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): July 26, 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 8.01. Other Events.

On June 26, 2021, BeiGene, Ltd. (the "Company" or "BeiGene") announced that BRUKINSA® (zanubrutinib) has been approved by Health Canada for the treatment of mantle cell lymphoma (MCL) in adult patients who have received at least one prior therapy. This is the second approval for BRUKINSA in Canada, following its initial approval in March 2021 for adult patients with Waldenström's macroglobulinemia (WM). 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 June 29, 2021, the Company announced positive topline results from an interim analysis of the Phase 3 SEQUOIA trial comparing BRUKINSA® (zanubrutinib) to bendamustine and rituximab (B+R) in patients with treatment-naïve (TN) chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) whose tumor did not exhibit the deletion of chromosome 17p13.1 (del[17p]). 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. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release titled "BeiGene Announces Approval in Canada of BRUKINSA® (Zanubrutinib) for the Treatment of Patients with Mantle Cell Lymphoma", issued by BeiGene, Ltd. on June 26, 2021.
99.2	Press Release titled "BeiGene Announces Positive Topline Results from Phase 3 SEQUOIA Trial Comparing BRUKINSA® (Zanubrutinib) to Bendamustine Plus Rituximab in Patients with Treatment-Naïve Chronic Lymphocytic Leukemia", issued by BeiGene, Ltd. on June 29, 2021.
104	The cover page from this Current Report on Form 8-K, formatted in Inline XBRL

Exhibit Index

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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: July 30, 2021

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

Exhibit 99.1

BeiGene Announces Approval in Canada of BRUKINSA® (Zanubrutinib) for the Treatment of Patients with Mantle Cell Lymphoma

Second approval for BTK Inhibitor BRUKINSA in Canada

CAMBRIDGE, Mass. and BEIJING, China, July 26, 2021 -- BeiGene, Ltd. (NASDAQ: BGNE; HKEX: 06160), a global, science-driven biotechnology company focused on developing innovative and affordable medicines to improve treatment outcomes and access for patients worldwide, today announced that BRUKINSA® (zanubrutinib) has been approved by Health Canada for the treatment of mantle cell lymphoma (MCL) in adult patients who have received at least one prior therapy. This is the second approval for BRUKINSA in Canada, following its initial approval in March 2021 for adult patients with Waldenström's macroglobulinemia (WM).

"BRUKINSA was specifically designed by BeiGene scientists to provide deep and durable responses for patients with hematologic malignancies, while also reducing the frequency of certain off-target side effects seen with first-generation BTK inhibitors. Today's approval in Canada for patients with MCL follows its approval for patients with WM earlier in the year, where Canada was the first country to grant approval for BRUKINSA in patients with WM," said Jane Huang, M.D., Chief Medical Officer, Hematology, BeiGene. "We are excited to continue working with patients and physicians in Canada, as well as in other markets, as part of our broad clinical development program for BRUKINSA investigating eight indications in over 25 clinical trials, with more than 3,100 patients participating."

"For many patients treated with previously approved BTK inhibitors for MCL, adequate responses are not achievable, or they can be forced to discontinue treatment early due to side effects. Today, we have a new option for our adult patients in Canada who have received one prior systemic or targeted therapy and are living with MCL, an aggressive blood cancer that is often diagnosed at a more advanced stage," said John Kuruvilla, M.D., FRCPC, Associate Professor of Medicine at the University of Toronto and Clinical Investigator at the Princess Margaret Cancer Centre in Toronto.

"The approval of BRUKINSA as a second line therapy is positive news for patients undergoing treatment for mantle cell lymphoma," said Antonella Rizza, Chief Executive Officer at Lymphoma Canada. "Expanded treatment options have the potential to transform the patient experience and provide hope to people living with a mantle cell diagnosis."

The Health Canada approval for BRUKINSA in MCL is based on efficacy results from two single-arm clinical trials. Across both trials, as assessed by independent review committee (IRC) per 2014 Lugano Classification BRUKINSA achieved an overall response rate (ORR) of 84%, defined as the combined rate of complete responses (CRs) and partial responses (PRs).

In the multicenter Phase 2 trial of zanubrutinib in patients with relapsed or refractory (R/R) MCL BGB-3111-206 (NCT03206970), with a median follow-up time of 18.5 months, the ORR was 84% (95% CI: 74, 91), including 69% CRs (FDG-PET scan required) and 15% PRs; the median duration of response (DoR) was 19.5 months (95% CI: 16.6, NE). In the global Phase 1/2 trial BGB-3111-AU-003 (NCT02343120), with a media follow-up time of 18.8 months, the ORR was 84% (95% CI: 67, 95), including 25% CRs (FDG-PET scan not required) and 59% PRs; the median DoR was 18.5 months (95% CI: 12.6, NE).

