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): July 14, 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 July 14, 2022, BeiGene, Ltd. ("BeiGene") announced that the U.S. Food and Drug Administration (FDA) has deferred action on the Biologics License Application (BLA) for tislelizumab as a second-line (2L) treatment for patients with unresectable or metastatic esophageal squamous cell carcinoma (ESCC). 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 Provides Regulatory Update on the U.S. Biologics License Application (BLA) for PD-1 Inhibitor Tislelizumab in 2L ESCC" issued by BeiGene, Ltd. on July 14, 2022
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: July 15, 2022

By: /s/ Julia Wang
Name: Julia Wang
Title: Chief Financial Officer

Exhibit 99.1

BeiGene Provides Regulatory Update on the U.S. Biologics License Application (BLA) for PD-1 Inhibitor Tislelizumab in 2L ESCC

FDA Defers Action on BLA Until Required Inspections Can Be Completed

Due to COVID Travel Restrictions, Inspections Could Not Be Completed During Review Period

CAMBRIDGE, Mass., & BASEL, Switzerland & BEIJING – July 14, 2022 – BeiGene (NASDAQ: BGNE; HKEX: 06160; SSE: 688235), a global oncology biotechnology company focused on developing innovative and affordable medicines to improve treatment outcomes and access for patients worldwide, today announced that the U.S. Food and Drug Administration (FDA) has deferred action on the Biologics License Application (BLA) for tislelizumab as a second-line (2L) treatment for patients with unresectable or metastatic esophageal squamous cell carcinoma (ESCC). The FDA has been unable to conduct required inspections in China due to COVID-19 related travel restrictions. As a result, the FDA is deferring action on the application until the inspections are complete.

In the letter, the FDA cited only travel restrictions and the inability to complete inspections as the reason for the deferral. The application remains under review, and the FDA did not provide a new anticipated action date as they continue to monitor the public health situation and travel restrictions. BeiGene and Novartis will continue to work actively with the FDA to support scheduling the required inspections as soon as possible.
"We are working with our partner, Novartis, to facilitate the required inspections and bring tislelizumab to patients with second-line esophageal cancer in the U.S. following regulatory approval," said John V. Oyler, Co-Founder, Chairman and CEO of BeiGene.

In September 2021, the FDA accepted the BLA for tislelizumab in 2L ESCC and provided a Prescription Drug User Fee Act (PDUFA) goal date of July 12, 2022. The evidence base for the BLA submission includes results from RATIONALE 302, a randomized, open-label, multi-regional Phase 3 trial that enrolled 512 patients from Europe, U.S. and Asia and safety data on 1,972 patients who received tislelizumab as a monotherapy from seven clinical trials. The RATIONALE 302 trial demonstrated a 30% reduction in the risk of death (HR=0.70, 95% CI: 0.57-0.85, p=0.0001) and extended median overall survival by 2.3 months compared to chemotherapy in people with unresectable recurrent locally advanced or metastatic ESCC who had received prior systemic therapy. Study results were published in Journal of Clinical Oncology in May 2022.[i]

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 drug from BeiGene's immuno-oncology biologics program and is being developed internationally as a monotherapy and in combination with other therapies for the treatment of a broad array of both solid tumor and hematologic cancers.

The global tislelizumab clinical development program includes more than 9,000 subjects enrolled to-date in more than 35 countries and regions. BeiGene has initiated or completed more than 20 potentially registration-enabling clinical trials, including 17 Phase 3 trials. More information on the clinical trial program for tislelizumab can be found here.

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 2,900 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, science-driven biotechnology company focused on developing innovative and affordable medicines to improve treatment outcomes and access for patients worldwide. With a broad portfolio of more than 40 clinical candidates, we are expediting development of our diverse pipeline of novel therapeutics through our own capabilities and collaborations. We are committed to radically improving access to medicines for two billion more people by 2030. BeiGene has a growing global team of over 8,000 colleagues across five continents. 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 2L ESCC, the expected timing for FDA onsite inspections, review and potential approval of the BLA for tislelizumab in 2L ESCC, plans to make tislelizumab available to patients with 2L ESCC following approval, 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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