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 18, 2020

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. o

Item 8.01 Other Events.

On June 18, 2020, BeiGene, Ltd. (the “Company” or "BeiGene") issued a press release announcing that its marketing authorization application (MAA) for BRUKINSA® (zanubrutinib) for the treatment of patients with Waldenström’s macroglobulinemia (WM) who have received at least one prior therapy or as first-line treatment for patients unsuitable for chemo-immunotherapy has been validated for regulatory review by the European Medicines Agency (EMA). 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.

On June 19, 2020, 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) of BeiGene’s anti-PD-1 antibody tislelizumab in combination with chemotherapy for first-line treatment of patients with advanced non-squamous non-small cell lung cancer (NSCLC). The full text of this press release is filed as Exhibit 99.2 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 “BeiGene Announces European Medicines Agency Acceptance of its Marketing Authorization Application for BRUKINSA® (Zanubrutinib) for the Treatment of Patients with Waldenström’s Macroglobulinemia,” issued on June 18, 2020
99.2	Press Release titled “BeiGene Announces Acceptance of a Supplemental New Drug Application for Tislelizumab in Combination with Chemotherapy in First-Line Advanced Non-Squamous Non-Small Cell Lung Cancer in China,” issued on June 19, 2020
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: June 24, 2020

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

BeiGene Announces European Medicines Agency Acceptance of its Marketing Authorization Application for BRUKINSA® (Zanubrutinib) for the Treatment of Patients with Waldenström's Macroglobulinemia

CAMBRIDGE, Mass. and BEIJING, China, June 18, 2020 (GLOBE NEWSWIRE) -- BeiGene, Ltd. (NASDAQ: BGNE; HKEX: 06160), a commercial-stage biotechnology company focused on developing and commercializing innovative molecularly-targeted and immuno-oncology drugs for the treatment of cancer, today announced that its marketing authorization application (MAA) for BRUKINSA® (zanubrutinib) for the treatment of patients with Waldenström's macroglobulinemia (WM) who have received at least one prior therapy or as first-line treatment for patients unsuitable for chemo-immunotherapy has been validated for regulatory review by the European Medicines Agency (EMA).

"This is our first submission to the EMA and the first for WM, marking a significant milestone for BRUKINSA, which has demonstrated efficacy and clinically meaningful improvements in safety and tolerability in patients with WM compared to the first-generation BTK inhibitor, ibrutinib, in our head-to-head ASPEN trial. BRUKINSA has been approved in the U.S. and China in other indications, and we are excited to continue its broad, global development program to help patients with B-cell lymphomas," said Jane Huang, M.D., Chief Medical Officer, Hematology at BeiGene. "WM is typically a disease of older individuals, and we are hopeful that BRUKINSA's cardiovascular safety advantages over ibrutinib may help it become a preferred treatment option for patients in Europe with WM."

Clinical data in the MAA include the Phase 3 randomized, open-label, multicenter ASPEN clinical trial (NCT03053440) that evaluated zanubrutinib versus ibrutinib in patients with relapsed/refractory (R/R) or treatment-naïve (TN) WM which was recently presented at the 2020 American Society of Clinical Oncology (ASCO) Virtual Scientific Program and the 25th European Hematology Association (EHA) Congress. The safety package in the MAA included pooled safety data from 779 patients with B-cell malignancies treated with BRUKINSA in six clinical trials.

About Waldenström's Macroglobulinemia (WM)

WM is a rare lymphoma representing approximately 1% of all non-Hodgkin lymphomas and typically progresses slowly after diagnosis.[1] In Europe, the estimated incidence of WM is approximately 7 for every 1 million men and 4 for every 1 million women.[2]

About the Zanubrutinib Clinical Trial Program

Clinical trials of zanubrutinib include:

- Fully-enrolled Phase 3 ASPEN clinical trial in patients with Waldenström's macroglobulinemia (WM) comparing zanubrutinib to ibrutinib (NCT03053440), currently the only approved BTK inhibitor for WM;

