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 13, 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 13, 2021, BeiGene, Ltd. (“BeiGene”) announced that its anti-PD-1 antibody tislelizumab has received approval from the China National Medical Products Administration (NMPA) for use in combination with two chemotherapy regimens as a first-line treatment for patients with advanced squamous non-small cell lung cancer (NSCLC). This is the third approval in China for tislelizumab, and its first in a lung cancer indication. 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 "China National Medical Products Administration Approves Tislelizumab in Combination with Chemotherapy in First-Line Advanced Squamous Non-Small Cell Lung Cancer" issued on January 13, 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 "China National Medical Products Administration Approves Tislelizumab in Combination with Chemotherapy in First-Line Advanced Squamous Non-Small Cell Lung Cancer" issued on January 13, 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 14, 2021

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

Exhibit 99.1

China National Medical Products Administration Approves Tislelizumab in Combination with Chemotherapy in First-Line Advanced Squamous Non-Small Cell Lung Cancer

BEIJING, China and CAMBRIDGE, Mass., January 13, 2021 -- BeiGene, Ltd. (NASDAQ: BGNE; HKEX: 06160), a commercial-stage biotechnology company focused on developing and commercializing innovative medicines worldwide, today announced that its anti-PD-1 antibody tislelizumab has received approval from the China National Medical Products Administration (NMPA) for use in combination with two chemotherapy regimens as a first-line treatment for patients with advanced squamous non-small cell lung cancer (NSCLC). This is the third approval in China for tislelizumab, and its first in a lung cancer indication.

"This approval for tislelizumab is an important milestone for BeiGene, for tislelizumab, and for the patients and healthcare practitioners in China fighting advanced squamous NSCLC," commented Xiaobin Wu, Ph.D., General Manager of China and President of BeiGene. "This is our sixth global approval for an internally-developed product, and our first approval for tislelizumab in a lung cancer indication, an area where we believe tislelizumab can have a large impact for patients."

"With the recent announcement that the RATIONALE 303 trial met its primary endpoint of overall survival at its interim analysis, three Phase 3 trials of tislelizumab in NSCLC have achieved a positive outcome at interim analysis," commented Yong (Ben) Ben, M.D., Chief Medical Officer, Immuno-Oncology at BeiGene. "Tislelizumab is being investigated in a broad clinical program, including five Phase 3 trials in lung cancer indications. We believe that it is an important immunotherapy and demonstrates our work at BeiGene to bring innovative, impactful, and quality treatments to patients in need."

"Lung cancer is the leading cause of cancer-related death in China, and with NSCLC comprising the most common form of the disease, there is significant patient need. We are grateful to have a new treatment available in the front-line setting for patients with advanced squamous non-small cell lung cancer," said Jie Wang, M.D., Ph.D., National Cancer Center/Cancer Hospital, Chinese Academy of Medical Sciences & Peking Union Medical College. "In its Phase 3 trial in this indication, tislelizumab, combined with standard chemotherapy demonstrated a clinically meaningful benefit as assessed by progression-free survival and response rates."

"The approval of tislelizumab for patients with advanced squamous NSCLC was made possible by the courageous patients who participated in the trial, the dedicated clinicians who helped conduct the trial, and our hard-working team at BeiGene. We are humbled by the expeditious review of our supplemental new drug application and hope our broad development program for tislelizumab will continue its momentum and benefit additional patients," said Wendy Yan, Senior Vice President and Global Head of Regulatory Affairs at BeiGene.

The approval of tislelizumab for the treatment of patients with advanced squamous NSCLC was supported by clinical results from a Phase 3 trial of tislelizumab combined with either paclitaxel and carboplatin or nab-paclitaxel (ABRAXANE®) and carboplatin compared to paclitaxel and carboplatin alone in patients with untreated stage IIIB or IV squamous NSCLC from mainland China (NCT03594747). A total of 360 patients were randomized 1:1:1 to receive tislelizumab in combination with either chemotherapy regimen or chemotherapy alone. As announced in January 2020, the trial met the primary endpoint of statistically significant improvement in progression-free survival (PFS), as assessed by independent review committee (IRC), in the pre-planned interim analysis. The safety profile of tislelizumab in both combinations was consistent with the known risks of each study treatment, and no new safety signals were identified. The results of the interim analysis of the trial were presented at the 2020 American Society of Clinical Oncology (ASCO) Virtual Scientific Program.

About Non-Small Cell Lung Cancer

In contrast to most Western countries, where lung cancer death rates are decreasing, the lung cancer incidence rate is still increasing in China.[i,ii] 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.[iii] Non-small cell lung cancer (NSCLC) is the most common form of lung cancer, accounting for approximately 80 to 85 percent of all case.[iv]

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.[v] 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. Complete 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.

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 5,000+ 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 BeiGene’s further advancement of, and 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 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; and 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
Craig West
+1 857-302-5189
ir@beigene.com

Media Contact
Liza Heapes or Vivian Ni
+1 857-302-5663 or + 1 857-302-7596
media@beigene.com

ABRAXANE® is a registered trademark of Abraxis Bioscience LLC, a Bristol-Myers Squibb company.

[i] Jemal A, Bray F, Center MM, et al. Global cancer statistics. CA Cancer J Clin 2011;61:69-90.

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

[iii] The Global Cancer Observatory. Available at "https://gco.iarc.fr/today/data/factsheets/populations/160-china-fact-sheets.pdf" https://gco.iarc.fr/today/data/factsheets/populations/160-china-fact-sheets.pdf. Accessed December 2020.

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

[v] Zhang, T., Song, X., Xu, L., Ma, J., Zhang, Y., Gong, W., Zhang, Y., Zhou, X., Wang, Z., Wang, Y., Shi, Y., Bai, H., Liu, N., Yang, X., Cui, X., Cao, Y., Liu, Q., Song, J., Li, Y., Tang, Z., … Li, K. (2018). The binding of an anti-PD-1 antibody to FcγRI has a profound impact on its biological functions. Cancer immunology, immunotherapy : CII, 67(7), 1079–1090. "https://doi.org/10.1007/s00262-018-2160-x" https://doi.org/10.1007/s00262-018-2160-x.