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): November 17, 2022

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 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 November 17, 2022, BeiGene, Ltd. ("BeiGene") announced that the European Commission has approved BRUKINSA® (zanubrutinib) for the treatment of adult patients with treatment-naïve or relapsed/refractory chronic lymphocytic leukemia. 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 November 22, 2022, BeiGene announced that the results of the final progression free survival analysis of the ALPINE trial will be presented at a late-breaking oral presentation session at the 64th American Society of Hematology Annual Meeting in New Orleans. ALPINE is a global Phase 3 trial comparing BRUKINSA® (zanubrutinib) with IMBRUVICA® (ibrutinib) in patients with relapsed/refractory chronic lymphocytic leukemia or small lymphocytic leukemia. The results will be presented at 10:15 am CST during the late-breaking abstract session on Tuesday, December 13, 2022 in the Ernest N. Morial Convention Center, Hall E. 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.	
99.1	Press release titled "BeiGene Receives European Commission Approval for BRUKINSA® (zanubrutinib) for the Treatment of Adults with Chronic Lymphocytic Leukemia " issued by BeiGene, Ltd. on November 17, 2022
99.2	Press release titled "BeiGene to Present Final PFS Results from ALPINE Trial Demonstrating Superior PFS for BRUKINSA® Versus IMBRUVICA® in Late-Breaking Oral Session at ASH 2022" issued by BeiGene, Ltd. on November 22, 2022
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: November 22, 2022

By: /s/ Chan Lee
Name: Chan Lee
Title: Senior Vice President, General Counsel

Exhibit 99.1

BeiGene Receives European Commission Approval for BRUKINSA® (zanubrutinib) for the Treatment of Adults with Chronic Lymphocytic Leukemia (CLL)

BRUKINSA is the only Bruton's Tyrosine Kinase (BTK) inhibitor to achieve superiority over IMBRUVICA® (ibrutinib) in relapsed/refractory CLL.

BRUKINSA also showed superiority to chemoimmunotherapy in treatment naive CLL.

BRUKINSA had a favorable safety profile, including lower rates of atrial fibrillation/flutter compared with IMBRUVICA.

CAMBRIDGE, Mass., & BASEL, Switzerland & BEIJING – November 17, 2022 – BeiGene (NASDAQ: BGNE; HKEX: 06160; SSE: 688235), a global biotechnology company, today announced that the European Commission (EC) has approved BRUKINSA® (zanubrutinib) for the treatment of adult patients with treatment-naïve (TN) or relapsed/refractory (R/R) CLL.

"This approval represents an important milestone for CLL patients and their physicians who now have a new chemotherapy-free treatment option, and an alternative to current BTKi treatment options," said Mehrdad Mobasher, M.D., M.P.H., Chief Medical Officer, Hematology at BeiGene. "Given that BRUKINSA has demonstrated consistent benefit across patient subgroups, regardless of risk status, we believe BRUKINSA could now be the preferred treatment option for newly diagnosed and relapsed/refractory CLL patients."

The EC approval is based on positive results from two Phase 3 clinical trials: SEQUOIA (NCT03336333), in patients with previously untreated CLL, and ALPINE (NCT03734016), in patients with R/R CLL. In these two trials, BRUKINSA demonstrated superior efficacy versus either bendamustine plus rituximab (B+R) or ibrutinib in first-line or R/R CLL, respectively. BRUKINSA is the only BTKi to achieve superiority versus ibrutinib in R/R CLL, as assessed by independent review committee, with an overall response rate (ORR) of 80.4% vs 72.9% (p=0.0264).[i] Additionally, more BRUKINSA patients than ibrutinib patients had a sustained response at 1 year with rates of 90% vs 78%.[i] The adverse events within the two trials were consistent with the overall safety profile of BRUKINSA. Subsequent to the regulatory submission, BeiGene announced topline results of the final PFS analysis of the head-to-head ALPINE trial, in which BRUKINSA demonstrated superior PFS compared with ibrutinib in patients with R/R CLL.

Prof. Clemens Wendtner, Head of Hematology and Oncology at Munich Clinic, an academic teaching hospital of the University of Munich, Germany, commented, "BRUKINSA has demonstrated clinically meaningful improvements as a next-generation BTKi over the first generation BTKi, and is proven to be significantly more effective and tolerable. Ensuring medicines are safe and tolerable for this patient population is critical, given the long-term treatment needed for CLL. Combined with the flexible dosing options, this approval offers a practice-changing option for patients with CLL, one of the most common types of leukemia in adults."

"We're pleased with the significant progress we've made to date bringing BRUKINSA to patients with hematological malignancies globally," noted Gerwin Winter, Senior Vice President, Head of Europe at BeiGene. "With this notable approval, we welcome the opportunity to expand BeiGene's presence in Europe and provide this innovative treatment option to CLL patients across the region."

BRUKINSA is currently approved in the EU for the treatment of adult patients with WM who have received at least one prior therapy or as the first-line treatment for patients unsuitable for chemoimmunotherapy and adult patients with MZL who have received at least one prior anti-CD20-based therapy.