- Phase 3 SEQUOIA trial comparing zanubrutinib with bendamustine plus rituximab in patients with treatment-naive (TN) chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) (NCT03336333);
- Phase 3 ALPINE trial comparing zanubrutinib to ibrutinib in patients with relapsed/refractory (R/R) CLL/SLL (NCT03734016);
- Phase 3 MANGROVE trial comparing zanubrutinib and rituximab to bendamustine and rituximab in patients with untreated mantle cell lymphoma (MCL) (NCT04002297);
- Phase 2 MAGNOLIA trial in patients with R/R marginal zone lymphoma (MZL) (NCT03846427);
- Phase 2 ROSEWOOD trial (NCT03332017) in China comparing obinutuzumab and zanubrutinib vs obinutuzumab alone in treating patients with R/R FL;
- Phase 2 trial (NCT04382586) in the U.S. comparing zanubrutinib plus supportive care to placebo plus supportive care for the treatment of patients with COVID-19 disease and pulmonary distress;
- Phase 2 trial (NCT04116437) in the U.S. in patients with previously treated B-cell lymphoma intolerant of prior treatment with ibrutinib and/or acalabrutinib;
- Phase 2 trial (NCT03332173) in China in patients with R/R WM; and
- Completed Phase 2 trials in China in patients with R/R MCL (NCT03206970) and R/R CLL/SLL (NCT03206918).

About BRUKINSA® (zanubrutinib)

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 pivotal clinical program as a monotherapy and in combination with other therapies to treat various B-cell malignancies.

BRUKINSA was approved by the U.S. FDA to treat adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy on November 14, 2019. 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.

BRUKINSA was approved in China for the treatment of MCL in adult patients who have received at least one prior therapy and CLL/SLL in adult patients who have received at least one prior therapy in June 2020.

BRUKINSA is not approved outside of the United States and China.

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 bleeding events including intracranial and gastrointestinal hemorrhage, hematuria and hemothorax have been reported in 2% of patients treated with BRUKINSA monotherapy. Bleeding events of any grade, including purpura and petechiae, occurred in 50% 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 23% of patients treated with BRUKINSA monotherapy. The most common Grade 3 or higher infection was 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 (27%), thrombocytopenia (10%), and anemia (8%) based on laboratory measurements, were reported in patients treated with BRUKINSA monotherapy.

Monitor complete blood counts during treatment and treat using growth factor or transfusions, as needed.

Second Primary Malignancies

Second primary malignancies, including non-skin carcinoma, have occurred in 9% of patients treated with BRUKINSA monotherapy. The most frequent second primary malignancy was skin cancer (basal cell carcinoma and squamous cell carcinoma of skin), reported in 6% of patients. Advise patients to use sun protection.

Cardiac Arrhythmias

Atrial fibrillation and atrial flutter have occurred in 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 0.6% 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 at least 1 week after the last dose. Advise men to avoid fathering a child during treatment and for at least 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 in > 10% of patients who received BRUKINSA were neutrophil count decreased (53%), platelet count decreased (39%), upper respiratory tract infection (38%), white blood cell count decreased (30%), hemoglobin decreased (29%), rash (25%), bruising (23%), diarrhea (20%), cough (20%), musculoskeletal pain (19%), pneumonia (18%), urinary tract infection (13%), hematuria (12%), fatigue (11%), constipation (11%), and hemorrhage (10%). The most frequent serious adverse reactions were pneumonia (11%) and hemorrhage (5%).

Of the 118 patients with MCL treated with BRUKINSA, 8 (7%) patients discontinued treatment due to adverse reactions in the trials. The most frequent adverse reaction leading to treatment discontinuation was pneumonia (3.4%). One (0.8%) patient experienced an adverse reaction leading to dose reduction (hepatitis B).

Drug Interactions

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

CYP3A Inducers: Avoid co-administration 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.

INDICATION

BRUKINSA is a kinase inhibitor indicated for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy.

This indication is 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.

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

About BeiGene

BeiGene is a global, commercial-stage biotechnology company focused on discovering, developing, manufacturing, and commercializing innovative medicines to improve treatment outcomes and access for patients worldwide. Our 3,800+ employees in China, the United States, Australia, and Europe are committed to expediting the development of a diverse pipeline of novel therapeutics for cancer. We currently market two internally-discovered oncology products: BTK inhibitor BRUKINSA® (zanubrutinib) in the United States and China, and anti-PD- 1 antibody tislelizumab in China. We also market or plan to market in China additional oncology products licensed from Amgen Inc., Celgene Logistics Sàrl, a Bristol Myers Squibb (BMS) company, and EUSA Pharma. To learn more about BeiGene, please visit www.beigene.com and follow us on Twitter at @BeiGeneUSA.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws, including statements regarding clinical data for patients from the ASPEN trial and advantages compared to ibrutinib; BeiGene's advancement of, and anticipated clinical development, regulatory milestones and commercialization of its products and drug candidates; and continuing and further development

