FINAL CLINICAL STUDY REPORT

Study Title:	A Phase 2 Study to Assess the Efficacy and Safety of GS-1101 (CAL-101) in Patients with Relapsed or Refractory Hodgkin Lymphoma
Name of Test Drug:	Idelalisib (Zydelig®; GS-1101; formerly CAL-101)
Dose and Formulation:	Starting dose: 150 mg twice daily Dose level +2: 300 mg twice daily Dose level +1: 200 mg twice daily Dose level -1: 100 mg twice daily Dose level -2: 75 mg twice daily Formulations: 75-, 100-, and 150-mg tablets
Indication:	Hodgkin lymphoma
Sponsor:	Gilead Sciences, Inc. 199 East Blaine Street Seattle, WA 98102 USA
Study No.:	101-11
Phase of Development:	Phase 2
IND No.:	101254
EudraCT No.:	Not Applicable
ClinicalTrials.gov Identifier:	NCT01393106
Study Start Date:	15 September 2011 (first subject screened)
Study End Date:	28 August 2014 (last subject observation)
Principal or Coordinating Investigator:	Name: Ajay Gopal, MD Affiliation: PPD
Gilead Responsible Medical Monitor:	Name: Lyndah Dreiling, MD Telephone: PPD Fax: PPD
Report Date:	25 June 2015
Previous Report Date:	21 June 2013

STUDY SYNOPSIS
Study 101-11
Gilead Sciences, Inc.
199 East Blaine Street
Seattle, WA 98102
USA

Title of Study: A Phase 2 Study to Assess the Efficacy and Safety of GS-1101 (CAL-101) in Patients with Relapsed or Refractory Hodgkin Lymphoma

Investigators: PPD Ajay K. Gopal, MD; PPD PPD

Study Centers: 3 sites in the United States: Houston, TX; Seattle, WA; New York, NY
PPD

Publications: None

Study Period:

15 September 2011 (first subject screened)

28 August 2014 (last subject observation)

Phase of Development: Phase 2

Objectives:

The primary objective of this study was as follows:

- To evaluate tumor regression as determined by overall response rate (ORR) in subjects receiving idelalisib for treatment of relapsed or refractory Hodgkin lymphoma (HL)

The secondary objectives of this study were as follows:

- To determine the onset, magnitude, and duration of tumor control and of treatment success in subjects receiving idelalisib
- To characterize health-related quality of life (HRQL) as reported by subjects with HL receiving idelalisib
- To evaluate the effects of idelalisib on subject performance status
- To characterize the pharmacodynamic effects of idelalisib
- To evaluate idelalisib treatment administration and compliance with idelalisib therapy
- To describe the safety profile of idelalisib
- To characterize peak and trough idelalisib plasma concentrations over time

The exploratory objective of this study was as follows:

- To assess phosphatidylinositol 3-kinase p110δ isoform (PI3Kδ) activation and gene expression in lymph node tissue from subjects enrolled in the study

Interim results for this study were presented in the Interim Synoptic Clinical Study Report (CSR) (dated 21 June 2013). The present CSR presents the final results for Study 101-11.

Methodology: This was a Phase 2, open-label, single-arm, 2-stage, efficacy, safety, and pharmacodynamic study in subjects with relapsed or refractory HL. Eligible subjects initiated oral therapy at a starting dose of 150 mg twice daily given continuously. Lower dose levels were provided in case a subject required a dose reduction. After ≥ 8 weeks of study treatment, individual subjects could have had the dose escalated, if the investigator felt that a dose escalation was medically warranted (eg, for lack of response or for disease progression in a subject who was tolerating the current dose level of idelalisib therapy). As deemed medically appropriate, a 2-level increase in dose could have been considered. Intrasubject dose escalations to as high as 300 mg/dose twice daily (the highest idelalisib dose that was currently being tested as part of the Phase 3 study program) were allowed. Subjects were followed in the clinic at 2-week intervals through the first 12 weeks of treatment, at 4-week intervals from 12 to 24 weeks of treatment, at 6-week intervals from 24 to 48 weeks of treatment, and at 12-week intervals thereafter. Tumor response was evaluated at baseline; at 8, 16, and 24 weeks of therapy; and every 12 weeks thereafter using standard criteria.