In Europe, BeiGene has now obtained reimbursement for BRUKINSA for the treatment of WM in Austria, Belgium, Denmark, England and Wales, Germany, Iceland, Ireland, Italy, Luxembourg, Scotland, Spain, Switzerland, and The Netherlands, while additional EU countries are currently going through the reimbursement process.

About Chronic Lymphocytic Leukemia (CLL)

A slow-growing, life-threatening and incurable cancer of adults, CLL is a type of mature B-cell malignancy in which abnormal leukemic B lymphocytes (a type of white blood cells) arise from the bone marrow and flood peripheral blood, bone marrow, and lymphoid tissues.[ii-iv] CLL is one of the most common types of leukemia, accounting for about one-quarter of new cases of leukemia.[v] In Europe, the estimated incidence is 4.92/100,000 persons per year.[vi,vii]

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. BRUKINSA was specifically designed to deliver targeted 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 supported by a broad clinical program which includes more than 4,700 subjects in 35 trials in more than 25 countries and regions. To date, BRUKINSA is approved in 58 markets, including the United States, China, the European Union Great Britain, Canada, Australia, South Korea, Switzerland, and additional international markets.

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 and medical affairs team of approximately 3,500 colleagues dedicated to advancing more than 100 clinical trials that have involved more than 20,000 subjects. Our expansive portfolio is directed predominantly by our internal colleagues supporting clinical trials in more than 45 countries and regions. Hematology-oncology, and solid tumor targeted therapies, and immuno-oncology are key focus areas for the Company, with both monotherapies and combination therapies prioritized in our research and development. BeiGene currently has three approved medicines discovered and developed in our own labs: BTK inhibitor BRUKINSA® in the U.S., China, the European Union, Great Britain, Canada, Australia, South Korea, Switzerland, and additional international markets; and the non-FC-gamma receptor binding anti-PD-1 antibody tislelizumab as well as the poly adenosine diphosphate-ribose polymerase (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, Bristol Myers Squibb, EUSA Pharma, and Bio-Thera. We also plan to address greater areas of unmet need globally through our other collaborations including Mirati Therapeutics, Seagen, and Zymeworks.

In January 2021 BeiGene and Novartis announced a collaboration granting Novartis rights to co-develop, manufacture, and commercialize BeiGene's anti-PD-1 antibody tislelizumab in North America, Europe, and Japan. Building upon this productive collaboration, BeiGene and Novartis announced an option, collaboration, and license agreement in December 2021 for BeiGene's TIGIT inhibitor ociperlimab that is in Phase 3 development. Novartis and BeiGene also entered into a strategic commercial agreement through which BeiGene will promote five approved Novartis oncology products across designated regions of China.

About BeiGene

BeiGene is a global biotechnology company that is developing and commercializing innovative and affordable oncology medicines to improve treatment outcomes and access for far more patients worldwide. With a broad portfolio, we are expediting development of our diverse pipeline of novel therapeutics through our internal capabilities and collaborations. We are committed to radically improving access to medicines for far more patients who need them. Our growing global team of more than 9,000 colleagues spans five continents, with administrative offices in Beijing, China; Cambridge, U.S.; and Basel, Switzerland. To learn more about BeiGene, please visit www.beigene.com 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 the potential for BRUKINSA to provide clinical benefit to patients with CLL, the future development, regulatory filing and approval, commercialization, and market access of BRUKINSA in the European Union and other markets, the potential commercial opportunity for 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 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; and the impact of the COVID-19 pandemic on BeiGene's clinical development, regulatory, commercial, manufacturing, 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.

IMBRUVICA® is a registered trademark of Pharmacyclics LLC and Janssen Biotech, Inc.

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[iv] American Cancer Society. What is chronic lymphocytic leukemia? Updated May 10, 2018. Accessed December 6, 2020. https://www.cancer.org/cancer/chronic-lymphocytic-leukemia/about/what-is-cll.html
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Exhibit 99.2

BeiGene to Present Final PFS Results from ALPINE Trial Demonstrating Superior PFS for BRUKINSA® Versus IMBRUVICA® in Late-Breaking Oral Session at ASH 2022

CAMBRIDGE, U.S., & BASEL, Switzerland & BEIJING – November 22, 2022 – BeiGene (NASDAQ: BGNE; HKEX: 06160; SSE: 688235) a global biotechnology company, today announced that the results of the final progression free survival (PFS) analysis of the ALPINE trial will be presented at a late-breaking oral presentation session at the 64th American Society of Hematology (ASH) Annual Meeting in New Orleans. ALPINE is a global Phase 3 trial comparing BRUKINSA (zanubrutinib) with IMBRUVICA® (ibrutinib) in patients with relapsed/refractory (R/R) chronic lymphocytic leukemia (CLL) or small lymphocytic leukemia (SLL). The results will be presented at 10:15 am CST during the late-breaking abstract session on Tuesday, December 13,2022 in the Ernest N. Morial Convention Center, Hall E.

