
**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): April 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 April 16, 2018, BeiGene, Ltd. (the "Company") issued a press release announcing that the first patient was dosed in a global Phase 2 clinical trial of tislelizumab, an investigational anti-PD-1 antibody, in patients with relapsed or refractory mature T- and natural killer (NK)-cell lymphomas. 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 April 16, 2018, the Company issued a press release announcing that preliminary clinical data from an ongoing Phase 1 trial of its investigational PARP inhibitor pamiparib in Chinese patients with locally advanced or metastatic high-grade non-mucinous ovarian cancer, including fallopian cancer, or triple-negative breast cancer, who had disease progression following at least one line of chemotherapy were presented at the 2018 American Association for Cancer Research (AACR) Annual Meeting, being held in Chicago. 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 .

Exhibit No.	Description
99.1	Press Release titled "BeiGene Initiates Global Phase 2 Trial of Anti-PD-1 Antibody Tislelizumab in Patients with Relapsed or Refractory Mature T-and NK-Cell Lymphomas" issued on April 16, 2018
99.2	Press Release titled "BeiGene Presents Clinical Data on Pamiparib in Chinese Patients with Ovarian Cancers or Triple-Negative Breast Cancer at the American Association for Cancer Research Annual Meeting" issued on April 16, 2018

Exhibit Index

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99.1	<u>Press Release titled "BeiGene Initiates Global Phase 2 Trial of Anti-PD-1 Antibody Tislelizumab in Patients with Relapsed or Refractory Mature T-and NK-Cell Lymphomas" issued on April 16, 2018</u>
99.2	<u>Press Release titled "BeiGene Presents Clinical Data on Pamiparib in Chinese Patients with Ovarian Cancers or Triple-Negative Breast Cancer at the American Association for Cancer Research Annual Meeting" issued on April 16, 2018</u>

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: April 16, 2018

By: /s/ Scott A. Samuels

Scott A. Samuels

Senior Vice President, General Counsel

BeiGene Initiates Global Phase 2 Trial of Anti-PD-1 Antibody Tislelizumab in Patients with Relapsed or Refractory Mature T-and NK-Cell Lymphomas

CAMBRIDGE, Mass. and BEIJING, China, April 16, 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, announced today that the first patient was dosed in a global Phase 2 clinical trial of tislelizumab, an investigational anti-PD-1 antibody, in patients with relapsed or refractory mature T- and natural killer (NK)-cell lymphomas. Tislelizumab is also being studied in global Phase 3 trials in solid tumors, including non-small cell lung cancer, hepatocellular carcinoma, and esophageal squamous cell carcinoma, and two pivotal Phase 2 trials in China in relapsed/refractory classical Hodgkin lymphoma and urothelial cancer.

“We are pleased to be enrolling patients in our first global Phase 2 study in hematology of tislelizumab, for which we maintain global development and commercial rights,” commented John V. Oyler, Founder, Chief Executive Officer, and Chairman of BeiGene.

“We believe that patients with relapsed or refractory mature T-cell and NK-cell lymphomas represent a significant unmet need. There are no currently approved treatments for the majority of mature T-cell lymphomas, in particular extranodal NK/T-cell lymphomas. We believe that these virally-associated diseases represent logical targets for checkpoint inhibition and we are excited to evaluate tislelizumab as a potential treatment option for these patients,” commented Jane Huang, M.D., Chief Medical Officer, Hematology, at BeiGene.

The Phase 2, open-label, multi-center trial is designed to assess the efficacy and safety of tislelizumab in patients with relapsed or refractory mature T- and NK-cell neoplasms. Patients will receive 200 mg of tislelizumab every three weeks in each of the trial’s two histological cohorts:

- Cohort 1 – patients with relapsed or refractory extranodal NK/T cell lymphoma (nasal or non-nasal type); and
- Cohort 2 – patients with other mature T-cell neoplasms, limited to histologies including peripheral T-cell lymphoma not otherwise specified (NOS), angioimmunoblastic T-cell lymphoma, and anaplastic large cell lymphoma.

