
**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 11, 2016**

BEIGENE, LTD.

(Exact name of registrant as specified in its charter)

Cayman Islands
(State or other jurisdiction
of incorporation)

001-37686
(Commission File Number)

98-1209416
(I.R.S. Employer Identification No.)

c/o Mourant 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))
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Item 8.01 Other Events.

On November 11, 2016, BeiGene, Ltd. (the “Company”) issued a press release announcing updated clinical data from its BGB-A317 clinical trial that was presented at the Society for Immunotherapy of Cancer (SITC) 31st Annual Meeting held in National Harbor, Maryland on November 11, 2016. The full text of the Company’s 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 No.</u>	<u>Description</u>
99.1	Press Release issued on November 11, 2016

SIGNATURES

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 11, 2016

By: /s/ Howard Liang
Name: Howard Liang
Title: Chief Financial Officer and Chief Strategy Officer

Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued on November 11, 2016



BeiGene Presents Updated Clinical Data on PD-1 Antibody BGB-A317 in Patients with Advanced Solid Tumors at the Society for Immunotherapy of Cancer 31st Annual Meeting

WALTHAM, Mass., November 11, 2016, BeiGene, Ltd. (NASDAQ:BGNE), a clinical-stage biopharmaceutical company developing innovative molecularly-targeted and immuno-oncology drugs for the treatment of cancer, today presented updated clinical data from an ongoing Phase I study of anti-PD-1 antibody BGB-A317 in patients with advanced solid tumors in a poster presentation at the Society for Immunotherapy of Cancer (SITC) 31st Annual Meeting held in National Harbor, Maryland. BGB-A317 is an investigational humanized monoclonal antibody against the immune checkpoint inhibitor PD-1. The updated clinical data suggest that BGB-A317 is well-tolerated with anti-tumor activity observed across multiple tumor types.

"We continue to see promising anti-tumor activity with BGB-A317 and a safety profile that is consistent with this class of molecules," said Jayesh Desai, MD, FRACP, a medical oncologist at The Royal Melbourne Hospital and Peter MacCallum Cancer Centre in Melbourne, Australia, coordinating principal investigator of the study.

"The anti-tumor activity from single-agent BGB-A317 is encouraging—to date, we have observed 15 confirmed responses in a variety of solid tumors. We anticipate sharing data from our Phase Ib combination trials with BGB-3111, our BTK inhibitor, and with BGB-290, our PARP inhibitor, in 2017," commented Amy Peterson, MD, Chief Medical Officer, Immuno-oncology at BeiGene.

Summary of Results from an Ongoing Phase 1 Study

The multi-center, open-label Phase I trial of BGB-A317 is being conducted in Australia and New Zealand to evaluate the safety, tolerability, pharmacokinetics, and anti-tumor activity of BGB-A317 in patients with advanced solid tumors. As of August 15, 2016, 103 patients were treated with BGB-A317 as a monotherapy. 22 patients were treated across four dose escalation cohorts with biweekly (Q2W) intravenous doses ranging from 0.5 to 10 mg/kg, and 81 patients were treated across four schedule expansion cohorts, receiving 2 or 5 mg/kg intravenously either Q2W or once every three weeks (Q3W). A single dose-limiting toxicity (DLT) of grade 3 colitis was observed in the 5 mg/kg Q2W dose escalation cohort containing six patients; a maximum tolerated dose was not reached. The study is currently evaluating flat dosing of 200 and 300 mg Q3W and further exploring BGB-A317

activity in multiple tumor types in the Phase 1b part of the study.

At the time of the data cutoff for the current safety analysis, the most common treatment-related adverse events (AEs) ($\geq 5\%$) were fatigue (19%), diarrhea (13%), rash (11%), pruritus (11%), nausea (8%), hypothyroidism (7%), and infusion related reactions (6%). Treatment-related serious adverse events (SAEs) included four cases of colitis, two cases of hypotension, and one case each of diarrhea, diabetes mellitus, diabetic ketoacidosis, dyspnea, hypoxia, infusion-related reaction, and pneumonitis. Among these, \geq grade 3 treatment-related SAEs included the two cases of hypotension and one case each of colitis, diabetes mellitus, diabetic ketoacidosis, dyspnea, hypoxia, and pneumonitis. Other treatment-related grade ≥ 3 AEs included two cases each of fatigue and hyperglycemia, and one case each of back pain, elevated alanine aminotransferase (ALT), and elevated gamma-glutamyl transferase (GGT).

Among 99 patients evaluable for efficacy as of September 30, 2016, evidence of anti-tumor activity included 15 confirmed partial responses (PRs) and 23 cases of stable disease (SD). 13 responding patients remain on treatment with duration of response ranging from 28—47 weeks. Confirmed PRs were observed in three of nine renal cell carcinoma patients, three of six urothelial carcinoma patients, two of four gastric cancer patients, two of two Merkel cell carcinoma patients, one of four nasopharyngeal cancer patients, one of one penis squamous cell carcinoma patient, one of one duodenal carcinoma patient, one evaluable patient of two patients with microsatellite instability high (MSI-h) colorectal cancer (CRC) among 13 CRC patients, and one pancreatic cancer patient with MSI-h status among two pancreatic cancer patients.

Four patients who discontinued treatment before the first tumor imaging assessment due to symptomatic deterioration (three cases) or grade 2 infusion reaction (one case) were not evaluable for efficacy. One of seven patients with mesothelioma discontinued therapy due to treatment-related grade 3 pneumonitis prior to obtaining confirmation of an initial PR. Additionally, two of 23 patients with ovarian cancer and one of five patients with cervical cancer had significant tumor shrinkage qualifying for a PR in one imaging assessment but not confirmed in the subsequent assessment due to disease progression.

Additional tumor types enrolled in the study include endometrial, esophageal,

gallbladder, breast, and thyroid cancers, cholangiocarcinoma, sarcoma, glioblastoma, hepatocellular, anal squamous cell, cutaneous squamous cell, adrenocorticoid, and adenoid cystic carcinomas, adenocarcinoma of mandible, and undifferentiated adenocarcinoma from teratoma, with one to five patients each.

About BGB-A317

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. BGB-A317 has high affinity and specificity for PD-1, and we believe it is differentiated from the currently approved PD-1 antibodies with the ability to bind Fc gamma receptor I specifically engineered out. BGB-A317 is being developed as a monotherapy and in combination with other therapies for the treatment of various cancers.

About BeiGene

BeiGene is a global, clinical-stage, research-based biotechnology company focused on molecularly targeted and immuno-oncology cancer therapeutics. With a team of over 300 scientists, clinicians and staff in mainland China, the United States, Australia and Taiwan, BeiGene is advancing a pipeline consisting of novel oral small molecules and monoclonal antibodies for cancer. BeiGene is working to create combination solutions aimed to have both a meaningful and lasting impact on cancer patients.

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 BGB-A317, the potential implications of these data for the future development of BGB-A317, and BeiGene's advancement of, and anticipated clinical development and regulatory milestones and plans related to BGB-A317. 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 the 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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