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): September 4, 2020

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 8.01 Other Events.

On September 4, 2020, BeiGene, Ltd. (the "Company" or "BeiGene") announced that the Company's ordinary shares, which trade on the Hong Kong Stock Exchange, will be included in the Shanghai-Hong Kong Stock Connect and Shenzhen-Hong Kong Stock Connect programs, effective on September 7, 2020. In addition, BeiGene's ordinary shares will be included in the Hang Seng Composite Index (HSCI). 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.

On September 9, 2020, BeiGene issued a press release announcing that its New Drug Submission ("NDS") for BRUKINSA® (zanubrutinib) for the treatment of patients with Waldenström's macroglobulinemia ("WM") has been accepted by Health Canada and granted priority review status. The full text of this press release is filed as Exhibit 99.2 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 issued by BeiGene, Ltd. on September 4, 2020
99.2	Press release issued by BeiGene, Ltd. on September 9, 2020
104	The cover page from the Current Report on Form 8-K, formatted in Inline XBRL

Exhibit Index

Exhibit No.	Description
99.1	Press release issued by BeiGene, Ltd. on September 4, 2020
99.2	Press release issued by BeiGene, Ltd. on September 9, 2020
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: September 9, 2020

By: /s/ Scott A. Samuels

Name: Scott A. Samuels

Title: Senior Vice President, General Counsel

BeiGene Announces Inclusion of Its Shares in the Shanghai-Hong Kong and Shenzhen-Hong Kong Stock Connect Programs

BEIJING, China and CAMBRIDGE, MA, September 4, 2020 -- BeiGene, Ltd. (NASDAQ: BGNE; HKEX: 06160), a commercial-stage biotechnology company focused on developing and commercializing innovative medicines worldwide, today announced that the company's ordinary shares, which trade on the Hong Kong Stock Exchange, will be included in the Shanghai-Hong Kong Stock Connect and Shenzhen-Hong Kong Stock Connect programs, effective on September 7, 2020. In addition, BeiGene's ordinary shares will be included in Hang Seng Composite Index (HSCI).

"We are excited to be included in the Stock Connect programs and the HSCI, as one of the first biotech companies listed in Hong Kong and the first biotech company with dual primary listings on NASDAQ and the Hong Kong Stock Exchange," commented John V. Oyler, Chairman, Co-Founder and Chief Executive Officer of BeiGene. "We expect that the inclusion in the Stock Connects and the HSCI can allow us to access a broader investor base in mainland China."

About the Stock Connect Programs

The Stock Connect programs are a unique collaboration between the Hong Kong, Shanghai and Shenzhen stock exchanges. The Stock Connects allow international and mainland Chinese investors to trade securities in each other's markets through the trading and clearing facilities of the participating exchanges. The Stock Connects established a two-way trading link between stock exchanges in mainland China and Hong Kong. The Stock Connects allow qualified mainland China investors to access eligible Hong Kong shares (Southbound) as well as Hong Kong and overseas investors to trade eligible A shares (Northbound), subject to specified daily quotas.

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 4,200+ 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 the potential effects of inclusion in the Stock Connects and the Hang Seng Index. 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.

Investor Contact
Craig West or Gabrielle Zhou
+1 857-302-5189 or +86 10-5895-8058
ir@beigene.com

Media Contact
Liza Heapes or Vivian Ni
+1 857-302-5663 or + 1 857-302-7596
media@beigene.com

BeiGene Announces Acceptance and Priority Review by Health Canada of New Drug Submission for BRUKINSA® (zanubrutinib) in Waldenström's Macroglobulinemia

CAMBRIDGE, Mass, and BEIJING, China, Sept. 9, 2020 – BeiGene, Ltd. (NASDAQ: BGNE; HKEX: 06160), a commercial-stage biotechnology company focused on developing and commercializing innovative medicines worldwide, today announced that its New Drug Submission ("NDS") for BRUKINSA® (zanubrutinib) for the treatment of patients with Waldenström's macroglobulinemia ("WM") has been accepted by Health Canada and granted priority review status.