Approximately 90 patients who had previously received appropriate first-line systemic therapy and experienced disease progression are planned to be enrolled in Greater China (including Hong Kong and Taiwan), Italy, Germany, France and the United States. The primary efficacy endpoint is objective response rate as determined by independent central review. Secondary endpoints include duration of response, progression-free survival, overall survival, rate of complete response or complete metabolic response, and time to response.

“Tislelizumab has shown promising anti-tumor activity and has been generally well-tolerated in clinical trials to-date in patients with a variety of cancers. We are excited to test the efficacy and safety of this agent in NK/-T cell lymphomas, where new treatment options are badly needed,” said Huiqiang Huang, M.D., Chief Physician at the Sun Yat-sen University Cancer Center, Guangdong Province, China, and a member of the steering committee of the trial.

For more information about the trial, patients and physicians should email BeiGene at clinicaltrials@beigene.com.

About Mature T- and NK-cell Neoplasms

T-lymphocytes (T-cells) are a type of white blood cell that can develop into lymphoma, or blood cancer. T-cell lymphomas account for approximately 10-15 percent of all non-Hodgkin’s lymphomas.ⁱ Natural killer (NK) cell neoplasms are more rare but are generally grouped with other T-cell lymphomas.ⁱⁱ The World Health Organization classifies several different types of leukemia under the term Mature (peripheral) T-cell Neoplasms (abnormal mass of tissue or blood), including: T-cell prolymphocytic leukemia, T-cell granular lymphocytic leukemia, aggressive NK-cell leukemia, adult T-cell lymphoma/leukemia (HTLV-1 positive), extranodal NK/T-cell lymphoma/ nasal type, enteropathy-type T-cell lymphoma, hepatosplenic gamma-delta T-cell lymphoma, subcutaneous panniculitis-like T-cell lymphoma, mycosis fungoides/Sezary syndrome, anaplastic large-cell lymphoma, T-/null cell, primary cutaneous type; peripheral T-cell lymphoma; angioimmunoblastic T-cell lymphoma, anaplastic large-cell lymphoma, T-/null cell, primary systemic type.

About Tislelizumab

Tislelizumab (BGB-A317) is an investigational humanized monoclonal antibody that belongs to a class of immuno-oncology agents known as immune checkpoint inhibitors. It is designed to bind to PD-1, a cell surface receptor that plays an important role in downregulating the immune system by preventing the activation of T-cells. Tislelizumab has demonstrated high affinity and specificity for PD-1. It is potentially differentiated from the currently approved PD-1 antibodies in an engineered Fc region, which is believed to minimize potentially negative interactions with other immune cells, based on preclinical data. Tislelizumab is being developed as a monotherapy and in combination with other therapies for the treatment of a broad array of both solid tumor and hematologic cancers. BeiGene and Celgene Corporation have a global strategic collaboration for the development of tislelizumab in solid tumor cancers outside of Asia (except Japan).

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 900 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.ⁱⁱⁱ

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 BeiGene’s advancement of, and anticipated clinical development, regulatory milestones and commercialization of tislelizumab. 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 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 annual report on Form 10-K, 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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ⁱ <https://www.ncbi.nlm.nih.gov/pubmed/9209634>

ⁱⁱ <http://www.lymphoma.org/site/pp.asp?c=bkLTKaOQLmK8E&b=6300161>

ⁱⁱⁱ ABRAXANE[®], REVLIMID[®], and VIDAZA[®] are registered trademarks of Celgene Corporation.

BeiGene Presents Clinical Data on Pamiparib in Chinese Patients with Ovarian Cancers or Triple-Negative Breast Cancer at the American Association for Cancer Research Annual Meeting

BEIJING, China and CAMBRIDGE, Mass., April 16, 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 announced that preliminary clinical data from an ongoing Phase 1 trial of its investigational PARP inhibitor pamiparib in Chinese patients with locally advanced or metastatic high-grade non-mucinous ovarian cancer (HGOC), including fallopian cancer, or triple-negative breast cancer (TNBC), who had disease progression following at least one line of chemotherapy were presented at the 2018 American Association for Cancer Research (AACR) Annual Meeting, being held in Chicago. Data presented from the dose-escalation phase of the ongoing Phase 1 trial confirmed the recommended Phase 2 dose (RP2D) of 60mg twice daily (BID) in Chinese patients and demonstrated that pamiparib showed antitumor activity and was generally well tolerated in these patients.

