
**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): June 15, 2018

BEIGENE, LTD.

(Exact Name of Registrant as Specified in Charter)

Cayman Islands

(State or Other Jurisdiction of Incorporation)

001-37686

(Commission File Number)

98-1209416

(I.R.S. Employer Identification Number)

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2). Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01. Other Events.

On June 15, 2018, BeiGene, Ltd. (the “Company”) issued a press release announcing results on its investigational BTK inhibitor zanubrutinib from two poster presentations at the 23rd Congress of the European Hematology Association (EHA), taking place in Stockholm, Sweden. In the press release, the Company also provided updates on its planned development program for zanubrutinib. The full text of this press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit</u> <u>No.</u>	<u>Description</u>
99.1	Press Release titled “BeiGene Provides Development Update and Presents Clinical Data on Zanubrutinib at the 23rd Congress of the European Hematology Association” issued on June 15, 2018

Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release titled “BeiGene Provides Development Update and Presents Clinical Data on Zanubrutinib at the 23rd Congress of the European Hematology Association” issued on June 15, 2018

SIGNATURE

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: June 15, 2018

By: /s/ Scott A. Samuels

Scott A. Samuels

Senior Vice President, General Counsel

BeiGene Provides Development Update and Presents Clinical Data on Zanubrutinib at the 23rd Congress of the European Hematology Association

Investor Call Scheduled Today, June 15, 2018, at 8:00 am EDT

CAMBRIDGE, Mass. and BEIJING, China, June 15, 2018 (GLOBE NEWSWIRE) -- BeiGene, Ltd. (NASDAQ:BGNE), a commercial-stage biopharmaceutical company focused on developing and commercializing innovative molecularly-targeted and immuno-oncology drugs for the treatment of cancer, today presented results on its investigational BTK inhibitor zanubrutinib, from two poster presentations at the 23rd Congress of the European Hematology Association (EHA). The EHA meeting is taking place in Stockholm, Sweden from June 14-17, 2018.

“We continue to be encouraged by the quality and durability of response with zanubrutinib in the treatment of patients with Waldenström macroglobulinemia (WM), particularly with the observation that 43 percent of the evaluable patients achieved a very good partial response (VGPR). Additionally, the safety results from the combined experience in four ongoing monotherapy trials demonstrate that zanubrutinib was generally well-tolerated,” commented Jane Huang, M.D., Chief Medical Officer, Hematology, at BeiGene. “As these results mature, and as we near completion of enrollment in our Phase 3 trial comparing zanubrutinib with ibrutinib in patients with WM, we are hopeful that zanubrutinib, if approved, may represent a valuable treatment option for patients with this disease.”

In addition to zanubrutinib data presentations, BeiGene is providing the following updates to its planned development program for zanubrutinib:

- BeiGene has received results from the independent review of response data from the 86-patient single-arm pivotal Phase 2 study of zanubrutinib in Chinese patients with relapsed or refractory mantle cell lymphoma (MCL). The overall response rate (ORR) of 84 percent (59% complete response rate) met the pre-specified criteria for a positive trial, and the median duration of response has not been reached with 8.3 months median follow-up. The safety profile was consistent with previously reported clinical data for zanubrutinib. BeiGene plans to submit its first new drug application (NDA) for zanubrutinib in China for the treatment of patients with relapsed or refractory MCL later this year. Full results of the study are planned to be presented at an upcoming major medical conference.
- The global Phase 3 study comparing zanubrutinib to ibrutinib in patients with WM has met its enrollment target. The trial has closed new patient screening and is expected to complete enrollment in July. The Company plans to submit its first NDA in the United States for zanubrutinib in patients with WM in 2019.