Number of Subjects (Planned and Analyzed):

Planned: At least 21 evaluable subjects
Analyzed: 25 treated subjects

- Intent-to-Treat (ITT) Analysis Set: 25 subjects
- Per Protocol (PP) Analysis Set: 24 subjects
- Responding Analysis Set: 5 subjects
- Evaluable Analysis Set for HRQL: 20 subjects
- Evaluable Analysis Set for Performance Status: 7 subjects

Diagnosis and Main Criteria for Inclusion: Subjects must have met all of the following inclusion criteria to be eligible for participation in this study: ≥12 years of age; histologically confirmed diagnosis of classic HL; nodal HL that showed measurable fluorodeoxyglucose avidity; relapsed or refractory HL after prior myeloablative therapy with autologous stem cell transplantation or after ≥ 2 prior chemotherapy-containing regimens; and a Karnofsky performance score of ≥ 60 (Eastern Cooperative Oncology Group performance score of 0, 1, or 2) or a Lansky performance score of ≥ 60 for subjects < 16 years of age.

Duration of Treatment: Subjects could continue receiving idelalisib until tumor progression or unacceptable toxicity.

Test Product, Dose, Mode of Administration, and Lot No.:

Starting dose: idelalisib 150 mg twice daily, oral
Dose level +2: 300 mg twice daily
Dose level +1: 200 mg twice daily
Dose level -1: 100 mg twice daily
Dose level -2: 75 mg twice daily

Lower dose levels were allowed for subjects who required a dose reduction. Dose escalations (maximum of 300 mg twice daily) were allowed if an investigator decided it was medically warranted for a lack of response or for disease progression in a subject tolerating the current dose level.

Lot No. for 75-mg tablets: CV1103B1

Lot No. for 100-mg tablets: CV1102B1, CV1106B1, CV1107B2, CV1110C1, CY1201B1

Lot No. for 150-mg tablets: CV1101B1, CV1105B1, CV1104D1, DV1107D2, CV1110D2, CV1205D1

Reference Therapy, Dose, Mode of Administration, and Lot No.: None

Criteria for Evaluation:

Efficacy:

Primary Endpoint

- ORR, which was defined as the proportion of subjects who achieved a complete response (CR) or partial response (PR) during idelalisib treatment based on standard criteria

Secondary Endpoints

- Progression-free survival (PFS), which was defined as the interval from the start of idelalisib treatment to the earlier of the first documentation of disease progression or death from any cause
- Percent change from baseline in the sum of the product of the greatest perpendicular diameters (SPD) of target lymph nodes (measureable lesions) as documented radiographically
- Time to response (TTR), which was defined as the interval from the start of idelalisib treatment to the first documentation of CR or PR
- Duration of response (DOR), which was defined as the interval from the first documentation of CR or PR to the earlier of the first documentation of disease progression or death from any cause
- Overall survival (OS), which was defined as the time from study Day 1 until the date of death due to any cause, including data from long-term follow-up
- Changes in HRQL as reported by subjects using the Functional Assessment of Cancer Therapy - Lymphoma (FACT-Lym)
- Changes in performance status as documented using the Karnofsky performance criteria for subjects ≥ 16 years of age

Pharmacokinetics:

- Trough (predose) and peak (1.5 hours postdose) plasma concentrations of idelalisib and GS-563117 (major metabolite)

Safety:

- Overall safety profile of idelalisib as characterized by the type, frequency, severity, timing, and relationship to study drug of any adverse events (AEs) or abnormalities of physical findings, laboratory tests, or electrocardiograms (ECGs); drug discontinuation due to AEs; or serious AEs (SAEs)

Statistical Methods:

Analysis Sets: The ITT Analysis Set included subjects who received at least 1 dose of idelalisib. The Responding Analysis Set included all subjects who achieved a best response of CR or PR. Subjects in the ITT Analysis Set who did not have a diagnosis of lymphoma, did not have measurable nodal disease at baseline, or did not have baseline and on-study tumor evaluation were not included in the PP Analysis Set. The Evaluable Analysis Set for HRQL was defined as all subjects in the ITT Analysis Set who had baseline and at least 1 postbaseline subscale assessment in FACT-Lym. The Evaluable Analysis Sets for Performance Status was defined as all subjects in the ITT Analysis Set who had baseline and at least 1 postbaseline performance status assessment.

Efficacy: The exact binomial test was used in the final analyses of ORR.