"Following our recent submissions for WM in Europe and Australia, we are pleased to continue advancing the global registration of BRUKINSA with this new filing in Canada. BRUKINSA has approvals in the U.S. and China and is being developed with the goal of making it accessible to patients around the world who can benefit from it. For patients with WM, BRUKINSA has demonstrated efficacy and clinically meaningful improvements in safety and tolerability," said Jane Huang, M.D., Chief Medical Officer, Hematology at BeiGene. "We believe that BRUKINSA's safety advantages over ibrutinib as demonstrated in our head-to-head ASPEN trial, including reduced risk for certain cardiovascular issues, may help it become a preferred treatment option for patients with WM in Canada and around the world."

Clinical data in the Canadian NDS include data from the Phase 3 randomized, open-label, multicenter ASPEN clinical trial (NCT03053440) that evaluated zanubrutinib versus ibrutinib in patients with relapsed/refractory (R/R) or treatment-naïve (TN) WM, which were presented at the 2020 American Society of Clinical Oncology (ASCO) Virtual Scientific Program and the 25th European Hematology Association (EHA) Congress. In that study, zanubrutinib demonstrated more frequent VGPRs (28.4% vs.19.2% in overall population), although the primary endpoint of statistical superiority related to deep response (VGPR or better) was not met. Zanubrutinib also demonstrated advantages in safety and tolerability compared to ibrutinib. The safety package in the NDS includes pooled safety data from 779 patients with B-cell malignancies treated with BRUKINSA in six clinical trials.

About Waldenström's Macroglobulinemia (WM)

WM is a rare lymphoma representing approximately 1% of all non-Hodgkin lymphomas and typically progresses slowly after diagnosis.[1] In Canada and the United States, the incidence rate of WM is about five cases per million people per year.[2]

About the Zanubrutinib Clinical Trial Program

Clinical trials of zanubrutinib include:

- Fully-enrolled Phase 3 ASPEN clinical trial in patients with Waldenström's macroglobulinemia (WM) comparing zanubrutinib to ibrutinib (NCT03053440), currently the only approved BTK inhibitor for WM;
- Phase 3 SEQUOIA trial comparing zanubrutinib with bendamustine plus rituximab in patients with treatment-naive (TN) chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) (NCT03336333);
- Phase 3 ALPINE trial comparing zanubrutinib to ibrutinib in patients with relapsed/refractory (R/R) CLL/SLL (NCT03734016);
- Phase 3 MANGROVE trial comparing zanubrutinib and rituximab to bendamustine and rituximab in patients with untreated mantle cell lymphoma (MCL) (NCT04002297);
- Phase 2 MAGNOLIA trial in patients with R/R marginal zone lymphoma (MZL) (NCT03846427);
- Phase 2 ROSEWOOD trial (NCT03332017) in China comparing obinutuzumab and zanubrutinib vs obinutuzumab alone in treating patients with R/R FL;
- Phase 2 trial (NCT04382586) in the U.S. comparing zanubrutinib plus supportive care to placebo plus supportive care for the treatment of patients with COVID-19 disease and pulmonary distress;
- Phase 2 trial (NCT04116437) in the U.S. in patients with previously treated B-cell lymphoma intolerant of prior treatment with ibrutinib and/or acalabrutinib;
- Phase 2 trial (NCT03332173) in China in patients with R/R WM; and
- Completed Phase 2 trials in China in patients with R/R MCL (NCT03206970) and R/R CLL/SLL (NCT03206918).

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[1] Lymphoma Research Foundation. Getting the Facts: Waldenström Macroglobulinemia. Accessed May 2020. Available at <https://lymphoma.org/wp-content/uploads/2018/04/LRF_FACTSHEET_WALDENSTR%C3%96M_MACROGLOBULINEMIA.pdf>

[2] Waldenstrom's Macroglobulinemia Foundation of Canada. https://wmfc.ca/what-we-do/what-is-wm/

About BRUKINSA® (zanubrutinib)

BRUKINSA 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 by the U.S. FDA 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.

BRUKINSA was approved 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.

BRUKINSA is not approved outside of the United States and China.

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 4,200+ 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.

BeiGene's 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 future development and potential commercialization of BRUKINSA in Canada and other new markets, plans for making BRUKINSA accessible to more patients globally, and the potential 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.

BeiGene Contacts

Investors Contact
Craig West
(857) 302-5189
ir@beigene.com

Media Contacts
Liza Heapes or Vivian Ni
(857) 302-5663 or (857) 302-7596
media@beigene.com