and commercialization efforts and transactions with third parties. Actual results may differ materially from those indicated in the forward-looking statements as a result of various important factors, including BeiGene's ability to demonstrate the efficacy and safety of its drug candidates; the clinical results for its drug candidates, which may not support further development or marketing approval; actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials and marketing approval; BeiGene's ability to achieve commercial success for its marketed products and drug candidates, if approved; BeiGene's ability to obtain and maintain protection of intellectual property for its technology and drugs; BeiGene's reliance on third parties to conduct drug development, manufacturing and other services; BeiGene's limited operating history and BeiGene's ability to obtain additional funding for operations and to complete the development and commercialization of its drug candidates; the impact of the COVID-19 pandemic on the Company's clinical development, commercial and other operations, as well as those risks more fully discussed in the section entitled "Risk Factors" in BeiGene's most recent quarterly report on Form 10-Q, as well as discussions of potential risks, uncertainties, and other important factors in BeiGene's subsequent filings with the U.S. Securities and Exchange Commission. All information in this press release is as of the date of this press release, and BeiGene undertakes no duty to update such information unless required by law.

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[1] Lymphoma Research Foundation. Getting the Facts: Waldenström Macroglobulinemia. Accessed May 2020. Available at <https://lymphoma.org/wp-content/uploads/2018/04/LRF_FACTSHEET_WALDENSTR%C3%96M_MACROGLOBULINEMIA.pdf>.

[2] Buske, S, et al. Treatment and outcome patterns in European patients with Waldenström's macroglobulinaemia: a large, observational, retrospective chart review. The Lancet Haematology 2018; 5: e0299-309.

BeiGene Announces Acceptance of a Supplemental New Drug Application for Tislelizumab in Combination with Chemotherapy in First-Line Advanced Non-Squamous Non-Small Cell Lung Cancer in China

BEIJING, China and CAMBRIDGE, Mass., June 19, 2020 (GLOBE NEWSWIRE) -- BeiGene, Ltd. (NASDAQ: BGNE; HKEX: 06160), a commercial-stage biotechnology company focused on developing and commercializing innovative molecularly-targeted and immuno-oncology drugs for the treatment of cancer, 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) of BeiGene's anti-PD-1 antibody tislelizumab in combination with chemotherapy for first-line treatment of patients with advanced non-squamous non-small cell lung cancer (NSCLC).

"We are pleased to submit our second sNDA in first-line advanced NSCLC and the fourth potential indication for tislelizumab in China. We credit the continued momentum of our tislelizumab clinical program to the strong expertise of our teams and the support of clinicians and patients who participated in the trials. We have three additional Phase 3 trials for tislelizumab in lung cancer and we are looking forward to continuing to expand the label for tislelizumab in lung cancer and other indications," commented Xiaobin Wu, Ph.D., General Manager of China and President of BeiGene. "Together with the previously accepted filing in patients with squamous histology, we look forward to continuing our dialogue with the CDE and to hope to bring this innovative treatment to hundreds of thousands of Chinese patients and families impacted by this devastating disease every year."

The sNDA in non-squamous NSCLC is supported by clinical results from a Phase 3 trial of tislelizumab in combination with pemetrexed and platinum chemotherapy of investigator's choice – either carboplatin or cisplatin – in patients with previously untreated stage IIIB or stage IV non-squamous NSCLC and with no EGFR mutations or ALK translocations (NCT03663205). A total of 334 patients were randomized 2:1 to receive tislelizumab in combination with chemotherapy or chemotherapy alone. As announced in April 2020, the trial met its 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 pemetrexed and platinum chemotherapy was consistent with the known risks of each study treatment, and no new safety signals were identified. Full results of the trial will be presented at an upcoming meeting.

About Non-Small Cell Lung Cancer

In contrast to most Western countries, where lung cancer death rates are decreasing, lung cancer incidence rates are still increasing in China.[12] There were approximately 770,000 new cases of lung cancer in China in 2018, and it is the leading cause of cancer-related death in both men and women, with approximately 690,500 deaths in China in 2018.[3] Non-small cell lung cancer comprises the most common form of lung cancer in China.[4]

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.

Tislelizumab is approved by the China National Medical Products Administration (NMPA) as a treatment for patients with classical Hodgkin's lymphoma who received at least two prior therapies and for 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.

In addition, the Center for Drug Evaluation (CDE) of the NMPA has accepted two supplemental new drug applications (sNDAs) for tislelizumab in combination with chemotherapy, one for first-line treatment of patients with advanced squamous non-small cell lung cancer (NSCLC) and the other for first-line treatment of patients with advanced non-squamous NSCLC.

Currently, 16 potentially registration-enabling clinical trials are being conducted in China and globally, including 12 Phase 3 trials and four pivotal Phase 2 trials.

Tislelizumab is not approved for use outside of China.

