Division Of Bone Marrow Transplantation & Leukemia 660 South Euclid Ave., Box 8007 St. Louis, MO 63110-1093 United States Of America	[redacted]	13

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
	[redacted]	Barnes Jewish Hosp. (Pt. Treat.) South Campus One Barnes-Jewish Hosp. Plaza St. Louis, MO 63110-1094 United States Of America Washington Univ. School Of Med. (Pt. Treat.) Siteman Cancer Ctr 7th Fl Ctr For Advanced Med. 4921 Parkview Place St. Louis, MO 63110 United States Of America Barnes Jewish Hosp. (Pt. Treat.) North Campus 216 S. Kingshighway St. Louis, MO 63110 United States Of America		
006	[redacted]	Oregon Health & Science Univ. (Office) 3181 Sw Sam Jackson Park Rd Dept Of Hem/Med Onc L592 Portland, OR 97239 United States Of America	[redacted]	5

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
	[redacted]	Oregon Health & Science Univ. (Prev. Office) 3181 Sw Sam Jackson Park Rd Dept Of Hem/Med Onc 1592 Portland, OR 97239 United States Of America Oregon Health & Science Univ. (Pt. Treat.) 3181 Sw Sam Jackson Park Rd Portland, OR 97239-3098 United States Of America		
007	[redacted]	Emory Univ. School Of Med. (Office) Winship Cancer Inst. 1365 Clifton Road Ne Hem/Onc, Med, Pharmacology And Otolaryngology Atlanta, GA 30322 United States Of America Emory Univ. Hosp. (Pt. Treat.) 1364 Clifton Rd, Ne Atlanta, GA 30322 United States Of America The Emory Clin. (Pt. Treat.) 1365 Clifton Rd, Ne Atlanta, GA 30322 United States Of America	[redacted]	12

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
	[redacted]	Winship Cancer Inst. (Pt. Treat.) 1365c Clifton Road, Ne Atlanta, GA 30322 United States Of America Emory Univ. Hosp. (Pt. Treat.) Drug Shipment Address Investigational Pharmacy Room F506 1364 Clifton Road Ne Atlanta, GA 30322 United States Of America		
008	[redacted]	Seattle Cancer Care Alliance (Office) Fred Hutchinson Cancer Ctr 825 Eastlake Ave. East Mailstop G6-800 Seattle, WA 98109 United States Of America Seattle Cancer Care Alliance (Pt. Treat.) 825 Eastlake Ave. East Seattle, WA 98109 United States Of America Univ. Of Washington Hosp. (Pt. Treat.) 1959 Ne Pacific St. Seattle, WA 98195 United States Of America	[redacted]	6

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
009	[redacted]	Wayne State Univ. (Office) Barbara Ann Karmanos Cancer Inst. 4100 John R Hudson-Webber Cancer Res. Ctr. - 4th Flr. Detroit, MI 48201 United States Of America Barbara Ann Karmanos Cancer Inst. (Pt. Treat.) Wertz Clin. Cancer Ctr. 4100 John R. Detroit, MI 48201 United States Of America Barbara Ann Karmanos Cancer Inst. (Pt. Treat.) Weisberg Cancer Treat. Ctr. 31995 Northwestern Highway Farmington Hills, MI 48334 United States Of America	[redacted]	3
010	[redacted]	New York Presbyterian Hosp. (Office) Weill Med. College Of Cornell Univ. 520 East 70th St., Starr 341 New York, NY 10021 United States Of America	[redacted]	11

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
010	[redacted]	New York Presbyterian Hosp. (Prev. Office) Weill Med. College Of Cornell Univ. 520 East 70th St., Starr 3 New York, NY 10021 United States Of America New York Presbyterian Hosp. (Pt. Treat.) 520 East 70th St. New York, NY 10021 United States Of America New York Presbyterian Hosp. (Pt. Treat.) 525 East 68th St. New York, NY 10021 United States Of America		
011	[redacted]	Dana-Farber Cancer Inst. (Office) 44 Binney St. Boston, MA 02115 United States Of America Dana-Farber Cancer Inst. (Prev. Office) 44 Binney St. Room D-840 Boston, MA 02115 United States Of America	[redacted]	5

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
	[redacted]	Dana-Farber Cancer Inst. (Pt. Treat.) 44 Binney St. Boston, MA 02115 United States Of America Brigham & Women'S Hosp. (Pt. Treat.) 75 Francis St. Boston, MA 02115 United States Of America Massachusetts General Hosp. (Pt. Treat.) 55 Fruit St. Boston, MA 02114 United States Of America Beth Israel Deaconess Med. Ctr. (Pt. Treat.) One Deaconess Road Boston, MA 02215 United States Of America	[redacted]	

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
013	[redacted]	Istituto Di Ematologia Seragnoli (Office) Policlinico Sant'Orsola Malpighi Via Massarenti 9 Bologna 40138 Italy Universita' Di Bologna (Prev. Office) Istituto Di Ematologia Lorenzo E Ariosto Seragnoli Ospedale S.Orsola Via Massarenti 9 Bologna 40138 Italy Istituto Di Ematologia Seragnoli (Pt. Treat.) Policlinico Sant'Orsola Malpighi Via Massarenti 9 Bologna 40138 Italy Universita' Di Bologna (Prev. Pt. Treat.) Istituto Di Ematologia Lorenzo E Ariosto Seragnoli Ospedale S.Orsola Via Massarenti 9 Bologna 40138 Italy	[redacted]	7

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
014	[redacted]	Ospedale S.Eugenio (Office) Divisione Di Ematologia A Malattie Del Ricambio Piazzale Dell'Umanesimo 10 Roma 00144 Italy Ospedale S.Eugenio (Prev. Office) Dipartimento Di Ematologia Piazzale Dell'Umanesimo 10 Roma 00144 Italy Ospedale S.Eugenio (Pt. Treat.) Divisione Di Ematologia A Malattie Del Ricambio Piazzale Dell'Umanesimo 10 Roma 00144 Italy Ospedale S.Eugenio (Prev. Pt. Treat.) Dipartimento Di Ematologia Piazzale Dell'Umanesimo 10 Roma 00144 Italy	[redacted]	5

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
015	[redacted]	Azienda Ospedaliera S.Luigi Gonzaga (Office) Dipartimento Di Medicina Interna Ii Ed Ematologia Regione Gonzole, 10 Orbassano (To) 10043 Italy Azienda Ospedaliera S. Luigi (Prev. Office) Dipartimento Di Medicina Interna Ii Ed Ematologia Regione Gonzole, 10 Orbassano (To) 10043 Italy Azienda Ospedaliera S.Luigi Gonzaga (Pt. Treat.) Dipartimento Di Medicina Interna Ii Ed Ematologia Regione Gonzole, 10 Orbassano (To) 10043 Italy Azienda Ospedaliera S. Luigi (Prev. Pt. Treat.) Dipartimento Di Medicina Interna Ii Ed Ematologia Regione Gonzole, 10 Orbassano (To) 10043 Italy	[redacted]	6

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
017	[redacted]	Univ. Of Maryland (Office) Greenebaum Cancer Ctr. 22 South Greene St. Baltimore, MD 21201-1595 United States Of America Univ. Of Maryland (Pt. Treat.) Greenebaum Cancer Ctr. 22 South Greene St. Baltimore, MD 21201 United States Of America	[redacted]	1
018	[redacted]	Uppsala Univ. Hosp. (Office) Dept Of Hematology Uppsala 751 85 Sweden Uppsala Univ. Hosp. (Pt. Treat.) Dept Of Hematology Uppsala 751 85 Sweden	[redacted]	2
019	[redacted]	Universitaetsklinikum Eppendorf (Office) Onkologisches Zentrum Studienzenentrale Der Med Klinik Ii Gebaude O28, 2. Stock Martinistr. 52 Hamburg 20246 Germany	[redacted]	9

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
	[redacted]	Universitaetsklinikum Hamburg-Eppendorf (Prev. Office) Medizinische Klinik Ii Onkologie Und Haematologie Martinistrasse 52 Hamburg 20246 Germany Universitaetsklinikum Eppendorf (Pt. Treat.) Onkologisches Zentrum Studienzenentrale Der Med Klinik Ii Gebaude O28, 2. Stock Martinistr. 52 Hamburg 20246 Germany Universitaetsklinikum Hamburg-Eppendorf (Prev. Pt. Treat.) Medizinische Klinik Ii Onkologie Und Haematologie Martinistrasse 52 Hamburg 20246 Germany		
020	[redacted]	Klinikum D. Joh.-Gutenb.-Uni (Office) Med. Klinik Und Poliklinik Langenbeckstr. 1 Mainz 55131 Germany Klinikum D. Joh.-Gutenb.-Uni (Pt. Treat.) Med. Klinik Und Poliklinik Langenbeckstr. 1 Mainz 55131 Germany	[redacted]	4

