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 20, 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**
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 8.01. Other Events.

On January 20, 2022, BeiGene, Ltd. ("the Company") issued a press release announcing that the Center for Drug Evaluation (CDE) of the China National Medical Products Administration (NMPA) has accepted a supplemental new drug application (sNDA) for BeiGene's BTK inhibitor BRUKINSA® (zanubrutinib) as a treatment for adult patients with Waldenström's macroglobulinemia (WM). A copy of this press release is attached hereto as Exhibit 99.1, and is incorporated herein by reference.

On January 24, 2022, the Company issued a press release announcing positive findings from the global Phase 3 RATIONALE 305 trial of tislelizumab versus placebo in combination with chemotherapy as a first-line treatment for patients with locally advanced, unresectable or metastatic gastric or gastroesophageal junction (G/GEJ) adenocarcinoma. At the interim analysis, tislelizumab in combination with chemotherapy met the primary endpoint of overall survival (OS) in patients with PD-L1 expression, with additional follow-up needed to confirm OS benefits in the intention-to-treat (ITT) population. The safety profile of tislelizumab was consistent with that observed in previous trials, with no new safety signals identified with the addition of chemotherapy. A copy of this press release is attached hereto as Exhibit 99.2, 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 New Drug Application in China for BRUKINSA (zanubrutinib) in Waldenström's Macroglobulinemia," issued by BeiGene, Ltd. on January 20, 2022.
99.2	Press Release titled "BeiGene Announces Positive Findings from Phase 3 Trial of Tislelizumab in Combination with Chemotherapy in First-Line Gastric or Gastroesophageal Junction Cancer," issued by BeiGene, Ltd. on January 24, 2022.
104	The cover page from this Current Report on Form 8-K, formatted in Inline XBRL

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: January 25, 2022

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

Exhibit 99.1

BeiGene Announces Acceptance of a Supplemental New Drug Application in China for BRUKINSA (zanubrutinib) in Waldenström's Macroglobulinemia

BRUKINSA received the China NMPA approval for the treatment of patients with relapsed or refractory Waldenström's macroglobulinemia (WM) in June 2021

The submission, supported by the ASPEN trial results, could potentially expand BRUKINSA to front-line care of WM

CAMBRIDGE, Mass., and BEIJING – January 20, 2022 -- 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 Center for Drug Evaluation (CDE) of the China National Medical Products Administration (NMPA) has accepted a supplemental new drug application (sNDA) for BeiGene's BTK inhibitor BRUKINSA® (zanubrutinib) as a treatment for adult patients with Waldenström's macroglobulinemia (WM).

"The sNDA acceptance is welcoming news, and following BRUKINSA's recent NMPA approval for patients with WM in the relapsed or refractory setting, this represents an opportunity to expand access to more WM patients in China, subject to NMPA approval. As demonstrated in the ASPEN trial, BRUKINSA can offer an efficacious treatment option with improved safety in regard to certain cardiovascular events, such as atrial fibrillation, for patients with WM" commented Jane Huang, M.D., Chief Medical Officer, Hematology, BeiGene. "The ASPEN trial has supported BRUKINSA's approval for patients with WM in the U.S., Canada, Australia, and the European Union. We look forward to continued discussions with the CDE and the opportunity to bring this potential best-in-class therapy to more people in the WM community in China."

The sNDA is supported by clinical results from the randomized, open-label, multicenter Phase 3 ASPEN trial (NCT03053400) comparing BRUKINSA to ibrutinib in patients with relapsed or refractory (R/R) or treatment-naïve (TN) WM.

As assessed by an independent review committee (IRC) based on the modified Sixth International Workshop on Waldenström's Macroglobulinemia (IWWM-6) response criteria (Treon 2015), the combined rate of complete response (CR) and very good partial response (VGPR) in the overall intention-to-treat (ITT) population was 28% with BRUKINSA (95% CI: 20, 38), compared to 19% with ibrutinib (95% CI: 12, 28). While this difference was not statistically significant (p=0.09), BRUKINSA did achieve numerically higher VGPR rates and trends towards increased response quality.[1]

In the ASPEN trial, BRUKINSA demonstrated a more favorable safety profile compared to ibrutinib with lower frequency of certain adverse events, including atrial fibrillation or flutter (2% vs. 15%) and major hemorrhage (6% vs. 9%). Of the 101 patients with WM treated with BRUKINSA, 4% of patients discontinued due to adverse events, and adverse events leading to dose reduction occurred in 14% of patients.[4]

