
**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 22, 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 22, 2018, BeiGene, Ltd. (the “Company”) issued a press release announcing that preliminary clinical data from an ongoing Phase 1 trial of its investigational PARP inhibitor, pamiparib, in combination with low-dose temozolomide in patients with locally advanced or metastatic solid tumors were presented at the European Society for Medical Oncology (ESMO) 2018 Congress in Munich, Germany. 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.

On October 24, 2018, the Company issued a press release announcing acceptance of its New Drug Application in China and top-line pivotal data for its investigational Bruton's tyrosine kinase (BTK) inhibitor, zanubrutinib, in patients with relapsed/refractory chronic lymphocytic leukemia or small lymphocytic lymphoma. The full text of this press release is filed as Exhibit 99.2 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>
<u>99.1</u>	<u>Press Release titled “BeiGene Presents Preliminary Clinical Data on PARP Inhibitor Pamiparib in Combination with Low-Dose Temozolomide in Patients with Solid Tumors at European Society for Medical Oncology (ESMO) 2018 Congress” issued on October 22, 2018</u>
<u>99.2</u>	<u>Press Release titled “BeiGene Announces Acceptance of its New Drug Application in China and Top-Line Pivotal Data for Zanubrutinib in Patients With Relapsed/Refractory Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma” issued on October 24, 2018</u>

Exhibit Index

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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 25, 2018

By: /s/ Scott A. Samuels

Scott A. Samuels

Senior Vice President, General Counsel

BeiGene Presents Preliminary Clinical Data on PARP Inhibitor Pamiparib in Combination with Low-Dose Temozolomide in Patients with Solid Tumors at European Society for Medical Oncology (ESMO) 2018 Congress

CAMBRIDGE, Mass. and BEIJING, China, Oct. 22, 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 that preliminary clinical data from an ongoing Phase 1 trial of its investigational PARP inhibitor, pamiparib, in combination with low-dose temozolomide in patients with locally advanced or metastatic solid tumors were presented at the European Society for Medical Oncology (ESMO) 2018 Congress, being held in Munich, Germany. Discovered by BeiGene scientists in Beijing, pamiparib is currently in Phase 3 trials globally and in China as a monotherapy and in Phase 1/2 trials in combination with chemotherapy or immunotherapy for a variety of solid tumors.

"In prior non-clinical studies, pamiparib has been shown to not only inhibit PARP from repairing damaged DNA, but also trap PARP on DNA undergoing repair, which we believe furthers its potential for anti-tumor activity. This study evaluates the combination of low-dose temozolomide, a DNA damaging agent, with full-dose pamiparib to assess the potential for PARP trapping, and is part of our effort to advance the global development of pamiparib as both a monotherapy and in combination," commented Amy Peterson, M.D., Chief Medical Officer for Immuno-Oncology of BeiGene.

"Preliminary results demonstrate antitumor activity across a variety of indications and regardless of known BRCA mutation status. That, combined with the preliminary safety and tolerability profile, support the continued development of this combination," said Melissa Johnson, M.D., Associate Director, Lung Cancer Research Program, Sarah Cannon Research Institute and lead author of the poster presentation.

Summary of Preliminary Results

This open-label, multi-center Phase 1b dose-escalation trial of pamiparib plus low-dose temozolomide (TMZ) (NCT03150810) was designed to evaluate the safety, tolerability, maximum tolerated dose (MTD), and preliminary antitumor activity of the combination in patients with locally advanced and metastatic tumors. Patients received full-dose pamiparib (60mg twice a day) in combination with escalating doses of TMZ, administered in both pulse and continuous dosing schedules.

As of August 24, 2018, a total of 40 patients with solid tumors have been enrolled in the study. The most frequent tumor types were prostate cancer (n=7), small cell lung cancer (n=6), breast cancer (n=4), epithelial ovarian cancer (n=4), and pancreatic cancer (n=3). Patients had received a median of four prior lines of therapy (1-10). The median duration of treatment was 1.6 months (0-9). As of the data cutoff, a total of 18 patients (45%) remained on pamiparib and TMZ treatment.

The combination was shown to be generally well tolerated. Dose-limiting grade 4 neutropenia was observed in two patients treated with 120 mg TMZ Days 1-7 and two patients treated with 100 mg TMZ Days 1-7. The most common treatment-emergent adverse events (TEAEs), regardless of grade or attribution, were nausea (52.5%), anemia (37.5%), neutropenia (30%), thrombocytopenia (27.5%), and fatigue (27.5%). TEAEs grade ≥ 3 occurred in 18 patients. The most common grade 3 or 4 adverse events (AEs) were neutropenia (27.5%), anemia (22.5%), and thrombocytopenia (20%). Cytopenias were manageable and reversible. Two patients experienced AEs that resulted in discontinuation of pamiparib and TMZ, one of which was considered related to study treatment. Serious AEs considered related to study treatment occurred in four patients (neutropenia, abdominal abscess, thrombocytopenia and leukopenia, and dehydration). There were no AEs with fatal outcome.

Twenty-three patients with solid tumors other than prostate cancer were evaluable per RECIST v1.1 (defined as having at least one post-baseline tumor assessment or at least nine weeks of follow-up). Preliminary data showed that two patients achieved a confirmed partial response (PR), including one patient with pancreatic cancer (treated with 40 mg TMZ Days 1-28), and one patient with small cell lung cancer (80 mg TMZ Days 1-7). Two additional patients achieved an unconfirmed PR, including one patient with BRCA-mutated triple-negative breast cancer treated with 80 mg TMZ Days 1-7, and one patient with urothelial cancer treated with 40mg TMZ Days 1-7. Ten patients had a best response of stable disease (SD); four patients had a best response of disease progression; and five patients were not evaluable for RECIST response either due to lack of a post-baseline tumor assessment or non-measurable disease at baseline.

