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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

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**Form 8-K**

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**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 11, 2022

**BEIGENE, LTD.**

(Exact Name of Registrant as Specified in Charter)

<b>Cayman Islands</b> (State or Other Jurisdiction of Incorporation)	<b>001-37686</b> (Commission File Number)	<b>98-1209416</b> (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) <b>+1 (345) 949-4123</b> (Registrant's telephone number, including area code)		
<b>Not Applicable</b> (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 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.

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**Item 8.01. Other Events.**

On March 11, 2022, BeiGene, Ltd. (“BeiGene”) announced that the China National Medical Products Administration (NMPA) has granted conditional approval to BeiGene’s anti-PD-1 antibody, tislelizumab, for the treatment of adult patients with advanced unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumors. 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.

<b>Exhibit No.</b>	<b>Description</b>
99.1	Press Release titled “China NMPA Approves Tislelizumab for Patients with Microsatellite Instability-High or Mismatch Repair-Deficient Solid Tumors,” issued by BeiGene, Ltd. on March 11, 2022.
104	The cover page from this Current Report on Form 8-K, formatted in Inline XBRL

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## Exhibit Index

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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: March 17, 2022

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

## China NMPA Approves Tislelizumab for Patients with Microsatellite Instability-High or Mismatch Repair-Deficient Solid Tumors

*Tislelizumab is now approved in seven indications in China*

**CAMBRIDGE, Mass., BEIJING, and BASEL – March 11, 2022** -- BeiGene, Ltd. (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 granted conditional approval to BeiGene's anti-PD-1 antibody, tislelizumab, for the treatment of adult patients with advanced unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumors, including:

- Patients with advanced colorectal cancer (CRC) who had been treated with fluoropyrimidine, oxaliplatin and irinotecan; and
- Other advanced solid tumors who develop disease progression after prior treatment and have no satisfactory alternative treatment options.

“Results from the clinical trial of tislelizumab in patients with MSI-H and dMMR solid tumors demonstrated that tislelizumab’s treatment effect was consistent and durable across tumor types and endpoints. We are proud of this approval in China as it underscores our ongoing commitment to pursuing the full potential of tislelizumab and expanding its access where there is unmet medical need,” commented Mark Lanasa, M.D., Ph.D., Senior Vice President, Chief Medical Officer, Solid Tumors, at BeiGene.

“With seven approved indications in China, our 3,100+ science-based commercial team is working to make tislelizumab 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. “Today’s approval is a great step for patients in China with MSI-H and dMMR solid tumors.”

“In the pivotal Phase 2 trial, we observed consistent responses across tumor types with tislelizumab and it was generally well tolerated,” said Lin Shen, Ph.D., Vice President at the Beijing Cancer Hospital, and the principal investigator of the trial. “The NMPA’s approval of tislelizumab is welcoming news to patients with MSI-H and dMMR solid tumors, which are particularly prevalent among the many patients with cancers of the gastrointestinal tract. We are pleased to have a tissue-agnostic treatment approach with tislelizumab now available to those patients in need.”

This approval was supported by clinical results from a single-arm, multi-center, open-label, pivotal Phase 2 clinical trial (NCT03736889) to evaluate efficacy and safety of tislelizumab as monotherapy in patients with previously treated locally advanced unresectable or metastatic MSI-H or dMMR solid tumors, with an enrollment of 80 patients in China. Patients received tislelizumab 200 mg intravenously every three weeks until disease progression, unacceptable toxicity, or withdrawal. The primary endpoint of this trial is objective response rate (ORR) as assessed by independent review committee (IRC) per RECIST v1.1; secondary endpoints include time to response (TTR), duration of response (DoR), disease control rate (DCR), and progression-free survival (PFS) as assessed by investigator and IRC, overall survival (OS), and safety and tolerability. Results of this study were presented at the 2021 American Society of Clinical Oncology Annual Meeting.

### About Microsatellite Instability-High or Mismatch Repair Deficient Solid Tumors

Microsatellite instability-high (MSI-H) cancer cells have a greater than normal number of genetic markers called microsatellites, which are short, repeated sequences of DNA. Cancer cells that have large numbers of microsatellites may have defects in the ability to correct mistakes (also known as mismatch repair deficiency, or dMMR) that occur when DNA is copied in the cell. MSI-H and dMMR tumors are found most often in colorectal cancer, other types of gastrointestinal cancer and endometrial cancer, although they may also be found in cancers of the breast, prostate, bladder and thyroid.<sup>1</sup>

## 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 seven 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. The NMPA has 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, for the treatment of patients with hepatocellular carcinoma (HCC) who have received at least one systemic therapy, and for the treatment of patients with advanced unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumors. Full approval for these indications is contingent upon results from ongoing randomized, controlled confirmatory clinical trials or other confirmatory trials approved by the health authority.

In addition, two supplemental Biologics License Applications for tislelizumab are under review by the Center for Drug Evaluation (CDE) of the NMPA, including 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);
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- 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 and medical affairs team of approximately 2,900 colleagues dedicated to advancing more than 100 clinical trials that have involved more than 14,500 subjects. 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 and U.K., 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 other collaborations including with Mirati Therapeutics, Seagen, and Zymeworks.

In January 2021 BeiGene and Novartis announced a collaboration granting Novartis rights to co-develop, manufacture, and commercialize BeiGene's anti-PD1 antibody tislelizumab in North America, Europe, and Japan. Building upon this productive collaboration, including a biologics license application (BLA) under FDA review, BeiGene and Novartis announced an option, collaboration and license agreement in December 2021 for BeiGene's TIGIT inhibitor ociperlimab that is in Phase 3 development. Novartis and BeiGene also entered into a strategic commercial agreement through which BeiGene will promote five approved Novartis Oncology products across designated regions of China.

### **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 over 8,000 colleagues across five continents. To learn more about BeiGene, please visit [www.beigene.com](http://www.beigene.com) and follow us on Twitter at [@BeiGeneGlobal](https://twitter.com/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 results from the Phase 2 trial of tislelizumab in patients with previously treated locally advanced unresectable or metastatic MSI-H or dMMR solid tumors, BeiGene's plans to pursue the full potential of tislelizumab and expand access where there is unmet medical need, BeiGene's efforts to make tislelizumab more broadly available in China, the potential for tislelizumab to treat patients with MSI-H or dMMR solid tumors, 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 of its drug candidates and achieve and maintain profitability; the impact of the COVID-19 pandemic on BeiGene's clinical development, regulatory, commercial manufacturing, 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.

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<sup>1</sup> National Cancer Institute. Available at <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/mismatch-repair-deficiency>. Accessed June 2021.