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 1, 2019**

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 Governance 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 April 1, 2019, BeiGene, Ltd. (the "Company") issued a press release announcing the presentation of long-term Phase 1 data and results of structural and binding mechanistic analyses on its investigational anti PD-1 inhibitor, tiselizumab, in two posters at the American Association for Cancer Research (AACR) Annual Meeting 2019, taking place March 29-April 3, 2019 in Atlanta, Georgia. 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 Phase 1 Long-Term Exposure Data and Results from Structural and Mechanistic Analyses on Tiselizumab at the AACR Annual Meeting" issued on April 1, 2019

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: April 2, 2019

BEIGENE, LTD.

By: /s/ Scott A. Samuels

Name: Scott A. Samuels

Title: Senior Vice President, General Counsel

BeiGene

BeiGene Announces Phase 1 Long-Term Exposure Data and Results from Structural and Mechanistic Analyses on Tislelizumab at the AACR Annual Meeting

CAMBRIDGE, Mass. and BEIJING, China; April 1, 2019 (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 the presentation of long-term Phase 1 data and results of structural and binding mechanistic analyses on its investigational anti-PD1 inhibitor, tislelizumab, in two posters at the American Association for Cancer Research (AACR) Annual Meeting 2019, taking place March 29-April 3, 2019, in Atlanta, Georgia.

"We believe that these two presentations further support the broad development program for tislelizumab as a potentially differentiated anti-PD1 antibody," said Yong (Ben) Ben, M.D., Chief Medical Officer, Immuno-Oncology, at BeiGene. "The long-term single-agent exposure data on tislelizumab demonstrated that it was generally well-tolerated when given for more than 12 months and that it elicited durable responses in patients with a variety of tumor types, regardless of PD-L1 status. The non-clinical research poster on tislelizumab looked, for the first time, to identify key areas where its molecular binding mechanism may be differentiated from approved anti-PD-1 antibodies, which may help direct our research and development efforts in indications where we can improve outcomes for patients in need."

Long-Term Exposure to Tislelizumab, an Investigational Anti-PD-1 Antibody, in a First-in-Human Phase 1 Study

Phase 1 Poster Data (Poster number CT084, board number 8)

The multi-center, open-label Phase 1 trial (ClinicalTrials.gov Identifier: 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. This first-in-human (FIH) trial is fully enrolled with over 450 patients.

As of October 27, 2018, 65 patients received tislelizumab for more than 12 months and were included in this long-term exposure (LTE) analysis. These 65 patients were from both the dose-escalation and dose-expansion phases. Most patients (n=46) with LTE received tislelizumab at 5 mg/kg Q3W, while additional patients received 2 mg/kg Q3W (n=9), 2 mg/kg Q2W (n=2), 5 mg/kg Q2W (n=5), and 200 mg Q3W (n=3). The most common tumor types (defined as ≥5 patients with LTE) were non-small cell lung cancer (NSCLC; n=9), hepatocellular cancer (HCC; n=8) and bladder and ovarian cancers (n=5 each).

With a median follow-up of 27.2 months, the objective response rate (ORR) among patients with LTE was 68 percent. Four patients achieved complete response (CR), including patients with cutaneous squamous cell carcinoma, endometrial, bladder and esophageal cancers (n=1 each). All four patients were PD-L1 positive. Partial responses (PR) and stable disease (SD) were observed in both PD-L1 positive and PD-L1 negative tumors. The median duration of response (DoR) was 21.1 months in those with LTE.

LTE to tislelizumab was generally well-tolerated when given for more than 12 months. As of the data cutoff, 52 of 65 patients (80%) experienced one or more treatment-related adverse event (TRAE), most of which were mild to moderate in severity. Rash was the only TRAE reported in more than 15% of patients, and no rash event of grade 3 or higher occurred. TRAEs of grade 3 or higher were arthritis, diarrhea, fatigue, granuloma, hyperglycemia, increased alanine aminotransferase, rash papular, and lichenoid keratosis (n=1 each).