Time-to-event endpoints (DOR and PFS) were summarized using Kaplan-Meier (KM) methods. Subjects who did not have disease progression or died within 30 days after discontinuation of the study drug were censored on the date of the last tumor assessment (including assessments with a NE outcome). Subjects who started new antitumor therapy without prior documented disease progression were censored on the date of the last tumor assessment (including assessments with a NE outcome) prior to the start of the antitumor therapy. Subjects who progressed or died after ≥ 2 consecutive missing tumor assessments were censored on the date of the last tumor assessment (including assessments with a NE outcome) prior to the missing assessments. For PFS, surviving subjects without adequate baseline or postbaseline tumor response evaluation were censored on study Day 1. Additional exploratory analyses were conducted for PFS and DOR including long-term follow-up data. PFS was analyzed using the ITT and PP Analysis Sets. Duration of response was analyzed using the Responding Analysis Sets.

The percentage change from baseline in SPD was summarized at each postbaseline visit using descriptive statistics. In addition, the best percentage change from baseline in SPD during the study was summarized using descriptive statistics. These analyses were performed on the ITT and PP Analysis Sets.

Time to response was summarized using descriptive statistics for the Responding Analysis Set.

Overall survival was analyzed using KM methods and the ITT Analysis Set. Data from surviving subjects was censored at the last time that the subject was known to be alive.

The HRQL values and change from baseline to each postbaseline visit were summarized for the subscale and composite scores. The best change from baseline during the study, defined as the highest positive value among all postbaseline visits minus the baseline value, was also summarized. Analyses were conducted using the Evaluable Analysis Set for HRQL.

Karnofsky performance status scores and the change from baseline scores to each subsequent assessment were summarized. The best and worst changes from baseline during the study were also summarized. The best change from baseline was defined as the highest change from baseline score. The worst change from baseline was defined as the lowest change from baseline score. Analyses for Karnofsky performance status scores were performed on the Evaluable Analysis Set for Performance Status.

Pharmacokinetics: Trough (predose) and peak (1.5 hours postdose) plasma concentrations of idelalisib and GS-563117 (major metabolite) are provided in this report.

Safety: Adverse events were coded with Medical Dictionary for Regulatory Activities (MedDRA), Version 17.1. The severity of AEs was graded by the investigator according to the Common Terminology Criteria for Adverse Events (CTCAE), Version 4.03, whenever possible. If a CTCAE criterion did not exist, the grade corresponding to the appropriate adjective was used by the investigator to describe the maximum intensity of the AE: Grade 1 (mild), Grade 2 (moderate), Grade 3 (severe), Grade 4 (life threatening), or Grade 5 (fatal). Adverse events were considered as related to study drug if the investigator answered "Yes" to the question "Related to Study Drug."

Hematology and serum biochemistry values were programmatically graded according to CTCAE 4.03, when applicable. Laboratory values at each visit and change from baseline were summarized. Summary tables were presented for each relevant laboratory test to show the number of subjects having treatment-emergent laboratory abnormalities by CTCAE severity grade with corresponding percentages. Shift tables for hematology and serum biochemistry were also presented to show change in CTCAE severity grade from baseline to worst postbaseline grade. Number and percentage of subjects who had Grade 3 or 4 alanine aminotransferase (ALT) or aspartate aminotransferase (AST) elevations and resolution of the elevations are summarized. For immunophenotyping data, cell counts at baseline and at each assessment were summarized. For immunoglobulin data, the concentrations at baseline and at each assessment were summarized.

Blood pressure parameters were programmatically flagged as high (systolic $\geq$ 140 mmHg, diastolic $\geq$ 90 mmHg) or low (systolic $<$ 90 mmHg and diastolic blood pressure $<$ 60 mmHg).

The ECG QT interval and change in the corrected QT interval (QTc) interval were corrected by both the Bazett and Fridericia methods and categorized separately into standard classifications.

SUMMARY OF RESULTS:

Subject Disposition and Demographics:

Disposition: Of the 32 subjects screened, 25 were enrolled and received study drug. No subjects remain on study drug**;** reasons for permanently discontinuing study drug included progressive disease (PD; 20 subjects, 80.0%), AEs (3 subjects, 12.0%), lack of efficacy (1 subject, 4.0%), and withdrawal by subject (1 subject, 4.0%). The majority of subjects (64.0%) discontinued study drug before Week 16.