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
021	[redacted]	Johann Wolfgang Goethe Universitaet (Office) Theodor-Stern-Kai 7 Frankfurt 60590 Germany Johann Wolfgang Goethe Universitaet (Prev. Office) Theodor-Stern-Kai 7 Frankfurt/Main 60590 Germany Johann Wolfgang Goethe Universitaet (Pt. Treat.) Theodor-Stern-Kai 7 Frankfurt 60590 Germany	[redacted]	24
	[redacted]	Johann Wolfgang Goethe Universitaet (Prev. Pt. Treat.) Ambulanz F. Molekulare Therapien Haus 33, Eingang B, 1 Og Theodor-Stern-Kai 7 Frankfurt/Main 60590 Germany		

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
022	[redacted]	Fakultaet F.Klin.Med. Mannheim (Office) Theodor-Kutzer-Ufer 1-3 Mannheim 68163 Germany Fakultaet F.Klin.Med. Mannheim (Pt. Treat.) Studienzentrale,Iii.Med.Klinik Wiesbadenerstr. 7-11 Mannheim 68163 Germany	[redacted]	11
023	[redacted]	The Univ. Of Chicago (Office) 5841 S. Maryland Ave., Mc 2115 Chicago, IL 60637 United States Of America Univ. Of Chicago (Prev. Office) 5841 S. Maryland Ave., Mc 2115 Chicago, IL 60637 United States Of America	[redacted]	4

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
	[redacted]	The Univ. Of Chicago Hosp. (Pt. Treat.) Section Of Hematology/Oncology 5841 South Maryland Ave Chicago, IL 60637 United States Of America Univ. Of Chicago (Prev. Pt. Treat.) 5841 S. Maryland Chicago, IL 60637 United States Of America	[redacted]	

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
024	[redacted]	The Sarah Cannon Res. Inst. (Office) 250 25th Ave N Ste. 110 Nashville, TN 37203 United States Of America Tennessee Oncology, Pllc (Pt. Treat.) 250 25th Ave. N. Ste. 100 Nashville, TN 37203 United States Of America Tennessee Oncology, Pllc (Pt. Treat.) 300 20th Ave. N. Ste. 301 Nashville, TN 37203 United States Of America Tennessee Oncology, Pllc (Pt. Treat.) 509 E. Bell St., Ste. 224 Murfreesboro, TN 37130 United States Of America Tennessee Oncology, Pllc (Pt. Treat.) 397 Wallace Road Bldg. C, Ste. 201 Nashville, TN 37211 United States Of America	[redacted]	2

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
	[redacted]	Tennessee Oncology, Pllc (Pt. Treat.) 300 Steam Plant Rd., Ste. 230 Gallatin, TN 37066 United States Of America Tennessee Oncology, Pllc (Pt. Treat.) 4230 Harding Road Ste. 707 Nashville, TN 37205 United States Of America Tennessee Oncology, Pllc (Pt. Treat.) 300 Stone Crest Blvd., Ste. 400 Smyrna, TN 37167 United States Of America Tennessee Oncology, Pllc (Pt. Treat.) 5653 Frist Blvd., Ste. 434 Hermitage, TN 37076 United States Of America The Sarah Cannon Res. Inst. (Pt. Treat.) 250 25th Ave. North Ste. 110 Nashville, TN 37203 United States Of America	[redacted]	

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
	[redacted]	Tennessee Oncology, Pllc (Pt. Treat.) 115 Winwood Dr., Ste. 205 Lebanon, TN 37087 United States Of America Tennessee Oncology, Pllc (Pt. Treat.) 100 Covey Dr. Ste. 111 Franklin, TN 37067 United States Of America Tennessee Oncology, Pllc (Pt. Treat.) 3443 Dickerson Rd., Ste. 760 Nashville, TN 37207 United States Of America Tennessee Oncology, Pllc (Prev. Pt. Treat.) 4230 Harding Rd., Ste. 523 Nashville, TN 37205 United States Of America Tennessee Oncology, Pllc (Prev. Pt. Treat.) 1411 Baddour Pkwy. Lebanon, TN 37087 United States Of America		

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
	[redacted]	Tennessee Oncology, Pllc (Prev. Pt. Treat.) 1805 N. Jackson, Ste. 12 Tullahoma, TN 37388 United States Of America Tennessee Oncology, Pllc (Prev. Pt. Treat.) 201 Uffleman Dr., Ste. A Clarksville, TN 37043 United States Of America The Sarah Cannon Res. Inst. (Prev. Pt. Treat.) (Drug Shipment Address) 250 25th Ave. N. Ste. 110 Nashville, TN 37203 United States Of America Tennessee Oncology, Pllc (Prev. Pt. Treat.) (Drug Shipment Address) 250 25th Ave. N Ste. 110 Nashville, TN 37203 United States Of America		

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
	[redacted]	Tennessee Oncology, Pllc (Prev. Pt. Treat.) 397 Wallace Rd., Ste. 201 Nashville, TN 37211 United States Of America Tennessee Oncology, Pllc (Prev. Pt. Treat.) 1750 Cedar Lane, Ste. 200 Tullahoma, TN 37388 United States Of America Tennessee Oncology, Pllc (Prev. Pt. Treat.) 397 Wallace Rd Ste. C-201 Nashville, TN 37211 United States Of America		
026	[redacted]	Edgardo Rebagliati National Hosp. (Office) Rebagliati Ave. 490 8th Flr. Jesus Maria, Lima 11 Peru Hosp. Nacional Edgardo Rebagliati Martins (Prev. Office) Hematologia 8a Av Edgardo Rebagliati 490 Lima, Lima LIMA 11 Peru	[redacted]	4

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
	[redacted]	Edgardo Rebagliati National Hosp. (Pt. Treat.) Rebagliati Ave. 490 Jesus Maria, Lima 11 Peru Hosp. Nacional Edgardo Rebagliati Martins (Prev. Pt. Treat.) Hematologia 8a Av Edgardo Rebagliati 490 Lima, Lima LIMA 11 Peru		
027	[redacted]	Hosp. Britanico (Office) Perdriel 74 Capital Federal, Buenos Aires 1280 Argentina Hosp. Britanico (Pt. Treat.) Perdriel 74 Capital Federal, Buenos Aires 1280 Argentina	[redacted]	10
029	[redacted]	Hosp. Privado Centro Médico De Córdoba (Office) Naciones Unidas 346 Córdoba, Cordoba 5016 Argentina	[redacted]	0

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
	[redacted]	Hosp. Privado Centro Médico De Córdoba (Pt. Treat.) Naciones Unidas 346 Córdoba, Cordoba 5016 Argentina		
030	[redacted]	Gordon And Leslie Diamond Health Care Centre (Office) Vancouver General Hosp. Hematology Administration Room 10149, 10th Flr. - 2775 Laurel St. Vancouver, BC V5Z 1M9 Canada Vancouver General Hosp. (Prev. Office) Dept Of Med/Div Of Hem 910 West 10th Ave., Room 3300 Vancouver, BC V5Z 4E3 Canada Gordon And Leslie Diamond Health Care Centre (Prev. Office) Hematology Administration Room 10149, 10th Flr. - 2775 Laurel St. Vancouver, BC V5Z 1M9 Canada	[redacted]	3

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
	[redacted]	Vancouver General Hosp. (Pt. Treat.) Centennial Pavilion, 6th Flr. 855 West 12th Ave. Vancouver, BC V5Z 1M9 Canada Vancouver General Hosp. (Pt. Treat.) Dept. Of Med. Division Of Hematology 910 West 10th Ave. Vancouver, BC V5Z 4E3 Canada Lancaster Med. Supplies And Prescriptions (Pt. Treat.) 1-601 West Broadway Vancouver, BC V5Z 4C2 Canada Vancouver General Hosp. (Prev. Pt. Treat.) 855 West 12th Ave Vancouver, BC V5Z 1M9 Canada		

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
	[redacted]	Vancouver General Hosp. (Prev. Pt. Treat.) Dept Of Med/Div Of Hem 910 West 10th Ave., Room 3300 Vancouver, BC V5Z 4E3 Canada Vancouver General Hosp. (Prev. Pt. Treat.) Vancouver Hosp. Laboratory 899 West 12th Ave. Vancouver, BC V5Z 1M9 Canada		
031	[redacted]	Royal Victoria Hosp. (Office) 687 Pine Ave. West Hematology Division Room C6-82 Montreal, QC H3A 1A1 Canada Jewish General Hosp. (Pt. Treat.) 3755 Cote-Ste-Catherine Rd Montreal, QC H3T 1E2 Canada	[redacted]	2

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
	[redacted]	Royal Victoria Hosp. (Pt. Treat.) 687 Pine Ave. West Montreal, QC H3A 1A1 Canada St.Mary'S Hosp. (Pt. Treat.) 3830 Lacombe Montreal, QC H3T 1M5 Canada Mcgill Univ. (Pt. Treat.) Dept Of Oncology Clin. Res. Program 546 Pine Ave. West Montreal, QC H2W 1S6 Canada		
032	[redacted]	Cross Cancer Inst. (Office) 11560 Univ. Ave. Nw Edmonton, AB T6G 1Z2 Canada Cross Cancer Inst. (Pt. Treat.) 11560 Univ. Ave. Nw Edmonton, AB T6G 1Z2 Canada	[redacted]	3

