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 21, 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 July 21, 2023, BeiGene, Ltd. announced that the Committee for Medicinal Products for Human Use of the European Medicines Agency has issued a positive opinion recommending approval for tislelizumab as monotherapy for the treatment of adult patients with unresectable, locally advanced or metastatic esophageal squamous cell carcinoma after prior platinum-based chemotherapy. 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 Positive CHMP Opinion for Tislelizumab as a Treatment for Advanced or Metastatic ESCC" issued by BeiGene, Ltd. on July 21, 2023
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 Positive CHMP Opinion for Tislelizumab as a Treatment for Advanced or Metastatic ESCC" issued by BeiGene, Ltd. on July 21, 2023
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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 24, 2023

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

Exhibit 99.1

BeiGene Announces Positive CHMP Opinion for Tislelizumab as a Treatment for Advanced or Metastatic ESCC

BASEL, Switzerland & BEIJING & CAMBRIDGE, Mass., July 21, 2023, BeiGene (Nasdaq: BGNE; HKEX: 06160; SSE: 688235), a global biotechnology company, today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has issued a positive opinion recommending approval for tislelizumab as monotherapy for the treatment of adult patients with unresectable, locally advanced or metastatic esophageal squamous cell carcinoma (ESCC) after prior platinum-based chemotherapy.

"Tislelizumab is the first medicine to come from BeiGene's immuno-oncology research program and our team partnered with patients, caregivers, and clinical researchers across the world to generate the evidence supporting this CHMP recommendation," said Lai Wang, Ph.D., Global Head of R&D at BeiGene. "We continue to make progress in our mission to bring the highest quality therapies to more people around the world and look forward to working with Novartis and health authorities on regulatory filings for tislelizumab."

The Marketing Authorization Application (MAA) for ESCC is based on results from BeiGene's RATIONALE 302, a global, randomized, open-label, Phase 3 study (NCT03430843) to investigate the efficacy and safety of tislelizumab when compared with investigator's choice chemotherapy as a second-line treatment for patients with unresectable, locally advanced or metastatic ESCC. The study enrolled 513 patients from 132 research sites in 11 countries in Asia, Europe, and North America. The study met its primary endpoint with a statistically significant and clinically meaningful survival benefit for tislelizumab compared with chemotherapy (HR 0.70 [95%CI 0.57 - 0.85]; one-sided P=.0001; median overall survival 8.6 vs 6.3 months). The safety profile for tislelizumab was consistent with previous trials.[i] The MAA included safety data for 1,972 patients who received tislelizumab monotherapy in seven clinical trials.

Tislelizumab is not currently authorized for use in Europe.

About ESCC[ii]
Globally, esophageal cancer (EC) is the sixth most common cause of cancer-related deaths and ESCC is the most common histologic subtype, accounting for more than 85% of ECs. An estimated 957,000 new EC cases are projected in 2040, an increase of nearly 60% from 2020 that underscores the need for additional effective treatments.

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.

In 2021, BeiGene and Novartis announced a collaboration agreement to jointly develop tislelizumab in the United States, Canada, Mexico, member countries of the European Union, United Kingdom, Norway, Switzerland, Iceland, Liechtenstein, Russia, and Japan. Under the agreement Novartis is responsible for regulatory submission and has the right to commercialize in these licensed countries following regulatory approval.

The EMA is reviewing a MAA for tislelizumab as a treatment for locally advanced or metastatic non-small cell lung cancer (NSCLC) after prior chemotherapy, and in combination with chemotherapy for previously untreated locally advanced or metastatic NSCLC. Regulatory submissions for tislelizumab are also under review by authorities in the U.S., U.K., Australia, China, New Zealand, Brazil, Korea, and Switzerland.

More than 12,000 patients from across the world have participated in the tislelizumab development program that encompasses 21 registration-enabling clinical trials in more than 30 countries and regions. To date, BeiGene has announced positive readouts from 10 Phase 3 pivotal studies across multiple tumor types and disease settings such as NSCLC, Small Cell Lung Cancer, Gastric Cancer, ESCC, Hepatocellular Cancer, and Nasopharyngeal Cancer. More information on the clinical trial program for tislelizumab can be found at: https://www.beigene.com/en-us/science-and-product-portfolio/pipeline.

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 BeiGene's progress to expand the highest quality therapies to more people around the world; the future development, regulatory filing and approval 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 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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[i] Shen, L., Kato, K., Kim, S. B., Ajani, J. A., Zhao, K., He, Z., ... & Van Cutsem, E. (2022). Tislelizumab versus chemotherapy as second-line treatment for advanced or metastatic esophageal squamous cell carcinoma (RATIONALE-302): A randomized phase III study. Journal of Clinical Oncology, 40(26), 3065-3076. DOI: 10.1200/JCO.21.01926

[ii] Morgan, E., Soerjomataram, I., Rumgay, H., Coleman, H. G., Thrift, A. P., Vignat, J., ... & Arnold, M. (2022). The global landscape of esophageal squamous cell carcinoma and esophageal adenocarcinoma incidence and mortality in 2020 and projections to 2040: new estimates from GLOBOCAN 2020. Gastroenterology, 163(3), 649-658.