“In these heavily pre-treated patients with ovarian and breast cancers, the preliminary results support the recommended pamiparib dosing regimen and demonstrated antitumor activity, including partial responses in platinum-resistant or refractory patients with ovarian cancer. We saw no dose-limiting toxicities and found pamiparib to be generally well tolerated among these patients,” said Binghe Xu, M.D., Director of the Department of Medical Oncology, at the Cancer Hospital, Chinese Academy of Medical Sciences in Beijing, China, and the lead author of the poster presentation.

“In China, there are no currently approved PARP inhibitors, yet there are an aggregate of approximately 75,000 new cases of ovarian cancer¹ and triple-negative breast cancer diagnosed each year^{1, 2}, and it is estimated that between 25 and 30 percent of ovarian cancer³ and between 15 and 20⁴ percent of triple-negative breast cancer patients harbor a germline mutation in BRCA1/2 and therefore may benefit from a PARP inhibitor. We look forward to advancing pamiparib’s development in China as well as initiating a global Phase 3 trial,” commented Amy Peterson, M.D., Chief Medical Officer for Immuno-Oncology of BeiGene.

Summary of Results from the Ongoing Phase 1 Trial

This open-label, multi-center Phase 1 dose-escalation trial of pamiparib (NCT03333915) was designed to confirm RP2D and to evaluate its safety, tolerability and antitumor activity in Chinese patients with locally advanced or metastatic HGOC, including fallopian and primary peritoneal cancer, or patients with TNBC. Patients were dosed at 20mg, 40mg, or 60mg BID. As of September 25, 2017, 15 female patients were enrolled, nine with HGOC and six with TNBC. Nine patients received four or more prior lines of therapies. All nine patients with HGOC were platinum-resistant (n=8) or refractory (n=1). Seven patients had a confirmed BRCA1/2 mutation (BRCAm), including five patients with HGOC and two patients with TNBC and the remaining patients had BRCA 1/2 wildtype (BRCA-WT). The median duration of treatment was 2.5 months (range: 8-260 days).

Pamiparib was shown to be generally well tolerated. No dose-limiting toxicities were reported across the dose range, with RP2D confirmed as 60mg BID. Asthenia (n=12) and nausea (n=12) were the most commonly reported treatment-emergent adverse events (AE). Severity of all adverse events was grade 3 or less. Overall, three patients experienced a serious AE (grade 2 abdominal infection, n=1; grade 3 pleural effusion, n=1; grade 3 ileus, n=1), none of which were considered related to treatment. Two of the serious AEs led to treatment withdrawal (abdominal infection, n=1; pleural effusion, n=1).

As of September 25, 2017, 13 of the 15 patients were evaluable for antitumor activity; five patients remained on treatment. Two of the nine HGOC patients achieved a confirmed partial response including one platinum-refractory patient with BRCA wildtype status and one platinum-resistant patient with BRCA1/2 mutation, six HGOC patients had stable disease (BRCAm, n=4 and BRCA-WT, n=2) and one patient discontinued before the first radiographic assessment. Of the six treated TNBC patients, five (BRCAm, n=1, BRCA-WT, n=4) experienced disease progression and one patient (BRCAm) discontinued before the first radiographic assessment. Four of these evaluable TNBC patients were BRCA-WT and all experienced disease progression during the previous platinum-based chemotherapy.

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. Pamiparib is being evaluated in a pivotal clinical trial in China. It is currently in global clinical development as a monotherapy, and in combination with other agents, including BeiGene’s investigational anti-PD1 antibody, tislelizumab (BGB-A317), 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 900 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.⁵

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 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; 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 annual report on Form 10-K, 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

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¹ Chen et al., CA Cancer J Clin, 2016.

² Li et al, Asian Pac J Cancer Prev, 2013.

³ BeiGene market research

⁴ Engel et al., BMC Cancer, 2018.

⁵ ABRAXANE[®], REVLIMID[®], and VIDAZA[®] are registered trademarks of Celgene Corporation.