All seven patients with prostate cancer were evaluated per the Prostate Cancer Working Group 2 (PCWG2) criteria. Of these, one patient (confirmed BRCA wildtype) achieved a visceral PR and prostate-specific antigen (PSA) response at the first post-baseline tumor assessment, and one patient achieved SD, who remains on study for over 270 days.

About Pamiparib

Pamiparib (BGB-290) is an investigational inhibitor of PARP1 and PARP2 which has demonstrated pharmacological properties such as brain penetration and PARP-DNA complex trapping in preclinical models. Discovered by BeiGene scientists in Beijing, pamiparib is currently in global clinical development as a monotherapy and in combination with other agents for a variety of solid tumor malignancies.

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 pamiparib and BeiGene's advancement of, and anticipated clinical development and regulatory milestones and plans related to pamiparib. 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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¹ ABRAXANE[®], REVLIMID[®], and VIDAZA[®] are registered trademarks of Celgene Corporation.

BeiGene Announces Acceptance of its New Drug Application in China and Top-Line Pivotal Data for Zanubrutinib in Patients With Relapsed/Refractory Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma

BEIJING, China, and CAMBRIDGE, Mass., Oct. 24, 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 the acceptance by the China National Medical Products Administration (NMPA) of a new drug application (NDA) for zanubrutinib, an investigational Bruton's tyrosine kinase (BTK) inhibitor, for the treatment of patients with relapsed/refractory (R/R) chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL). Zanubrutinib was discovered in BeiGene's research facilities in Beijing, China, and is being developed globally by BeiGene as a monotherapy and in combination with other therapies to treat various hematologic malignancies. In August, the NMPA accepted BeiGene's first NDA for zanubrutinib for the treatment of patients with R/R mantle cell lymphoma (MCL).

"Our team has made three NDA submissions in China this year, including two for zanubrutinib and one for tislelizumab, our investigational anti-PD-1 antibody. We are hopeful that these submissions, if approved, could further transform BeiGene as well as bring important new treatment options to cancer patients," commented John Oyler, co-founder, CEO and Chairman of BeiGene.

"We are delighted that the submission for zanubrutinib in patients with relapsed/refractory CLL/SLL was accepted by the NMPA in China, and we are excited to announce the top-line pivotal data for zanubrutinib in these patients, which demonstrated a high overall response rate of 80 percent despite a relatively short follow-up. These results in China are also consistent with the data from our global studies," said Dr. Xiaobin Wu, General Manager of China and President of BeiGene, Ltd.

The NDA is supported by an extensive clinical, non-clinical and chemistry, manufacturing and control (CMC) data package, including the results from a 91-patient single-arm pivotal Phase 2 study in Chinese patients with R/R CLL/SLL treated with zanubrutinib, dosed at 160 mg orally twice daily. An independent review of response data from this study, with a data cut-off of June 15, 2018 and a median follow-up of 9.1 months, showed an overall response rate (ORR) of 80 percent, inclusive of complete response (2%), partial response (39%), and partial response with lymphocytosis (40%). The median duration of response has not been reached, as a majority of the responders remain in a response. The safety profile was consistent with previously reported clinical data for zanubrutinib. Updated data with additional follow-up of the patients in the study will be submitted to the NMPA as an additional document of the NDA and are planned to be presented at an upcoming medical conference.

Zanubrutinib was recently granted Fast Track Designation by the U.S. Food and Drug Administration (FDA) for the treatment of patients with Waldenström macroglobulinemia (WM). BeiGene plans to submit an NDA to the FDA for zanubrutinib as a potential treatment for patients with WM in the first half of 2019 based on results from a global Phase 1 study.

Zanubrutinib is being evaluated in a broad global registration program, including a fully enrolled Phase 3 clinical trial in patients with WM, comparing zanubrutinib with ibrutinib, the currently approved BTK inhibitor for WM. Zanubrutinib is also being studied in comparison to bendamustine/ rituximab in a Phase 3 clinical trial in patients with previously untreated CLL/SLL, as well as in a pivotal randomized Phase 2 trial in combination with GAZYVA (obinutuzumab) in patients with R/R follicular lymphoma. In China, besides the pivotal Phase 2 trials in R/R MCL and R/R CLL/SLL, BeiGene has completed enrollment in a pivotal Phase 2 clinical trial in patients with WM. BeiGene also plans to initiate a Phase 3 trial comparing zanubrutinib to ibrutinib in patients with R/R CLL/ SLL.

About Chronic Lymphocytic Leukemia and Small Lymphocytic Lymphoma

Chronic lymphocytic leukemia (CLL) and small lymphocytic lymphoma (SLL) are forms of non-Hodgkin lymphoma, a type of blood cancer, that arise from B lymphocytes. CLL and SLL are essentially the same disease, with the only difference being the location where the cancer primarily occurs.ⁱ When most of the cancer cells are located in the bloodstream and the bone marrow, the disease is referred to as CLL, although the lymph nodes and spleen are often involved. When the cancer cells are located mostly in the lymph nodes, the disease is called SLL.ⁱⁱ

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 B cell malignancies.

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 1,700 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.

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ⁱ “Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma” Fact Sheet, Lymphoma Research Foundation. Accessed at: https://www.lymphoma.org/wp-content/uploads/2018/04/LRF_FACTSHEET_CLL_SLL.pdf

ⁱⁱ “Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma,” Lymphoma Research Foundation. Accessed at: <https://www.lymphoma.org/aboutlymphoma/cll/>

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