Of the 118 patients with MCL who received at least one prior therapy and received BRUKINSA treatment, 13.6% of patients discontinued treatment due to adverse events in the trials, with the most frequent being pneumonia (3.4%). Adverse events leading to dose reduction occurred in 3.4% of patients, including hepatitis B, neutropenia, allergic dermatitis, and peripheral sensory neuropathy (in one patient each).

The overall safety profile of BRUKINSA is based on pooled data from 779 patients with B-cell malignancies treated with BRUKINSA in clinical trials. The most common adverse reactions (≥10%) with BRUKINSA were neutropenia, thrombocytopenia, upper respiratory tract infection, anemia, rash, musculoskeletal pain, diarrhea, cough, contusion, pneumonia (grouped terms), urinary tract infection, hemorrhage (grouped terms), and hematuria. Overall, 18% of patients experienced serious adverse reactions. The most frequent (≥2%) serious adverse reactions were pneumonia (10.0%) and hemorrhage (2.1%).

The recommended dose of BRUKINSA is either 160 mg twice daily or 320 mg once daily, taken orally with or without food. The dose may be adjusted for adverse reactions and reduced for patients with severe hepatic impairment and certain drug interactions.

BRUKINSA is available in Canada for the treatment of MCL and Waldenström's macroglobulinemia through the myBeiGene® patient support program, established to support patients, caregivers, and health care providers.

About Mantle Cell Lymphoma (MCL)

Mantle cell lymphoma is a B-cell non-Hodgkin lymphoma (NHL). It develops in the outer edge of a lymph node called the mantle zone. Mantle cell lymphoma occurs more often in men than in women. It is usually diagnosed in people in their early 60s.[i] Approximately one out of 200,000 individuals per year are diagnosed with MCL.[ii] MCL usually has a poor prognosis, with a median survival of three to four years, and is often diagnosed at a later stage of disease.[iii]

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 clinical program as a monotherapy and in combination with other therapies to treat various B-cell malignancies. Because new BTK is continuously synthesized, BRUKINSA was specifically designed to deliver complete and sustained inhibition of the BTK protein by optimizing bioavailability, half-life, and selectivity. With differentiated pharmacokinetics compared to other approved BTK inhibitors, BRUKINSA has been demonstrated to inhibit the proliferation of malignant B cells within a number of disease relevant tissues.

About myBeiGene® Patient Support Program

The myBeiGene® patient support program is designed to support patients, caregivers, and healthcare providers with access to BRUKINSA®. It goes beyond financial assistance support to provide patients and caregivers with education about their disease and treatment with BRUKINSA, as well provide practical and emotional support by connecting them to third-party resources that can address their individual needs. Oncology Nurse Advocates are available Monday through Friday from 8 a.m. to 5 p.m. Eastern Time at 1-833-234-4366.

BeiGene Oncology

BeiGene is committed to advancing best and first-in-class clinical candidates internally or with like-minded partners to develop impactful and affordable medicines for patients across the globe. We have a growing R&D team of approximately 2,300 colleagues dedicated to advancing more than 90 clinical trials involving more than 13,000 patients and healthy volunteers. Our expansive portfolio is directed by a predominantly internalized clinical development team supporting trials in more than 40 countries. Hematology-oncology and solid tumor targeted therapies and immuno-oncology are key focus areas for the Company, with both mono- and combination therapies prioritized in our research and development. We currently market three medicines discovered and developed in our labs: BTK inhibitor BRUKINSA in the United States, China, Canada, and additional international markets; and non-FC-gamma receptor binding anti-PD-1 antibody tislelizumab and PARP inhibitor pamiparib in China.

BeiGene also partners with innovative companies who share our goal of developing therapies to address global health needs. We commercialize a range of oncology medicines in China licensed from Amgen and Bristol Myers Squibb. We also plan to address greater areas of unmet need globally through our collaborations including with Amgen, Bio-Thera, EUSA Pharma, Mirati Therapeutics, Seagen, and Zymeworks. BeiGene has also entered into a collaboration with Novartis granting Novartis rights to develop, manufacture, and commercialize tislelizumab in North America, Europe, and Japan.

About BeiGene

BeiGene is a global, science-driven biotechnology company focused on developing innovative and affordable medicines to improve treatment outcomes and access for patients worldwide. With a broad portfolio of more than 40 clinical candidates, we are expediting development of our diverse pipeline of novel therapeutics through our own capabilities and collaborations. We are committed to radically improving access to medicines for two billion more people by 2030. BeiGene is headquartered in Cambridge, Mass., and Beijing, with a growing global team of over 6,000 colleagues across five continents. To learn more about BeiGene, please visit www.beigene.ca and follow us on Twitter at @BeiGeneGlobal.

