
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d) OF
THE SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): **December 5, 2016**

BEIGENE, LTD.

(Exact name of registrant as specified in its charter)

Cayman Islands
(State or other jurisdiction
of incorporation)

001-37686
(Commission File Number)

98-1209416
(I.R.S. Employer Identification No.)

c/o Maurant Ozannes Corporate Services (Cayman) Limited
94 Solaris Avenue, Camana Bay
Grand Cayman KY1-1108
Cayman Islands
(Address of principal executive offices) (Zip Code)

+1 (345) 949 4123
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 8.01 Other Events.

On December 5, 2016, BeiGene, Ltd. (the “Company”) issued two press releases announcing updated clinical data from its BGB-3111 clinical trials that was presented at the 2016 American Society of Hematology Annual Meeting in San Diego, California on December 5, 2016. The full text of the Company’s press releases are filed as Exhibit 99.1 and Exhibit 99.2 to this Current Report on Form 8-K and are incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued on December 5, 2016
99.2	Press Release issued on December 5, 2016

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

BEIGENE, LTD.

Date: December 5, 2016

By: /s/ Howard Liang
Name: Howard Liang
Title: Chief Financial Officer and Chief Strategy Officer

Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued on December 5, 2016
99.2	Press Release issued on December 5, 2016



BeiGene Presents Updated Clinical Data on BTK Inhibitor BGB-3111 in Patients with Chronic Lymphocytic Leukemia and Small Lymphocytic Leukemia at the 2016 American Society of Hematology Annual Meeting

WALTHAM, Mass., December 5, 2016, BeiGene, Ltd. (NASDAQ:BGNE) a clinical-stage biopharmaceutical company developing innovative molecularly-targeted and immuno-oncology drugs for the treatment of cancer, today presented updated clinical data from an ongoing Phase I study of BTK inhibitor BGB-3111 in patients with chronic lymphocytic leukemia (CLL) and small lymphocytic leukemia (SLL) at the 2016 American Society of Hematology (ASH) Annual Meeting in San Diego, California. The preliminary clinical data demonstrate that BGB-3111 is well-tolerated and highly active in CLL / SLL, with an overall response rate of 96%, and no cases of disease progression, at a median follow-up time of 8.6 months.

“The preliminary BGB-3111 data presented at this year’s ASH Annual Meeting demonstrate that BGB-3111 can achieve complete target inhibition in lymph nodes while remaining highly tolerable. BGB-3111 is highly active and the lack of disease progression to date is notable,” commented Constantine Tam, MD, Disease Group Lead for Low Grade Lymphoma and Chronic Lymphocytic Leukemia at Peter MacCallum Cancer Centre, Australia, coordinating principal investigator of the study, “Late-stage clinical trials will reveal whether BGB-3111’s excellent tolerability and high target occupancy will translate into improvements in disease control, rates of drug resistance, and rates of treatment-limiting adverse events.”

“The efficacy and safety data presented for BGB-3111 this year at ASH in CLL and SLL underscore our plans to advance BGB-3111 into late-stage development globally and in China, and to continue to develop BGB-3111 broadly both as a monotherapy and in combination regimens for a range of B-cell malignancies,” commented Jane Huang, MD, Chief Medical Officer, Hematology at BeiGene.

Summary of Results from an Ongoing Phase 1 Study

The multi-center, open-label Phase 1 trial of BGB-3111 as monotherapy in B-cell malignancies is being conducted in Australia, New Zealand, South Korea, and the US and includes two parts – dose-escalation and dose-expansion in disease-specific cohorts, including relapsed / refractory and treatment naïve CLL / SLL patients. The dose-escalation component of the trial tested total daily doses between 40 mg and 320 mg, and the ongoing dose-expansion component is testing doses of 160 mg twice a day

(BID) or 320 mg once a day (QD). As of November 21, 2016, 63 patients with CLL or SLL were enrolled in the study. The data presented at the ASH Annual Meeting were from a total of 46 CLL / SLL patients who had at least 12 weeks of follow-up or discontinued treatment prior to week 12, by the data cutoff of October 3, 2016.

