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): August 23, 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 August 23, 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 combination with chemotherapy as first-line treatment in patients with unresectable locally advanced, recurrent or metastatic esophageal squamous cell 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.	Description
99.1	Press release titled "BeiGene Announces Acceptance of 11th Regulatory Submission for PD-1 Inhibitor Tislelizumab in China" issued by BeiGene, Ltd. on August 23, 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 11th Regulatory Submission for PD-1 Inhibitor Tislelizumab in China" issued by BeiGene, Ltd. on August 23, 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: August 25, 2022

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

Exhibit 99.1

BeiGene Announces Acceptance of 11th Regulatory Submission for PD-1 Inhibitor Tislelizumab in China

Submission seeks marketing authorization for first-line use in combination with chemotherapy in advanced esophageal squamous cell carcinoma

CAMBRIDGE, U.S., & BASEL, Switzerland & BEIJING – August 23, 2022 – BeiGene (NASDAQ: BGNE; HKEX: 06160; SSE: 688235), a global biotechnology company focused on developing and commercializing innovative and affordable oncology medicines to improve treatment outcomes and access for patients worldwide, today 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 combination with chemotherapy as first-line treatment in patients with unresectable locally advanced, recurrent or metastatic esophageal squamous cell carcinoma (ESCC).

Esophageal cancers are classified based on the type of cells involved and ESCC is the most common subtype, accounting for more than 85% of esophageal cancers worldwide.[i,ii] In China, esophageal cancer is the fourth leading cause of death due to malignancy and remains a significant threat to public health with 246,000 new diagnoses reported in 2015.[iii]

"Our global clinical development program for tislelizumab encompasses more than 20 registration-enabling trials and we are pleased that our robust clinical data for tislelizumab are contributing to advancing the treatment landscape for solid tumors in China," said Lai Wang, Ph.D., Global Head of R&D at BeiGene. "We look forward to working with NMPA on this submission and to progressing global regulatory submissions based on the clinically meaningful overall survival benefit seen in the RATIONALE 306 trial."

The sBLA is supported by data from an interim analysis of the RATIONALE 306 (NCT03783442) global clinical trial that enrolled 649 patients from research centers across Asia-Pacific, Europe, and North America. RATIONALE 306 results were presented as a late-breaking oral presentation at the 2022 European Society for Medical Oncology (ESMO) World Congress on Gastrointestinal Cancer in June.

Tislelizumab is approved by the China NMPA as a treatment for nine indications, including approval for use in patients with locally advanced or metastatic ESCC who have disease progression or are intolerant to first-line standard chemotherapy. 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 11,000 subjects enrolled to-date in 30 countries and regions. More information on the tislelizumab development program, including clinical trials and regulatory submissions, can be found on the Tislelizumab Fact Sheet in our corporate press kit.

About RATIONALE 306

RATIONALE 306 (NCT03783442) is a randomized, placebo-controlled, double-blind, global Phase 3 study to evaluate the efficacy and safety of tislelizumab in combination with chemotherapy as a first-line treatment in patients with advanced or metastatic ESCC. The primary endpoint of the trial is overall survival (OS). Secondary endpoints include progression free survival, overall response rate, duration of response per RECIST v1.1, and OS in patients with PD-L1 score ≥ 10%, as well as health-related quality of life measures and safety.

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 tislelizumab to treat patients with advanced or metastatic ESCC, plans for regulatory approvals for tislelizumab in ESCC, BeiGene's advancement of anticipated clinical development, regulatory milestones and commercialization of tislelizumab, 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 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] Wang QL, et al. Clin Epidemiol 2018;10:717-728;

[ii] Huang FL, Yu SJ. Asian J Surg 2018;41:210-215;

[iii] Guidelines for Diagnosis and Treatment of Esophageal Cancer of the National Health Commission of China (2022 Edition)