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
033	[redacted]	Royal Melbourne Hosp. (Office) Grattan St. Parkville, Victoria 3050 Australia Royal Melbourne Hosp. (Pt. Treat.) Dept. Of Haematology Grattan St. Parkville, Victoria 3050 Australia	[redacted]	4
034	[redacted]	Imvs (Office) Frome Road Adelaide, South Australia 5000 Australia Royal Adelaide Hosp. (Pt. Treat.) Haematology And Bone Marrow Transplant Unit North Terrace Adelaide, South Australia 5000 Australia	[redacted]	2

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
035	[redacted]	Royal North Shore Hosp. (Office) Pacific Highway St Leonards, New South Wales 2065 Australia Royal North Shore Hosp. (Pt. Treat.) Dept. Of Haematology Pacific Highway St Leonards, New South Wales 2065 Australia	[redacted]	8
037	[redacted]	The Mater Private Centre For Haematology & Oncology (Office) Mater Med. Centre Level 5 293 Vulture St. South Brisbane, Queensland 4101 Australia Mater Adult Hosp. (Prev. Office) Raymond Terrace South Brisbane, Queensland 4101 Australia	[redacted]	2

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
	[redacted]	Mater Private Hosp. (Pt. Treat.) 301 Vulture St. South Brisbane, Queensland 4101 Australia The Mater Private Centre For Haematology & Oncology (Pt. Treat.) Mater Med. Centre Level 5 293 Vulture St. South Brisbane, Queensland 4101 Australia Mater Adult Hosp. (Prev. Pt. Treat.) Dept. Of Haematology Level 6 Raymond Terrace South Brisbane, Queensland 4101 Australia		
038	[redacted]	Universitaetsspital Basel (Office) Petersgraben 4 Basel 4031 Switzerland	[redacted]	4

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
039	[redacted]	Hammersmith Hosp. (Office) Haematology, 4 Flr., Commonwealth Bldg. London, Greater London W12 ONN United Kingdom Hammersmith Hosp. (Pt. Treat.-Hosp./Med. Ctr.) 2nd Flr. Catherine Lewis Cntr Du Cane Rd London, Greater London W12 ONN United Kingdom	[redacted]	6
040	[redacted]	The Univ. Of North Carolina At Chapel Hill (Office) Division Of Hematology/Oncology Phys. Office Bldg., Cb#7305, 3rd Flr. 170 Manning Dr. Chapel Hill, NC 27599-7305 United States Of America The Univ. Of North Carolina At Chapel Hill (Prev. Office) Division Of Hematology/Oncology 3009 Old Clin. Bldg. Cb# 7305 Chapel Hill, NC 27599-7305 United States Of America	[redacted]	7
	[redacted]	Unc Hosp. (Pt. Treat.) The Univ. Of North Carolina At Chapel Hill 101 Manning Dr. Chapel Hill, NC 27599-7600 United States Of America		

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
042	[redacted]	Centre Investigation Clinique (Office) Rue De La Miletrie Bp 577 Poitiers Cedex 86021 France Centre Hospitalier Universitaire De Poitiers (Prev. Office) Rue De La Miletrie Bp 577 Poiters Cedex 86021 France Centre Investigation Clinique (Pt. Treat.-Hosp./Med. Ctr.) Chu Jean Bernard 2 Rue De La Miletrie Poitiers 86021 France Centre Hospitalier Universitaire De Poitiers (Prev. Pt. Treat.) Rue De La Miletrie Bp 577 Poiters Cedex 86021 France	[redacted]	2

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
043	[redacted]	Centre Hospitalier Universitaire (Office) Hopital Haut Leveque Centre Francois Magendie Service Des Maladies Du Sang Ave. De Magellan Pessac 33604 France Groupe Hospitalier Sud (Pt. Treat.-Hospital/Med. Ctr.) Chu François Magendie Ave. De Magellan Pessac 33604 France Centre Hospitalier Universitaire (Prev. Pt. Treat.) Hopital Haut Leveque Centre Francois Magendie Service Des Maladies Du Sang Ave. De Magellan Pessac 33604 France	[redacted]	7
044	[redacted]	Hopital Saint Louis (Office) Service Myosotis 1 Av C Vellefaux Paris Cedex 10 75475 France	[redacted]	6

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
	[redacted]	Hopital Saint Louis (Pt. Treat.-Hosp./Med. Ctr.) Hôpital Saint Louis 1 Av. C. Vellefaux Paris 75475 France Hopital Saint Louis (Prev. Pt. Treat.) Service Myosotis 1 Ave. Claude Vellefaux Paris Cedex 10 75475 France		
045	[redacted]	Glasgow Royal Infirmary (Office) Garnavel General Hosp. 21 Shelley Road Univ. Of Glasgow Glasgow, Scotland G12 OXB United Kingdom Glasgow Royal Infirmary (Prev. Office) Division Of Cancer Sciences And Molecular Pathology 3rd Flr. Univ. Bldg. 10 Alexandra Parade Glasgow, Lanarkshire G4 OSF United Kingdom	[redacted]	2

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
	[redacted]	Glasgow Royal Infirmary (Prev. Office) Glasgow, Lanarkshire G4 OSF United Kingdom Beatson Oncology Centre (Pt. Treat.-Hosp./Med. Ctr.) 1053 Great Western Rd Glasgow, Central G11 6NT United Kingdom Glasgow Royal Infirmary (Prev. Pt. Treat.-Hosp./Med. Ctr.) St Mungo Unit Ward 42 Glasgow, Central G4 OSF United Kingdom		
046	[redacted]	The Med. School, Univ. Of Newcastle (Office) Clin. & Laboratory Science Newcastle, Tyne And Wear NE2 4HH United Kingdom The Med. School, Univ. Of Newcastle (Prev. Office) Clin. & Laboratory Science Newcastle, Tyne And Wear NE2 2DR United Kingdom	[redacted]	6

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
	[redacted]	The Med. School, Univ. Of Newcastle (Pt. Treat.-Hosp./Med. Ctr.) Clin Res. Facility 4 Flr. Leazes Wing Royal Victoria Infirmary Newcastle, Tyne And Wear NE1 4LP United Kingdom		
047	[redacted]	The Cancer Ctr. At Hackensack Univ. Med. Ctr. (Office) 20 Prospect Ave. Hackensack, NJ 07601 United States Of America Hackensack Univ. Med. Ctr. (Pt. Treat.) 30 Prospect Ave Hackensack, NJ 07601 United States Of America The Cancer Ctr. At Hackensack Univ. Med. Ctr. (Pt. Treat.) 20 Prospect Ave. Ste. 400 Hackensack, NJ 07601 United States Of America	[redacted]	6
	[redacted]	The Cancer Ctr. At Hackensack Univ. Med. Ctr. (Pt. Treat.) 360 Essex St., Ste 302 Hackensack, NJ 07601 United States Of America		

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
050	[redacted]	Georgetown Univ. Med. Ctr. Lombardi Cancer Ctr. (Office) 3800 Reservoir Road Nw Washington, DC 20057 United States Of America Georgetown Univ. Hosp. (Pt. Treat.) 3800 Reservoir Rd, Nw Washington, DC 20007 United States Of America Georgetown Univ. Med. Ctr. (Pt. Treat.) Drug Shipment Address & Pharmacist Designees: Oladeep Kolawole & Maureen Rose Dept. Of Pharmacy, Res. 3800 Reservoir Road, Nw; 7 Main, Room M7103 Washington, DC 20007-2197 United States Of America	[redacted]	0
051	[redacted]	Universidade Estadual De Campinas (Office) Rua Carlos Chagas, 480-Cp 6198 Predio Do Hemocentro Barao Geraldo Cep Campinas, Sao Paulo 13083-970 Brazil Universidade Estadual De Campinas (Pt. Treat.) Rua Carlos Chagas, 480-Cp 6198 Predio Do Hemocentro Barao Geraldo Cep Campinas, Sao Paulo 13083-970 Brazil	[redacted]	9

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
052	[redacted]	Hosp. Israelita Albert Einstein (Office) Av Albert Einstein, 627 Departamento De Oncologia - 2o Subsolo Morumbi, Sao Paulo 05652-000 Brazil Hosp. Israelita Albert Einstein (Pt. Treat.) Av Albert Einstein, 627 Departamento De Oncologia - 2o Subsolo Morumbi, Sao Paulo 05652-000 Brazil	[redacted]	3
053	[redacted]	Dept. Fuer Haematologie (Office) Klinik F. Innere Medizin Akh Wien Waehringer Guertel 18-20 Wien 1090 Austria Dept. Fuer Haematologie (Pt. Treat.) Klinik F. Innere Medizin Akh Wien Waehringer Guertel 18-20 Wien 1090 Austria	[redacted]	5