One subject (4.0%) discontinued from study drug and did not enter long-term follow-up, 10 subjects (40.0%) remain in long-term follow-up, and 14 subjects (56.0%) permanently discontinued from long-term follow-up (11 due to death, 2 due to other reasons, and 1 due to withdrawal by subject).

Demographics: Subjects ranged in age from 21 to 80 years. The median age of subjects was 42 years; 11 subjects (44.0%) were male, and 19 subjects (76.0%) were white. Median (range) weight, height, and body mass index were 73.7 kg (range: 44.1 to 138.4 kg), 172.5 cm (range: 153.0 to 185.5 cm), and 25.1 kg/m^2 (range: 15.6 to 42.7 kg/m^2), respectively.

Baseline Disease Characteristics: At baseline, the median time since diagnosis was 2.6 years (range: 0.8 to 21.6 years). Twenty-three subjects (92.0%) had nodular sclerosis as the pathologic HL subtype, and 2 subjects (8.0%) had the lymphocyte-rich subtype. At screening, 1 subject (4.0%) was Stage I; 8 subjects (32.0%) were Stage II, 6 subjects (24.0%) were Stage III, and 10 subjects (40.0%) were Stage IV. Eight subjects (32.0%) had a lymph node biopsy collected at screening; sites of lymph node biopsy included axillary (4 subjects, 16.0%), other (3 subjects, 12.0%), and inguinal (1 subject, 4.0%). At baseline, the median Karnofsky score was 80 (range: 70 to 90) (N = 13).

Prior Therapy: All 25 subjects (100.0%) had received prior antitumor therapies, with a median of 5 prior therapies received (range: 2 to 9). Eleven subjects had previously received brentuximab vedotin, with best clinical response of CR for 1 subject, PR for 1 subject, PD for 8 subjects, and unknown for 1 subject. Eighteen subjects (72.0%) had undergone autologous stem cell transplant, and 11 subjects (44.0%) received prior radiation therapy (median number of prior regimens: 1 [range: 1 to 7]). The median time since last therapy was 7.3 weeks (range: 3.1 to 109.6 weeks). The best clinical response to prior therapy was PR (11 subjects, 44.0%), CR (10 subjects, 40.0%), and PD (4 subjects, 16.0%).

Efficacy Results:

Best Overall Response: For the ITT Analysis Set, the ORR (CR + PR) was 20.0% (95% CI: 6.8%, 40.7%). One subject (4.0%) experienced CR and 4 subjects (16.0%) experienced PR, whereas 7 subjects (28.0%) experienced SD, 12 subjects (48.0%) experienced PD, and 1 subject (4.0%) was classified as not done (ND). For the PP Analysis Set, the ORR was similar (20.8%; 95% CI: 7.1%, 42.2%).

Progression-Free Survival: Nineteen subjects (76.0%) had disease progression (data for 5 subjects were censored; ITT Analysis Set). The KM estimate of median PFS was 2.3 months. The KM estimate of the proportion of subjects with PFS at 6 months was 28.9%. Similar results were obtained using the PP Analysis Set.

Progression-free survival including long-term follow-up data was also evaluated. Twenty subjects (80.0%) had disease progression (data for 2 subjects were censored; ITT Analysis Set). The KM estimate of median PFS was 2.3 months. The KM estimate of the proportion of subjects with PFS at 6 months was 32.0%.

Time to Response and Duration of Response: These analyses were based on the subjects who responded. Median TTR was 2.0 months (range: 1.9 to 16.8 months). Of the 5 responding subjects, 3 subjects (60.0%) discontinued study drug due to PD, 1 subject discontinued study drug due to an AE, and 1 subject withdrew from the study. The KM estimate of median DOR was 8.4 months. The DOR was the same when long-term follow-up data were included in the analysis.

Percent Change in Tumor Size (SPD): At Week 8, the median percent change from baseline in tumor size (SPD) for the 24 subjects on study was -14.1% (range: -73.1% to 112.5%). The median percent change in tumor size at Week 48 (N = 5) was -45.9% (range: -92.6% to 7.8%). The median percent change in tumor size for the 1 subject on study at Continuing Treatment Visit 6 was -20.4%. The median best percent change from baseline in tumor size (N = 24) was -24.1% (range: -92.6% to 112.5%). Results for the percent change from baseline in tumor size were the same for the PP Analysis Set.

