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): June 23, 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 June 23, 2021, BeiGene, Ltd. announced that the China National Medical Products Administration (NMPA) has granted its anti-PD-1 antibody tislelizumab approval for the first-line treatment of patients with advanced non-squamous non-small cell lung cancer and conditional approval for the treatment of patients with hepatocellular carcinoma who have been previously treated with at least one systemic therapy. 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 NMPA Approves Tislelizumab in Non-Small Cell Lung Cancer and Hepatocellular Carcinoma", issued by BeiGene, Ltd. on June 23, 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 NMPA Approves Tislelizumab in Non-Small Cell Lung Cancer and Hepatocellular Carcinoma", issued by BeiGene, Ltd. on June 23, 2021.
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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: June 24, 2021

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

Exhibit 99.1

China NMPA Approves Tislelizumab in Non-Small Cell Lung Cancer and Hepatocellular Carcinoma

Tislelizumab is approved for the first-line treatment of advanced non-squamous non-small cell lung cancer following the previously approved squamous histology

Tislelizumab receives its first approval in liver cancer in previously treated hepatocellular carcinoma

CAMBRIDGE, Mass. and BEIJING, China, June 23, 2021 -- BeiGene, Ltd. (NASDAQ: BGNE; HKEX: 06160), a global biotechnology company focused on developing and commercializing innovative medicines worldwide, today announced that the China National Medical Products Administration (NMPA) has granted its anti-PD-1 antibody tislelizumab approval for the first-line treatment of patients with advanced non-squamous non-small cell lung cancer (NSCLC) and conditional approval for the treatment of patients with hepatocellular carcinoma (HCC) who have been previously treated with at least one systemic therapy.

"With today's approvals, tislelizumab is now available in China in five indications covering lung, liver, bladder, and lymphoma, and is becoming an important immunotherapy in the world's most populous country," commented Xiaobin Wu, Ph.D., President, Chief Operating Officer, and General Manager of China at BeiGene. "This remarkable achievement, which began approximately 18 months ago with tislelizumab's initial approval, was made possible through BeiGene's integrated global clinical development approach. We hope to make tislelizumab available broadly in China through our science-based commercial team and globally through our collaboration with Novartis, in furtherance of our goal of expanding access to innovative, quality cancer treatments for more people worldwide."

"We are pleased about the concurrent approvals for tislelizumab in China – in first-line non-squamous NSCLC following the previous approval for NSCLC patients with squamous histology earlier this year, and in second- or third-line HCC, which was based on the results from the largest global single-arm pivotal trial of any anti-PD-1 antibody in this indication," said Yong (Ben) Ben, M.D., Chief Medical Officer, Immuno-Oncology at BeiGene. "The pivotal clinical program of tislelizumab has seen tremendous progress lately, including two positive Phase 3 trials, one in esophageal cancer and the other in nasopharyngeal cancer. We credit our accomplishment to the dedication of our BeiGene team, and most importantly, the trust from participating patients and their loved ones, as well as investigators leading these clinical trials."

NMPA Approval in First-Line Advanced Non-Squamous NSCLC

"NSCLC comprises the most common form of lung cancer, although diagnoses are usually delayed with most patients diagnosed at advanced stage. In the Phase 3 RATIONALE 304 trial, tislelizumab in combination with pemetrexed and platinum chemotherapy demonstrated a clinically significant improvement in progression-free survival along with a high response rate, and was generally well-tolerated for treatment-naïve patients with advanced non-squamous NSCLC," commented Shun Lu, M.D., Ph.D., Professor of Shanghai Chest Hospital at Jiao Tong University and lead investigator for the trial. "I believe that this approval could help meet the significant demand in the front-line care of NSCLC, and I also look forward to the overall survival data readout."

The approval of tislelizumab for the first-line treatment of patients with advanced non-squamous NSCLC was supported by clinical results from a Phase 3 trial (NCT03663205) of tislelizumab in combination with pemetrexed and platinum chemotherapy (either carboplatin or cisplatin) in patients with stage IIIB or stage IV non-squamous NSCLC, compared to pemetrexed and platinum alone. A total of 334 patients in China were enrolled in the trial, randomized 2:1 to either the tislelizumab and chemotherapy arm or the chemotherapy arm. As announced in April 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 combination with chemotherapy 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 European Society for Medical Oncology (ESMO) Virtual Congress 2020 in September 2020.