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
054	[redacted]	Erasmus Med. Ctr. - Daniel Den Hoed Cancer Ctr. (Office) Groene Hilledijk 301 Rotterdam 3075 EA Netherlands Erasmus Med. Ctr. - Daniel Den Hoed Cancer Ctr. (Pt. Treat.-Hosp./Med. Ctr.) Groene Hilledijk 301 Rotterdam 3075 EA Netherlands	[redacted]	2
055	[redacted]	Hosp. Das Clinicas - Fundacao Pro-Sangue - Hemocentro (Office) Av. Eneas De Carvalho Aguir 155-1 Andar Sao Paulo, Sao Paulo 05403 Brazil Hosp. Das Clinicas - Fundacao Pro-Sangue - Hemocentro (Pt. Treat.) Av. Eneas De Carvalho Aguir 155-1 Andar Sao Paulo, Sao Paulo 05403 Brazil	[redacted]	16

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
056	[redacted]	Univ. Hosp. Gasthuisberg (Office) Dienst Hematologie Herestraat 49 B-Leuven 3000 Belgium Univ. Hosp. Gasthuisberg (Pt. Treat.-Hosp./Med. Ctr.) Dienst Hematologie Herestraat 49 B-Leuven 3000 Belgium	[redacted]	4

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
057	[redacted]	Ut Southwestern Med. Ctr. (Office) 5323 Harry Hines Bvd Dallas, TX 75390-8852 United States Of America Ut Southwestern Med. Ctr. At Dallas (Prev. Office) 5323 Harry Hines Blvd. Dallas, TX 75390-8852 United States Of America Zale Lipshy Univ. Hosp. (Pt. Treat.) 5151 Harry Hines Blvd Dallas, TX 75235 United States Of America Parkland Health And Hosp. System (Pt. Treat.) 5201 Harry Hines Blvd. Dallas, TX 75235 United States Of America Aston Ambulatory Care Ctr. (Pt. Treat.) 5323 Harry Hines Blvd Dallas, TX 75390 United States Of America	[redacted]	0

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
	[redacted]	Simmons Cancer Ctr. (Prev. Pt. Treat.) 2201 Inwood Road Dallas, TX 75390 United States Of America Zale Lipshy Univ. Hosp. (Prev. Pt. Treat.) 5151 Harry Hines Blvd Dallas, TX 75235-7786 United States Of America Investigational Drug Service (Pharmacy) (Prev. Pt. Treat.) 2201 Inwood Road Dallas, TX 75390-9015 United States Of America		
060	[redacted]	Univ. Of Kentucky (Office) Markey Cancer Hemotological Program Blood And Bone Marrow Transplant Unit 800 Rose St., Room Cc404 Lexington, KY 40536-0098 United States Of America	[redacted]	1

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
	[redacted]	Univ. Of Kentucky (Pt. Treat.) Med. Ctr. 800 Rose St. Lexington, KY 40536 United States Of America Univ. Of Kentucky (Pt. Treat.) Med. Ctr. Markey Cancer Ctr. 800 Rose St. Lexington, KY 40536 United States Of America Univ. Of Kentucky (Pt. Treat.) Med. Ctr. Clin. Res. Organization 740 S. Limestone St., C201 Lexington, KY 40536 United States Of America		
061	[redacted]	Instituto Nacional De Cancer (Office) Praca Cruz Vermelha,23 - Centro Servicio De Hematologia Rio De Janeiro, Rj 20230-130 Brazil Instituto Nacional De Cancer (Pt. Treat.) Praca Cruz Vermelha,23 - Centro Servicio De Hematologia Rio De Janeiro, Rj 20230-130 Brazil	[redacted]	2

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
062	[redacted]	Univ. Of Alabama-Birmingham (Office) Comprehensive Cancer Ctr. 1824 6th Ave. South Birmingham, AL 35294 United States Of America Univ. Of Alabama At Birmingham (Pt. Treat.) 625 19th St. South Birmingham, AL 35294 United States Of America Univ. Of Alabama At Birmingham (Pt. Treat.) The Kirklin Clin. 2000 6th Ave. South Birmingham, AL 35233 United States Of America UAB CCC Clin. Stuides Unit (Pt. Treat.) 219 New Hillman Bldg. 619 19th St. South Birmingham, AL 35249-3300 United States Of America Univ. Of Alabama At Birmingham (Pt. Treat.) Investigational Drug Service North Pavilion, N3470 1802 6th Ave S Birmingham, AL 35294 United States Of America	[redacted]	3

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
	[redacted]	Uab Russell Ambulatory Pharmacy (Prev. Pt. Treat.) 1813 6th Ave. South Room 117 Birmingham, AL 35294 United States Of America UAB CCC Clin. Stuides Unit (Prev. Pt. Treat.) 2001 3rd Ave. South, Ste 301 Liberty National Bldg, West Tower Birmingham, AL 35233-2115 United States Of America		
063	[redacted]	Universitair Ziekenhuis Antwerpen (Office) Dienst Hematologie Wilrijkstraat 10 Edegem 2650 Belgium Universitair Ziekenhuis Antwerpen (Pt. Treat.) Wilrijkstraat 10 Edegem 2650 Belgium	[redacted]	0

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
068	[redacted]	Western Pennsylvania Cancer Inst. (Office) 4800 Friendship Ave. Ste. 2303 Pittsburgh, PA 15224 United States Of America Western Pennsylvania Hosp. (Prev. Office) 4800 Friendship Ave. Pittsburgh, PA 15224 United States Of America The Western Pennsylvania Hosp. (Prev. Office) 4800 Friendship Ave. Pittsburgh, PA 15224 United States Of America The Western Pennsylvania Hosp. (Pt. Treat.) 4800 Friendship Ave. Pittsburgh, PA 15224 United States Of America	[redacted]	5
069	[redacted]	Seoul Mary'S Hosp. (Office) #505 Banpo-Dong Seocho-Ku Seoul 137-040 Korea, Republic Of	[redacted]	19

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
	[redacted]	The Catholic Univ. Of Korea College Of Med. (Prev. Office) Dept. Of Internal Med. #62 Youido-Dong, Youngdeungpo-Gu Seoul 150-713 Korea, Republic Of The Catholic Univ. Of Korea (Prev. Office) Uijeongbu St. Mary'S Hosp. Dept. Of Internal Med. 65-1 Kumoh-Dong Uijeongbu Kyunggi-Do 480-130 Korea, Republic Of Seoul Mary'S Hosp. (Pt. Treat.) #505 Banpo-Dong Seocho-Ku Seoul 137-040 Korea, Republic Of The Catholic Univ. Of Korea (Prev. Pt. Treat.) Uijeongbu St. Mary'S Hosp. 65-1 Kumoh-Dong Uijeongbu Kyunggi-Do 480-130 Korea, Republic Of		
	[redacted]	The Catholic Univ. Of Korea (Prev. Pt. Treat.) St, Mary'S Hosp. #62 Youido-Dong Youngdeungpo-Gu Seoul 150-713 Korea, Republic Of		

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
070	[redacted]	Asan Med. Ctr. (Office) Dept. Of Internal Med. 388-1 Pungnap-2 Dong, Songpagu Seoul 138-736 Korea, Republic Of Asan Med. Ctr. (Pt. Treat.) 388-1 Pungnap-2 Dong, Songpagu Seoul 138-736 Korea, Republic Of	[redacted]	7
071	[redacted]	National Taiwan Univ. Hosp. (Office) Section Of Hematology-Oncology Dept. Of Internal Med. 7, Chung Shan South Road Taipei 100 Taiwan National Taiwan Univ. Hosp. (Pt. Treat.) 7, Chung Shan South Road Taipei 100 Taiwan	[redacted]	5

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
072	[redacted]	Veterans General Hosp.-Taipei (Office) Section Of Med. Oncology Dept. Of Internal Med. 201 Shih-Pai Road, Section 2 Taipei 112 Taiwan Veterans General Hosp.-Taipei (Pt. Treat.) 201, Shih-Pai Road, Section 2 Taipei 112 Taiwan	[redacted]	1
073	[redacted]	Chang Gung Med. Foundation, Linkou Branch (Office) Division Of Hematology-Oncology Dept. Of Internal Med. No. 5, Fu-Shing St. Kueishan Shiang Taoyuan 333 Taiwan Chang Gung Memorial Hosp., Linkou Branch (Prev. Office) Division Of Hematology-Oncology Dept. Of Internal Med. 5 Fu-Shing St., Kweishan Shiang Taoyuan 333 Taiwan	[redacted]	2

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
	[redacted]	Chang Gung Med. Foundation, Linkou Branch (Pt. Treat.) No. 5, Fu-Shing St. Kueishan Shiang Taoyuan 333 Taiwan Chang Gung Memorial Hosp., Linkou Branch (Prev. Pt. Treat.) 5 Fu-Shing St. Kweishan Shiang Taoyuan 333 Taiwan		
074	[redacted]	St Luke'S Med. Ctr. (Office) Rm. 222 Med. Arts Bldg. E. Rodriguez Ave. Quezon City 1102 Philippines St Luke'S Med. Ctr. (Pt. Treat.) E. Rodriguez Ave Quezon City 1102 Philippines	[redacted]	8
075	[redacted]	Indiana Univ. Cancer Ctr. (Office) 535 Barnhill Dr. Room 473 Indianapolis, IN 46202 United States Of America	[redacted]	7