BGB-3111 was well-tolerated. Only one patient to date has discontinued BGB-3111 treatment for an adverse event, a grade 2 pleural effusion. The most frequent AEs ($\geq 20\%$) of any attribution were petechiae / purpura / contusion (48%), upper respiratory tract infection (33%), fatigue (28%), diarrhea (20%), cough (20%), and headache (20%), all of which were grade 1 or 2 in severity except for one case of grade 3 purpura. Three serious AEs (SAEs) were assessed as possibly related to BGB-3111, including one case each of grade 2 cardiac failure, grade 2 pleural effusion, and grade 3 purpura. Other grade 3 or greater events considered possibly related to treatment included three cases of neutropenia and one case of atrial fibrillation (AF), which was the only AF case reported. The case of purpura was the only major bleeding event ; no other cases of serious hemorrhage (defined as \geq grade 3 hemorrhage or CNS hemorrhage of any grade) were reported.

After a median follow-up of 8.6 months (2.2-20.9 months), the rate of overall response was 96% (44/46) with partial response (PR) in 67% (31/46) and PR with lymphocytosis (PR-L) in 28% (13/46) of patients. Stable disease (SD) was observed in 2% (1/46) of patients. The patient who discontinued prior to week 12 due to pleural effusion was not evaluable for response. No instances of disease progression or Richter's transformation have occurred.

About BGB-3111

BGB-3111 is a potent and highly selective investigational small molecule inhibitor of BTK. BGB-3111 has demonstrated higher selectivity against BTK than ibrutinib (the only BTK inhibitor currently approved by the U.S. Food and Drug Administration and the European Medicines Agency) based on biochemical assays, higher exposure than ibrutinib based on their respective Phase I experience, and sustained 24-hour BTK occupancy in both the blood and the lymph node.

About BeiGene

BeiGene is a global, clinical-stage, research-based biotechnology company focused on molecularly targeted and immuno-oncology cancer therapeutics. With a team of over 300 scientists, clinicians and staff in mainland China, the United States,

Australia and Taiwan, BeiGene is advancing a pipeline consisting of novel oral small molecules and monoclonal antibodies for cancer. BeiGene is working to create combination solutions aimed to have both a meaningful and lasting impact on cancer patients.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws, including statements regarding the encouraging clinical data of BGB-3111, the potential implications of these data for the future development of BGB-3111, and BeiGene's advancement of, and anticipated clinical development and regulatory milestones and plans related to BGB-3111. Actual results may differ materially from those indicated in the forward-looking statements as a result of various important factors, including BeiGene's ability to demonstrate the efficacy and safety of its drug candidates; the clinical results for its drug candidates, which may not support further development; actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials; BeiGene's ability to achieve market acceptance in the medical community necessary for commercial success; BeiGene's ability to obtain and maintain protection of intellectual property for its technology and drugs; BeiGene's reliance on third parties to conduct preclinical studies and clinical trials; BeiGene's limited operating history and BeiGene's ability to obtain additional funding for operations and to complete the development and commercialization of its drug candidates, as well as those risks more fully discussed in the section entitled "Risk Factors" in BeiGene's most recent quarterly report on Form 10-Q, as well as discussions of potential risks, uncertainties, and other important factors in BeiGene's subsequent filings with the U.S. Securities and Exchange Commission. All information in this press release is as of the date of this press release, and BeiGene undertakes no duty to update such information unless required by law.

Investor/Media Contact

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BeiGene Presents Updated Clinical Data on BTK Inhibitor BGB-3111 in Patients with Waldenström's Macroglobulinemia at the 2016 American Society of Hematology Annual Meeting

WALTHAM, Mass., December 5, 2016, BeiGene, Ltd. (NASDAQ:BGNE) a clinical-stage biopharmaceutical company developing innovative molecularly-targeted and immuno-oncology drugs for the treatment of cancer, today presented updated clinical data from an ongoing Phase I study of BTK inhibitor BGB-3111 in patients with Waldenström's macroglobulinemia (WM) at the 2016 American Society of Hematology (ASH) Annual Meeting in San Diego, California. The updated clinical data continue to demonstrate that BGB-3111 is well-tolerated and highly active in WM, with an overall response rate of 94%, including a major response rate of 78% and a very good partial response (VGPR) rate of 34%, at a median follow-up time of 9.6 months.

