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): December 30, 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 December 30, 2022, BeiGene, Ltd. ("BeiGene") announced that the Center for Drug Evaluation of the China National Medical Products Administration has accepted a supplemental biologics license application for tislelizumab in patients with first-line unresectable or metastatic hepatocellular carcinoma. 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 Announces Acceptance of 12th Regulatory Submission in China for PD-1 Inhibitor Tislelizumab" issued by BeiGene, Ltd. on December 30, 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 Announces Acceptance of 12th Regulatory Submission in China for PD-1 Inhibitor Tislelizumab" issued by BeiGene, Ltd. on December 30, 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: January 5, 2023

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

Exhibit 99.1

BeiGene Announces Acceptance of 12th Regulatory Submission in China for PD-1 Inhibitor Tislelizumab

Submission seeks marketing authorization for first-line treatment of unresectable or metastatic hepatocellular carcinoma

CAMBRIDGE, Mass., & BASEL, Switzerland & BEIJING – December 30, 2022 – BeiGene (NASDAQ: BGNE; HKEX: 06160; SSE: 688235), a global biotechnology company announced that the Center for Drug Evaluation (CDE) of the China National Medical Products Administration (NMPA) has accepted a supplemental biologics license application (sBLA) for tislelizumab in patients with first-line unresectable or metastatic hepatocellular carcinoma (HCC).

Hepatocellular carcinoma is the most common type of primary liver cancer worldwide and is associated with a very poor prognosis.[1] New cases and deaths due to HCC in China account for half of the global numbers and the 5-year survival rate for patients with HCC in China is only 14%.[2]

"While the incidence of HCC is increasing in China, the treatment landscape has not advanced accordingly; survival benefits with newer treatments are modest and multi-kinase inhibitors have sub-optimal tolerability," said Lai Wang, Ph.D., Global Head of R&D at BeiGene. "We believe the evidence from our rigorously conducted global clinical development program for tislelizumab in HCC support the efficacy and favorable tolerability profile and look forward to working with NMPA on this submission and bringing a new treatment option to patients with HCC in China."

The sBLA is supported by data from the RATIONALE 301 clinical trial (NCT03412773) that enrolled 674 patients from research centers across Asia, Europe, and the United States. RATIONALE 301 results were presented as a late-breaking oral presentation at the 2022 European Society for Medical Oncology (ESMO) Congress in Paris.

Tislelizumab was approved by the China NMPA as a treatment for nine indications, including conditional approval 'for the treatment of patients with hepatocellular carcinoma (HCC) who have been previously treated with at least one systemic therapy'. Additional tislelizumab's sBLAs under review at CDE include: combination with chemotherapy as a first-line treatment for patients with advanced or metastatic gastric or gastroesophageal junction adenocarcinoma whose tumors express PD-L1; combination with chemotherapy as first-line treatment in patients with unresectable locally advanced, recurrent or metastatic esophageal squamous cell carcinoma. Tislelizumab is not approved for use outside of China.

About Tislelizumab

Tislelizumab is a humanized IgG4 anti-PD-1 monoclonal antibody specifically designed to minimize binding to Fc-gamma (Fcγ) receptors on macrophages, helping to aid the body's immune cells to detect and fight tumors. In pre-clinical studies, binding to Fcγ receptors on macrophages has been shown to compromise the anti-tumor activity of PD-1 antibodies through activation of antibody-dependent macrophage-mediated killing of T effector cells.

Tislelizumab is the first investigational medicine from BeiGene's immuno-oncology biologics program and is being evaluated in solid tumor and hematologic malignancies, as monotherapy and in combination.

The global tislelizumab clinical development program includes more than 11,500 subjects enrolled to-date in 21 registration-enabling trials, from more than 30 countries and regions.

About RATIONALE 301

RATIONALE 301 (NCT03412773) is a global, Phase 3, randomized, open-label study of tislelizumab compared with sorafenib as a first-line treatment in adult patients with unresectable HCC. The primary endpoint of the study is non-inferiority of Overall Survival between the two treatment groups. The key secondary endpoint is Overall Response Rate, as assessed by Blinded Independent Review Committee (BIRC) per RECIST v1.1. Other secondary endpoints include other efficacy assessments such as Progression Free Survival, Duration of Response, and Time to Progression per BIRC, as well as measures of health-related quality of life, and safety and tolerability.

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 Cambridge, U.S., & Basel, Switzerland & Beijing, China. 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 tislelizumab to treat patients with HCC, plans for regulatory approvals for tislelizumab in HCC, BeiGene's advancement of anticipated clinical development, regulatory milestones and commercialization of tislelizumab, 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 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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[1]Sung, H, Ferlay, J, Siegel, RL, Laversanne, M, Soerjomataram, I, Jemal, A, Bray, F. Global cancer statistics 2020: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. *CA Cancer J Clin*. 2021: 71: 209- 249. https://doi.org/10.3322/caac.21660

[2]Zheng R, Qu C, Zhang S, Zeng H, Sun K, Gu X, Xia C, Yang Z, Li H, Wei W, Chen W, He J. Liver cancer incidence and mortality in China: Temporal trends and projections to 2030. Chin J Cancer Res. 2018 Dec;30(6):571-579. https://doi.org/10.21147/j.issn.1000-9604.2018.06.01.