In this final PFS analysis, BRUKINSA achieved superior PFS compared with ibrutinib, as assessed by both Independent Review Committee (IRC) and investigator (HR: 0.65 [95% CI, 0.49-0.86] p =.0024, for both investigator and IRC). The PFS results favored zanubrutinib consistently across major pre-defined subgroups including IGHV status and patients with del(17p)/TP53, regardless of IRC or investigator assessment.

“BRUKINSA is the only BTK inhibitor to demonstrate superior efficacy over ibrutinib in any treatment setting; The ALPINE trial results demonstrate superiority for both PFS and ORR versus ibrutinib in relapsed or refractory CLL/SLL,” said Mehrdad Mobasher, M.D., M.P.H. Chief Medical Officer, Hematology at BeiGene. “With nearly 30 months of follow up in this trial, we have seen a very consistent safety and tolerability profile for BRUKINSA and look forward to sharing detailed results from this analysis at ASH.”

CLL is one of the most common types of leukemia, accounting for about one-quarter of new cases of leukemia[i]. The condition is characterized by consecutive relapses, with response to therapy ultimately determining clinical benefit, including survival.

At this pre-defined response analysis with a median follow up of 29.6 months, BRUKINSA was generally well-tolerated with a safety profile consistent with previous reports. Overall discontinuation rates were lower with BRUKINSA (26.3%) compared to ibrutinib (41.2%), as well as discontinuations due to adverse events (16.2 vs 22.8%) or progressive disease (7.3 vs 12.9%).

Cardiac safety measures at this analysis favored BRUKINSA compared with ibrutinib: the rate of atrial fibrillation/flutter in the BRUKINSA arm remained low (5.2%) compared with ibrutinib (13.3%) and there were zero grade 5 adverse events due to cardiac disorders with BRUKINSA versus six in the ibrutinib arm.

Investor Events

- **Sunday, December 11, 2022** – BeiGene will host an ancillary event in New Orleans at 8:00 pm CST for investors and analysts attending ASH. BeiGene senior management will review highlights of the presented data, and special guests will join them for a Q&A panel.
- **Tuesday, December 13, 2022** – BeiGene will host a webcast following the ALPINE late-breaker presentation at 2:00 pm CST. BeiGene senior management along with invited medical experts will review the presented data and join for a Q&A panel.
- **Tuesday, December 13, 2022** – BeiGene will host a webcast in Chinese at 6:00 pm CST / December 14,2022 8:00 am China time to capture Company presentations at ASH. BeiGene senior management will review highlights of the presented data.

These events can be accessed live from the investors section of BeiGene’s website athttp://ir.beigene.com, http://hkexir.beigene.com or https://sseir.beigene.com. Archived replays will be posted for 90 days following the events.

About BRUKINSA

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IMBRUVICA® is a registered trademark of Pharmacyclics LLC and Janssen Biotech, Inc.

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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 hemorrhage events including intracranial and gastrointestinal hemorrhage, hematuria and hemothorax have been reported in 3.4% of patients treated with BRUKINSA monotherapy. Hemorrhage events of any grade occurred in 35% 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 27% of patients, most commonly 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 (26%), thrombocytopenia (11%) and anemia (8%) based on laboratory measurements, were reported in patients treated with BRUKINSA monotherapy. Grade 4 neutropenia occurred in 13% of patients, and Grade 4 thrombocytopenia occurred in 3.6% of patients.

Monitor complete blood counts regularly during treatment and interrupt treatment, reduce the dose, or discontinue treatment as warranted. Treat using growth factor or transfusions, as needed.

Second Primary Malignancies

Second primary malignancies, including non-skin carcinoma, have occurred in 14% of patients treated with BRUKINSA monotherapy. The most frequent second primary malignancy was non-melanoma skin cancer, reported in 8% of patients. Other second primary malignancies included malignant solid tumors (4.0%), melanoma (1.7%) and hematologic malignancies (1.2%). Advise patients to use sun protection and monitor patients for the development of second primary malignancies.

Cardiac Arrhythmias

Atrial fibrillation and atrial flutter were reported in 3.2% 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 1.1% 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 1 week after the last dose. Advise men to avoid fathering a child during treatment and for 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, including laboratory abnormalities, in ≥ 30% of patients who received BRUKINSA (N = 847) included decreased neutrophil count (54%), upper respiratory tract infection (47%), decreased platelet count (41%), hemorrhage (35%), decreased lymphocyte count (31%), rash (31%) and musculoskeletal pain (30%).

Drug Interactions

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

CYP3A Inducers: Avoid coadministration 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.

INDICATIONS

- 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.

- BRUKINSA is indicated for the treatment of adult patients with Waldenström's macroglobulinemia (WM).

- BRUKINSA is indicated for the treatment of adult patients with relapsed or refractory marginal zone lymphoma (MZL) who have received at least one anti-CD20-based regimen.

  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.

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[i] Yao Y, Lin X, Li F, Jin J, Wang H. The global burden and attributable risk factors of chronic lymphocytic leukemia in 204 countries and territories from 1990 to 2019: analysis based on the global burden of disease study 2019. Biomed Eng Online. 2022 Jan 11;21(1):4. doi: 10.1186/s12938-021-00973-6. PMID: 35016695; PMCID: PMC8753864.