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 plans for development and commercialization of BRUKINSA in Canada and other markets, plans for making BRUKINSA accessible to patients in Canada, the potential for BRUKINSA to provide improved clinical benefit to patients, and BeiGene's plans, commitments, aspirations and goals under the headings "BeiGene Oncology" and "About BeiGene". 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 medicines and drug candidates, if approved; BeiGene's ability to obtain and maintain protection of intellectual property for its medicines and technology; BeiGene's reliance on third parties to conduct drug development, manufacturing and other services; BeiGene's limited experience in obtaining regulatory approvals and commercializing pharmaceutical products and its ability to obtain additional funding for operations and to complete the development and commercialization of its drug candidates and achieve and maintain profitability; the impact of the COVID-19 pandemic on the BeiGene's clinical development, regulatory, 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] Canadian Cancer Society. Available at https://www.cancer.ca/en/cancer-information/cancer-type/non-hodgkin-lymphoma/non-hodgkin-lymphoma/mantle-cell-lymphoma/?region=on. Access July 2021

[ii] National Organization for Rare Disorders. Available at https://rarediseases.org/rare-diseases/mantle-cell-lymphoma/. Access July 2021

[iii] Philip J. Bierman, James O. Armitage, in Goldman's Cecil Medicine (Twenty Fourth Edition), 2012

Exhibit 99.2

BeiGene Announces Positive Topline Results from Phase 3 SEQUOIA Trial Comparing BRUKINSA® (Zanubrutinib) to Bendamustine Plus Rituximab in Patients with Treatment-Naïve Chronic Lymphocytic Leukemia

Trial met the primary endpoint at interim analysis, with BRUKINSA significantly prolonging progression-free survival compared to chemoimmunotherapy and safety and tolerability consistent with its known profile

SEQUOIA is the second positive global Phase 3 trial of BRUKINSA in chronic lymphocytic leukemia, following ALPINE in relapsed or refractory setting

CAMBRIDGE, Mass. & BEIJING, China – July 29, 2021 – BeiGene, Ltd. (NASDAQ: BGNE; HKEX: 06160), a global, science-driven biotechnology company, today announced positive topline results from an interim analysis of the Phase 3 SEQUOIA trial comparing BRUKINSA® (zanubrutinib) to bendamustine and rituximab (B+R) in patients with treatment-naïve (TN) chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) whose tumor did not exhibit the deletion of chromosome 17p13.1 (del[17p]).

With a median follow-up of 25.8 months, the SEQUOIA trial met the primary endpoint of progression-free survival (PFS) as assessed by independent review committee (IRC), as BRUKINSA achieved a highly statistically significant improvement in PFS compared to B+R.

In addition, the trial demonstrated a statistically significant improvement in PFS per investigator assessment, a secondary endpoint. BRUKINSA was also generally well-tolerated, consistent with its known safety profile.

"The combined clinical evidence from SEQUOIA, ALPINE[1], the 205 trial[2], and the AU-003 trial[3] validates our confidence in BRUKINSA as a regimen which can offer improvements in treatment outcomes for hundreds of thousands of patients living with CLL," said Jane Huang, M.D., Chief Medical Officer, Hematology at BeiGene. "We are pleased to see that at the interim analysis of the SEQUOIA trial, BRUKINSA significantly prolonged progression-free survival for treatment-naïve CLL patients, and that the demonstrated safety profile was consistent with what we have observed in its global development program with more than 2,300 patients treated with BRUKINSA to date."

1. Results from the interim analysis of ALPINE with a median follow-up time of 15.3 months were reported at the 2021 European Hematology Association (EHA2021) Congress in June 2021. Available at EHA Open Access Library.

2. Long-term results from BGB-3111-205 with a median follow-up time of 34 months were reported at the EHA2021 Congress in June 2021. Available at EHA Open Access Library.

3. Long-term results from BGB-3111-AU-003 in relapsed or refractory CLL with a median follow-up time of 39.4 months were shared at the BeiGene Investor Conference Call in June 2021. Available ir.beigene.com.

About SEQUOIA

SEQUOIA is a randomized, multicenter, global Phase 3 trial (NCT03336333) designed to evaluate the efficacy and safety of BRUKINSA compared to B+R in patients with TN CLL or SLL. The trial consists of three cohorts:

- Cohort 1 (n=479): randomized 1:1 to receive BRUKINSA (n=241) or B+R (n=238) until disease progression or unacceptable toxicity, in patients not harboring del(17p); data from this group comprise the primary endpoint;

- Cohort 2 (n=110): patients with del(17p) receiving BRUKINSA as a monotherapy; and

- Cohort 3 (enrollment ongoing): patients with del(17p) or pathogenic TP53 variant receiving BRUKINSA in combination with venetoclax.