Overall Survival: Fifteen subjects (60.0%) died (data for 10 subjects were censored) in the ITT Analysis Set. The KM estimate of median overall survival was 19.8 months. The KM estimate of the proportion of surviving subjects at 6 months was 88.0%.

Change in HRQL (FACT-Lym): The median FACT-Lym total score at Week 8 (N = 14) was 84.5 (range: 35.0 to 106.0) and at Week 48 (N = 5) was 71.3 (range: 34.0 to 102.0). For the 1 subject remaining on study at the Continuing Treatment Visit 5, the FACT-Lym total score was 62.0. The median change from baseline in FACT-Lym total score at Week 8 was 3.0 (range: -18.0 to 13.0) and at Week 48 was -2.0 (range: -13.8 to 5.0). The median best change from baseline in FACT-Lym total score was 6.0 (range: -11.0 to 21.2).

Change in Performance Status: The median best change from baseline in performance status among the 7 evaluable subjects with Karnofsky scores was 10 (range: 0 to 10). The median worst change from baseline in performance status among the 7 evaluable subjects with Karnofsky scores was 0 (range: -10 to 10).

Pharmacokinetics Results: In general, idelalisib plasma concentrations appeared to be at steady state by Week 4; trough levels were comparable at predose or 1.5 hours postdose between Week 4 and Week 16; this was also observed for concentrations of the primary metabolite, GS-563117. Mean trough concentrations of idelalisib were comparable to those observed in other studies (eg, Study 101-02) and to the population PK modeling estimates following idelalisib 150 mg twice daily monotherapy. In addition, these levels were much greater than the EC_{50} for inhibition of PI3Kδ activity in a whole blood basophil activation assay (39 nM).

Safety Results:

Exposure: Exposure to idelalisib ranged from 0.5 to 25.2 months, with a median of 3.6 months. Nine subjects (36.0%) had at least 1 dose modification. Five subjects (20.0%) had at least 1 dose reduction, with 2 subjects reduced to the lowest administered dose of 75 mg twice daily. Six subjects (24.0%) had at least 1 dose escalation, with 5 subjects escalated to the highest administered dose of 300 mg twice daily.

Adverse Events: Twenty-four of 25 subjects (96.0%) reported at least 1 AE. The most commonly reported AEs were fatigue (8 subjects, 32.0%); pyrexia (7 subjects, 28.0%); and AST increased, constipation, and vomiting (6 subjects, 24.0%, each).

Twelve subjects (48.0%) had at least 1 ≥ Grade 3 AE. The most commonly reported ≥ Grade 3 AEs was ALT increased (2 subjects, 8.0%). All other ≥ Grade 3 AEs were reported by 1 subject (4.0%) each: anemia, AST increased, fall, herpes zoster, hospitalization not otherwise specified (NOS), hypertension, hypoxia, neutropenia, pneumonia, pruritus, rash, rash maculo-papular, skin infection, and vomiting.

Nineteen subjects (76.0%) experienced AEs reported by the investigator as related to idelalisib. The most commonly reported AEs considered related to idelalisib were ALT increased, AST increased, and vomiting (5 subjects, 20.0%, each). Grade 3 or higher AEs reported by the investigator as related to idelalisib included ALT increased (2 subjects, 8.0%), and AST increased, herpes zoster, hospitalization NOS, hypoxia, rash, and vomiting (1 subject, 4.0% each).

Deaths: A total of 15 deaths (60.0%) occurred during the study or during long-term follow-up. One death occurred during the study treatment period or within 30 days following the last dose of study drug: Subject PPD who had a history of cough and shortness of breath, experienced an AE of hypoxia (Grade 5) beginning on Day 19 that was reported to be ongoing on Day 53, the date of the subject's death. A chest CT showed a range of findings including innumerable bilateral pulmonary nodules, peribronchovascular thickening, interlobular septal thickening and ground glass opacities, focal lobar atelectasis/consolidations, and increased large bilateral pleural effusions; a definitive diagnosis was not provided, but treatment included Bactrim and prednisone. The subject died 24 days after having discontinued study drug following hospitalization for hypoxia and was receiving palliative chemotherapy at the time of death when she collapsed and later that day died of cardiac arrest. The other 14 deaths occurred during long-term follow-up.

