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): January 27, 2021

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 registered or 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 January 27, 2021, BeiGene, Ltd. (“BeiGene”) announced that the global Phase 3 RATIONALE 302 trial of its anti-PD-1 antibody tislelizumab versus investigator’s choice chemotherapy in patients with advanced unresectable or metastatic esophageal squamous cell carcinoma (ESCC) who have received prior systemic treatment met its primary endpoint of overall survival (OS). In the trial results, tislelizumab demonstrated a statistically significant and clinically meaningful improvement in OS in the intention-to-treat (ITT) population, when compared to chemotherapy. The safety profile of tislelizumab was consistent with its known risks, with no new safety signals identified. 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 Topline Results for Global Phase 3 Trial of Tislelizumab in Esophageal Squamous Cell Carcinoma" issued on January 27, 2021.
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 Topline Results for Global Phase 3 Trial of Tislelizumab in Esophageal Squamous Cell Carcinoma" issued on January 27, 2021.
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 28, 2021

By: /s/ Scott A. Samuels
Name: Scott A. Samuels
Title: Senior Vice President, General Counsel

Exhibit 99.1

BeiGene Announces Positive Topline Results for Global Phase 3 Trial of Tislelizumab in Esophageal Squamous Cell Carcinoma

Tislelizumab prolonged the survival of patients with advanced unresectable or metastatic ESCC who received prior systemic treatment compared to chemotherapy

Safety findings of tislelizumab were consistent with known risks

CAMBRIDGE, Mass. and BEIJING, China – January 27, 2021 -- BeiGene, Ltd. (NASDAQ: BGNE; HKEX: 06160), a commercial-stage biotechnology company focused on developing and commercializing innovative medicines worldwide, today announced that the global Phase 3 RATIONALE 302 trial of its anti-PD-1 antibody tislelizumab versus investigator's choice chemotherapy in patients with advanced unresectable or metastatic esophageal squamous cell carcinoma (ESCC) who have received prior systemic treatment met its primary endpoint of overall survival (OS). In the trial results, tislelizumab demonstrated a statistically significant and clinically meaningful improvement in OS in the intention-to-treat (ITT) population, when compared to chemotherapy. The safety profile of tislelizumab was consistent with its known risks, with no new safety signals identified.

"We are excited to announce the improved overall survival observed in another Phase 3 trial for tislelizumab when compared to chemotherapy standard of care. This is our fourth positive Phase 3 readout for tislelizumab and the first from our large Phase 3 program in gastrointestinal cancers that also include liver, stomach cancers as well as esophageal cancer," commented Yong (Ben) Ben, M.D., Chief Medical Officer, Immuno-Oncology at BeiGene. "With our ongoing evaluation of tislelizumab across multiple tumor types, we are working to provide clinical evidence and bring this potentially differentiated anti-PD-1 antibody to far more patients around the world."

BeiGene plans to discuss the RATIONALE 302 data with health authorities globally and present data at an upcoming medical conference.

"Esophageal cancer represents a significant unmet medical need with rapid progression and high mortality. Recent years have seen a paradigm-shift in advanced ESCC treatment from chemotherapy and radiation to immunotherapy. The positive topline results from the RATIONALE 302 trial demonstrated that tislelizumab may offer a new treatment option for those living with this devastating disease and bring hope to patients and their families," said Lin Shen, M.D., Vice President of Clinical Oncology at Beijing Cancer Hospital and lead investigator for the trial.

RATIONALE 302 Trial of Tislelizumab Versus Chemotherapy in Advanced ESCC

RATIONALE 302 is a randomized, open-label, multicenter global Phase 3 trial (NCT03430843) designed to evaluate the efficacy and safety of tislelizumab when compared to investigator's choice chemotherapy in patients with advanced unresectable or metastatic ESCC who have received prior systemic treatment.

The primary endpoint of the trial is OS in the ITT population. A total of 512 patients enrolled in the trial in 11 countries across Asia, Europe, and North America, randomized 1:1 to either the tislelizumab arm or the chemotherapy arm (investigator's choice of paclitaxel, docetaxel, or irinotecan).

About Esophageal Squamous Cell Carcinoma (ESCC)

Esophageal squamous cell carcinoma (ESCC) is the most common subtype of esophageal cancer globally, the sixth leading cause of cancer-related death in the world.[i] In 2020, there were more than 600,000 new cases of esophageal cancer and approximately 550,000 deaths worldwide.[ii] Esophageal cancer is a rapidly fatal disease and more than two-thirds of the patients have advanced or metastatic disease at the time of diagnosis, with a median survival of eight to 10 months and an expected five-year survival rate of less than five percent.[iii]

About Tislelizumab

Tislelizumab (BGB-A317) is a humanized IgG4 anti-PD-1 monoclonal antibody specifically designed to minimize binding to FcγR on macrophages. In pre-clinical studies, binding to FcγR 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 China National Medical Products Administration (NMPA) has granted tislelizumab full approval for first-line treatment of patients with advanced squamous non-small cell lung cancer (NSCLC) in combination with chemotherapy. Tislelizumab has also received conditional approval from the NMPA for the treatment of patients with classical Hodgkin's lymphoma who received at least two prior therapies and for the treatment of patients with locally advanced or metastatic urothelial carcinoma with PD-L1 high expression whose disease progressed during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. Full approval for these indications is contingent upon results from ongoing randomized, controlled confirmatory clinical trials.