About Waldenström's Macroglobulinemia

Waldenström's macroglobulinemia is a rare, slow-growing lymphoma, characterized by bone marrow infiltration with monoclonal immunoglobulin M (IgM) secreting lymphoplasmacytic cells, that occurs in less than two percent of patients with non-Hodgkin's lymphoma (NHL).[1] The disease usually affects older adults and is primarily found in the bone marrow, although it may also impact lymph nodes and the spleen.[2] In China, there are an estimated 88,200 patients diagnosed with lymphoma each year. Approximately 91% of these cases are classified as NHL, amounting to ~1,000 newly diagnosed WM patients per year in China.[3]

About BRUKINSA

BRUKINSA is a small molecule inhibitor of Bruton's tyrosine kinase (BTK) discovered by BeiGene scientists that is currently being evaluated globally in a broad clinical program as a monotherapy and in combination with other therapies to treat various B-cell malignancies. Because new BTK is continuously synthesized, BRUKINSA was specifically designed to deliver complete and sustained inhibition of the BTK protein by optimizing bioavailability, half-life, and selectivity. With differentiated pharmacokinetics compared to other approved BTK inhibitors, BRUKINSA has been demonstrated to inhibit the proliferation of malignant B cells within a number of disease relevant tissues.

BRUKINSA is approved in the following indications and regions:

- For the treatment of mantle cell lymphoma (MCL) in adult patients who have received at least one prior therapy (United States, November 2019)*;
- For the treatment of MCL in adult patients who have received at least one prior therapy (China, June 2020)**;
- For the treatment of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) in adult patients who have received at least one prior therapy (China, June 2020)**;
- For the treatment of MCL in patients who have received at least one prior therapy (Israel, January 2021);
- For the treatment of relapsed or refractory MCL (United Arab Emirates, February 2021);
- For the treatment of Waldenström's macroglobulinemia (WM) in adult patients (Canada, March 2021);
- For the treatment of adult patients with WM who have received at least one prior therapy (China, June 2021)**;
- For the treatment of MCL in adult patients who have received at least one prior therapy (Canada, July 2021);
- For the treatment of MCL in adult patients who have received at least one prior therapy (Chile, July 2021);
- For the treatment of adult patients with MCL who have received at least one previous therapy (Brazil, August 2021);
- For the treatment of adult patients with WM (United States, August 2021);
- For the treatment of adult patients with marginal zone lymphoma (MZL) who have received at least one anti-CD20-based regimen (United States, September 2021)*;
- For the treatment of adult patients with MCL who have received at least one previous therapy (Singapore, October 2021);
- For the treatment of adult patients with WM who have received at least one prior therapy, or in first line treatment for patients unsuitable for chemo-immunotherapy (Australia, October 2021);
- For the treatment of adult patients with MCL who have received at least one prior therapy (Australia, October 2021);
- For the treatment of adult patients with MCL who have received at least one previous therapy (Russia, October 2021);
- For the treatment of adult patients with MCL who have received at least one previous therapy (Saudi Arabia, November 2021);
- For the treatment of adult patients with WM who have received at least one prior therapy or first-line treatment of patients unsuitable for chemo-immunotherapy (European Union plus Iceland, Lichtenstein, and Norway, November 2021);
- For the treatment of eligible adult patients with Waldenström's macroglobulinemia (WM) who have received at least one prior therapy or for the first-line treatment of eligible patients unsuitable for chemo-immunotherapy (Great Britain, December 2021); and
- For the treatment of adult patients with MCL who have received at least one previous therapy (Ecuador, December 2021).

To date, more than 20 marketing authorization applications have been submitted for BRUKINSA for various indications.

* This indication was approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

** This indication was approved under conditional approval. Complete approval for this indication may be contingent upon results from ongoing randomized, controlled confirmatory clinical trials.

IMPORTANT U.S. SAFETY INFORMATION FOR BRUKINSA (ZANUBRUTINIB)

Warnings and Precautions

Hemorrhage

Fatal and serious hemorrhagic events have occurred in patients with hematological malignancies treated with BRUKINSA monotherapy. Grade 3 or higher hemorrhage including intracranial and gastrointestinal hemorrhage, hematuria and hemothorax have been reported in 3.4% of patients treated with BRUKINSA monotherapy. Hemorrhage events of any grade occurred in 35% of patients treated with BRUKINSA monotherapy.

Bleeding events have occurred in patients with and without concomitant antiplatelet or anticoagulation therapy. Co-administration of BRUKINSA with antiplatelet or anticoagulant medications may further increase the risk of hemorrhage.