Zanubrutinib in WM from Phase 1 Trial (EHA #PS1186)

A Phase 1 trial of zanubrutinib as a monotherapy in patients with different subtypes of B-cell malignancies, including WM, is being conducted in Australia, New Zealand, the United States, Italy, and South Korea. As of November 3, 2017, 67 patients with WM have been enrolled in the trial and were evaluable for safety. Fifty-one patients were evaluable for efficacy, excluding those with less than 12 weeks of follow-up (n=13) and those with IgM less than 5 g/L at baseline (n=3). Of the 51 patients evaluable for efficacy, 12 were treatment naïve and 39 patients were relapsed or refractory to prior treatment. At the time of the data cutoff, 59 patients remained on study treatment. Results included:

- For the 51 patients with WM evaluable for response, the ORR was 92 percent (47/51), and major response rate was 80 percent, with 43 percent of patients achieving a VGPR (defined as a $\geq 90\%$ reduction in baseline IgM levels and improvement of extramedullary disease by CT scan).
- The 12-month progression-free survival (PFS) was estimated at 91 percent. The median PFS had not yet been reached.
- Median time to response (partial response or higher) was 88 days (range, 77-279).
- The median IgM decreased from 32.5 g/L (range, 5.3-88.5) at baseline to 4.9 g/L (range, 0.1-57).
- Of 22 patients with hemoglobin <10 g/dL at baseline, the median increased from 8.7 g/dL (range, 6.3-9.8) to 13.8 g/dL (range, 7.7-15.8).
- While the presence of MYD88^{L265P} appears to be associated with response and depth of response with zanubrutinib treatment, significant activity was also observed in patients with MYD88^{WT} (ORR 83%, major response rate 50%, VGPR rate 17%).
- The most frequent adverse events (AEs) (>15%, all Grade 1-2 but one) of any attribution were petechia/purpura/contusion (37%), upper respiratory tract infection (34%), constipation (18%) and diarrhea (18%). Grade 3-4 AEs of any attribution reported in two or more patients included anemia (7%), neutropenia (6%), basal cell carcinoma (3%), hypertension (3%), squamous cell carcinoma (3%), pyrexia (3%), pneumonia (3%), major hemorrhage (3%), and actinic keratosis (3%).
- Serious AEs (SAEs) were seen in 22 patients (33%), with events in five patients (7%) considered possibly related to zanubrutinib treatment: febrile neutropenia, colitis, atrial fibrillation, hemothorax (spontaneous), and headache.
- Atrial fibrillation/flutter was experienced by four patients (6%), all Grade 1-2. Major hemorrhage was seen in two patients (3%).
- Four patients (6%) discontinued due to AEs: fatal worsening bronchiectasis, prostate cancer, gastric adenocarcinoma, and acute myeloid leukemia.
- Two patients (3%) discontinued study treatment due to disease progression as assessed by investigator and one patient remains on treatment post disease progression.

“Zanubrutinib continues to demonstrate robust activity in patients with WM. Deeper response rates have been maintained with longer follow-up in the Phase 1 trial and we are optimistic that zanubrutinib will demonstrate both high rates of activity and tolerability for patients, based on its potency and high-degree of selectivity,” said Judith Trotman, M.D., Director, Clinical Research Unit in Haematology, Concord Hospital, and Professor at the University of Sydney, Australia.

Pooled Analysis of Safety Data from Zanubrutinib Monotherapy Trials (EHA #PF445)

Pooled safety data from patients with various B-cell lymphomas in four ongoing zanubrutinib monotherapy studies, totaling 476 patients with a median exposure of seven months, will be presented at the EHA meeting. Overall, the data suggest that exposure levels of zanubrutinib resulting in complete and sustained BTK inhibition can be achieved and that zanubrutinib was generally well-tolerated. Results included:

