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): April 20, 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 April 20, 2023, BeiGene, Ltd. announced that the global RATIONALE 305 trial met its primary endpoint of overall survival, with tislelizumab in combination with chemotherapy demonstrating superior overall survival compared with chemotherapy in patients with advanced unresectable or metastatic gastric or gastroesophageal junction adenocarcinoma, regardless of PD-L1 status. 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 Phase 3 Tislelizumab Trial in Advanced Gastric or Gastroesophageal Junction Adenocarcinoma" issued by BeiGene, Ltd. on April 20, 2023
104	The cover page from this Current Report on Form 8-K, formatted in Inline XBRL

Exhibit Index

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99.1	Press release titled "BeiGene Announces Positive Phase 3 Tislelizumab Trial in Advanced Gastric or Gastroesophageal Junction Adenocarcinoma" issued by BeiGene, Ltd. on April 20, 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: April 20, 2023

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

Exhibit 99.1

BeiGene Announces Positive Phase 3 Tislelizumab Trial in Advanced Gastric or Gastroesophageal Junction Adenocarcinoma

Superior overall survival for tislelizumab plus chemotherapy versus chemotherapy in first-line treatment setting

BASEL, Switzerland, BEIJING, CAMBRIDGE, Mass. — April 20, 2023 — BeiGene (NASDAQ: BGNE; HKEX: 06160; SSE: 688235), a global biotechnology company, today announced the global RATIONALE 305 trial met its primary endpoint of overall survival, with tislelizumab in combination with chemotherapy demonstrating superior overall survival (OS) compared with chemotherapy in patients with advanced unresectable or metastatic gastric or gastroesophageal junction (G/GEJ) adenocarcinoma, regardless of PD-L1 status. No new safety signals were identified for tislelizumab.

BeiGene previously announced superior OS for the combination compared with chemotherapy in the PD-L1 high group at a planned interim analysis[1] and the trial continued according to pre- specified statistical hierarchy testing. At the final analysis, tislelizumab, in combination with chemotherapy, demonstrated superior OS compared with chemotherapy in the intent-to-treat (ITT) population. Results will be submitted for presentation at an upcoming medical conference.

"At the recent ASCO GI meeting, we presented results from an interim analysis demonstrating a statistically significant and clinically meaningful improvement in overall survival in the high PD-L1 expression group in RATIONALE 305 and we are pleased that the final analysis demonstrated a significant survival benefit and consistent safety profile in the entire study population," said Mark Lanasa, M.D., Ph.D., Chief Medical Officer, Solid Tumors at BeiGene. "Gastric cancer is the fifth most common cancer globally, and the prognosis for patients with advanced or metastatic conditions remains inadequate; these data support tislelizumab combined with chemotherapy as a potential first-line treatment option for patients with locally advanced, unresectable or metastatic gastric or gastroesophageal junction cancer."

Tislelizumab is currently under review by the U.S. Food and Drug Administration and the European Medicines Agency (EMA) for advanced or metastatic esophageal squamous cell carcinoma after prior chemotherapy. The EMA is also reviewing tislelizumab for advanced or metastatic non-small cell lung cancer (NSCLC) after prior chemotherapy, and in combination with chemotherapy for previously untreated advanced or metastatic NSCLC.

Tislelizumab is approved in 10 indications in China, including a recent approval for use in combination with fluoropyrimidine and platinum chemotherapy for the first-line treatment of patients with locally advanced unresectable or metastatic G/GEJ adenocarcinoma with high PD- L1 expression. The 2023 update to the National Reimbursement Drug List issued by China's National Healthcare Security Administration includes nine reimbursed indications for tislelizumab. Tislelizumab is not currently approved for use outside of China.

About RATIONALE 305 (NCT03777657)

RATIONALE 305 is a randomized, double-blind, placebo-controlled, global Phase 3 trial comparing the efficacy and safety of tislelizumab combined with platinum and fluoropyrimidine chemotherapy and placebo combined with platinum and fluoropyrimidine chemotherapy as a first- line treatment for patients with advanced unresectable or metastatic G/GEJ adenocarcinoma. A total of 997 patients from 13 countries and regions across the world were enrolled and randomized 1:1 to receive either tislelizumab or placebo in combination with chemotherapy.

The primary endpoint for the trial is OS, with prespecified hierarchy testing for the PD-L1 high population followed by the ITT population. High PD-L1 expression is defined as PD-L1 score ≥ 5% by VENTANA SP263 assay, assessed by blinded independent central laboratory. OS analysis in ITT population would be performed only after the OS analysis in the PD-L1 high population is statistically significant, favoring the tislelizumab and chemotherapy arm. Secondary endpoints include progression-free survival, overall response rate, duration of response, and safety.

Interim results were shared in an oral presentation at the 2023 ASCO Gastrointestinal Cancers Symposium. In patients with G/GEJ adenocarcinoma with high PD-L1 expression, tislelizumab plus chemotherapy demonstrated statistically significant and clinically meaningful improvement in OS versus placebo plus chemotherapy [median OS: 17.2 vs 12.6 months; HR 0.74 (95% CI 0.59, 0.94); P=0.0056] with a manageable safety profile, and no new safety signals were identified[1].

About Tislelizumab

Tislelizumab is a humanized IgG4 anti-PD-1 monoclonal antibody specifically designed to minimize binding to Fc-gamma (Fcγ) receptors on macrophages. 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.

An expansive global clinical trial program supports tislelizumab development, with 21 registration- enabling clinical trials and more than 11,800 subjects enrolled across the world. More information on the clinical trial program for tislelizumab can be found at:

https://www.beigene.com/our-science-and-medicines/our-clinical-trials/

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 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 plus chemotherapy to be a first-line treatment option for patients with locally advanced, unresectable or metastatic G/GEJ adenocarcinoma and the survival benefit and safety profile of such treatment for those patients; the future development and 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 annual report on Form 10-K, 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] Moehler, Markus H., et al. "Rationale 305: Phase 3 study of tislelizumab plus chemotherapy vs placebo plus chemotherapy as first-line treatment (1L) of advanced gastric or gastroesophageal junction adenocarcinoma (GC/GEJC)." Journal of Clinical Oncology 41, no. 4_suppl (February 01, 2023) 286-286 DOI: 10.1200/JCO.2023.41.4_suppl.286