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 19, 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 September 19, 2022, BeiGene, Ltd. ("BeiGene") announced that the Committee for Medicinal Products for Human Use of the European Medicines Agency has issued a positive opinion recommending approval of BRUKINSA® (zanubrutinib) for the treatment of adult patients with marginal zone lymphoma who have received at least one prior anti-CD20-based therapy. 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 20, 2022, BeiGene announced that England's health technology assessment institute, the National Institute for Health and Care Excellence, has issued a final appraisal document recommending BRUKINSA® (zanubrutinib) for the treatment of Waldenström's Macroglobulinemia in adults who have had at least one treatment, only if bendamustine plus rituximab is also suitable. 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 Receives Positive CHMP Opinion for BRUNKINSA® (zanubrutinib) for the Treatment of Adults with Marginal Zone Lymphoma" issued by BeiGene on September 19, 2022
99.2	Press release titled "NICE Recommends BeiGene's BRUKINSA® (zanubrutinib) for Patients with Waldenström's Macroglobulinemia who have at least One Treatment" issued by BeiGene, Ltd. on September 20, 2022
104	The cover page from this Current Report on Form 8-K, formatted in Inline XBRL

Exhibit Index

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99.2	Press release titled "NICE Recommends BeiGene's BRUKINSA® (zanubrutinib) for Patients with Waldenström's Macroglobulinemia who have had at Least One Treatment" issued by BeiGene, Ltd. on September 20, 2022
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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: September 22, 2022

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

Exhibit 99.1

BeiGene Receives Positive CHMP Opinion for BRUKINSA® (zanubrutinib) for the Treatment of Adults with Marginal Zone Lymphoma

CHMP recommends approval of BRUKINSA for the treatment of relapsed or refractory marginal zone lymphoma

If approved, BRUKINSA will be the first and only approved Bruton's Tyrosine Kinase (BTK) inhibitor for marginal zone lymphoma in Europe

CAMBRIDGE, Mass., & BASEL, Switzerland & BEIJING – September 19, 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 marginal zone lymphoma (MZL) who have received at least one prior anti-CD20-based therapy.

"There are currently no BTK inhibitors approved for MZL in Europe and with this positive opinion, we are one step closer to bringing forward a chemotherapy-free treatment option for this rare blood cancer. We look forward to a decision from the European Commission in the coming months," said Mehrdad Mobasher, M.D., M.P.H., Chief Medical Officer, Hematology at BeiGene. "We have undertaken a broad development program to evaluate BRUKINSA as a potential treatment for various B-cell malignancies in over 4,500 patients, which continues to generate evidence to support BRUKINSA as an effective and well-tolerated treatment option for blood cancer patients around the world."

The CHMP recommendation is based on positive results from the Phase 2, open-label, multicenter, single-arm MAGNOLIA trial (NCT03846427) in 66 patients with relapsed or refractory (R/R) MZL who received at least one anti-CD20-based regimen. In the study, the overall response rate (ORR) was 68% (95% CI: 55.6, 79.1) with 26% of patients achieving complete response (CR) and 42% achieving partial response (PR). The median time to response was 2.8 months (range: 1.7 to 11.1 months) and ORRs for MZL subtypes extranodal, nodal, splenic, and unknown were 64%, 76%, 67%, and 50%, respectively.

BRUKINSA demonstrated favorable and well-defined tolerability consistent with its known safety profile. The most common (≥30%) adverse reactions, including laboratory abnormalities, in the pooled safety population of 847 patients were decreased neutrophil count, upper respiratory tract infection, decreased platelet count, and hemorrhage. The observed cardiac safety profile was consistent with previous BRUKINSA studies, with low rates of atrial fibrillation (3%) and atrial flutter (0.4%). BRUKINSA was well-tolerated, as demonstrated by low rates of discontinuation due to adverse events (6%).

Pier Luigi Zinzani, MD., PhD., Full Professor of Haematology at the Institute of Haematology "Seràgnoli", University of Bologna, Italy commented, "Marginal zone lymphoma encompasses a number of subtypes. As a highly selective BTK inhibitor, the clinical trial data for BRUKINSA showed deep and sustained overall responses regardless of subtype, along with a well-established safety profile. If approved, BRUKINSA has the potential to deliver meaningful outcomes for MZL patients in Europe who otherwise have no approved treatment options."

This opinion is an important milestone as we work to bring a BTK inhibitor for the first time to European MZL patients," notes Gerwin Winter, Senior Vice President, Head of Europe at BeiGene. "We look forward to combining our global scale and local expertise to deliver innovative medicines to patients across Europe."

Following the CHMP positive opinion, the European Commission will consider BeiGene's Marketing Application, with a final decision expected within 67 days 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 Waldenström's macroglobulinemia (WM) who have received at least one prior therapy or for the first-line treatment of patients unsuitable for chemo-immunotherapy.

BeiGene has obtained reimbursement for BRUKINSA for the treatment of Waldenström's macroglobulinemia in Austria, Belgium, Denmark, England and Wales, Germany, Ireland, Spain, and Switzerland while additional EU countries are currently going through the reimbursement process.

