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 17, 2021

BEIGENE, LTD.
(Exact Name of Registrant as Specified in Charter)

Cayman Islands	**001-37686**	**98-1209416**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification Number)

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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
American Depositary Shares, each representing 13 Ordinary Shares, par value $0.0001 per share	**BGNE**	**The NASDAQ Global Select Market**
Ordinary Shares, par value $0.0001 per share*	**06160**	**The Stock Exchange of Hong Kong Limited**

*Included in connection with the registration of the American Depositary Shares with the Securities and Exchange Commission. The ordinary shares are not registered or listed for trading in the United States but are listed for trading on The Stock Exchange of Hong Kong Limited.

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 7.01. Regulation FD Disclosure.

BeiGene, Ltd. (the "Company") expects to announce its financial results for the three months and year ended December 31, 2020 on February 25, 2021.

Item 8.01. Other Events.

On February 17, 2021, the Company announced that the U.S. Food and Drug Administration (FDA) has accepted a supplemental new drug application (sNDA) for BRUKINSA® (zanubrutinib) for the treatment of adult patients with Waldenström's Macroglobulinemia (WM). The Prescription Drug User Fee Act (PDUFA) target action date is October 18, 2021. 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. Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release titled "BeiGene Announces U.S. FDA Acceptance of Supplemental New Drug Application for BRUKINSA (Zanubrutinib) in Waldenström's Macroglobulinemia" issued on February 17, 2021.
104	The cover page from this Current Report on Form 8-K, formatted in Inline XBRL.

Exhibit Index

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99.1	Press Release titled "BeiGene Announces U.S. FDA Acceptance of Supplemental New Drug Application for BRUKINSA (Zanubrutinib) in Waldenström's Macroglobulinemia" issued on February 17, 2021.
104	The cover page from this Current Report on Form 8-K, formatted in Inline XBRL.

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 17, 2021

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

Exhibit 99.1

BeiGene Announces U.S. FDA Acceptance of Supplemental New Drug Application for BRUKINSA (Zanubrutinib) in Waldenström's Macroglobulinemia

CAMBRIDGE, Mass. and BEIJING, China – February 17, 2021 -- BeiGene, Ltd. (NASDAQ: BGNE; HKEX: 06160), a commercial-stage biotechnology company focused on developing and commercializing innovative medicines worldwide, today announced that the U.S. Food and Drug Administration (FDA) has accepted a supplemental new drug application (sNDA) for BRUKINSA® (zanubrutinib) for the treatment of adult patients with Waldenström's Macroglobulinemia (WM). The Prescription Drug User Fee Act (PDUFA) target action date is October 18, 2021.

"We are pleased that the FDA has accepted the sNDA for BRUKINSA in WM, a rare disease with significant morbidity. BTK inhibitors have transformed the treatment of WM in recent years, but discrepancies in response exist in patients with different subtypes, and toxicity can remain an issue," said Jane Huang, M.D., Chief Medical Officer, Hematology, at BeiGene. "We look forward to continuing our communications with the FDA in the coming months and hope that BRUKINSA will become a new treatment option for patients with WM in the United States."

The sNDA package, which includes data from 351 patients with WM, was primarily based on safety and efficacy data from the global Phase 3 ASPEN trial of zanubrutinib compared to ibrutinib for the treatment of WM (NCT03053440), with supportive data from the pivotal Phase 2 trial of zanubrutinib in relapsed/refractory WM conducted in China (NCT03332173) and the global Phase 1/2 trial in patients with B-cell malignancies (NCT02343120). In addition, safety data from 779 patients in six clinical trials of BRUKINSA were included in the submission.

In addition to the United States, BRUKINSA is also under regulatory review as a treatment for patients with WM in the European Union, Canada, Australia, China, Taiwan, and South Korea.

