
**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): January 2, 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 January 2, 2018, BeiGene, Ltd. (the “Company”) issued a press release announcing t hat the first patient was dosed in a global Phase 3 clinical trial of tislelizumab (BGB-A317), an investigational anti-PD-1 antibody, in patients with previously untreated advanced hepatocellular carcinoma. 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>
<u>99.1</u>	Press Release issued on January 2, 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: January 2, 2018

By: /s/ Scott A. Samuels

Scott A. Samuels

Senior Vice President, General Counsel

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
<u>99.1</u>	Press Release issued on January 2, 2018

BeiGene Initiates Global Phase 3 Trial of Anti-PD-1 Antibody Tislelizumab in Patients with Hepatocellular Carcinoma

CAMBRIDGE, Mass. and BEIJING, China, Jan. 02, 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 in December 2017 the first patient was dosed in a global Phase 3 clinical trial of tislelizumab, an investigational anti-PD-1 antibody, in patients with previously untreated advanced hepatocellular carcinoma (HCC or liver cancer). Along with two pivotal Phase 2 trials in China in relapsed/refractory classical Hodgkin lymphoma and urothelial cancer, and a global Phase 3 trial in patients with non-small cell lung cancer, tislelizumab is now being evaluated in pivotal trials in four distinct indications.

“We are pleased to announce the initiation of this global Phase 3 trial of tislelizumab as part of our collaboration with our partner Celgene. We look forward to continuing to leverage our strong presence in Asia and global clinical development organization to broadly develop tislelizumab,” commented John V. Oyler, Founder, Chief Executive Officer, and Chairman of BeiGene.

“Advanced liver cancer is a serious and prevalent disease, with few treatment options. We are hopeful that this Phase 3 trial will establish safety and efficacy of tislelizumab in a head-to-head comparison to sorafenib, the current global standard of care for advanced liver cancer,” commented Amy Peterson, M.D., Chief Medical Officer for Immuno-Oncology of BeiGene.

The Phase 3, open-label, multi-center, randomized trial is designed to compare the efficacy and safety of tislelizumab versus sorafenib as a potential first-line treatment in patients with unresectable HCC. Approximately 640 patients will be enrolled at approximately 110 cancer centers in China, the United States, Japan, the United Kingdom, Germany, Spain, Czech Republic, France, and Italy. Patients will be randomized to receive either tislelizumab at 200 mg every three weeks or sorafenib at 400 mg twice daily.

The trial’s primary endpoint is overall survival, and secondary endpoints include overall response rate, progression free survival, duration of response, time to progression, health-related quality of life, disease control rate, clinical benefit rate, and safety profile.

“The expected median survival in patients with advanced liver cancer is typically less than one year, and patients can face difficulties tolerating sorafenib,” said Qin Shukui, M.D., Hospital Deputy Director and Director of the Cancer Center at the People’s Liberation Army 81 Hospital, Nanjing, China, and co-lead investigator of the trial. “I look forward to testing tislelizumab in the hopes that we can further advance treatment options for patients with advanced liver cancer.”

“I am excited for the opportunity to evaluate the safety and efficacy of tislelizumab, which has been dosed in more than 850 patients in either monotherapy or combination clinical trials. Based on preliminary data from a dose expansion cohort of HCC patients in a Phase 1 trial, we are hopeful that tislelizumab will be well-tolerated and exhibit meaningful anti-tumor activity in this Phase 3 trial,” said Andrew Zhu, M.D., Ph.D., Director of Liver Cancer Research at Massachusetts General Hospital, Professor of Medicine at Harvard Medical School and co-lead investigator of the trial.

For more information about the trial, patients and physicians should email BeiGene at BGBA317clinicaltrials@beigene.com.

About Hepatocellular Carcinoma

HCC is a major global health problem, accounting for 85-90 percent of all reported cases of liver cancer. ⁱ Liver cancer is the sixth most common type of cancer, with an estimated 782,000 new cases per year worldwide; it was also the second most common cause of cancer-related mortality, responsible for an estimated 746,000 deaths. ⁱⁱ China accounts for approximately 50 percent of both new HCC cases and HCC-related deaths worldwide. ⁱⁱ

About Tislelizumab (BGB-A317)

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 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. 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 tislelizumab for solid tumors 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 700 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 and regulatory milestones and plans related to 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 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 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.

Investor Contact

Lucy Li, Ph.D.
+1 781-801-1800
ir@beigene.com

Media Contact

Liza Heapes
+ 1 857-302-5663
media@beigene.com

ⁱ Nordenstedt H, White DL, El-Serag HB. The changing pattern of epidemiology in hepatocellular carcinoma. Digestive and Liver Disease. 2010;42(Suppl 3):S206-S214. doi:10.1016/S1590-8658(10)60507-5.

ⁱⁱ GLOBOCAN 2012: http://globocan.iarc.fr/Pages/fact_sheets_cancer.aspx. Accessed December 27, 2017.

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