Serious TRAEs occurred in three patients, including pyrexia (n=2) and arthritis (n=1) and all resolved. Three patients experienced AEs that eventually led to discontinuation. There were no fatal AEs.

The Molecular Binding Mechanism of Tislelizumab, an Investigational Anti-PD-1 Antibody, is Differentiated from Pembrolizumab and Nivolumab
Preclinical Poster Data (Poster number 2383, board number 7)

In this non-clinical study, the co-crystal structure of the PD-1 extracellular domain with the antigen-binding fragment (Fab) of tislelizumab was solved to reveal the molecular binding mechanism, and structure-guided mutagenesis and surface plasmon resonance studies were performed to compare the binding of tislelizumab, pembrolizumab and nivolumab to PD-1.

Tislelizumab was shown to form extensive interactions with PD-1 with three complementarity-determining regions (CDR) of VL domain and two CDRs of VH domain. The dissociation rate of tislelizumab from wild type PD-1 was about 100-fold and 50-fold slower than that of pembrolizumab and nivolumab, respectively.

Tislelizumab was shown to have a different binding orientation to PD-1 compared to pembrolizumab and nivolumab. The binding surface on PD-1 for tislelizumab partially overlaps with that for pembrolizumab but differs significantly from that for nivolumab. The amino acids Gln75, Thr76, Asp77 and Arg86 in PD-1 were identified to be critical epitopes for tislelizumab binding but not pembrolizumab or nivolumab, as mutations of these epitopes showed relatively little effect on binding of PD-1 to pembrolizumab

and nivolumab as compared to tislelizumab.

Tislelizumab was demonstrated to be differentiated from pembrolizumab and nivolumab by a distinctive binding orientation, the unique epitopes, and binding kinetics to PD-1.

About Tislelizumab

Tislelizumab (BGB-A317) is an investigational humanized IgG4 anti–PD-1 monoclonal antibody specifically designed to minimize binding to FcγR on macrophages. In pre-clinical studies, binding to FcγR on macrophages has been shown to compromise the anti-tumor activity of PD-1 antibodies through activation of antibody-dependent macrophage-mediated killing of T effector cells. Tislelizumab is the first drug candidate produced from BeiGene's immuno-oncology biologic program, and 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.

Clinical trials of tislelizumab include a global Phase 3 clinical trial in patients with second-line non-small cell lung cancer (NSCLC); a global Phase 3 clinical trial in first-line patients with hepatocellular carcinoma (HCC); a global Phase 3 clinical trial in second-line patients with esophageal squamous carcinoma (ESCC); a global Phase 3 clinical trial in first-line patients with gastric cancer (GC); a global Phase 3 clinical trial in first-line patients with ESCC; a global Phase 3 trial in patients with Stage III NSCLC; a global Phase 2 clinical trial in second- or third-line patients with HCC; a global Phase 1 clinical trial in patients with relapsed/refractory (R/R) NK/T-cell lymphomas; and a global Phase 1 clinical trial in patients with solid tumors. In China, BeiGene has completed a pivotal Phase 2 clinical trial in patients with R/R classical Hodgkin's lymphoma (cHL), and is conducting a Phase 3 clinical trial in first-line patients with non-squamous NSCLC; a Phase 3 clinical trial in first-line patients with squamous NSCLC; a Phase 2 clinical trial in second-line urothelial cancers (UC); and a Phase 2 clinical trial in patients with MSI-H or dMMR solid tumors.

The new drug application (NDA) in China for R/R cHL has been accepted by the China National Medical Products Administration (NMPA) and granted priority review.

BeiGene and Celgene Corporation have a global strategic collaboration for the development of tislelizumab in solid tumor cancers outside of Asia (except Japan).

BeiGene

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 2,200 employees in China, the United States, Australia and Europe, 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.[i]

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 from clinical trials of tislelizumab, the mechanism of action of tislelizumab, and 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 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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