Patients with del(17p) were not randomized to B+R, as they experience poor clinical outcomes and poor response to chemoimmunotherapy. The primary endpoint of the trial is IRC-assessed PFS. Secondary endpoints include investigator-assessed PFS, IRC- and investigator-assessed overall response rate (ORR), overall survival (OS), PFS and ORR in patients with del(17p), and safety.

Cohort 2, representing high-risk patients treated with BRUKINSA monotherapy, was previously presented at the American Society for Hematology (ASH) Annual Meeting in December 2020. This cohort of patients with del(17p) achieved significant efficacy with an 18-month PFS of 90.6%, as assessed by investigator.

BeiGene plans to consult with global regulatory authorities on next steps and present these data at an upcoming major medical conference.

About Chronic Lymphocytic Leukemia and Small Lymphocytic Lymphoma

Chronic lymphocytic leukemia (CLL) is the most common form of leukemia in adults, with a global incidence of approximately 114,000 new cases in 2017.[1,2] CLL affects white blood cells or lymphocytes in the bone marrow.[1] Proliferation of cancer cells (leukemia) in the marrow result in reduced ability to fight infection and spread into the blood, which affects other parts of the body including the lymph nodes, liver and spleen.[1,3] The BTK pathway is a known route that signals malignant B cells and contributes to the onset of CLL.[4] Small lymphocytic lymphoma (SLL) is a non-Hodgkin's lymphoma affecting the B-lymphocytes of the immune system, which shares many similarities to CLL but with cancer cells found mostly in lymph nodes.[5]

About BRUKINSA

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 clinical program as a monotherapy and in combination with other therapies to treat various B-cell malignancies. Because new BTK is continuously synthesized, BRUKINSA was specifically designed to deliver complete and sustained inhibition of the BTK protein by optimizing bioavailability, half-life, and selectivity. With differentiated pharmacokinetics compared to other approved BTK inhibitors, BRUKINSA has been demonstrated to inhibit the proliferation of malignant B cells within a number of disease relevant tissues.

BRUKINSA is approved in the following indications and regions:

- For the treatment of mantle cell lymphoma (MCL) in adult patients who have received at least one prior therapy (United States, November 2019)*;
- For the treatment of MCL in adult patients who have received at least one prior therapy (China, June 2020)**;
- For the treatment of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) in adult patients who have received at least one prior therapy (China, June 2020)**;
- For the treatment of relapsed or refractory MCL (United Arab Emirates, February 2021);
- For the treatment of Waldenström's macroglobulinemia (WM) in adult patients (Canada, March 2021);
- Registered and reimbursed for the treatment of MCL in patients who have received at least one prior therapy (Israel, April 2021);

- For the treatment of adult patients with WM who have received at least one prior therapy (China, June 2021)**; and
- For the treatment of MCL in adult patients who have received at least one prior therapy (Canada, July 2021).

To date, more than 30 marketing authorization applications in multiple indications have been submitted covering the United States, the European Union and more than 20 other countries or regions.

* 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.

** This indication was approved under conditional approval. Complete approval for this indication may be contingent upon results from ongoing randomized, controlled confirmatory clinical trials.

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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 results from the interim analysis of the Phase 3 SEQUOIA trial, the potential clinical benefits and advantages of BRUKINSA compared to chemoimmunotherapy, BeiGene's plans to consult with global regulatory authorities and present the data, BeiGene's plans for the advancement, and anticipated clinical development, regulatory milestones and commercialization of BRUKINSA, and BeiGene's plans, commitments, aspirations, and goals under the headings "BeiGene Oncology" and "About BeiGene". Actual results may differ materially from those indicated in the forward-looking statements as a result of various important factors, including the risk that preliminary data from the interim analysis of the Phase 3 SEQUOIA trial may differ at the final analysis; the risk that interim and/or final results of the SEQUOIA trial will not support filings for regulatory approvals of BRUKINSA for the treatment of patients with CLL, and the timing of any such filings and potential approvals; clinical data continue to support a risk-benefit profile for BRUKINSA; 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 medicines and drug candidates, if approved; BeiGene's ability to obtain and maintain protection of intellectual property for its medicines and technology; BeiGene's reliance on third parties to conduct drug development, manufacturing and other services; BeiGene's limited experience in obtaining regulatory approvals and commercializing pharmaceutical products and its ability to obtain additional funding for operations and to complete the development and commercialization of its drug candidates and achieve and maintain profitability; the impact of the COVID-19 pandemic on the BeiGene's clinical development, regulatory, 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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