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
	[redacted]	Indiana Univ. Hosp. (Pt. Treat.) 550 N Univ. Blvd Indianapolis, IN 46202 United States Of America Indiana Univ. Cancer Ctr. (Pt. Treat.) 535 Barnhill Dr. Indianapolis, IN 46202 United States Of America Wishard Health Services (Pt. Treat.) 1001 W 10th St. Indianapolis, IN 46202 United States Of America Indiana Univ. (Prev. Pt. Treat.) Clarian Health Partners 550 N. Univ. Blvd Indianapolis, IN 46202 United States Of America	[redacted]	
076	[redacted]	Loma Linda Univ. Cancer Ctr. (Office) 11185 Mountain View, Ste. 155 Loma Linda, CA 92354 United States Of America	[redacted]	6

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
	[redacted]	Loma Linda Univ. Cancer Inst. (Prev. Office) 11185 Mountain View Ste. 151 Loma Linda, CA 92354 United States Of America Loma Linda Univ. Med. Ctr. (Pt. Treat.) 11234 Anderson St. Loma Linda, CA 92354 United States Of America Llu Faculty Med. Offices (Prev. Pt. Treat.) 11370 Anderson St. Loma Linda, CA 92354 United States Of America	[redacted]	
079	[redacted]	The Cancer Inst. Of New Jersey (Office) 195 Little Albany St New Brunswick, NJ 08901 United States Of America The Cancer Inst. Of New Jersey (Pt. Treat.) 195 Little Albany St New Brunswick, NJ 08901 United States Of America	[redacted]	2

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
	[redacted]	Robert Wood Johnson Univ. Hosp. (Pt. Treat.) One Robert Wood Johnson Place New Brunswick, NJ 08901 United States Of America		
080	[redacted]	Ucl Mont-Godinne (Office) Service Hematologie Ave. Dr. G. Therasse 1 Yvoir 5530 Belgium Ucl Mont-Godinne (Pt. Treat.-Hosp./Med. Ctr.) Ave. Dr. G. Therasse 1 Mont-Godinne 5530 Belgium Ucl Mont-Godinne (Prev. Pt. Treat.) Service Hematologie Ave. Dr. G. Therasse 1 Mont-Godinne 5530 Belgium	[redacted]	6

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
084	[redacted]	Northwestern Univ. (Office) Feinberg School Of Med. Hematology/Oncology Division 676 N. St. Clair St., Ste. 850 Chicago, IL 60611 United States Of America Northwestern Memorial Hosp. (Pt. Treat.) Main Labs 251 E. Huron - Feinberg Chicago, IL 60611 United States Of America Northwestern Med. Faculty Foundation (Nmff) (Pt. Treat.) Division Of Hematology/Oncology 675 N. St. Clair St. - Galter 21st Flr. Chicago, IL 60611 United States Of America Northwestern Med. Faculty Foundation (Nmff) (Prev. Pt. Treat.) 675 N. St. Clair Ste. 21st Flr. Chicago, IL 60611 United States Of America	[redacted]	5
	[redacted]	Northwestern Memorial Hosp. (Prev. Pt. Treat.) 251 E. Huron - Feinberg Chicago, IL 60611 United States Of America		

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
085	[redacted]	Hosp. Clin. I Provincial (Office) Servico Hematologia Esc 4-4 Piso C-Villarroel, 170 Barcelona 08036 Spain Hosp. Clin. De Barcelona (Pt. Treat.-Hosp./Med. Ctr.) Villarroel, 170 Barcelona 08036 Spain Hosp. Clin. I Provincial (Prev. Pt. Treat.) Servico Hematologia Esc 4-4 Piso C-Villarroel, 170 Barcelona 08036 Spain	[redacted]	1
086	[redacted]	Hosp. Ramon Y Cajal (Office) Servicio De Hematologia, Pl 8 Ctra Colmenar Viejo, Rm 9, 10 Madrid 28034 Spain Hosp. Ramon Y Cajal (Pt. Treat.-Hosp./Med. Ctr.) Carretera De Colmenar Km. 9,1 Madrid 28034 Spain	[redacted]	2

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
087	[redacted]	Hosp. De La Princesa (Office) Servicio Hematologia, Pl 2 / Consulta 6 Diego De Leon, 62 Madrid 28006 Spain Hosp. De La Princesa (Pt. Treat.-Hosp./Med. Ctr.) Servicio Hematologia, Pl 2 Diego De Leon, 62 Madrid 28006 Spain	[redacted]	2
090	[redacted]	Hosp. Das Clinicas De Curitiba (Office) Rua General Cameiro 181-15 O Andar Curitiba, Parana 80060-900 Brazil Hosp. Das Clinicas De Curitiba (Pt. Treat.) Rua General Cameiro 181-15 O Andar Curitiba, Parana 80060-900 Brazil	[redacted]	20

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
092	[redacted]	Ospedale Policlinico Consorziale (Office) Unita' Operativa Di Ematologia Piazza Giulio Cesare, 11 Bari 70124 Italy Ospedale Policlinico Consorziale (Pt. Treat.) Unita' Operativa Di Ematologia Piazza Giulio Cesare, 11 Bari 70124 Italy	[redacted]	1
093	[redacted]	Universita' Degli Studi Di Napoli Federico Ii (Office) Divisione Di Ematologia Clinica Via Sergio Pansini, 5 Napoli 80131 Italy Universita' Degli Studi Di Napoli Federico Ii (Pt. Treat.) Divisione Di Ematologia Clinica Via Sergio Pansini, 5 Napoli 80131 Italy	[redacted]	1

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
094	[redacted]	Hopital Edouard Herriot (Office) 5, Place D'Arsonval Lyon Cedex 03 69437 France Hopital Edouard Herriot (Pt. Treat.-Hosp./Med. Ctr.) Service Hematologie 5, Place D'Arsonval Lyon Cedex 03 69437 France	[redacted]	7

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
095	[redacted]	Centre Hospitalier Regional Et Universitaire De Lille (Office) Hopital C. Huriet Service Des Maladies Du Sang Av. M. Polonowski Lille Cedex 59037 France Hopital Claude Huriez (Pt. Treat.-Hosp./Med. Ctr.) Service Hématologie Chu De Lille Rue Michel Polonovski Lille 59037 France Centre Hospitalier Regional Et Universitaire De Lille (Prev. Pt. Treat.) Hopital C. Huriet Service Des Maladies Du Sang Av. M. Polonowski Lille Cedex 59037 France	[redacted]	6
096	[redacted]	Hopital De Hautepierre (Office) Service Hematologie 1, Place De L'Hopital Strasbourg Cedex 67091 France	[redacted]	10

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
	[redacted]	Hopital Civil (Prev. Office) Service Hematologie 1, Place De L'Hopital Strasbourg 67091 France Hopital De Hautepierre (Pt. Treat.-Hosp./Med. Ctr.) Departement D' Hematologie Et Oncologie 1 Place De L'Hopital Strasbourg Cedex 67091 France Hopital Civil (Prev. Pt. Treat.) Service Hematologie 1, Place De L'Hopital Strasbourg 67091 France		
097	[redacted]	Chu Hotel Dieu (Office) Service Hematologie Clinique Place Alexis Ricordeau Nantes 44000 France	[redacted]	4

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
	[redacted]	Centre Hospitalier Universitaire De Nantes (Pt. Treat.-Hospital/Med. Ctr.) Service Hématologie 1 Place Alexis Ricordeau Nantes 44035 France Chu Hotel Dieu (Prev. Pt. Treat.) Service Hematologie Clinique Place Alexis Ricordeau Nantes 44000 France		
099	[redacted]	Aarhus Univ. Hosp. (Office) Hematology Dept/ Aarhus Univ Hosp Tage Hansens Gade 2 Aarhus C 8000 Denmark Aarhus Univ. Hosp. (Prev. Office) Dept Of Hematology Aarhus Kommunehospital Aarhus 8000 Denmark	[redacted]	5

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
	[redacted]	Aarhus Univ. Hosp. (Pt. Treat.) Hematology Dept/ Aarhus Univ Hosp Tage Hansens Gade 2 Aarhus C 8000 Denmark Aarhus Univ. Hosp. (Prev. Pt. Treat.) Dept. Of Haematology Tage Hansens Gade 2 Aarhus C 8000 Denmark		
100	[redacted]	Helsinki Univ. Hosp. (Office) Dept Of Medicin/Division Hematology Haartmaninkatu 8 Helsinki 00029 Finland Helsinki Univ. Hosp. (Prev. Office) Div. Of Haemotalogy Haarmaninkatu 8 Helsinki 00029 Finland Helsinki Univ. Hosp. (Pt. Treat.) Dept Of Medicin/Division Hematology Haartmaninkatu 8 Helsinki 00029 Finland	[redacted]	4

