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): **August 31, 2018**

BEIGENE, LTD.
(Exact name of registrant as specified in its charter)

Cayman Islands	**001-37686**	**98-1209416**
(State or other jurisdiction of incorporation)	(Commission File Number)	(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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 or Rule 12b-2 of the Securities Exchange Act of 1934.

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 August 31, 2018, BeiGene, Ltd. (the "Company") issued a press release announcing acceptance by the National Medical Products Administration of China (NMPA, formerly known as CFDA or CDA) of a new drug application (NDA) for tislelizumab, an investigational anti-PD-1 antibody, as a potential treatment for patients with relapsed/refractory classical Hodgkin's lymphoma (R/R cHL). 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 Acceptance of New Drug Application for Anti-PD-1 Antibody Tislelizumab in Hodgkin's Lymphoma in China" issued on August 31, 2018

Exhibit Index

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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.

Date: August 31, 2018

BEIGENE, LTD.

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

Exhibit 99.1

BeiGene Announces Acceptance of New Drug Application for Anti-PD-1 Antibody Tislelizumab in Hodgkin's Lymphoma in China

BEIJING, China, and CAMBRIDGE, Mass., August 31, 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 that the National Medical Products Administration of China (NMPA, formerly known as CFDA or CDA) has accepted the new drug application (NDA) for tislelizumab, an investigational anti-PD-1 antibody, as a potential treatment for patients with relapsed/refractory classical Hodgkin's lymphoma (R/R cHL).

"The acceptance of our first NDA for tislelizumab represents an important milestone for BeiGene and for Chinese patients with Hodgkin's lymphoma. Patients who relapse or don't respond to standard treatment with chemotherapy or radiation often have poor prognoses. We are encouraged by the potential for tislelizumab to provide a new treatment option for these patients," said Jane Huang, M.D., Chief Medical Officer, Hematology, at BeiGene.

The NDA is supported by a clinical and non-clinical data package, including the results from a pivotal Phase 2 study of tislelizumab in Chinese patients with R/R cHL. A recent independent review of data from all 70 enrolled patients in an intent-to-treat analysis showed that with a minimum of 24 weeks of follow-up and a median follow-up time of 7.85 months at the data cutoff, overall response rate (ORR) was 85.7 percent, including 61.4 percent complete response (CR). Frequency and severity of adverse events were generally consistent with previously reported Phase 1 safety and tolerability data for tislelizumab, or, in the case of certain immune-related events such as hypothyroidism and fever, consistent with previous reports of other PD-1 antibodies for the treatment of cHL. Full results of the study are planned to be presented at an upcoming medical conference.

"We are excited by the response rates, including high complete response rates we have seen in our pivotal study in R/R cHL, and look forward to working closely with the NMPA to make tislelizumab available to patients in China as quickly as possible," said Wendy Yan, Global Head of Regulatory Affairs at BeiGene.

In addition to the pivotal Phase 2 clinical trial in R/R cHL, tislelizumab is also being studied in global Phase 3 trials in a number of malignancies, including non-small cell lung cancer, hepatocellular carcinoma, and esophageal squamous cell carcinoma; as well as two global Phase 2 trials in patients with previously treated hepatocellular carcinoma or with R/R mature T- and NK-cell lymphomas, and an additional pivotal Phase 2 trial in China in urothelial cancer.

About Classical Hodgkin's Lymphoma

Hodgkin's lymphoma is one of the two major types of lymphoma that begin in the lymph nodes and tissues of the lymphatic system. All other lymphomas are classified as non-Hodgkin's lymphomas. Classical Hodgkin's lymphoma, the most common form representing about 95 percent of the patients with Hodgkin's lymphoma, is characterized by the presence of very large cells called Reed-Sternberg cells. There were approximately 2,100 diagnosed cases of Hodgkin's lymphoma in China in 2012.(i) Although the cancer can occur in both children and adults, it is most commonly diagnosed in young adults between the ages of 15 and 35 and in older adults over age 50.

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. Discovered by BeiGene scientists in Beijing, tislelizumab 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 1,300 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.(ii)

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 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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