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 6, 2022

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 (NASDAQ)**
Ordinary Shares, par value $0.0001 per share*	**06160**	**The Stock Exchange of Hong Kong Limited (HKEx)**
RMB Shares, par value $0.0001 per share**	**688235**	**The Science and Technology Innovation Board of the Shanghai Stock Exchange (STAR)**

*Included in connection with the registration of the American Depositary Shares ("ADSs") 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 HKEx.

**The RMB shares are ordinary shares of the company issued to permitted investors in the People's Republic of China and listed and traded on the STAR in Renminbi. The RMB shares are not listed for trading in the United States or on the HKEx and are not fungible with the ordinary shares listed on the HKEx or the ADSs representing the ordinary shares listed on NASDAQ, and in no event will any RMB shares be able to be converted into the ordinary shares listed on the HKEx or the ADSs listed on NASDAQ, or vice versa.

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 7.01. Regulation FD Disclosure.

As previously announced, the following medicines and/or new indications of BeiGene, Ltd. (the "Company") have been included in the updated National Reimbursement Drug List ("NRDL") in China at the NRDL payment standard set forth below, effective January 1, 2022. For innovative medicines, such as our medicines, the NRDL payment standard is determined through negotiation between the marketing authorization holder ("MAH") and the National Healthcare Security Administration (NHSA), and applied nationwide for the reimbursement of such medicines through China's public medical insurance system.

- Tislelizumab is included in the NRDL in all five of its approved indications – three new indications included since January 2022 and two indications included since March 2021 (NRDL payment standard: RMB 1,450 per 100mg vial):
    - For use in combination with pemetrexed and platinum chemotherapy as a first-line treatment in patients with unresectable, locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC), with EGFR genomic tumor aberrations negative and ALK genomic tumor negative (approved in June 2021 and included in the NRDL since January 2022);
    - For the treatment of patients with hepatocellular carcinoma (HCC) who have been previously treated with at least one systemic therapy (conditionally approved in June 2021 and included in the NRDL since January 2022);
    - For use in combination with paclitaxel and carboplatin as a first-line treatment in patients with unresectable, locally advanced or metastatic squamous NSCLC (approved in January 2021 and included in the NRDL since January 2022);
    - 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 (conditionally approved in April 2020 and included in the NRDL since March 2021); and
    - For the treatment of patients with classical Hodgkin's lymphoma (cHL) who have received at least two prior therapies (conditionally approved in December 2019 and included in the NRDL since March 2021).
- BRUKINSA® is included in the NRDL in all three of its approved indications – one new indication since January 2022 and two indications since March 2021 (NRDL payment standard: RMB 85 per 80mg capsule (64 capsules per bottle)):
    - For the treatment of adult patients with Waldenström's macroglobulinemia (WM) who have received at least one prior therapy (conditionally approved in June 2021 and included in the NRDL since January 2022);
    - For the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy (conditionally approved in June 2020 and included in the NRDL since January 2022); and
    - For the treatment of adult patients with chronic lymphocytic leukemia (CLL) /small lymphocytic lymphoma (SLL) who have received at least one prior therapy (conditionally approved in June 2020 and included in the NRDL since March 2021).
- Pamiparib is included in the NRDL since January 2022 in its approved indication (NRDL payment standard: RMB 53.60 per 20mg capsule (60 capsules per bottle)):
    - For the treatment of patients with germline BRCA (gBRCA) mutation-associated recurrent advanced ovarian, fallopian tube, or primary peritoneal cancer who have been treated with two or more lines of chemotherapy (conditionally approved in May 2021 and included in the NRDL since January 2022).

Item 8.01. Other Events.