In addition, two supplemental new drug applications for tislelizumab have been accepted by the Center for Drug Evaluation (CDE) of the NMPA and are under review for first-line treatment of patients with advanced non-squamous NSCLC in combination with chemotherapy, and for previously treated unresectable hepatocellular carcinoma.

Currently, 15 potentially registration-enabling clinical trials are being conducted in China and globally, including 13 Phase 3 trials and two pivotal Phase 2 trials.

In January 2021, BeiGene and Novartis entered into a collaboration and license agreement to develop, manufacture, and commercialize tislelizumab in North America, Europe, and Japan, and the transaction is expected to close in the first quarter of 2021, subject to expiration or early termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act.

Tislelizumab is not approved for use outside of China.

About Tislelizumab Clinical Program

Clinical trials of tislelizumab include:

- Phase 3 trial comparing tislelizumab to salvage chemotherapy in patients with relapsed/refractory classical Hodgkin Lymphoma (NCT04486391);
- Phase 3 trial in patients with locally advanced or metastatic urothelial carcinoma (NCT03967977);
- Phase 3 trial comparing tislelizumab with docetaxel in the second- or third-line setting in patients with NSCLC (NCT03358875);
- Phase 3 trial of tislelizumab in combination with chemotherapy versus chemotherapy as first-line treatment for patients with advanced squamous NSCLC (NCT03594747);
- Phase 3 trial of tislelizumab in combination with chemotherapy versus chemotherapy as first-line treatment for patients with advanced non-squamous NSCLC (NCT03663205);
- Phase 3 trial of tislelizumab in combination with platinum-based doublet chemotherapy as neoadjuvant treatment for patients with NSCLC (NCT04379635);
- Phase 3 trial of tislelizumab combined with platinum and etoposide versus placebo combined with platinum and etoposide in patients with extensive-stage small cell lung cancer (NCT04005716);
- Phase 3 trial comparing tislelizumab with sorafenib as first-line treatment for patients with hepatocellular carcinoma (HCC; NCT03412773);
- Phase 2 trial in patients with previously treated unresectable HCC (NCT03419897);
- Phase 3 trial comparing tislelizumab with chemotherapy as second-line treatment for patients with advanced esophageal squamous cell carcinoma (ESCC; NCT03430843);

- Phase 3 trial of tislelizumab in combination with chemotherapy as first-line treatment for patients with ESCC (NCT03783442);
- Phase 3 trial of tislelizumab versus placebo in combination with chemoradiotherapy in patients with localized ESCC (NCT03957590);
- Phase 3 trial of tislelizumab combined with chemotherapy versus placebo combined with chemotherapy as first-line treatment for patients with gastric cancer (NCT03777657);
- Phase 2 trial in patients with MSI-H/dMMR solid tumors (NCT03736889); and
- Phase 3 trial of tislelizumab combined with chemotherapy versus placebo combined with chemotherapy as first-line treatment in patients with nasopharyngeal cancer (NCT03924986).

About BeiGene

BeiGene is a global, commercial-stage biotechnology company focused on discovering, developing, manufacturing, and commercializing innovative medicines to improve treatment outcomes and access for patients worldwide. Our 5,200+ employees in China, the United States, Australia, Europe, and elsewhere are committed to expediting the development of a diverse pipeline of novel therapeutics. We currently market two internally discovered oncology products: BTK inhibitor BRUKINSA® (zanubrutinib) in the United States and China, and anti-PD-1 antibody tislelizumab in China. We also market or plan to market in China additional oncology products licensed from Amgen Inc., Celgene Logistics Sàrl, a Bristol Myers Squibb (BMS) company, and EUSA Pharma. To learn more about BeiGene, please visit www.beigene.com and follow us on Twitter at @BeiGeneUSA.

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 data from the RATIONALE-302 global Phase 3 trial of tislelizumab versus chemotherapy in the second-line setting in patients with advanced unresectable or metastatic esophageal squamous cell carcinoma, the potential implications of clinical data for patients, BeiGene's plans to present the data at an upcoming medical conference, and BeiGene's advancement, anticipated clinical development, regulatory milestones and commercialization of tislelizumab, and the expected closing of the collaboration with Novartis. 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 products and drug candidates, if approved; BeiGene's ability to obtain and maintain protection of intellectual property for its technology and drugs; BeiGene's reliance on third parties to conduct drug development, manufacturing and other services; BeiGene's limited operating history and BeiGene's ability to obtain additional funding for operations and to complete the development and commercialization of its drug candidates; the impact of the COVID-19 pandemic on the Company's clinical development, commercial 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.

Investor Contact	**Media Contact**
Craig West	Liza Heapes or Vivian Ni
+1 857-302-5189	+1 857-302-5663 or + 1 857-302-7596
ir@beigene.com	media@beigene.com

[i] Abbas, G., & Krasna, M. (2017). Overview of esophageal cancer. Annals of cardiothoracic surgery, 6(2), 131–136. https://doi.org/10.21037/acs.2017.03.03

[ii] Globocan 2020. Available at "https://gco.iarc.fr/today/data/factsheets/cancers/6-Oesophagus-fact-sheet.pdf" Accessed in January 2021.

[iii] Parkin, 1999; Lin M, 2016; Drahos J, 2013