
**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): February 9, 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 February 9, 2018, BeiGene, Ltd. (the “Company”) issued a press release announcing preliminary clinical data from patients with urothelial carcinoma (UC) enrolled in an ongoing Phase 1 clinical trial of tislelizumab, an investigational anti-PD-1 antibody, presented at the 2018 Genitourinary Cancers Symposium in San Francisco. The preliminary Phase 1 data suggest that tislelizumab was generally well tolerated and exhibited objective responses in patients with UC. 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.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued on February 9, 2018

Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued on February 9, 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: February 9, 2018

By: /s/ Scott A. Samuels

Scott A. Samuels

Senior Vice President, General Counsel

BeiGene Presents Preliminary Phase 1 Data on Tislelizumab in Patients with Urothelial Carcinoma at 2018 Genitourinary Cancers Symposium

CAMBRIDGE, Mass., and BEIJING, China, Feb. 09, 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, presented preliminary clinical data from patients with urothelial carcinoma (UC) enrolled in an ongoing Phase 1 clinical trial of tislelizumab, an investigational anti-PD-1 antibody, at the 2018 Genitourinary Cancers Symposium in San Francisco. The preliminary Phase 1 data suggest that tislelizumab was generally well tolerated and exhibited objective responses in patients with UC.

"Tislelizumab administration resulted in objective responses, including a complete response, and a disease-control rate of 53 percent. Tislelizumab was generally well-tolerated in patients with urothelial carcinoma," said Shahneen Sandhu, M.D., medical oncologist at the Peter MacCallum Cancer Center in Melbourne, Australia and lead author. "We are highly encouraged by these results and that further study of tislelizumab may lead to a new treatment for patients with urothelial cancer."

"Tislelizumab is currently being evaluated in five pivotal trials globally and in China, including a pivotal trial in patients with previously treated, PD-L1-positive, locally advanced or metastatic urothelial carcinoma in China. This is the first presentation of tislelizumab data in the population with urothelial cancer, an area of unmet need. We are pleased by these preliminary results, which we believe provide an important foundation for our clinical understanding of tislelizumab's efficacy and safety in specific patient populations both as a single agent and in combination," commented Amy Peterson, M.D., Chief Medical Officer, Immuno-Oncology, at BeiGene.

Summary of Results from the Ongoing Phase 1 Trial

The multi-center, open-label Phase 1 trial (NCT02407990) of tislelizumab as monotherapy in advanced solid tumors is being conducted in Australia, New Zealand, the United States, Taiwan, and South Korea and consists of dose escalation, schedule expansion, fixed dose expansion, and indication expansion in disease-specific cohorts.

Data presented at the Genitourinary Cancers Symposium included 16 patients with urothelial carcinoma. Of these, 12 had one or more prior systemic anticancer treatment for metastatic disease and the remaining four had progressed after receiving platinum-based regimen in the neoadjuvant or adjuvant setting. In addition, five patients had prior radiotherapy. At the time of the data cutoff on August 28, 2017, median treatment duration was 4.3 months (range of 0.7 to 18.3 months). A total of six patients remained on treatment.

Adverse events (AEs) assessed by the investigator to be related to treatment occurred in 14 patients (88%). Of those, fatigue (31%), rash (19%), infusion related reactions (13%), nausea (13%), pain in extremity (13%), and proteinuria (13%) occurred in more than one patient. All of the treatment-related AEs were grade 1 or 2 except one case each of fatigue, hyperglycemia, and diabetes mellitus. One adverse event of muscle weakness, which was associated with disease progression and occurred more than one month after the last dose of the study drug, had a fatal outcome; this event was considered not related to treatment.

At the time of the data cutoff, 15 patients were evaluable, defined as having a measurable baseline tumor assessment and at least one evaluable post-baseline tumor response assessment, or had progressed or died prior to the initial tumor assessment. One patient had a confirmed complete response (CR), four achieved a confirmed partial response (PR), and three achieved stable disease (SD). Nine evaluable patients had PD-L1 status determined. There was one CR, two PR and one SD among six PD-L1 high patients, and one PR among three PD-L1 low or negative patients.

About Urothelial Carcinoma

Cancer that begins in cells that line the urethra, bladder, ureters, renal pelvis, and some other organs are referred to as urothelial carcinoma. ⁱ Urothelial carcinoma is the most common type of bladder cancer and the fifth most common cancer in the United States. ⁱⁱ In 2017, it was estimated that there were 79,030 new cases of bladder cancer and 16,870 deaths. ⁱⁱⁱ

About Tislelizumab

Tislelizumab 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 850 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. ^{iv}

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 of tislelizumab and its potential commercial opportunity. 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 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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ⁱ <https://www.cancer.gov/publications/dictionaries/cancer-terms?cdrid=783188>

ⁱⁱ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4561017/#R1>

ⁱⁱⁱ <https://seer.cancer.gov/statfacts/html/urinb.html>

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