
**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): October 12, 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 October 12, 2018, BeiGene, Ltd. (the “Company”) issued a press release announcing updated results on its investigational BTK inhibitor zanubrutinib from an oral presentation at the 10th International Workshop on Waldenström’s Macroglobulinemia (IWWM). A corrected version of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference, with a change to the description of the percent of patients who discontinued treatment due to disease progression from four patients (3%) to four patients (5%).

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit</u> <u>No.</u>	<u>Description</u>
99.1	Press Release titled “BeiGene Announces Updated Results from the Phase 1 Clinical Trial of Zanubrutinib in Patients with Waldenström’s Macroglobulinemia” issued on October 12, 2018

Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release titled “BeiGene Announces Updated Results from the Phase 1 Clinical Trial of Zanubrutinib in Patients with Waldenström’s Macroglobulinemia” issued on October 12, 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: October 16, 2018

By: /s/ Scott A. Samuels

Scott A. Samuels

Senior Vice President, General Counsel

BeiGene Announces Updated Results from Phase 1 Clinical Trial of Zanubrutinib in Patients with Waldenström's Macroglobulinemia

CAMBRIDGE, Mass. and BEIJING, China, Oct. 12, 2018 (GLOBE NEWSWIRE) -- BeiGene, Ltd. (NASDAQ: BGNE; HKEX: 06160), a commercial-stage biopharmaceutical company focused on developing and commercializing innovative molecularly-targeted and immuno-oncology drugs for the treatment of cancer, today announced updated results from the Phase 1 clinical trial of its investigational BTK inhibitor zanubrutinib, in an oral presentation at the 10th International Workshop on Waldenström's Macroglobulinemia (IWWM). The IWWM meeting is taking place in New York City from October 11-13, 2018.

"As we prepare our first U.S. New Drug Application (NDA) filing for zanubrutinib, which we expect to file in the first half of 2019 in patients with Waldenström's Macroglobulinemia (WM), we are pleased to update data in patients with WM from the Phase 1 trial that will support our filing. With more than 70 patients with WM now treated, we continue to see a high rate of deep and durable responses across genotypes, including high rates of overall, major, and very good partial responses (VGPRs)," commented Jane Huang, M.D., Chief Medical Officer, Hematology, at BeiGene. "We believe that the maturing data across B-cell malignancies continue to support a multi-regional approval strategy for zanubrutinib, including the ongoing NDA review in China for zanubrutinib in patients with relapsed/refractory mantle cell lymphoma by The National Medical Products Administration. We are hopeful that zanubrutinib, if approved, will represent a valuable treatment option across the globe for patients with several forms of B-cell malignancy."

Updated Results of Zanubrutinib in WM from Phase 1 Trial

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 July 24, 2018, 77 patients with treatment-naïve or relapsed/refractory WM have been enrolled in the trial. Seventy-three patients were evaluable for efficacy in this analysis and the median follow-up time was 22.5 months (4.1-43.9). The median time to response (\geq PR) was 85 days (55-749). At the time of the data cutoff, 62 patients remained on study treatment. Updated results included:

- The overall response rate (ORR) was 92 percent (67/73), the major response rate (MRR) was 82 percent, and 41 percent of patients achieved 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 89 percent. The median PFS had not yet been reached.
- The median IgM decreased from 32.7 g/L (5.3-91.9) at baseline to 8.2 g/L (0.3-57.8).
- The median hemoglobin increased from 8.85 g/dL (6.3-9.8) to 13.4 g/dL (7.7-17.0) among 32 patients with hemoglobin $<$ 10 g/dL at baseline.
- MYD88 genotype was known in 63 patients. In the subset known to have the MYD88 ^{L265P} mutation (n=54), the ORR was 94 percent, the major response rate was 89 percent, and the VGPR rate was 46 percent. In the nine patients known to be MYD88 ^{WT}, a less common genotype that historically has had sub-optimal response to BTK inhibition, the ORR was 89 percent, the major response rate was 67 percent, and the VGPR rate was 22 percent.
- Treatment with zanubrutinib was generally well-tolerated and the majority of adverse events (AEs) were grade 1 or 2 in severity. The most frequent AEs of any attribution were petechia/purpura/contusion (43%), upper respiratory tract infection (42%), cough (17%), diarrhea (17%), constipation (16%), back pain (16%), and headache (16%).
- Grade 3-4 AEs of any attribution reported in three or more patients included neutropenia (9%), anemia (7%), hypertension (5%), basal cell carcinoma (5%), renal and urinary disorders (4%), and pneumonia (4%). Serious AEs (SAEs) were seen in 32 patients (42%), with events in five patients (7%) considered possibly related to zanubrutinib treatment: febrile neutropenia, colitis, atrial fibrillation, hemothorax, and pneumonia (n=1 each).
- Nine patients (12%) discontinued due to AEs: abdominal sepsis (fatal), septic shoulder, worsening bronchiectasis, scedosporium infection, gastric adenocarcinoma (fatal), prostate adenocarcinoma, metastatic neuroendocrine carcinoma, acute myeloid leukemia, or breast cancer (n=1 each, all considered by the investigator to be unrelated to treatment).
- Atrial fibrillation/flutter occurred in four patients (5%). Major hemorrhage was observed in two patients (3%).
- Four patients (5%) discontinued study treatment due to disease progression as assessed by investigator and one patient remains on treatment post-disease progression.

"We are encouraged that additional data on zanubrutinib in patients with WM confirms the initially reported experience, with consistent demonstration of robust activity and good tolerability. We are hopeful that zanubrutinib, if approved, could potentially provide an important new treatment option to patients with WM and other hematologic malignancies," said Constantine Tam, M.D., Director of Hematology, St. Vincent's Hospital and Consultant Hematologist, Peter MacCallum Cancer Center, in Australia.

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 1,300 employees in China, the United States, Australia, and Switzerland, 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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