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
101	[redacted]	Karolinska Hosp. (Office) Karolinska Univ. Sjh Solna Dep Of Hematology Stockholm 171 76 Sweden Karolinska Hosp. (Pt. Treat.) Karolinska Univ. Sjh Solna Dep Of Hematology Stockholm 171 76 Sweden	[redacted]	3
102	[redacted]	Sahlgrenska Univ. Hosp. (Office) Dept Of Hematology Vita Straket 12 Gothenburg 413 45 Sweden Sahlgrenska Univ. Hosp. (Prev. Office) Dep Of Hematology Gothenburg 413 45 Sweden Sahlgrenska Univ. Hosp. (Pt. Treat.) Dept Of Hematology Vita Straket 12 Gothenburg 413 45 Sweden	[redacted]	0

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
	[redacted]	Sahlgrenska Univ. Hosp. (Prev. Pt. Treat.) Dept. Of Haematology Gothenburg 413 45 Sweden		
103	[redacted]	Lund Univ. Hosp. (Office) Dep Of Hematology Lunds Univ. Hosp. Lund 22185 Sweden Lund Univ. Hosp. (Pt. Treat.) Dep Of Hematology Lunds Univ. Hosp. Lund 22185 Sweden	[redacted]	3
104	[redacted]	Norrlands Univ.Hospital (Office) Dept Of Med. Norrland Univ. Hosp. Umea 901 85 Sweden Norrlands Univ. Hosp. (Prev. Office) Dep Of Hematology Umea 901 85 Sweden	[redacted]	1

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
	[redacted]	Norrlands Univ.Hospital (Pt. Treat.) Dept Of Med. Norrland Univ. Hosp. Umea 901 85 Sweden Norrlands Univ. Hosp. (Prev. Pt. Treat.) Dep Of Hematology Umea 901 85 Sweden		
105	[redacted]	Azienda Ospedaliera Di Rilievo Nazionale A. Cardarelli (Office) Dipartimento Di Oncoematologia Via A. Cardarelli, 9 Napoli 80131 Italy Azienda Ospedaliera Di Rilievo Nazionale A. Cardarelli (Pt. Treat.) Dipartimento Di Oncoematologia Via A. Cardarelli, 9 Napoli 80131 Italy	[redacted]	2

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
106	[redacted]	St Olavs Hosp. (Office) St Olovs Hosp. Olavs Kyrres Gt 17 Trondheim 7006 Norway St Olavs Hosp. (Prev. Office) Dep Of Haematology Olavs Kyrres Gt 17 Trondheim 7006 Norway St Olavs Hosp. (Pt. Treat.) Olav Kyrres Gate 17 Trondheim 7006 Norway St Olavs Hosp. (Prev. Pt. Treat.) Dep Of Haematology Olavs Kyrres Gt 17 Trondheim 7006 Norway	[redacted]	3
107	[redacted]	Institut Jules Bordet (Office) Dept. Hematologie Rue Heger-Bordetsraat, 1 Bruxelles 1000 Belgium	[redacted]	2

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
	[redacted]	Institut Jules Bordet (Pt. Treat.-Hosp./Med. Ctr.) Centre Des Tumeurs Ulb Unite De Chimiotherapie 1 Rue Heger Bordetstraat 1 Bruxelles 1000 Belgium		
112	[redacted]	Univ. Of Kansas Med. Ctr. (Office) 3901 Rainbow Blvd. Kansas City, KS 66160 United States Of America Univ. Of Kansas Med. Ctr. (Pt. Treat.) 3901 Rainbow Blvd. Kansas City, KS 66160 United States Of America	[redacted]	0
115	[redacted]	Klinika Hematologii,Onkologii I Chorob Wew. Warszawskiego Um (Office) Banacha 1a Warsaw 02097 Poland Klinika Hematologii (Prev. Office) Onkologii I Chorob Wew. Am Banacha 1a Warsaw 02097 Poland	[redacted]	2

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
	[redacted]	Klinika Hematologii,Onkologii I Chorob Wew. Warszawskiego Um (Pt. Treat.) Banacha 1a Warsaw 02097 Poland Klinika Hematologii (Prev. Pt. Treat.) Onkologii I Chorob Wew. Am Banacha 1a Warsaw 02097 Poland		
116	[redacted]	Klinika Hematologii Um W Lodzi, Woj.Szpital Spec (Office) Ciolkowskiego 2a Lodz 93510 Poland Szpital Specjalistyczny (Prev. Office) Im Kopernika Knlika Hematologii Ciolkowskiego 2a Lodz 93510 Poland	[redacted]	4

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
	[redacted]	Klinika Hematologii Um W Lodzi, Woj.Szpital Spec (Pt. Treat.) Ciolkowskiego 2a Lodz 93510 Poland Szpital Specjalistyczny (Prev. Pt. Treat.) Im Kopernika Knlika Hematologii Ciolkowskiego 2a Lodz 93510 Poland		
118	[redacted]	Klinika Hemtologii I Transplantacji Szpiku (Office) Dabrowskiego 25 Katowice 40032 Poland Katedra I Klinika Hematologii I Transplantacji Szpiku (Prev. Office) W. Reymonta 8 Katowice 40 029 Poland	[redacted]	8

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
	[redacted]	Katedra I Klinika Hematologii I Transplantacji Szpiku (Prev. Office) W. Reymonta 8 Wroclaw 40029 Poland Klinika Hemtologii I Transplantacji Szpiku (Pt. Treat.) Dabrowskiego 25 Katowice 40032 Poland Katedra I Klinika Hematologii I Transplantacji Szpiku (Prev. Pt. Treat.) W. Reymonta 8 Katowice 40 029 Poland Katedra I Klinika Hematologii I Transplantacji Szpiku (Prev. Pt. Treat.) W. Reymonta 8 Wroclaw 40029 Poland		

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
119	[redacted]	Oddzial Hematoonkologii, Oddzial Transplantacji Szpiku (Office) Staszica 11 Lublin 20 950 Poland Katedra I Klinika Hematoonkologii I Transplantacji Szpiku Am (Prev. Office) Staszica 11 Lublin 20081 Poland Oddzial Hematoonkologii, Oddzial Transplantacji Szpiku (Pt. Treat.) Staszica 11 Lublin 20081 Poland Katedra I Klinika Hematoonkologii I Transplantacji Szpiku Am (Prev. Pt. Treat.) Staszica 11 Lublin 20081 Poland	[redacted]	2

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
120	[redacted]	Klinika Hematologii, Akademickie Centrum Kliniczne (Office) Debinki 7 Gdansk 80 211 Poland Klinika Hematologii, Akademickie Centrum Kliniczne (Office) Debinki 7 Gdansk 80211 Poland Klinika Hematologii (Prev. Office) Akademia Medyczna Debinki 7 Gdansk 86952 Poland Klinika Hematologii, Akademickie Centrum Kliniczne (Pt. Treat.) Debinki 7 Gdansk 86952 Poland	[redacted]	3
	[redacted]	Klinika Hematologii (Prev. Pt. Treat.) Akademia Medyczna Debinki 7 Gdansk 86952 Poland		

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
123	[redacted]	National Med. Ctr. (Office) Dept. Of Haematology And Transplantation Szabolcs U 33-35 Budapest 1135 Hungary National Med. Ctr. (Pt. Treat.) Dept. Of Haematology And Transplantation Szabolcs U 33-35 Budapest 1135 Hungary	[redacted]	8
124	[redacted]	St James Hosp. Dublin (Office) James St. Dublin, Dublin N/A Ireland St James Hosp. Dublin (Prev. Office) Cancer Clin. Trials Office James St. Dublin, Dublin N/A Ireland	[redacted]	4

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
	[redacted]	St James Hosp. Dublin (Pt. Treat.-Hosp./Med. Ctr.) Hematology Day Care Centre James St. Dublin 8, Dublin N/A Ireland St James Hosp. Dublin (Pt. Treat.) Cancer Clin. Trials Office James St. Dublin, Dublin N/A Ireland		
125	[redacted]	Univ. College Hosp. Galway (Office) Newcastle Road Co Galway, Galway NA Ireland		0
126	[redacted]	Royal Perth Hosp. (Office) Dept. Of Haematology Royal Perth Hosp. Perth Wa 6000 Australia Perth, Western Australia WA 6000 Australia Royal Perth Hosp. (Office) Royal Perth Hosp. 197 Wellington St. Perth, Western Australia 6001 Australia	[redacted]	4