About Marginal Zone Lymphoma

MZL is a group of ultra-rare, slow growing B-cell malignancies that begin in the marginal zones of lymph tissue. i Epidemiological data from Europe is limited, but the incidence rate of MZL is estimated to range between 20 and 30 per million per year.[ii,iii,iv] There are three different subtypes of MZL: extranodal marginal zone B-cell lymphoma, or mucosa-associated lymphoid tissue (MALT), which is most common; nodal marginal zone B-cell lymphoma which develops in the lymph nodes and is rare; and splenic marginal zone B-cell lymphoma which develops in the spleen, bone marrow, or both, and is the rarest form of the disease.[v]

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 more than 20 approvals covering more than 50 countries and regions, including the United States, China, the EU, Great Britain, Canada, Australia, and additional international markets. Currently, more than 40 additional regulatory submissions are in review around the world.

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 mono-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, and additional international markets; and the non-FC-gamma receptor binding anti-PD-1 antibody, tislelizumab, as well as the 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 with 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-PD1 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 8,500 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 MZL, 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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[i] Annals of Oncology, Marginal Zone Lymphomas: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up, January 6, 2020.
[ii] Cerhan, J.R. and T.M. Habermann, Epidemiology of Marginal Zone Lymphoma. Ann Lymphoma, 2021.
[iii] Smith, A., et al., Lymphoma incidence, survival and prevalence 2004-2014: sub-type analyses from the UK's Haematological Malignancy Research Network. Br J Cancer, 2015. 112(9): p. 1575-84.
[iv] Maynadie, M., et al., Splenic Marginal Zone Lymphoma: French Registries Population-Based Treatment and Survival Analyses (2002-2014). Blood, 2020. 136.
[v] Leukemia & Lymphoma Society, Marginal Zone Lymphoma. Available at: https://www.lls.org/research/marginal-zone-lymphoma-mzl.

Exhibit 99.2

NICE Recommends BeiGene's BRUKINSA® (zanubrutinib) for Patients with Waldenström's Macroglobulinemia who have had at Least One Treatment

BRUKINSA Is the First Bruton's Tyrosine Kinase (BTK) Inhibitor Recommended by NICE for Routine Use for WM

BRUKINSA Is the Only BTK Inhibitor Considered Cost Effective in WM

CAMBRIDGE, Mass. & BASEL, Switzerland, & BEIJING, China— September 20, 2022 — BeiGene (NASDAQ: BGNE; HKEX: 06160; SSE: 688235), a global biotechnology company that is developing and commercializing oncology medicines, today announced that England's health technology assessment institute, the National Institute for Health and Care Excellence (NICE), has issued a final appraisal document (FAD) recommending BRUKINSA (zanubrutinib) for the treatment of Waldenström's Macroglobulinemia (WM) in adults who have had at least one treatment, only if bendamustine plus rituximab is also suitable.

This decision from NICE marks BRUKINSA as the first and only treatment for WM to be recommended for routine use in England and Wales. The NICE Committee acknowledged the high unmet need for an effective and well tolerated treatment for WM "where current chemoimmunotherapy options can cause severe adverse reactions and the need for frequent hospital visits".[i]

WM is a rare form of B-cell lymphoma that occurs in less than two percent of patients with non-Hodgkin lymphomas. There are around 4,000 people living with WM in the UK.[ii]

"BRUKINSA is a highly selective BTK inhibitor," said Dr Shirley D'Sa, consultant hematologist and clinical lead at the University College London Hospitals Centre for WM and Associated Disorders. "NICE's positive recommendation for zanubrutinib allows eligible patients in England and Wales to access an important new treatment option that may offer improved outcomes compared to the current standard of care."

In its appraisal, NICE concluded that zanubrutinib could be considered "a step-change" in managing the disease as clinical evidence suggests that people with WM may live longer and have a better quality of life with zanubrutinib compared to standard of care. The NICE recommendation states that BRUKINSA is considered cost-effective at a threshold of £20,000- 30,000 per quality-adjusted life year (QALY).[i]

"I am very pleased that NICE have agreed that BRUKINSA is a valuable treatment option for eligible WM patients in England and Wales, enabling those patients to be among the first patients in Europe to have access to BRUKINSA," commented Dr. Robert Mulrooney, BeiGene General Manager, UK and Ireland. "BeiGene's mission is to achieve affordable access to our innovative medicines and we look forward to working with NICE and the National Health Service in the UK to create further treatment options for UK patients with blood cancers."

About Waldenström's Macroglobulinemia

WM is a rare B-cell lymphoma that occurs in less than two percent of patients with non-Hodgkin lymphomas.[iii] The disease usually affects older adults and is primarily found in bone marrow, although lymph nodes and the spleen may be involved.[iv] Typically, patients present between the ages of 60 and 70 years. For reasons that are unclear, WM is almost twice as common in men as in women and is more common in Caucasians than other ethnic groups.[v] Waldenström's macroglobulinemia is a rare cancer seen only in approximately three to five per million people per year.[iv]

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[i] National Institute for Health and Care Excellence. Final appraisal document – Zanubrutinib for treating Waldenstrom's macroglobulinaemia [ID1427]. September 2022
[ii] The UK Charity for Waldernstrom's Macroglobulinaemia. Available at https//wmuk.org.uk
[iii] Buske, C, et al. Treatment and outcome patterns in European patients with Waldenström's macroglobulinaemia: a large, observational, retrospective chart review. The Lancet Haematology 2018; 5: e0299-309.
[iv] Lymphoma Research Foundation. Getting the Facts: Waldenström Macroglobulinemia. Accessed March 2022. Available at https://lymphoma.org/wp-content/uploads/2021/12/LRF-Waldenstrom-Macroglobulinemia_Factsheet.pdf
[v] https://iwmf.com/frequently-asked-questions-waldenstrom-macroglobulinemia/