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): October 12, 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 October 12, 2022, BeiGene, Ltd. ("BeiGene") announced that BRUKINSA® (zanubrutinib) achieved superior Progression-Free Survival (PFS) versus IMBRUVICA® (ibrutinib) in a final analysis of the Phase 3 ALPINE trial, as assessed by an independent review committee (IRC) and investigator. 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 October 14, 2022, BeiGene announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has issued a positive opinion recommending approval of BRUKINSA® (zanubrutinib) for the treatment of adult patients with chronic lymphocytic leukemia (CLL). 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 Positive Topline Results from Final Progression-Free Survival Analysis of BRUKINSA® (zanubrutinib) Compared to IMBRUVICA® (ibrutinib) in Phase 3 Chronic Lymphocytic Leukemia (CLL) Trial" issued by BeiGene, Ltd. on October 12, 2022
99.2	Press release titled "BeiGene Receives Positive CHMP Opinion for BRUKINSA® (zanubrutinib) for the Treatment of Adults With CLL" issued by BeiGene, Ltd. on October 14, 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: October 14, 2022

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

Exhibit 99.1

BeiGene Announces Positive Topline Results from Final Progression-Free Survival Analysis of BRUKINSA® (zanubrutinib) Compared to IMBRUVICA® (ibrutinib) in Phase 3 Chronic Lymphocytic Leukemia (CLL) Trial

CAMBRIDGE, Mass. & BASEL, Switzerland & BEIJING – October 12, 2022 – BeiGene (NASDAQ: BGNE; HKEX: 06160; SSE: 688235), a global biotechnology company focused on developing innovative and affordable oncology medicines to improve treatment outcomes and access for patients worldwide, today announced that BRUKINSA® (zanubrutinib) achieved superior Progression-Free Survival (PFS) versus IMBRUVICA® (ibrutinib) in a final analysis of the Phase 3 ALPINE trial, as assessed by an independent review committee (IRC) and investigator. BRUKINSA was generally well tolerated; safety findings at the final PFS analysis were consistent with prior reports.

“This positive result adds to the growing body of evidence underpinning our belief in the potential for BRUKINSA to provide new hope for CLL patients facing this intractable disease. With this final PFS analysis, BRUKINSA has achieved superior progression free survival, as well as superiority in overall response rate versus ibrutinib,” said Mehrdad Mobasher, M.D., M.P.H., Chief Medical Officer, Hematology at BeiGene. “We look forward to sharing the full results with the medical and patient communities and will submit for presentation at a medical congress and for publication.”

BeiGene’s supplemental New Drug Application for BRUKINSA for the treatment of adult patients with CLL or small lymphocytic lymphoma (SLL) is currently under review with the FDA, with a target action date of January 20, 2023.

About ALPINE

ALPINE is a randomized, global Phase 3 trial (NCT03734016) comparing BRUKINSA against ibrutinib in previously treated patients with relapsed or refractory CLL or SLL. In the trial, a total of 652 patients across Europe (60%), the United States (17%), China (14%), New Zealand and Australia (9%) were randomized into two arms, with the first receiving BRUKINSA (160 mg orally twice daily) and the second receiving ibrutinib (420 mg orally once daily) until disease progression or unacceptable toxicity.

The primary endpoint of overall response rate (ORR), defined by pre-specified non-inferiority of BRUKINSA versus ibrutinib, was assessed by investigator and IRC using the modified 2008 iwCLL guidelines, with modification for treatment-related lymphocytosis for patients with CLL, and per Lugano Classification for non-Hodgkin’s lymphoma for patients with SLL. There was pre-specified hierarchical testing of non-inferiority followed by superiority in ORR as assessed by investigator and IRC. Key secondary endpoints include PFS and event rate of atrial fibrillation or flutter; other secondary endpoints include duration of response, overall survival, and incidence of adverse events. In April 2022, BeiGene announced results from the final response analysis showing BRUKINSA demonstrated superiority versus ibrutinib in ORR as assessed by an IRC.

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 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 4,500 subjects in 35 trials across 28 markets. To date, BRUKINSA has received approvals covering more than 55 countries and regions, including the United States, China, the EU, Great Britain, Switzerland, Canada, Australia, and additional international markets.