On January 6, 2022, the Company issued a press release announcing that the China National Medical Products Administration (NMPA) has approved BeiGene's anti-PD-1 antibody tislelizumab as a second- or third-line treatment for patients with locally advanced or metastatic non-small cell lung cancer. A copy of this press release is attached hereto as Exhibit 99.1, 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 as Second- or Third-Line Treatment for Patients with Locally Advanced or Metastatic Non-Small Cell Lung Cancer", issued by BeiGene, Ltd. on January 6, 2022.
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 as Second- or Third-Line Treatment for Patients with Locally Advanced or Metastatic Non-Small Cell Lung Cancer", issued by BeiGene, Ltd. on January 6, 2022.
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 10, 2022

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

Exhibit 99.1

China NMPA Approves Tislelizumab as Second- or Third-Line Treatment for Patients with Locally Advanced or Metastatic Non-Small Cell Lung Cancer

Tislelizumab is now approved in six indications in China

This marks tislelizumab's third approved lung cancer indication in China and first in a previously treated patient population

The approval was supported by results from the global Phase 3 trial RATIONALE 303, in which tislelizumab significantly prolonged overall survival in these patients compared to docetaxel and was generally well-tolerated, consistent with known risks

CAMBRIDGE, Mass. & BEIJING-- BeiGene (NASDAQ: BGNE; HKEX: 06160; SSE: 688235), a global, science-driven biotechnology company focused on developing innovative and affordable medicines to improve treatment outcomes and access for patients worldwide, today announced that the China National Medical Products Administration (NMPA) has approved BeiGene's anti-PD-1 antibody tislelizumab as a second- or third-line treatment for patients with locally advanced or metastatic non-small cell lung cancer (NSCLC). A supplemental biologics license application for tislelizumab in this indication was previously accepted for review by the China NMPA in March 2021.

"This latest approval for tislelizumab demonstrates BeiGene's commitment to bringing innovative, impactful treatments to patients in need. With six approved indications in China, tislelizumab has the potential to reach and help the country's large patient community, and our science-based commercial team of nearly 3,000 people in China is working to make it more broadly available to those who may benefit from this important immunotherapy," commented Xiaobin Wu, Ph.D., President, Chief Operating Officer, and General Manager of China at BeiGene. "As our strategic oncology collaboration with Novartis deepens, we look forward to continued opportunities to expand access to tislelizumab globally and further explore its therapeutic potential."

"As its third approved lung cancer indication in China, today's approval represents an important milestone, with tislelizumab now available in both front-line and second- or third-line care of NSCLC. We hope, as demonstrated in the promising results from the global RATIONALE 303 trial, that tislelizumab will become an important treatment option for these patients in China," commented Yong (Ben) Ben, M.D., Chief Medical Officer, Solid Tumors at BeiGene. "Tislelizumab's broad global development program of 13 Phase 3 trials and four pivotal Phase 2 trials is providing a growing body of clinical evidence on its efficacy and safety and establishing its therapeutic impact across multiple cancer types."

"In the global Phase 3 trial, tislelizumab demonstrated a significant improvement in overall survival and was well-tolerated in patients with previously treated NSCLC," said Caicun Zhou, M.D., Ph.D., Director of the Department of Oncology at Shanghai Pulmonary Hospital, Director of Cancer Institute of Tongji University, and the principal investigator of the trial. "The NMPA's approval of tislelizumab is welcoming news to the lung cancer community in China, and we hope this immunotherapy will help address the unmet needs in second- or third-line treatment of NSCLC."

The approval of tislelizumab was supported by clinical results from a randomized, open-label, global Phase 3 trial RATIONALE 303 (NCT03358875) comparing tislelizumab to docetaxel in the second- or third-line setting in patients with locally advanced or metastatic NSCLC who have progressed on prior platinum-based chemotherapy. A total of 805 patients in 10 countries across Asia, Europe, the Americas, and Oceania were enrolled in the trial, randomized 2:1 to either the tislelizumab arm or the docetaxel arm.

As announced in November 2020, the trial met the primary endpoint of overall survival (OS) at the planned interim analysis, as recommended by the independent Data Monitoring Committee (IDMC). Tislelizumab was generally well-tolerated, consistent with known safety risks from previously reported results across different tumor types, with no new safety signals identified. The results of the interim analysis of the trial were presented at the American Association for Cancer Research (AACR) Annual Meeting and announced by BeiGene in April 2021.