Serious Adverse Events: Overall, SAEs were reported for 9 subjects (36.0%). Two subjects (8.0%) reported SAEs of rash maculo-papular; all other SAEs were reported for 1 subject each. Six subjects (24.0%) experienced SAEs reported by the investigator as related to idelalisib.

Discontinuations Due to Adverse Events: Three subjects experienced at least 1 AE leading to permanent discontinuation of study drug. Adverse events leading to discontinuation of idelalisib included dyspnea, hospitalization NOS, and rash maculo-papular (1 subject each). Nine subjects (36.0%) experienced at least 1 AE that led to study drug interruption or dose change.

Dose Reductions Due to Adverse Events: Overall, 2 subjects had dose reductions due to AEs (AE of AST increased [1 subject] and SAEs of colitis, hypocalcemia, hypokalemia, hypomagnesemia, and platelet count decreased [1 subject]; all of these events were considered related to study drug).

Clinical Laboratory Evaluations: The most commonly reported ≥ Grade 3 hematologic laboratory abnormalities were decreased lymphocytes (12 subjects, 48.0%), decreased absolute neutrophils (2 subjects, 8.0%), anemia (1 subject, 4.0%), decreased platelets (1 subject, 4.0%), and decreased white blood cells (1 subject, 4.0%). Immunophenotyping showed that 5 subjects (20.0%) had ≥ Grade 3 decreased CD4+ lymphocytes. The most commonly reported ≥ Grade 3 clinical chemistry laboratory abnormalities were increased ALT (5 subjects, 20%) and increased AST (4 subjects, 16.0%). By laboratory evaluation, 5 subjects (20.0%) had any ≥ Grade 3 ALT/AST elevation; 4 of these subjects (80.0%) resolved to Grade 1 or less and 1 subject had ongoing ALT/AST elevations at the last study visit. These transaminase elevations were generally transient (resolved to Grade 1 or less) and asymptomatic. Of the 5 subjects who had any ≥ Grade 3 ALT/AST elevation, 3 had AEs of ALT and/or AST increased that led to temporary interruption of study drug, 1 had an AE of AST increased that led to a dose reduction, and 1 received his last dose of study drug the day before the Grade 3 AST/ALT elevation (he discontinued study drug due to disease progression).

Vital Signs: There were no trends of clinically relevant changes in temperature, blood pressure, or heart rate during the study. There were also no trends of clinically relevant changes in body weight during the study.

Electrocardiograms: Overall, at baseline, 14 subjects (56.0%) had normal ECG results; 10 subjects (40.0%) had abnormal, but not clinically significant ECG results; and 1 subject (4.0%) had a clinically significant abnormal ECG result. No subject had a shift from a normal or abnormal, but not clinically significant ECG result to a clinically significant ECG abnormality. No subject had a QTc interval (QTcB or QTcF) increase by > 60 msec at Week 16.

CONCLUSIONS:

- Idelalisib had a modest effect in this population of pretreated subjects with relapsed or refractory HL (ORR of 20.0% for the ITT Analysis Set). Among responders, responses to idelalisib were rapid (median TTR of 2.0 months). The KM estimate of median DOR was 8.4 months.
- Treatment with idelalisib decreased tumor size by 14.1% (median SPD) by Week 8.
- Among all subjects, median PFS was 2.3 months and the KM estimate of median overall survival was 19.8 months.
- Quality of life measures were generally stable on study (median best change in FACT-Lym was 6.0, and median best change in Karnofsky score was 10).
- Mean trough concentrations of idelalisib were comparable to those observed in other studies (eg, Study 101-02) and to the population PK modeling estimates following idelalisib 150 mg twice daily monotherapy. In addition, these levels were much greater than the EC_{50} for inhibition of PI3Kδ activity in a whole blood basophil activation assay (39 nM).
- Overall, 9 (36.0%) subjects experienced SAEs, and 6 (24.0%) had SAEs assessed by the investigator as related to study drug. Three subjects experienced AEs leading to permanent discontinuation of study drug (dyspnea, hospitalization NOS, and rash maculo-papular). Fifteen deaths (60.0%) occurred during the study or long-term follow-up; most were due to disease progression.
- Increases in ALT and AST that occurred in subjects receiving idelalisib were transient and asymptomatic.