"The updated data on BGB-3111 in Waldenström's macroglobulinemia continue to show deep and durable responses in a larger number of patients, notably a high rate of VGPRs, and no disease progression on treatment to date," commented Constantine Tam, MD, Disease Group Lead for Low Grade Lymphoma and Chronic Lymphocytic Leukemia at Peter MacCallum Cancer Centre, Australia, coordinating principal investigator of the study.

"Based on the continued strength of the efficacy and safety data from our Phase I trial of BGB-3111 in Waldenström's macroglobulinemia, we will begin a global Phase III trial of BGB-3111 versus ibrutinib in patients with Waldenström's macroglobulinemia in late 2016 or early 2017. We look forward to advancing BGB-3111 into late stage development both globally and in China for WM and other indications," commented Jane Huang, MD, Chief Medical Officer, Hematology at BeiGene.

Summary of Results from an Ongoing Phase 1 Study

The multi-center, open-label Phase 1 trial of BGB-3111 as monotherapy in B-cell malignancies is being conducted in Australia, New Zealand, South Korea, and the US and is comprised of two parts – dose-escalation and dose-expansion in disease-specific cohorts, including relapsed / refractory and treatment naïve WM patients. The dose-escalation component of the trial tested total daily doses ranging from 40 mg to 320 mg, and the ongoing dose-expansion component is testing doses of 160 mg twice a day (BID) or 320 mg once a day (QD). As of November 21, 2016, 45 patients with WM were

enrolled in the study. Responses were determined according to the modified Sixth International Workshop on WM (IWWM) criteria.

As of October 3, 2016, the cutoff date for the current analysis, 33 patients were included in the safety analysis, and 32 of the 33 patients were evaluable for response as one patient had IgM < 500mg/dl at baseline. Adverse events (AEs) were generally mild in severity, self-limited, and usually encountered only in the earlier part of the treatment course. The most frequent AEs ($\geq 20\%$) of any attribution were upper respiratory tract infection (39%), petechiae / purpura / contusion (33%), nausea (24%), diarrhea (24%), and constipation (21%), all of which were grade 1 or 2 in severity except for one case of diarrhea (3%). Four serious AEs (SAEs) were assessed as possibly related to BGB-3111, including one case each of grade 3 cryptococcal meningitis, grade 3 pneumonia, grade 2 atrial fibrillation (AF), and grade 2 vomiting. Other grade 3 or greater events considered possibly related to BGB-3111 included two cases of neutropenia and one case each of diarrhea, hypertension, increased liver function test, pulmonary hypertension, and vomiting. In total, three cases of atrial fibrillation were reported (all grade 1 or 2), and two of the three occurred in patients with pre-existing AF. No serious hemorrhage (\geq grade 3 hemorrhage or CNS hemorrhage of any grade) was reported. The only treatment discontinuation was due to exacerbation of pre-existing bronchiectasis in a patient who achieved a VGPR on BGB-3111, and the subsequent death of this patient was also the only fatal event in the study and was assessed by the investigator to be unrelated to study treatment.

After a median follow-up of 9.6 months (3.0-24.7 months), the rate of overall response, defined as minor response or better, was 94% (30/32). The major response rate, defined as partial response (PR) or better, was 78% (25/32). VGPRs ($\geq 90\%$ reduction or normalization of IgM and reduction in lymphadenopathy / splenomegaly) have been observed in 34% (11/32) and PRs (50-89% reduction in IgM and reduction in lymphadenopathy / splenomegaly) in 44% (14/32) of patients to date. There have been no cases of disease progression.

MYD88 and CXCR4 mutational analysis results were available for 23 patients who were evaluable for response at the data cutoff. Preliminary sequencing data showed that of 18 evaluable patients with the MYD88^{L265P} / CXCR4^{WT} genotype, eight achieved VGPRs, seven achieved PRs, two achieved MRs, and one had stable disease (SD). The two patients with the MYD88^{L265P} / CXCR4^{WHIM} genotype achieved a PR and an MR, respectively. Responses were also seen in MYD88^{WT} patients, including one PR,

one MR, and one SD among three evaluable patients. Analysis of patient response by genomic characteristics is ongoing.

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