Monitor for signs and symptoms of bleeding. Discontinue BRUKINSA if intracranial hemorrhage of any grade occurs. Consider the benefit-risk of withholding BRUKINSA for 3-7 days pre- and post-surgery depending upon the type of surgery and the risk of bleeding.

Infections

Fatal and serious infections (including bacterial, viral, or fungal) and opportunistic infections have occurred in patients with hematological malignancies treated with BRUKINSA monotherapy. Grade 3 or higher infections occurred in 27% of patients, most commonly pneumonia. Infections due to hepatitis B virus (HBV) reactivation have occurred.

Consider prophylaxis for herpes simplex virus, pneumocystis jiroveci pneumonia and other infections according to standard of care in patients who are at increased risk for infections. Monitor and evaluate patients for fever or other signs and symptoms of infection and treat appropriately.

Cytopenias

Grade 3 or 4 cytopenias, including neutropenia (26%), thrombocytopenia (11%) and anemia (8%) based on laboratory measurements, developed in patients treated with BRUKINSA monotherapy. Grade 4 neutropenia occurred in 13% of patients, and Grade 4 thrombocytopenia occurred in 3.6% of patients.

Monitor complete blood counts regularly during treatment and interrupt treatment, reduce the dose, or discontinue treatment as warranted. Treat using growth factor or transfusions, as needed.

Second Primary Malignancies

Second primary malignancies, including non-skin carcinoma, have occurred in 14% of patients treated with BRUKINSA monotherapy. The most frequent second primary malignancy was non-melanoma skin cancer, reported in 8% of patients. Other second primary malignancies included malignant solid tumors (4.0%), melanoma (1.7%) and hematologic malignancies (1.2%). Advise patients to use sun protection and monitor patients for the development of second primary malignancies.

Cardiac Arrhythmias

Atrial fibrillation and atrial flutter were reported in 3.2% of patients treated with BRUKINSA monotherapy. Patients with cardiac risk factors, hypertension, and acute infections may be at increased risk. Grade 3 or higher events were reported in 1.1% of patients treated with BRUKINSA monotherapy. Monitor signs and symptoms for atrial fibrillation and atrial flutter and manage as appropriate.

Embryo-Fetal Toxicity

Based on findings in animals, BRUKINSA can cause fetal harm when administered to a pregnant woman. Administration of zanubrutinib to pregnant rats during the period of organogenesis caused embryo-fetal toxicity including malformations at exposures that were 5 times higher than those reported in patients at the recommended dose of 160 mg twice daily. Advise women to avoid becoming pregnant while taking BRUKINSA and for 1 week after the last dose. Advise men to avoid fathering a child during treatment and for 1 week after the last dose.

If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus.

Adverse reactions

The most common adverse reactions, including laboratory abnormalities, in ≥ 30% of patients who received BRUKINSA (N = 847) included decreased neutrophil count (54%), upper respiratory tract infection (47%), decreased platelet count (41%), hemorrhage (35%), decreased lymphocyte count (31%), rash (31%) and musculoskeletal pain (30%).

Drug Interactions

CYP3A Inhibitors: When BRUKINSA is co-administered with a strong CYP3A inhibitor, reduce BRUKINSA dose to 80 mg once daily. For coadministration with a moderate CYP3A inhibitor, reduce BRUKINSA dose to 80 mg twice daily.

CYP3A Inducers: Avoid coadministration with moderate or strong CYP3A inducers.

Specific Populations

Hepatic Impairment: The recommended dose of BRUKINSA for patients with severe hepatic impairment is 80 mg orally twice daily.

Please see full U.S. Prescribing Information at www.beigene.com/PDF/BRUKINSAUSPI.pdf and Patient Information at www.beigene.com/PDF/BRUKINSAUSPPI.pdf.

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 two new agreements in December 2021 granting rights to Novartis to co-develop, manufacture, and commercialize BeiGene's TIGIT inhibitor ociperlimab that is in Phase 3 development and add five approved Novartis oncology products to the BeiGene product portfolio 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 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 the potential clinical benefits and advantages of BRUKINSA compared to other BTK inhibitors; BeiGene's plans for the advancement, and anticipated clinical development, regulatory milestones and commercialization of BRUKINSA, the potential commercial opportunity for BRUKINSA, plans for making BRUKINSA accessible to patients in China, the potential for BRUKINSA to be a best-in-class BTK inhibitor and to provide improved clinical benefits to patients, 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. Tam, et al. A randomized phase 3 trial of zanubrutinib vs ibrutinib in symptomatic Waldenström macroglobulinemia: the ASPEN study. Blood. October 2020. 136(18): 2038-2050.