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 results from the final analysis of PFS of the Phase 3 ALPINE trial and the potential implications of these data for patients, BeiGene's plan to submit the results for presentation at a medical congress and for publication, the timing of regulatory review and potential approval of BRUKINSA as a new treatment option for patients with CLL, BeiGene's plan 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 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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Exhibit 99.2

BeiGene Receives Positive CHMP Opinion for BRUKINSA® (zanubrutinib) for the Treatment of Adults With CLL

If approved, BRUKINSA would be the only BTK inhibitor for CLL in the European Union to achieve superior efficacy versus standard of care in head-to-head trials

With significantly lower rates of atrial fibrillation/flutter compared to standard of care, BRUKINSA has potential to offer a more tolerable treatment option for certain patients

CAMBRIDGE, Mass. & BASEL, Switzerland & BEIJING - October 14, 2022 - BeiGene (NASDAQ: BGNE; HKEX: 06160; SSE: 688235), a global biotechnology company focused on developing innovative and affordable oncology medicines to improve treatment outcomes and access for patients worldwide, today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has issued a positive opinion recommending approval of BRUKINSA® (zanubrutinib) for the treatment of adult patients with chronic lymphocytic leukemia (CLL).

"BRUKINSA was designed to overcome limitations in efficacy and safety of first-generation Bruton's Tyrosine Kinase inhibitors (BTKi). As a result, BRUKINSA became the only BTKi to demonstrate superiority versus ibrutinib in the largest head-to-head BTKi study in relapsed/refractory (R/R) CLL, in addition to demonstrating superior Progression-Free Survival (PFS) against bendamustine plus rituximab (BR) in treatment-naïve (TN) patients regardless of age, co-morbidities, mutation, or risk status," said Mehrdad Mobasher, M.D., M.P.H., Chief Medical Officer, Hematology at BeiGene. "This recommendation demonstrates the focus and urgency with which we are delivering on our mission to accelerate development and broaden access to innovative medicines around the globe."

The CHMP recommendation is based on two global head-to-head Phase 3 clinical trials in which BRUKINSA demonstrated superior efficacy: ALPINE (NCT03734016) comparing BRUKINSA to ibrutinib in patients with R/R CLL and SEQUOIA (NCT03336333) comparing BRUKINSA to BR in patients with TN CLL. These two studies enrolled patients from a total of 17 countries, including the United States, China, Australia, New Zealand, and multiple countries in Europe.

Prof. Clemens Wendtner, Head of Hematology and Oncology at Munich Clinic, an academic teaching hospital of the University of Munich, Germany, commented, "BTK inhibitors have proven to be highly effective oral treatments for CLL; however, the burden of adverse events and discontinuations have a negative impact on patients' prognosis. The findings from two large head-to-head Phase 3 trials of BRUKINSA in CLL demonstrated efficacy across lines of therapy in addition to consistently low rates of atrial fibrillation/flutter and discontinuation across trials. These clinical trial data suggest BRUKINSA has the potential to become a practice-changing treatment option for CLL."

"We are proud of the rapid progress we have made over the past year bringing BRUKINSA to the blood cancer community in Europe," noted Gerwin Winter, Senior Vice President, Head of Europe at BeiGene. "With this recommendation, we are looking forward to the opportunity to provide this important medicine to more people with hematologic malignancies in the European Union."

Following the CHMP positive opinion, the European Commission will consider BeiGene's Marketing Application, with a final decision expected within 67 days of receipt of the CHMP opinion. The decision will be applicable to all 27 member states of the European Union (EU), plus Iceland and Norway. 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 chemo-immunotherapy. Last month, CHMP issued a positive opinion recommending approval of BRUKINSA for the treatment of 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, Ireland, Italy, Spain, and Switzerland, 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.[i,ii,iii] CLL is one of the most common types of leukemia, accounting for about one-quarter of new cases of leukemia.[iv] In Europe, the estimated incidence is 4.92/100,000 persons per year.[v,vi]

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 4,500 subjects in 35 trials across 28 markets. To date, BRUKINSA has received approvals covering more than 55 countries and regions, including the United States, China, the EU, Switzerland, Great Britain, Canada, Australia, 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 3,300 colleagues dedicated to advancing more than 100 clinical trials that have involved more than 16,000 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 licensed medicines discovered and developed in our own labs: BTK inhibitor BRUKINSA® in the U.S., China, the European Union, Switzerland, Great Britain, Canada, Australia, 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.

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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 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.

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