In November 2019, BRUKINSA received accelerated approval in the United States as a treatment for mantle cell lymphoma (MCL) in adult patients who have received at least one prior therapy. In June 2020, BRUKINSA received conditional approval in China as a treatment for adult patients with chronic lymphocytic leukemia (CLL) /small lymphocytic lymphoma (SLL) who have received at least one prior therapy, and as a treatment for adult patients with MCL who have received at least one prior therapy. Currently, more than 20 marketing applications for BRUKINSA have been submitted, covering 45 countries and regions globally, including the United States, China, and European Union.

About Waldenström's Macroglobulinemia

Waldenström's macroglobulinemia (WM) is a rare indolent B-cell lymphoma that occurs in less than two percent of patients with non-Hodgkin's lymphoma (NHL). There are about 5,000 new cases of WM diagnosed each year in the United States. The disease usually affects older adults and is primarily found in the bone marrow, although lymph nodes and the spleen may be involved.[i]

About BRUKINSA® (zanubrutinib)

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

BRUKINSA was approved in the United States in November 2019 to treat adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy. This indication was approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial. A supplemental new drug application (sNDA) of BRUKINSA in patients with Waldenström's macroglobulinemia (WM) has been accepted for review by the FDA.

BRUKINSA received conditional approval in China in June 2020 for the treatment of MCL in adult patients who have received at least one prior therapy and the treatment of CLL/SLL in adult patients who have received at least one prior therapy. Complete approval for these indications may be contingent upon results from ongoing randomized, controlled confirmatory clinical trials. An sNDA of BRUKINSA in patients with relapsed/refractory WM has been accepted by the Center for Drug Evaluation (CDE) of the National Medical Products Administration and is currently under priority review.

A marketing authorization application (MAA) for BRUKINSA for the treatment of patients with WM who have received at least one prior therapy or as first-line treatment for patients unsuitable for chemo-immunotherapy has been accepted for review by the European Medicines Agency (EMA). In addition, 20 marketing applications for BRUKINSA have been submitted in 16 countries and regions.

IMPORTANT U.S. SAFETY INFORMATION FOR BRUKINSA (ZANUBRUTINIB)

Warnings and Precautions

Hemorrhage

Fatal and serious hemorrhagic events have occurred in patients with hematological malignancies treated with BRUKINSA monotherapy. Grade 3 or higher bleeding events including intracranial and gastrointestinal hemorrhage, hematuria and hemothorax have been reported in 2% of patients treated with BRUKINSA monotherapy. Bleeding events of any grade, including purpura and petechiae, occurred in 50% of patients treated with BRUKINSA monotherapy.

Bleeding events have occurred in patients with and without concomitant antiplatelet or anticoagulation therapy. Co-administration of BRUKINSA with antiplatelet or anticoagulant medications may further increase the risk of hemorrhage.

Monitor for signs and symptoms of bleeding. Discontinue BRUKINSA if intracranial hemorrhage of any grade occurs. Consider the benefit-risk of withholding BRUKINSA for 3-7 days pre- and post-surgery depending upon the type of surgery and the risk of bleeding.

Infections

Fatal and serious infections (including bacterial, viral, or fungal) and opportunistic infections have occurred in patients with hematological malignancies treated with BRUKINSA monotherapy. Grade 3 or higher infections occurred in 23% of patients treated with BRUKINSA monotherapy. The most common Grade 3 or higher infection was pneumonia. Infections due to hepatitis B virus (HBV) reactivation have occurred.

Consider prophylaxis for herpes simplex virus, pneumocystis jiroveci pneumonia and other infections according to standard of care in patients who are at increased risk for infections. Monitor and evaluate patients for fever or other signs and symptoms of infection and treat appropriately.

Cytopenias

Grade 3 or 4 cytopenias, including neutropenia (27%), thrombocytopenia (10%), and anemia (8%) based on laboratory measurements, were reported in patients treated with BRUKINSA monotherapy.

Monitor complete blood counts during treatment and treat using growth factor or transfusions, as needed.

Second Primary Malignancies

Second primary malignancies, including non-skin carcinoma, have occurred in 9% of patients treated with BRUKINSA monotherapy. The most frequent second primary malignancy was skin cancer (basal cell carcinoma and squamous cell carcinoma of skin), reported in 6% of patients. Advise patients to use sun protection.