2. Lymphoma Research Foundation. Available at https://lymphoma.org/aboutlymphoma/nhl/wm/. Accessed December 2020.

3. Chen, et al. Cancer statistics in China, 2015 [J]. CA: A Cancer Journal for Clinicians, 2016, 66(2):115-132.

4. Tam, et al. ASPEN: Results of a Phase 3 randomized trial of zanubrutinib versus ibrutinib for patients with Waldenström macroglobulinemia (WM). DOI: 10.1200/JCO.2020.38.15_suppl.8007 Journal of Clinical Oncology 38, no. 15_suppl (May 20, 2020) 8007-8007.

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Exhibit 99.2

BeiGene Announces Positive Findings from Phase 3 Trial of Tislelizumab in Combination with Chemotherapy in First-Line Gastric or Gastroesophageal Junction Cancer

In the RATIONALE 305 trial, tislelizumab combined with chemotherapy prolonged overall survival for patients with PD-L1 expression

Additional follow-up is needed to assess overall survival benefits in intention-to-treat patient population

Safety findings of tislelizumab were consistent with that observed in previous trials

RATIONALE 305 is the sixth positive Phase 3 trial in tislelizumab's broad clinical program

CAMBRIDGE, Mass. and BEIJING—January 24, 2022—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 positive findings from the global Phase 3 RATIONALE 305 trial of tislelizumab versus placebo in combination with chemotherapy as a first-line treatment for patients with locally advanced, unresectable or metastatic gastric or gastroesophageal junction (G/GEJ) adenocarcinoma. At the interim analysis, tislelizumab in combination with chemotherapy met the primary endpoint of overall survival (OS) in patients with PD-L1 expression, with additional follow-up needed to assess OS benefits in the intention-to-treat (ITT) population. The safety profile of tislelizumab was consistent with that observed in previous trials, with no new safety signals identified with the addition of chemotherapy.

"The addition of tislelizumab to chemotherapy significantly extended the overall survival for previously untreated patients with advanced or metastatic gastric or gastroesophageal junction adenocarcinoma whose tumor expressed PD-L1. We will continue to follow up to determine OS benefits across the patient population in the trial," commented Yong (Ben) Ben, M.D., Chief Medical Officer, Solid Tumors at BeiGene.

RATIONALE 305: Tislelizumab vs. Placebo in Combination with Chemotherapy in First-Line G/GEJ Adenocarcinoma

RATIONALE 305 is a randomized, double-blind, placebo-controlled global Phase 3 trial (NCT03777657) comparing the efficacy and safety of tislelizumab combined with platinum and fluoropyrimidine chemotherapy and placebo combined with platinum and fluoropyrimidine chemotherapy as a first-line treatment for patients with locally advanced, unresectable or metastatic G/GEJ adenocarcinoma. The primary endpoint of the trial is OS. Secondary endpoints include progression-free survival (PFS), overall response rate (ORR), duration of response (DoR), and safety. A total of 997 patients from 13 countries and regions globally, including close to 50 percent from outside of China, were enrolled and randomized 1:1 to receive either tislelizumab and chemotherapy or placebo and chemotherapy.

About Gastric Cancer

Gastric cancer (GC) is the fifth most common cancer worldwide and the third leading cause of cancer death, with more than one million cases and approximately 770,000 deaths in 2020.[1] Adenocarcinoma is the major histologic subtype of GC, representing 90% of cases.[2] About two-thirds are GC and the remainder are gastroesophageal junction (GEJ) cancers.[3]

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 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.

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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 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 plans for development of tislelizumab in locally advanced, unresectable or metastatic gastric or gastroesophageal junction (G/GEJ) adenocarcinoma 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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References

1. Globocan 2020. Available at https://gco.iarc.fr/today/data/factsheets/populations/900-world-fact-sheets.pdf. Accessed in November 2020.

2. Smyth EC, Verheij M, Allum W, Cunningham D, Cervantes A, Arnold D; ESMO Guidelines Committee. Gastric cancer: ESMO clinical practice guidelines for diagnosis, treatment and follow-up. *Ann Oncol*. 2016;27(suppl 5):38-49.

3. Colquhoun A, Arnold M, Ferlay J, Goodman KJ, Forman D, Soerjomataram I. Global patterns of cardia and non-cardia gastric cancer incidence in 2012. *Gut*. 2015; 64 (12):1881-1888.