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 2, 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 2, 2022, BeiGene, Ltd. ("BeiGene") announced that the European Commission granted marketing authorization of BRUKINSA® (zanubrutinib) for the treatment of adult patients with relapsed/refractory marginal zone lymphoma who have received at least one prior anti-CD20-based therapy. The approval is applicable to all 27 member states of the European Union, as well as Iceland and Norway. 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.

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 Marginal Zone Lymphoma" issued by BeiGene, Ltd. on November 2, 2022
104	The cover page from this Current Report on Form 8-K, formatted in Inline XBRL

Exhibit Index

Exhibit No.	Description
99.1	Press release titled "BeiGene Receives European Commission Approval for BRUKINSA® (zanubrutinib) for the Treatment of Adults with Marginal Zone Lymphoma" issued by BeiGene, Ltd. on November 2, 2022
104	The cover page from this Current Report on Form 8-K, formatted in Inline XBRL

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

BEIGENE, LTD.

Date: November 7, 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 Marginal Zone Lymphoma

BRUKINSA is the first and only Bruton's Tyrosine Kinase (BTK) inhibitor for marginal zone lymphoma approved in the European Union

CAMBRIDGE, U.S., & BASEL, Switzerland & BEIJING – November 2, 2022 – BeiGene (NASDAQ: BGNE; HKEX: 06160; SSE: 688235), a global biotechnology company, today announced that the European Commission (EC) has granted marketing authorization of BRUKINSA® (zanubrutinib) for the treatment of adult patients with relapsed/refractory (R/R) marginal zone lymphoma (MZL) who have received at least one prior anti-CD20-based therapy. The approval is applicable to all 27 member states of the European Union (EU), plus Iceland and Norway. BeiGene is focused on developing innovative and affordable oncology medicines to improve treatment outcomes and access for patients worldwide.

Notably, the EC granted an additional year of marketing protection because the data submitted for the therapeutic indication demonstrated a significant clinical benefit for BRUKINSA in comparison with existing therapies.

"We are proud of what this approval means for European MZL patients, who previously did not have an approved BTK inhibitor as a treatment option for this rare hematological malignancy," said Mehrdad Mobasher, M.D., M.P.H., Chief Medical Officer, Hematology at BeiGene. "This milestone builds on the track record we've built with BRUKINSA to date, with approvals in more than 55 countries and regions, as we continue to fulfill our commitment to build a transformational global R&D model that enables broader, faster access to novel medicines."

The EC approval follows a positive opinion granted in September by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) based on results from the multicenter, global, single-arm, open-label, Phase 2 MAGNOLIA trial in patients with R/R MZL who received at least one anti-CD-20 based regimen. In the trial, BRUKINSA achieved a high overall response rate of 68% with 26% of patients achieving complete remission, as assessed by an Independent Review Committee (IRC). Responses were observed in all patients regardless of MZL subtypes. BRUKINSA also delivered rapid and durable disease control with a median time to response of 2.8 months.[i]

BRUKINSA was generally well-tolerated and safety in MZL was consistent with its established profile. The most common grade ≥3 adverse events (>5%) included neutropenia (23%), pneumonia (11%), thrombocytopenia (8%) and anemia (8%). There were low rates of discontinuation due to adverse events at 3.5%, highlighting that BRUKINSA continued to be well-tolerated.[ii]

"This milestone marks the first and only approved BTK inhibitor for marginal zone lymphoma in Europe," comments Pier Luigi Zinzani, MD., PhD., Full Professor of Haematology at the Institute of Haematology "Seràgnoli", University of Bologna, Italy. "As there is no current standard of care in Europe, the approval of BRUKINSA provides a chemotherapy-free treatment option for people with MZL that has shown meaningful efficacy with durable and high response rates across MZL subtypes."

Gerwin Winter, Senior Vice President, Head of Europe at BeiGene, notes, "We are excited to bring the first and only BTKi approved for MZL to patients in Europe and look forward to continuing to work with our growing and dedicated teams to make our medicine accessible to patients who need them across Europe."

BRUKINSA is also 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, and last month, CHMP issued a positive opinion recommending approval of BRUKINSA for the treatment of adult patients with chronic lymphocytic leukemia (CLL).

BeiGene has obtained reimbursement for BRUKINSA for the treatment of WM in Austria, Belgium, Denmark, England and Wales, Germany, Italy, Iceland, Ireland, The Netherlands, Spain, and Switzerland, while additional countries across Europe 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.[iii] Epidemiological data from Europe is limited, but the incidence rate of MZL is estimated to range between 20 and 30 per million per year.[iv, v, vi] 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.[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 4,500 subjects in 35 trials across 28 markets. To date, BRUKINSA has received approvals covering more 55 countries and regions, including the United States, China, the EU, Great Britain, Switzerland, 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 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, Switzerland, 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 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 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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