Cardiac Arrhythmias

Atrial fibrillation and atrial flutter have occurred in 2% of patients treated with BRUKINSA monotherapy. Patients with cardiac risk factors, hypertension, and acute infections may be at increased risk. Grade 3 or higher events were reported in 0.6% of patients treated with BRUKINSA monotherapy. Monitor signs and symptoms for atrial fibrillation and atrial flutter and manage as appropriate.

Embryo-Fetal Toxicity

Based on findings in animals, BRUKINSA can cause fetal harm when administered to a pregnant woman. Administration of zanubrutinib to pregnant rats during the period of organogenesis caused embryo-fetal toxicity, including malformations at exposures that were 5 times higher than those reported in patients at the recommended dose of 160 mg twice daily. Advise women to avoid becoming pregnant while taking BRUKINSA and for at least 1 week after the last dose. Advise men to avoid fathering a child during treatment and for at least 1 week after the last dose. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus.

Adverse Reactions

The most common adverse reactions in > 10% of patients who received BRUKINSA were neutrophil count decreased (53%), platelet count decreased (39%), upper respiratory tract infection (38%), white blood cell count decreased (30%), hemoglobin decreased (29%), rash (25%), bruising (23%), diarrhea (20%), cough (20%), musculoskeletal pain (19%), pneumonia (18%), urinary tract infection (13%), hematuria (12%), fatigue (11%), constipation (11%), and hemorrhage (10%). The most frequent serious adverse reactions were pneumonia (11%) and hemorrhage (5%).

Of the 118 patients with MCL treated with BRUKINSA, 8 (7%) patients discontinued treatment due to adverse reactions in the trials. The most frequent adverse reaction leading to treatment discontinuation was pneumonia (3.4%). One (0.8%) patient experienced an adverse reaction leading to dose reduction (hepatitis B).

Drug Interactions

CYP3A Inhibitors: When BRUKINSA is co-administered with a strong CYP3A inhibitor, reduce BRUKINSA dose to 80 mg once daily. For co-administration with a moderate CYP3A inhibitor, reduce BRUKINSA dose to 80 mg twice daily.

CYP3A Inducers: Avoid co-administration with moderate or strong CYP3A inducers.

Specific Populations

Hepatic Impairment: The recommended dose of BRUKINSA for patients with severe hepatic impairment is 80 mg orally twice daily.

INDICATION

BRUKINSA is a kinase inhibitor indicated for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy.

This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

Please see full U.S. Prescribing Information at www.beigene.com/PDF/BRUKINSAUSPI.pdf and Patient Information at www.beigene.com/PDF/BRUKINSAUSPPI.pdf.

About BeiGene

BeiGene is a global, commercial-stage biotechnology company focused on discovering, developing, manufacturing, and commercializing innovative medicines to improve treatment outcomes and access for patients worldwide. Our 5,200+ employees in China, the United States, Australia, Europe, and elsewhere are committed to expediting the development of a diverse pipeline of novel therapeutics. We currently market two internally discovered oncology products: BTK inhibitor BRUKINSA® (zanubrutinib) in the United States and China, and anti-PD-1 antibody tislelizumab in China. We also market or plan to market in China additional oncology products licensed from Amgen Inc., Celgene Logistics Sàrl, a Bristol Myers Squibb (BMS) company, and EUSA Pharma. To learn more about BeiGene, please visit www.beigene.com and follow us on Twitter at @BeiGeneUSA.

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 regulatory review and approval of the company's U.S. sNDA for zanubrutinib for the treatment of adult patients with WM, future development, regulatory approvals, and potential commercialization of BRUKINSA in the United States and other markets, and the potential clinical benefit and commercial opportunity for BRUKINSA. 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; the impact of the COVID-19 pandemic on the Company's clinical development, commercial and other operations, 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] Lymphoma Research Foundation. Available at https://lymphoma.org/aboutlymphoma/nhl/wm/. Accessed December 2020