NMPA Approval in Second- or Third-Line HCC

The NMPA conditional approval of tislelizumab in patients with HCC who have received at least one systemic therapy is based on clinical results from a single-arm, open-label, multicenter, global pivotal Phase 2 trial (NCT03419897) conducted in 249 patients from eight countries and regions in Asia and Europe, including 138 patients (55.4%) who received one line of prior systemic therapy and 111 patients (44.6%) who received at least two lines of prior therapies. Of all the patients enrolled in the trial, the median age was 62 years and 63.9% of patients had history of viral hepatitis, with hepatitis B accounting for the majority (51.4%) followed by hepatitis C (14.5%).

“Hepatocellular carcinoma is a difficult-to-treat primary liver cancer, most commonly found in those living with chronic liver diseases, such as hepatitis B and C. Based on the encouraging efficacy and safety results in patients with advanced liver cancer from this trial, tislelizumab has the potential to bring long-term survival benefits to patients with second- or third-line HCC in China,” commented Zhenggang Ren, M.D., Ph.D., Professor at Zhongshan Hospital, Fudan University, and the trial’s leading investigator in China.

With a median follow-up time of 12.4 months, objective response rate (ORR) as assessed by IRC per RECIST v1.1 was 13.3% (95% CI: 9.3, 18.1), including three complete responses (CRs); disease control rate (DCR) was 53.0% (95% CI: 46.6, 59.3); among patients who achieved a CR or partial response (PR), 90.4% (95% CI: 73.1, 96.8) and 79.2% (95% CI: 59.3, 90.2) of them sustained response at six months and 12 months, respectively. Median overall survival (OS) was 13.2 months (95% CI: 10.8, 15.0) and PFS was 2.7 months (95% CI: 1.4, 2.8).

The safety profile of tislelizumab as a monotherapy in the label in China was based on 1,183 patients who received tislelizumab as a monotherapy in five clinical trials, including the pivotal Phase 2 trial in HCC. The most common adverse reactions (≥10%) were aspartate aminotransferase (AST) increased, alanine aminotransferase (ALT) increased, rash, and fatigue. Grade ≥3 adverse reactions occurred in 17.3% of patients, with the most common (≥1%) being AST increased, ALT increased, gamma-glutamyltransferase increased, anemia, pneumonitis, and lung infection. For tislelizumab as a monotherapy, the most common immune-mediated adverse reactions were immune-mediated pneumonitis, diarrhea and colitis, hepatitis, nephritis, endocrinopathies (hypothyroidism, hyperthyroidism, thyroiditis, adrenocortical insufficiency, and hyperglycemia and Type 1 diabetes mellitus), skin adverse reactions, pancreatitis, myocarditis, and myositis.

About Non-Small Cell Lung Cancer

Lung cancer is the second most common type of cancer and the leading cause of cancer-related death worldwide.[i] NSCLC accounts for approximately 85% of all lung cancer cases and is usually diagnosed at an advanced stage.[ii] For patients with advanced NSCLC that has metastasized to distant regions or organs in the body, the relative five-year survival rate is approximately 6%.[iii] In 2020, there were an estimate of 815,563 new cases of lung cancer in China, accounting for 37% of all incidences worldwide.[iv]

About Hepatocellular Carcinoma

HCC is a major global health problem, accounting for 85-90 percent of all reported cases of liver cancer.[v] Liver cancer is the sixth most common type of cancer, with an estimated 905,677 new cases in 2020 worldwide; it was also the third most common cause of cancer-related mortality, responsible for an estimated 830,180 deaths in 2020.[i] China accounts for approximately 50 percent of both new HCC cases and HCC-related deaths worldwide in 2020.[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. 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 in five indications, including full approval for first-line treatment of patients with advanced squamous non-small cell lung cancer (NSCLC) in combination with chemotherapy and for first-line treatment of patients with advanced non-squamous NSCLC in combination with chemotherapy; and conditional approval for the treatment of patients with classical Hodgkin's lymphoma (cHL) who received at least two prior therapies, 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, and for the treatment of patients with hepatocellular carcinoma (HCC) who have received at least one systemic therapy. Full approval for these indications is contingent upon results from ongoing randomized, controlled confirmatory clinical trials.

