
**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): November 16, 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 November 16, 2018, BeiGene, Ltd. (the “Company”) issued a press release announcing preliminary clinical data on its investigational PARP inhibitor, pamiparib, from a presentation at the 23rd Annual Scientific Meeting and Education Day of the Society for Neuro-Oncology (SNO). 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.

Exhibit No. Description

99.1	Press Release titled “BeiGene Announces Preliminary Clinical Data on PARP Inhibitor Pamiparib Presented at Annual Scientific Meeting and Education Day of the Society for Neuro-Oncology” issued on November 16, 2018
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EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
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99.1	Press Release titled "BeiGene Announces Preliminary Clinical Data on PARP Inhibitor Pamiparib Presented at Annual Scientific Meeting and Education Day of the Society for Neuro-Oncology" issued on November 16, 2018
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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: November 19, 2018

By: /s/ Scott A. Samuels
Scott A. Samuels
Senior Vice President, General Counsel

BeiGene Announces Preliminary Clinical Data on PARP Inhibitor Pamiparib Presented at Annual Scientific Meeting and Education Day of the Society for Neuro-Oncology

CAMBRIDGE, Mass., and BEIJING, China, Nov. 16, 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 presentation of preliminary clinical data from an ongoing Phase 1/2 trial of its investigational PARP inhibitor, pamiparib, in combination with radiation therapy (RT) and/or temozolomide (TMZ) in patients with newly diagnosed or recurrent/refractory (R/R) glioblastoma multiforme (GBM). These data are being presented at the 23rd Annual Scientific Meeting and Education Day of the Society for Neuro-Oncology (SNO), being held November 15 to 18 in New Orleans, LA. 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.

"There are limited treatment options available for patients with newly diagnosed and recurrent/refractory glioblastoma. This trial was designed to evaluate the potential synergies between DNA damaging therapies and/or agents and our investigational PARP inhibitor, pamiparib, which in pre-clinical studies has demonstrated brain penetration and PARP trapping activity. We are excited to continue to assess the potential of pamiparib combinations for a variety of difficult-to-treat cancers where there is urgent global need," commented Amy Peterson, M.D., Chief Medical Officer for Immuno-Oncology at BeiGene.

"While response data are still maturing, these preliminary results demonstrated signs of antitumor activity of pamiparib in combination with radiation therapy in patients with newly diagnosed glioblastoma, as well as in combination with low-dose TMZ in patients with recurrent/refractory glioblastoma including those who previously progressed on TMZ, and support the continued development of these combinations," said Kent Shih, M.D., Senior Investigator of the Neuro-Oncology Program at Sarah Cannon Research Institute.

Summary of Preliminary Results

This open-label, multi-center global Phase 1b/2 multiple-dose and dose-escalation trial of pamiparib plus RT and/or TMZ (NCT03150862) was designed to evaluate the safety, efficacy and clinical activity of the combination in patients with newly diagnosed or R/R GBM. Patients with newly diagnosed GBM with unmethylated MGMT promoter status (Arm A) received pamiparib (60 mg twice a day) over escalating time periods (two, four, or six weeks) in combination with RT over six to seven weeks. Patients with R/R GBM (Arm C) received pamiparib (60 mg twice a day) continuously plus TMZ administered on Days 1 to 21 of each 28-day cycle. After evaluation of safety and tolerability from Arm A and C, Arm B will enroll patients with newly diagnosed GBM and treat them with the triple combination of RT, pamiparib, and TMZ.

As of September 14, 2018, a total of 18 patients with newly diagnosed GBM were enrolled in Arm A (n=3, 6 and 9 in the two-, four-, and six-week cohorts respectively). The median study follow-up duration is 19 weeks (2-54). Five grade ≥ 3 adverse events (AE) (chills, diarrhea, fatigue, nausea, vertigo, one [5.6%] each) were considered related to pamiparib or RT. Dose-limiting toxicities of fatigue, vertigo, and chills (one each) were reported.

As of the data cutoff date, 15 of the 18 patients were evaluable for response per modified response assessment in neuro-oncology (mRANO) criteria. Two of 15 patients achieved a partial response (PR, one was confirmed) and six patients achieved stable disease (SD); the disease control rate was 53.3% (95% CI: 26.6-78.7).

In Arm C, eight patients received TMZ at a fixed dose of 40 mg for 21 of 28 days and seven patients received 20 mg TMZ. The median study follow-up duration is 12.9 weeks (0.3-31.4). Grade ≥ 3 AEs included anemia (20%), fatigue (13.3%), and decreased lymphocyte (13.3%), which were considered related to pamiparib or TMZ. Dose-limiting toxicities of nausea and neutropenia were reported. The combination of 21 days of 40 mg TMZ with pamiparib was not tolerable; a lower 20 mg TMZ dose evaluation in combination with pamiparib is ongoing.

Ten of the 15 patients were evaluable per mRANO criteria and there were two PRs (one unconfirmed and one confirmed after data cutoff) and three SD.

About Glioblastoma Multiforme

Glioblastoma multiforme, also called glioblastoma, is an aggressive type of cancer where malignant grade IV tumors occur in the brain or spinal cord.² These are the most common type of malignant brain tumors among adults.³ Symptoms include worsening headaches, nausea, vomiting and seizures. Patients can also present with neurological symptoms which are dependent on the tumor location (for example, weakness or sensory changes of face, arm or leg, balance difficulties and neurocognitive/memory issues).⁴ Glioblastoma can occur at any age but tends to occur more often in older adults. The five-year relative survival rates for patients with glioblastoma are: 19 percent (age 20-44), eight percent (age 44-54), and five percent (age 55-64).⁵

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 1,700 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. 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.

² "Glioblastoma." Mayo Clinic. Accessed Online at <https://www.mayoclinic.org/diseases-conditions/glioblastoma/cdc-20350148> on November 5, 2018.

³ "What Is Glioblastoma?" WebMD. Accessed online at <https://www.webmd.com/cancer/brain-cancer/what-is-glioblastoma#1> on November 5, 2018.

⁴ "Glioblastoma (GBM)." American Brain Tumor Association. Accessed online at https://www.abta.org/tumor_types/glioblastoma-gbm/ on November 5, 2018.

⁵ <https://www.cancer.org/cancer/brain-spinal-cord-tumors-adults/detection-diagnosis-staging/survival-rates.html>