About Tislelizumab Clinical Program

Clinical trials of tislelizumab include:

- Phase 3 trial in patients with locally advanced or metastatic urothelial carcinoma (NCT03967977);
- Phase 3 trial comparing tislelizumab with docetaxel in the second- or third-line setting in patients with NSCLC (NCT03358875);
- Phase 3 trial of tislelizumab in combination with chemotherapy versus chemotherapy as first-line treatment for patients with advanced squamous NSCLC (NCT03594747);
- Phase 3 trial of tislelizumab in combination with chemotherapy versus chemotherapy as first-line treatment for patients with advanced non-squamous NSCLC (NCT03663205);
- Phase 3 trial of tislelizumab in combination with platinum-based doublet chemotherapy as neoadjuvant treatment for patients with NSCLC (NCT04379635);

- Phase 3 trial of tislelizumab combined with platinum and etoposide versus placebo combined with platinum and etoposide in patients with extensive-stage small cell lung cancer (NCT04005716);

- Phase 3 trial comparing tislelizumab with sorafenib as first-line treatment for patients with hepatocellular carcinoma (HCC; NCT03412773);

- Phase 2 trial in patients with previously treated unresectable HCC (NCT03419897);

- Phase 3 trial comparing tislelizumab with chemotherapy as second-line treatment for patients with advanced esophageal squamous cell carcinoma (ESCC; NCT03430843);

- Phase 3 trial of tislelizumab in combination with chemotherapy as first-line treatment for patients with ESCC (NCT03783442);

- Phase 3 trial of tislelizumab versus placebo in combination with chemoradiotherapy in patients with localized ESCC (NCT03957590);

- Phase 3 trial of tislelizumab combined with chemotherapy versus placebo combined with chemotherapy as first-line treatment for patients with gastric cancer (NCT03777657);

- Phase 2 trial in patients with MSI-H/dMMR solid tumors (NCT03736889); and

- Phase 3 trial of tislelizumab combined with chemotherapy versus placebo combined with chemotherapy as first-line treatment in patients with nasopharyngeal cancer (NCT03924986).

About BeiGene

BeiGene is a global, commercial-stage biotechnology company focused on discovering, developing, manufacturing, and commercializing innovative medicines to improve treatment outcomes and access for patients worldwide. Our 3,800+ employees in China, the United States, Australia, and Europe are committed to expediting the development of a diverse pipeline of novel therapeutics for cancer. We currently market two internally-discovered oncology products: BTK inhibitor BRUKINSA® (zanubrutinib) in the United States and China, and anti-PD-1 antibody tislelizumab in China. We also market or plan to market in China additional oncology products licensed from Amgen Inc., Celgene Logistics Sàrl, a Bristol Myers Squibb (BMS) company, and EUSA Pharma. To learn more about BeiGene, please visit www.beigene.com and follow us on Twitter at @BeiGeneUSA.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws, including statements regarding BeiGene's further advancement of, and anticipated clinical development, regulatory milestones and commercialization of tislelizumab, as well as the planned presentation of results from the a Phase 3 trial of tislelizumab in combination with pemetrexed and platinum

chemotherapy of investigator’s choice – either carboplatin or cisplatin – in patients with previously untreated stage IIIB or stage IV non-squamous NSCLC and with no EGFR mutations or ALK translocations at an upcoming meeting. Actual results may differ materially from those indicated in the forward-looking statements as a result of various important factors, including BeiGene's ability to demonstrate the efficacy and safety of its drug candidates; the clinical results for its drug candidates, which may not support further development or marketing approval; actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials and marketing approval; BeiGene's ability to achieve commercial success for its marketed products and drug candidates, if approved; BeiGene's ability to obtain and maintain protection of intellectual property for its technology and drugs; BeiGene's reliance on third parties to conduct drug development, manufacturing and other services; BeiGene’s limited operating history and BeiGene's ability to obtain additional funding for operations and to complete the development and commercialization of its drug candidates; the impact of the COVID-19 pandemic on the Company’s clinical development, commercial and other operations, as well as those risks more fully discussed in the section entitled “Risk Factors” in BeiGene’s most recent quarterly report on Form 10-Q, as well as discussions of potential risks, uncertainties, and other important factors in BeiGene's subsequent filings with the U.S. Securities and Exchange Commission. All information in this press release is as of the date of this press release, and BeiGene undertakes no duty to update such information unless required by law.

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

[3] Feng et al. Cancer Communications (2019) 39:22 https://doi.org/10.1186/s40880-019-0368-6.

[4] Siegel R, DeSantis C, Virgo K, et al. Cancer treatment and survivorship statistics, 2012. CA Cancer J Clin 2012;62:220-41.