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
	[redacted]	Royal Perth Hosp. (Pt. Treat.) Dept. Of Haematology Royal Perth Hosp. Perth Wa 6000 Australia Perth, Western Australia WA 6000 Australia	[redacted]	
127	[redacted]	Royal Prince Alfred Hosp. (Office) Inst. Of Haematology Royal Prince Alfred Hosp. Missenden Road Camperdown, New South Wales 2050 Australia Royal Prince Alfred Hosp. (Pt. Treat.) Inst. Of Haematology Royal Prince Alfred Hosp. Missenden Road Camperdown, New South Wales 2050 Australia	[redacted]	0
128	[redacted]	Oddzial Kliniczny Kliniki Hematologii (Office) Kopernika 17 Krakow 31501 Poland	[redacted]	4

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
	[redacted]	Katedra I Klinika Hematologii, Cmuj (Prev. Office) Kopernika 17 Krakow 31501 Poland Oddzial Kliniczny Kliniki Hematologii (Pt. Treat.) Kopernika 17 Krakow 31501 Poland Katedra I Klinika Hematologii, Cmuj (Prev. Pt. Treat.) Kopernika 17 Krakow 31501 Poland		
133	[redacted]	Chris Hani Baragwanath Hosp. (Office) Bara Haem. Res. Syndicate Friends Of Bara, 2nd Flr., Room 17 Old Potch Road Soweto, Gauteng 6201 South Africa	[redacted]	0
	[redacted]	Chris Hani Baragwanath Hosp. (Pt. Treat.) Bara Haem. Res. Syndicate Friends Of Bara, 2nd Flr., Room 17 Old Potch Road Soweto, Gauteng 6201 South Africa		

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
134	[redacted]	Univ. Of Free State (Office) Faculty Of Health Sciences Dept Of Haem, Block B, 2nd Flr. D F Malherbe Ave. Bloemfontein, Free State 9301 South Africa Univ. Of Free State (Pt. Treat.) Faculty Of Health Sciences Dept Of Haem, Block B, 2nd Flr. D F Malherbe Ave. Bloemfontein, Free State 9301 South Africa	[redacted]	6
135	[redacted]	Mary Potter Oncology Centre (Office) Little Co Of Mary Hosp. 50 Totius St. Groenkloof, Gauteng 0181 South Africa	[redacted]	3
	[redacted]	Mary Potter Oncology Centre (Pt. Treat.) Little Co Of Mary Hosp. 50 Totius St. Groenkloof, Gauteng 0181 South Africa		

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
136	[redacted]	Wits Donald Gordon Cts (Office) Unv Of Wits Oncology 18 Eton Road Parktown, Gauteng 2193 South Africa Johannesburg Hosp. (Prev. Office) Area 495, Div Of Med Oncology 7 York Road Parktown, Gauteng 2193 South Africa Wits Donald Gordon Cts (Pt. Treat.) Unv Of Wits Oncology 18 Eton Road Parktown, Gauteng 2193 South Africa Johannesburg Hosp. (Prev. Pt. Treat.) Area 495, Div Of Med Oncology 7 York Road Parktown, Gauteng 2193 South Africa	[redacted]	1

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
137	[redacted]	Wits Donald Gordon Cts (Office) Unv Of Wits Oncology 18 Eton Road Parktown, Gauteng 2193 South Africa Wits Donald Gordon Med Centre (Prev. Office) 17 Eton Road Parktown, Gauteng 2193 South Africa Wits Donald Gordon Cts (Pt. Treat.) Unv Of Wits Oncology 18 Eton Road Parktown, Gauteng 2193 South Africa Wits Donald Gordon Med Centre (Prev. Pt. Treat.) 17 Eton Road Parktown, Gauteng 2193 South Africa	[redacted]	0

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
138	[redacted]	Univ. Of Cape Town Med. School (Office) Anzio Road Observatory, Western Cape 7925 South Africa Univ. Of Cape Town Med. School (Pt. Treat.) Anzio Road Observatory, Western Cape 7925 South Africa	[redacted]	1
139	[redacted]	Devetten, Marcel (Office) Hematology/Oncology Dept. Of Internal Med. 987680 Nebraska Med Ctr. Omaha, NE 68198-7680 United States Of America The Nebraska Med. Ctr. (Pt. Treat.) 42nd And Emile Omaha, NE 68105 United States Of America	[redacted]	1

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
140	[redacted]	Sheba Med. Ctr. (Office) Hematology Division Sheba Med. Ctr. Tel-Hashomer Hosp. Ramat-Gan 52621 Israel Sheba Med. Ctr. (Pt. Treat.) Hematology Division Sheba Med. Ctr. Tel-Hashomer Hosp. Ramat-Gan 52621 Israel	[redacted]	9
141	[redacted]	Instituto Nacional De Enfermedades Neoplasicas (Office) Oficina 234 Av. Angamos Este 2520 Lima, Lima 34 Peru Instituto Nacional De Enfermedades Neoplasicas (Pt. Treat.) Oficina 234 Av. Angamos Este 2520 Lima, Lima 34 Peru	[redacted]	1

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
143	[redacted]	Singapore General Hosp. (Office) Dept. Of Hematology Block 6, Level 5 Outram Road Singapore 169608 Singapore Singapore General Hosp. (Pt. Treat.) Outram Road Dept. Of Haematology, Block 6 Level 5, Room B6 Singapore 169608 Singapore Singapore General Hosp. (Prev. Pt. Treat.) Outram Road Singapore 169608 Singapore	[redacted]	20
144	[redacted]	Universitaetsklinikum Carl Gustav Carus (Office) Medizinische Klinik Und Poliklinik I Fetscherstrasse 74 Dresden 01307 Germany	[redacted]	4

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
145	[redacted]	Universitaetsklinikum Leipzig (Office) Universitaetsklinikum Abteilung Fur Haematologie Internistische Onkologie Und Haemostaseologie Leitung Studiensekrekretariat Johannisalle 32a Leipzig 04103 Germany Universitaetsklinikum Leipzig (Prev. Office) Philipp-Rosenthal-Str. 23-25 Leipzig 04103 Germany Universitaetsklinikum Leipzig (Pt. Treat.) Universitaetsklinikum Abteilung Fur Haematologie Internistische Onkologie Und Haemostaseologie Leitung Studiensekrekretariat Johannisalle 32a Leipzig 04103 Germany	[redacted]	9
146	[redacted]	Nebraska Methodist Hosp. (Office) 8303 Dodge St. Omaha, NE 68114-4123 United States Of America	[redacted]	1
	[redacted]	Nebraska Methodist Hosp. (Pt. Treat.) 8303 Dodge St. Omaha, NE 68114 United States Of America	[redacted]	

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
147	[redacted]	Pacific Cancer Med. Ctr. (Office) 1801 Romeya Dr. Ste. 203 Anaheim, CA 92801 United States Of America Pacific Cancer Med. Ctr. Inc (Pt. Treat.) 1801 West Romneya Dr. Ste. 203 Anaheim, CA 92801 United States Of America	[redacted]	0
148	[redacted]	Ramathibodi Hosp. (Office) Rama Vi Rd, Phayathai Bangkok 10400 Thailand Ramathibodi Hosp. (Prev. Office) Division Of Hematology Dept. Of Med. Ramathibodi Hosp., Mahidol Univ. Bangkok 10400 Thailand	[redacted]	2

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
	[redacted]	Ramathibodi Hosp. (Pt. Treat.) Bone Marrow Transplantation Program Rm #702, 7th Flr. Rama Vi Rd, Phayathai Bangkok 10400 Thailand Ramathibodi Hosp. (Prev. Pt. Treat.) Room #702 (Bone Marrow Transplant Program) 7th Flr. Sirikit Med. Ctr. Bangkok 10400 Thailand		
149	[redacted]	Seoul National Univ. Hosp. (Office) Dept Of Internal Med. 28 Yongon-Dong, Chongno-Gu Seoul 110-744 Korea, Republic Of Seoul National Univ. Hosp. (Pt. Treat.) 28 Yongon-Dong Chongno-Gu Seoul 110-744 Korea, Republic Of	[redacted]	3

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
150	[redacted]	Chonnam National Universtiy Hwasun Hosp. (Office) Dept. Of Internal Med. 160, Ilsim-Ri, Hwasun-Dup Hwasun-Gun Jeollanam-Do Korea, Republic Of Chonnam National Universtiy Hwasun Hosp. (Pt. Treat.) 160, Iisim-Ri, Hwasun-Eup Hwasun-Gun Jeollanam-Do 519-809 Korea, Republic Of	[redacted]	2
151	[redacted]	National Res. Hematology Ctr. (Office) 4a, Novozykovsky Pr Moscow 125167 Russian Federation National Res. Hematology Ctr. (Pt. Treat.) 4a, Novozykovsky Pr Moscow 125167 Russian Federation	[redacted]	11

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
152	[redacted]	St.Pet State Med. Univ. Named Afteri.P Pavlov (Office) 6/8 L.Tolstoy Str. St.Petersburg 197022 Russian Federation St.Pet State Med. Univ. Named Afteri.P Pavlov (Prev. Office) 6/8 L.Tolstoy Str. St.Petersburg 179089 Russian Federation St.Pet State Med. Univ. Named Afteri.P Pavlov (Pt. Treat.) 6/8 L.Tolstoy Str. Dept. Of Faculty Therapy St.Petersburg 197022 Russian Federation St.Pet State Med. Univ. Named Afteri.P Pavlov (Prev. Pt. Treat.) 6/8 L.Tolstoy Str.Level3 Dept. Of Faculty Therapy St.Petersburg 179089 Russian Federation	[redacted]	4

