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): May 6, 2023

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 May 6, 2023, BeiGene, Ltd. (the "Company") announced that the China National Medical Products Administration approved four applications for BRUKINSA® (zanubrutinib), the Company's Bruton's tyrosine kinase inhibitor, including two Supplemental New Drug Applications for treatment-naïve adults with chronic lymphocytic leukemia or small lymphocytic lymphoma and Waldenström's macroglobulinemia, and two Supplemental Applications for conversions from conditional approval to regular approval.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release titled "BeiGene Receives New Approvals for BRUKINSA® (zanubrutinib) in China" issued by BeiGene, Ltd. on May 6, 2023
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: May 8, 2023

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

Exhibit 99.1

BeiGene Receives New Approvals for BRUKINSA® (zanubrutinib) in China

BRUKINSA is approved for first-line treatment for CLL/SLL and WM in China and has multiple approved indications in more than 65 markets worldwide

BASEL, Switzerland & BEIJING & CAMBRIDGE, Mass., May 6, 2023, BeiGene (NASDAQ: BGNE; HKEX: 06160; SSE: 688235), a global biotechnology company, today announced the China National Medical Products Administration (NMPA) approved four applications for BRUKINSA (zanubrutinib), the company's Bruton's tyrosine kinase inhibitor (BTKi), including two Supplemental New Drug Applications for treatment-naïve adults with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) and Waldenström's macroglobulinemia (WM), and two Supplemental Applications for conversions from conditional approval to regular approval.

"These approvals further support BRUKINSA as the BTKi of choice in China for the treatment of B-cell malignancies such as CLL and WM," said Lai Wang, Ph.D., Global Head of R&D at BeiGene. "We look forward to bringing people living with CLL and WM a new first-line treatment option as we work to support the *Healthy China* initiative and reduce global health inequity."

BRUKINSA previously received conditional approvals from NMPA for the treatment of adult patients with CLL/SLL and mantle cell lymphoma (MCL) who have received at least one prior therapy (R/R CLL/SLL and R/R MCL) in June 2020, and conditional approval for the treatment of adult patients with WM who have received at least one prior therapy (R/R WM) in June 2021. NMPA converted these conditional approvals to regular approvals for R/R CLL/SLL and R/R WM in April 2023.

"CLL/SLL and WM patients are predominantly populated in the elderly, and there are increasing needs for improved efficacy and safety in CLL/SLL and WM treatments," said Professor Ma Jun, Director of the Harbin Institute of Hematology & Oncology, Chief Supervisor of Supervisory Committee at the Chinese Society of Clinical Oncology. "BRUKINSA has been recommended as the preferred regimen of multiple subtypes of lymphoma in both national and international guidelines[i, ii, iii, iv, v]. With these important approvals, BRUKINSA now becomes the only approved new-generation BTK inhibitor in China for the first-line treatment of adult CLL/SLL and WM patients, bringing healthcare providers in China with a new standard of care for their patients."

The new approvals of BRUKINSA for CLL/SLL are supported by data from SEQUOIA (NCT03336333), in patients with previously untreated CLL/SLL. The new approvals of BRUKINSA for WM are based on data from ASPEN (NCT03053440), the first and only global Phase 3 head-to-head clinical trial of BTK inhibitors in WM.

About Chronic Lymphocytic Leukemia (CLL) / Small Lymphocytic Lymphoma (SLL)
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[vi, vii, viii]. CLL is one of the most common types of leukemia, accounting for about one-quarter of new cases of leukemia[ix]. CLL and SLL are considered different manifestations of the same disease. Approximately 180 of every 100,000 people in China have CLL/SLL, accounting for 1% to 3% of all non-Hodgkin lymphoma cases[x].

About Waldenström's Macroglobulinemia (WM)
WM is a rare, slow-growing lymphoma that occurs in less than two percent of patients with non-Hodgkin's lymphoma (NHL)[xi]. The disease usually affects older adults and is primarily found in the bone marrow, although it may also impact lymph nodes and the spleen[xii]. In China, there are an estimated 88,200 patients diagnosed with lymphoma each year. Approximately 91% of these cases are classified as NHL, amounting to ~1,000 newly diagnosed WM patients per year in China[xiii, viii].

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 BeiGene
BeiGene is a global biotechnology company that is discovering and developing innovative oncology treatments that are more affordable and accessible to cancer 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 9,400 colleagues spans five continents, with administrative offices in Basel; Beijing; and Cambridge, U.S. 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 become the BTKi of choice in China for patients with CLL or WM, and the benefits of such treatment for those patients; BeiGene's efforts to make BRUKINSA more broadly available to patients in China and to reduce global health inequities; the future development and regulatory filing and approval of BRUKINSA in other markets; and BeiGene's plans, commitments, aspirations, and goals under the heading "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.

Investor Contact:
ir@beigene.com
Gabrielle Zhou
+86 10 5895 8058
Kevin Mannix
+1 240-410-0129

Media Contact:
media@beigene.com
Edith Tan
+86 10 6844 5311
Kathleen Cuca
+ 1 551-222-6790

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