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): March 5, 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. o

Item 8.01. Other Events.

On March 5, 2021, BeiGene, Ltd. (the "Company") announced that a supplemental Biologics License Application (sBLA) for anti-PD1 antibody tislelizumab was accepted by the Center for Drug Evaluation (CDE) of the China National Medical Products Administration (NMPA) for treatment in the second- or third-line setting of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) who have progressed on 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 Acceptance of a Supplemental Biologics License Application in China for Tislelizumab in Second- or Third-line Non-Small Cell Lung Cancer" issued on March 5, 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 Acceptance of a Supplemental Biologics License Application in China for Tislelizumab in Second- or Third-line Non-Small Cell Lung Cancer" issued on March 5, 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: March 5, 2021

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

Exhibit 99.1

BeiGene Announces Acceptance of a Supplemental Biologics License Application in China for Tislelizumab in Second- or Third-line Non-Small Cell Lung Cancer

BEIJING, China and CAMBRIDGE, Mass. – March 5, 2021 -- BeiGene, Ltd. (NASDAQ: BGNE; HKEX: 06160), a commercial-stage biotechnology company focused on developing and commercializing innovative medicines worldwide, today announced that a supplemental Biologics License Application (sBLA) for anti-PD1 antibody tislelizumab was accepted by the Center for Drug Evaluation (CDE) of the China National Medical Products Administration (NMPA) for treatment in the second- or third-line setting of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) who have progressed on prior platinum-based chemotherapy.

“We are excited to submit the third marketing application for tislelizumab from its broad program in lung cancer which consists of five completed or ongoing Phase 3 trials. Results from our Phase 3 RATIONALE 303 trial demonstrated improved overall survival over chemotherapy in advanced NSCLC patients who have progressed after treatment with chemotherapy at its interim analysis, which we have been able to file quickly with the CDE for its review,” commented Yong (Ben) Ben, M.D., Chief Medical Officer, Immuno-Oncology at BeiGene. “With three approvals for tislelizumab in China, as well as three sBLAs under review, we are excited to continue to build upon our broad development program for tislelizumab, a potentially differentiated checkpoint inhibitor and explore additional opportunities with our new partner Novartis.”

RATIONALE 303 Trial of Tislelizumab Compared to Docetaxel in Patients with Locally Advanced or Metastatic NSCLC Who Progressed on Prior Platinum-Based Chemotherapy

The sBLA is supported by clinical results from the Phase 3 RATIONALE 303 trial, a randomized, open-label, multicenter global Phase 3 clinical trial (NCT03358875) designed to evaluate the efficacy and safety of tislelizumab compared to docetaxel in the second- or third-line setting in patients with locally advanced or metastatic NSCLC who have progressed on a prior platinum-based chemotherapy. The primary endpoint of the trial is OS in all patients (the ITT population) and in patients with high PD-L1 expression; key secondary endpoints include objective response rate (ORR), duration of response (DoR), progression-free survival (PFS), and safety. A total of 805 patients in 10 countries across Asia, Europe, the Americas, and Oceania were randomized 2:1 to either the tislelizumab arm or the docetaxel arm.

As announced in November 2020, RATIONALE 303 met the primary endpoint of OS at the planned interim analysis, as recommended by the independent Data Monitoring Committee (DMC). The safety profile of tislelizumab was consistent with the known risks with no new safety signals identified. BeiGene expects to present results from the RATIONALE 303 trial at an upcoming medical conference in the first half of 2021.

About Non-Small Cell Lung Cancer

In China, the lung cancer incidence rate is increasing.[i] There were approximately 815,563 new cases of lung cancer in China in 2020, and it is the leading cause of cancer-related death in both men and women, with approximately 714,699 deaths in China in 2020.[ii] Non-small cell lung cancer (NSCLC) is the most common form of lung cancer, accounting for approximately 80 to 85 percent of all cases.[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 (cHL) who received at least two prior therapies, and for the treatment of patients with locally advanced or metastatic urothelial carcinoma (UC) 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, three supplemental Biologics License 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, for the second- or third-line treatment of patients with locally advanced or metastatic NSCLC who progressed on prior platinum-based chemotherapy, and for previously treated unresectable hepatocellular carcinoma.

Currently, 15 potentially registration-enabling clinical trials are being conducted in China and globally, including 12 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.

Tislelizumab is not approved for use outside of China.

About the Tislelizumab Clinical Program

Clinical trials of tislelizumab include:

- Phase 3 trial comparing tislelizumab with docetaxel in the second- or third-line setting in patients with NSCLC (NCT03358875);
- 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 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 5,400+ employees around the world are committed to expediting the development of a diverse pipeline of novel therapeutics. We currently market two internally discovered oncology medicines: 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 additional oncology products in China licensed from Amgen Inc.; Celgene Logistics Sàrl, a Bristol Myers Squibb (BMS) company; and EUSA Pharma; and have entered a collaboration with Novartis Pharma AG for Novartis to develop and commercialize tislelizumab in North America, Europe and Japan. 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-303 global Phase 3 trial of tislelizumab compared to docetaxel in the second- or third-line setting in patients with locally advanced or metastatic non-small cell lung cancer who have progressed on prior platinum-based chemotherapy, the filing and potential approval of a sBLA in China based on this data, 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. 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 medicines and technology; 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, regulatory, 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.

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] She J, Yang P, Hong Q, et al. Lung cancer in China: challenges and interventions. Chest 2013;143:1117-26

[ii] The Global Cancer Observatory. Available at https://gco.iarc.fr/today/data/factsheets/populations/160-china-fact-sheets.pdf. Accessed March 2021

[iii] American Cancer Society. Available at https://www.cancer.org/cancer/lung-cancer/about/what-is.html#:~:text=About%2080%25%20to%2085%25%20of,(outlook)%20are%20often%20similar. Accessed December 2020