In addition, two supplemental Biologics License Applications for tislelizumab have been accepted by the Center for Drug Evaluation (CDE) of the NMPA and are under review for second- or third-line treatment of patients with locally advanced or metastatic NSCLC who progressed on prior platinum-based chemotherapy and for patients with previously treated, locally advanced unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair-deficient (dMMR) solid tumors.

BeiGene has initiated or completed 17 potentially registration-enabling clinical trials in China and globally, including 13 Phase 3 trials and four pivotal Phase 2 trials.

In January 2021, BeiGene and Novartis entered into a collaboration and license agreement granting Novartis rights 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 or refractory classical Hodgkin Lymphoma (cHL; 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 2 trial in patients with locally advanced or metastatic urothelial bladder cancer (NCT04004221);
- 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 of tislelizumab in patients with relapsed or refractory cHL (NCT03209973);
- 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).

BeiGene Oncology

BeiGene is committed to advancing best and first-in-class clinical candidates internally or with like-minded partners to develop impactful and affordable medicines to patients across the globe. We have a growing R&D team of approximately 2,300 colleagues dedicated to advancing more than 90 clinical trials involving more than 13,000 patients and healthy volunteers. Our expansive portfolio is directed by a predominantly internalized clinical development team supporting trials in more than 40 countries. Hematology-oncology and solid tumor targeted therapies and immuno-oncology are key focus areas for the Company, with both mono- and combination therapies prioritized in our research and development. The Company currently markets three medicines discovered and developed in our labs: BTK inhibitor BRUKINSA in the United States, China, Canada, and additional international markets; and non-FC-gamma receptor binding anti-PD-1 antibody tislelizumab and PARP inhibitor pamiparib in China.

BeiGene also partners with innovative companies who share our goal of developing therapies to address global health needs. We commercialize a range of oncology medicines in China licensed from Amgen and Bristol Myers Squibb. We also plan to address greater areas of unmet need globally through our collaborations including with Amgen, Bio-Thera, EUSA Pharma, Mirati Therapeutics, Seagen, and Zymeworks. BeiGene has also entered into a collaboration with Novartis granting Novartis rights to develop, manufacture, and commercialize tislelizumab in North America, Europe, and Japan.

About BeiGene

BeiGene is a global, science-driven biotechnology company focused on developing innovative and affordable medicines to improve treatment outcomes and access for patients worldwide. With a broad portfolio of more than 40 clinical candidates, we are committed to expediting the development of our diverse pipeline of novel therapeutics through collaborations or our own internal capabilities, with the aspirational goal of radically improving access to medicines for two billion more people by 2030. BeiGene is a headquarter-less company by design, with a growing global team of approximately 6,000 colleagues across five continents. 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 deep commitment to cancer patients, BeiGene's plans to collaborate with Novartis, to make tislelizumab available to more patients worldwide, and to continue the evaluation of tislelizumab both as a monotherapy and in combination with other therapeutics, the potential for tislelizumab to bring long-term survival benefits to patients with second- or third-line HCC and first-line non-squamous NSCLC in China, BeiGene's advancement, anticipated clinical development, regulatory milestones and commercialization of tislelizumab, and BeiGene's plans, commitments, aspirations and goals under the headings "BeiGene Oncology" and "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; the impact of the COVID-19 pandemic on the BeiGene's clinical development, regulatory, 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.

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[i] Globocan 2020. Available at https://gco.iarc.fr/today/data/factsheets/populations/900-world-fact-sheets.pdf; accessed March 2021.

[ii] American Cancer Society. https://www.cancer.org/cancer/lung-cancer/about/what-is.html.

[iii] U.S National Institute of Health (NIH) National Cancer Institute Surveillance, Epidemiology, and End Results Program (SEER) Cancer Stat Facts. Available at https://seer.cancer.gov/statfacts/html/lungb.html; accessed May 2021.

[iv] Globocan 2020. Available at https://gco.iarc.fr/today/data/factsheets/populations/160-china-fact-sheets.pdf. Accessed March 2021.

[v] Nordenstedt H, White DL, El-Serag HB. The changing pattern of epidemiology in hepatocellular carcinoma. Digestive and Liver Disease. 2010;42(Suppl 3):S206-S214. doi:10.1016/S1590-8658(10)60507-5.