- Events of interest with BTK inhibitor therapy, such as atrial fibrillation/flutter (2%), major hemorrhage (2%), and Grade 3 and above diarrhea (1%) have been infrequent.
- Treatment discontinuation due to zanubrutinib-related AEs was uncommon (3%).
- The majority of patients (94%) experienced one or more AE of any attribution, primarily Grades 1 or 2. The most common Grade 3 or higher AEs of any attribution were neutropenia/neutrophil count decreased/febrile neutropenia (14%), anemia (7%) and thrombocytopenia/platelet count decreased (7%).
- SAEs were reported in 116 patients (24%), with 38 patients (8%) assessed by the investigator as related to zanubrutinib. The most common SAEs were pneumonia/lung infection (6%), pleural effusion (1%), and febrile neutropenia (1%). The only treatment-related SAE reported in greater than one percent of patients was pneumonia/lung infection (2%). No cases of pneumocystis jiroveci pneumonia (PJP) or cytomegalovirus (CMV) reactivation were reported.
- The most common bleeding events observed included petechiae/purpura/contusion (26%) and hematuria (11%). Major hemorrhage (2%) included gastrointestinal hemorrhage/melena (n=3), intraparenchymal CNS hemorrhage Grade 5, hematuria, purpura, hemorrhagic cystitis, renal hematoma, and hemothorax (1 each). The median time to first major hemorrhage was 1.2 months.
- Amongst patients with emergent atrial fibrillation/flutter (n=8), a majority had known risk factors including hypertension (n=2), pre-existing cardiovascular disease (n=2), and concurrent infection (n=1).
- The cumulative rates of Grade 3 or higher infections were 14 percent at six months, 19 percent at 12 months and 21 percent at 18 months. The exposure-adjusted incidence rate was 1.82 per 100 person-months.
- The most common second primary malignancies included basal cell carcinoma (3%) and squamous cell carcinoma of the skin (1%).

“While BTK inhibitor therapy has historically been shown to be highly effective in the treatment of certain chronic B cell malignancies, such as chronic lymphocytic leukemia (CLL), WM, and MCL, specific events such as atrial fibrillation, serious diarrhea, and CNS bleeding, as well as appreciable overall rates of discontinuation of treatment due to tolerability or toxicity, remain concerns. With this pooled safety analysis of zanubrutinib monotherapy, we wanted to further assess whether its selectivity profile would translate into tolerability. We are encouraged that the low rates of BTK inhibitor-associated events, as well as low rates of toxicity-related treatment discontinuation, may allow for continuous disease control. We are hopeful that, if approved, patients with these hematologic malignancies could potentially lessen drug safety concerns, to focus on their lives rather than their disease,” said Constantine Tam, M.D., Director of Haematology, St. Vincent’s Hospital and Consultant Haematologist, Peter MacCallum Cancer Center, in Australia.

Today’s Investor Conference Call & Webcast Information

- **Date and Time:** Friday, June 15, 2018, 8:00 am EDT (Friday, June 15, 2018, 8:00 pm China Standard Time)
- **Dial-In Numbers:** 1-844-461-9930 or 1-478-219-0535 (U.S.), 400-682-8609 or 800-870-0169 (China), 852-30114522 (Hong Kong), 65-66221010 (Singapore), 61-282239773 (Australia), 0856619361 (Sweden), or 1-478-219-0535 (International).
- **Conference ID Number:** 7756029
- **Webcast and Replay:** A live webcast and replay of the event will be available on BeiGene’s investor website, <http://ir.beigene.com>. The dial-in replay will be available approximately two hours after the conference and will be available for two days following the event. It can be accessed by dialing 1-855-859-2056 (U.S.) or 1-404-537-3406 (International), or 400-683-7185 (China).

About Zanubrutinib

Zanubrutinib (BGB-3111) is an investigational small molecule inhibitor of Bruton’s tyrosine kinase (BTK) that is currently being evaluated in a broad pivotal clinical program globally and in China as a monotherapy and in combination with other therapies to treat various lymphomas.

About BeiGene

BeiGene is a global, commercial-stage, research-based biotechnology company focused on molecularly-targeted and immuno-oncology cancer therapeutics. With a team of over 1,100 employees in China, the United States, and Australia, BeiGene is advancing a pipeline consisting of novel oral small molecules and monoclonal antibodies for cancer. BeiGene is also working to create combination solutions aimed to have both a meaningful and lasting impact on cancer patients. BeiGene markets ABRAXANE[®] (nanoparticle albumin-bound paclitaxel), REVLIMID[®] (lenalidomide), and VIDAZA[®] (azacitidine) in China under a license from Celgene Corporation.¹

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 for zanubrutinib and BeiGene’s advancement of, and anticipated clinical development and regulatory milestones and plans related to zanubrutinib. 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 or marketing approval; actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials and marketing approval; BeiGene’s ability to achieve commercial success for its marketed products and drug candidates, if approved; BeiGene’s ability to obtain and maintain protection of intellectual property for its technology and drugs; BeiGene’s reliance on third parties to conduct drug development,

manufacturing and other services; 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.

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