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 14, 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 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 January 14, 2019, BeiGene, Ltd. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy designation for the Company's Bruton's tyrosine kinase (BTK) inhibitor zanubrutinib for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy. 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 Receives U.S. FDA Breakthrough Therapy Designation for Zanubrutinib in Mantle Cell Lymphoma" issued on January 14, 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: January 14, 2019

BEIGENE, LTD.

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

Exhibit 99.1

BeiGene

BeiGene Receives U.S. FDA Breakthrough Therapy Designation for Zanubrutinib in Mantle Cell Lymphoma

CAMBRIDGE, Mass. and BEIJING, China; January 14, 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 that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy designation for its investigational Bruton's tyrosine kinase (BTK) inhibitor, zanubrutinib, for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy.

"We are very excited to receive the Breakthrough Therapy designation from the FDA," said Jane Huang, M.D., Chief Medical Officer, Hematology, at BeiGene. "Zanubrutinib has been designed to maximize BTK occupancy and minimize off-target effects. We believe that the Breakthrough Therapy designation underscores the potential of zanubrutinib as a meaningful treatment for patients with MCL who have received at least one prior therapy. More than 1,300 patients worldwide have been treated with zanubrutinib, and it's being developed in a broad clinical program that currently includes seven Phase 3 or pivotal trials conducted globally or in China."

About Breakthrough Therapy Designation
The FDA's Breakthrough Therapy designation program is intended to expedite the development and review of a drug candidate that is planned to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. According to the FDA's guidelines, the features of the program include more intensive FDA guidance on an efficient drug development program, an organizational commitment involving senior managers, and eligibility for rolling review and priority review. The Food and Drug Administration Safety and Innovation Act (FDASIA) requires the following actions, as appropriate: holding meetings with the sponsor and the review team throughout the development of the drug, providing timely advice to, and interactive communication with, the sponsor regarding the development of the drug to ensure that the development program to gather the nonclinical and clinical data necessary for approval is as efficient as practicable; taking steps to ensure that the design of the clinical trials is as efficient as practicable, when scientifically appropriate, such as by minimizing the number of patients exposed to a potentially less efficacious treatment; assigning a cross-disciplinary project lead for the FDA review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the cross-disciplinary members of the review team (i.e., clinical, pharmacology-toxicology, chemistry, manufacturing and control, compliance) for coordinated internal interactions and communications with the sponsor through the review division's regulatory health project manager; and involving senior managers and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review. The designation may be rescinded if the drug candidate does not continue to meet the criteria for Breakthrough Therapy designation.

About Mantle Cell Lymphoma
Lymphoma is a diverse group of malignancies that originates from B-, T- or NK- cells. Mantle cell lymphoma (MCL) is typically an aggressive form of non-Hodgkin lymphoma (NHL) that arises from B-cells originating in the "mantle zone." In the United States, about 70,800 new cases of NHL were expected in 2014, with MCL representing about six percent (about 4,200 cases) of all new cases of NHL in the United States. In 2013, the incidence of lymphoma was 4.2 per 100,000 and the mortality was 2.2 per 100,000 in mainland China, making it the eleventh most common cancer and the tenth leading cause of cancer death. MCL usually has a poor prognosis, with a median survival of three to four years, although occasionally patients may have an indolent course. Frequently, MCL is diagnosed at a later stage of disease.

About Zanubrutinib
Zanubrutinib (BGB-3111) is an investigational small molecule inhibitor of Bruton's tyrosine kinase (BTK) discovered by BeiGene scientists that is currently being evaluated in a broad pivotal clinical program globally as a monotherapy and in combination with other therapies to treat various B-cell malignancies.

Clinical trials of zanubrutinib include a fully-enrolled, global Phase 3 clinical trial in patients with Waldenström macroglobulinemia (WM) comparing zanubrutinib to ibrutinib, the currently only approved BTK inhibitor for WM; a global Phase 3 clinical trial in patients with previously untreated chronic lymphocytic leukemia (CLL)/small lymphocytic

lymphoma (SLL); a pivotal Phase 2 trial in patients with relapsed/refractory (R/R) follicular lymphoma in combination with GAZYVA® (obinutuzumab); a Phase 3 trial comparing zanubrutinib to ibrutinib in patients with R/R CLL/SLL; and a global Phase 1 trial. In China, BeiGene has completed two pivotal Phase 2 clinical trials of zanubrutinib in patients with MCL and CLL/SLL and the enrollment in the pivotal Phase 2 clinical trials in patients with WM.

Zanubrutinib has been granted Fast Track designation for the treatment of patients with WM and Breakthrough Therapy designation for the treatment of adult patients with MCL who have received at least one prior therapy by the U.S. Food and Drug Administration (FDA). The NDAs in China for R/R MCL and R/R CLL/SLL have been accepted by the China National Medical Products Administration (NMPA) and granted priority review.

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 1,700 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.

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 zanubrutinib. 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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