About Non-Small Cell Lung Cancer

Lung cancer remains the second most common type of cancer and the leading cause of cancer-related death worldwide.[1] NSCLC accounts for approximately 85% of all lung cancer cases and is usually diagnosed at an advanced stage.[2] The five-year survival rate with treatment for stage IIIB and stage IV NSCLC is 5% and 2%, respectively.[3] In China, the lung cancer incidence rate is increasing, with approximately 815,563 new cases in 2020.[4,5]

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 approved tislelizumab in six indications, including full approval for first-line treatment of patients with advanced squamous non-small cell lung cancer (NSCLC) in combination with chemotherapy, for first-line treatment of patients with advanced non-squamous NSCLC in combination with chemotherapy, and for second- or third-line treatment of patients with locally advanced or metastatic NSCLC who progressed on prior platinum-based chemotherapy. NMPA also granted 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, three supplemental Biologics License Applications for tislelizumab are under review by the Center for Drug Evaluation (CDE) of the NMPA, including for patients with previously treated, locally advanced unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair-deficient (dMMR) solid tumors, for the treatment of patients with locally advanced or metastatic esophageal squamous cell carcinoma (ESCC) who have disease progression following or are intolerant to first-line standard chemotherapy, and for first-line treatment of patients with recurrent or metastatic nasopharyngeal cancer (NPC).

In the U.S., a Biologics License Application for tislelizumab as a treatment for patients with unresectable recurrent locally advanced or metastatic ESCC after prior systemic therapy is currently under review by the U.S. Food and Drug Administration with a PDUFA target action date of July 12, 2022.

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 for patients across the globe. We have a growing R&D team of approximately 2,750 colleagues dedicated to advancing more than 90 ongoing or planned clinical trials (over 70 clinical trials are ongoing) involving more than 14,000 patients and healthy volunteers. Our expansive portfolio is directed predominantly by our internal colleagues supporting clinical trials in more than 45 countries and regions. 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. BeiGene currently has three approved medicines discovered and developed in our own labs: BTK inhibitor BRUKINSA in the United States, China, the EU, Great Britain, Canada, Australia, and additional international markets; and the non-FC-gamma receptor binding anti-PD-1 antibody tislelizumab as well as the 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, Bristol Myers Squibb, EUSA Pharma, and Bio-Thera. We also plan to address greater areas of unmet need globally through our collaborations including with Amgen, Mirati Therapeutics, Seagen, and Zymeworks.

In January 2021 BeiGene and Novartis announced a collaboration granting Novartis rights to develop, manufacture, and commercialize BeiGene's anti-PD1 antibody tislelizumab in North America, Europe, and Japan. Since closing the collaboration in February 2021, the companies have accomplished key objectives in their collaboration, including filing the first biologics license application (BLA) for tislelizumab outside of China. The U.S. Food and Drug Administration (FDA) accepted for review the BLA submission for patients with unresectable recurrent locally advanced or metastatic esophageal squamous cell carcinoma (ESCC) after prior systemic therapy. The Prescription Drug User Fee Act (PDUFA) target action date is July 12, 2022, and the companies are working closely together on launch preparation activities as well as other planned BLA submissions and combination strategies for tislelizumab within each company's product portfolio and pipeline. Building upon that progress and the shared commitment to expanding patient access to new treatments, the companies have entered into a new agreement to collaborate on the development, manufacturing and commercialization of BeiGene's investigational TIGIT inhibitor ociperlimab.

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 expediting development of our diverse pipeline of novel therapeutics through our own capabilities and collaborations. We are committed to radically improving access to medicines for two billion more people by 2030. BeiGene has a growing global team of approximately 8,000 colleagues across five continents. To learn more about BeiGene, please visit www.beigene.com.

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, the potential for tislelizumab to bring long-term survival benefits to patients as a second- or third-line treatment for patients with locally advanced or metastatic NSCLC in China, BeiGene's plans to collaborate with Novartis to make tislelizumab available to more patients worldwide, 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.

References

1. Globocan 2020. https://gco.iarc.fr/today/data/factsheets/populations/900-world-fact-sheets.pdf. Accessed March 2021.
2. American Cancer Society. https://www.cancer.org/cancer/lung-cancer/about/what-is.html
3. U.S. National Institute of Health, National Cancer Institute. SEER Cancer Statistics Review, 1975–2015.
4. She J, Yang P, Hong Q, et al. Lung cancer in China: challenges and interventions. Chest 2013;143:1117-26.
5. Globocan 2020. https://gco.iarc.fr/today/data/factsheets/populations/160-china-fact-sheets.pdf. Accessed March 2021.

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