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
169	[redacted]	Hosp. Universitario La Fe (Office) Servico Hematologia, 5a Pl Avda. Del Campanar, 21 Valencia 46009 Spain Hosp. La Fe (Prev. Office) Servicio Hematologia, 5a Pl Avda Del Campanar, 21 Valencia 46009 Spain Hosp. Universitario La Fe (Pt. Treat.-Hosp./Med. Ctr.) Servicio Hematologia, 5a Pl Avda. Del Campanar, 21 Valencia 46009 Spain	[redacted]	1
174	[redacted]	Centre Hospitalier Notre-Dame Et Reine Fabiola (Office) Grand Rue 3 Charleroi 6000 Belgium	[redacted]	3
	[redacted]	Centre Hospitalier Notre-Dame Et Reine Fabiola (Pt. Treat.-Hospital/Med. Ctr.) Grand Rue 3 Charleroi 6000 Belgium		

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
176	[redacted]	Az Sint-Jan (Office) Ruddershove 10 Brugge 8000 Belgium Az Sint-Jan (Pt. Treat.-Hosp./Med. Ctr.) Ruddershove 10 Brugge 8000 Belgium	[redacted]	1
187	[redacted]	Univ. Hosp. (Office) Interni Hematoonkologicka Klinika Jihlavska 20 Brno 625 00 Czech Republic	[redacted]	7
	[redacted]	Univ. Hosp. (Pt. Treat.-Hosp./Med. Ctr.) Interni Hematoonkologicka Klinika Jihlavska 20 Brno 625 00 Czech Republic		

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
188	[redacted]	Ustav Hematologie A Krevni Transfuze (Office) U Nemocnice 1 Prague 2 128 20 Czech Republic Ustav Hematologie A Krevni Transfuze (Pt. Treat.-Hosp./Med. Ctr.) U Nemocnice 1 Prague 2 128 20 Czech Republic	[redacted]	4
189	[redacted]	Cleveland Clin. Foundation (Office) 9500 Euclid Ave., R35 Cleveland, OH 44195 United States Of America	[redacted]	7
	[redacted]	The Cleveland Clin. Foundation (Prev. Office) 9500 Euclid Ave. Cleveland, OH 44195-0001 United States Of America Cleveland Clin. Foundation (Pt. Treat.) 9500 Euclid Ave. Cleveland, OH 44195 United States Of America	[redacted]	

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
191	[redacted]	Chu Albert Michallon (Office) Service D'Hematologie Clinique Bp217 Grenoble Cedex 9 38043 France Chu Albert Michallon (Pt. Treat.-Hosp./Med. Ctr.) Service D'Hematologie Clinique Bp217 Grenoble Cedex 9 38043 France	[redacted]	4
195	[redacted]	General Hosp. Of Athens "Evangelismos" (Office) 45-47 Ipsilantou Str Athens 10676 Greece	[redacted]	3
	[redacted]	General Hosp. Of Athens "Evangelismos" (Pt. Treat.) 45-47 Ipsilantou Str Athens 10676 Greece		

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
196	[redacted]	Azienda Ospedaliera San Gerardo (Office) U. O. Ematologia E Centro Trapianti Di Midollo Via Pergolesi, 33 Monza 20052 Italy Azienda Ospedaliera San Gerardo (Pt. Treat.) U. O. Ematologia E Centro Trapianti Di Midollo Via Pergolesi, 33 Monza (Mi) 20052 Italy	[redacted]	4
197	[redacted]	Universita' Degli Studi Sapienza Di Roma (Office) U. O. Ematologia Via Benevento, 6 Roma 00161 Italy	[redacted]	0
	[redacted]	Universita' Degli Studi Sapienza Di Roma (Pt. Treat.) U. O. Ematologia Via Benevento, 6 Roma 00161 Italy		

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
198	[redacted]	Washington Cancer Inst. At Washington Hosp. Ctr. (Office) At Washington Hosp. Ctr. 110 Irving St., Nw Ste. C-2149 Washington, DC 20010 United States Of America Washington Cancer Inst. At Washington Hosp. Ctr. (Pt. Treat.) 110 Irving St., Nw Ste. C-2149 Washington, DC 20010 United States Of America	[redacted]	3
205	[redacted]	Institut Paoli-Calmettes (Office) 232 Bd Sainte Marguerite Marseille Cedex 9 13273 France	[redacted]	10
	[redacted]	Institut Paoli-Calmettes (Pt. Treat.-Hosp./Med. Ctr.) Departement D' Onco-Hematologie 232 Bd Sainte Marguerite Marseille Cedex 9 13273 France		

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
207	[redacted]	Univ. Of Florida (Office) Dept. Of Med. 1600 Sw Archer Road Po Box 100277 Gainesville, FL 32610 United States Of America Shands Teaching Hosp. (Pt. Treat.) 1600 S.W. Archer Rd Gainesville, FL 32610 United States Of America	[redacted]	0
208	[redacted]	Hopital Henri Mondor (Aphp) (Office) Service Du Pr Reyes 51 Av Mal De Lattre De Tassigny Creteil Cedex 94010 France	[redacted]	3
	[redacted]	Hopital Henri Mondor (Aphp) (Pt. Treat.-Hosp./Med. Ctr.) Service Du Pr Reyes 51 Av Mal De Lattre De Tassigny Creteil Cedex 94010 France		

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
209	[redacted]	Univ. Of Miami (Office) Miller School Of Med./Jackson Memorial Hosp. 1475 N.W. 12th Ave. Miami, FL 33136 United States Of America Univ. Of Miami (Pt. Treat.) Hosp. And Clinics 1475 Nw 12th Ave. Miami, FL 33136 United States Of America Jackson Memorial Hosp. & Clinics (Pt. Treat.) 1611 Nw 12th Ave. Miami, FL 33136 United States Of America	[redacted]	3
210	[redacted]	Odense Univ. Hosp. (Office) Sdr. Blvd. 29 Dept Of Hematology Odense C 5000 Denmark Odense Univ. Hosp. (Pt. Treat.) Sdr. Blvd. 29 Odense C 5000 Denmark	[redacted]	1

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
211	[redacted]	Herlev Univ. Hosp. (Office) Dept. Of Hematology Herlev Ringvej 75 Herlev 2730 Denmark Herlev Univ. Hosp. (Pt. Treat.) Dept. Of Hematology Herlev Ringvej 75 Herlev 2730 Denmark	[redacted]	1
214	[redacted]	Royal Liverpool Univ. Hosp. (Office) Prescot St. Liverpool, Merseyside L7 8XP United Kingdom		6
	[redacted]	Royal Liverpool Univ. Hosp. (Pt. Treat.-Hosp./Med. Ctr.) G Clin. 7y Day Ward Prescot Road Liverpool, Merseyside L7 8XP United Kingdom		
216	[redacted]	Instituto Nacional De Cancerologia (Office) Av San Fernando #22 Col. Seccion Xvi Tlalpan, Distrito Federal C.P. 14000 Mexico Instituto Nacional De Cancerologia (Pt. Treat.) Av San Fernando #22 Col. Seccion Xvi Tlalpan, Distrito Federal C.P. 14000 Mexico	[redacted]	0

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
218	[redacted]	Med. Offices Of Drs. Byeff And Smith (Office) 55 Meriden Ave Ste. 1a Southington, CT 06489 United States Of America Med. Offices Of Drs. Byeff And Smith (Prev. Office) 55 Meriden Ave Southington, CT 06489 United States Of America	[redacted]	0
	[redacted]	Med. Offices Of Drs. Byeff And Smith (Pt. Treat.) 40 Hart St. Bldg. A New Britain, CT 06051 United States Of America Med. Offices Of Drs. Byeff And Smith (Pt. Treat.) 55 Meriden Ave Ste. 1a Southington, CT 06489 United States Of America Med. Offices Of Drs. Byeff And Smith (Prev. Pt. Treat.) 40 Hart St. Bldg. A New Britain, CT 06052 United States Of America		

Site No	Primary Investigator	Centre and Address	Subinvestigators & Responsible Med. Personnel (RMP)	# of Subjects Enrolled
225	[redacted]	Chu Caen (Office) Hematologie Clinique Ave. Georges Clemenceau Caen Cedex 14033 France	[redacted]	4
	[redacted]	Chr Clemenceau (Prev. Office) Service Hematologie Clinique Ave. George Clemenceau Caen Cedex 14033 France Chu Caen (Pt. Treat.-Hosp./Med. Ctr.) Hematologie Clinique Ave. Georges Clemenceau Caen Cedex 14033 France Chr Clemenceau (Prev. Pt. Treat.) Service Hematologie Clinique Ave. George Clemenceau Caen Cedex 14033 France	[redacted]	