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): May 19, 2021

BEIGENE, LTD.
(Exact Name of Registrant as Specified in Charter)

Cayman Islands	**001-37686**	**98-1209416**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification Number)

c/o Mourant Governance Services (Cayman) Limited
94 Solaris Avenue, Camana Bay
Grand Cayman KY1-1108
Cayman Islands
(Address of Principal Executive Offices) (Zip Code)
+1 (345) 949-4123
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
American Depositary Shares, each representing 13 Ordinary Shares, par value $0.0001 per share	**BGNE**	**The NASDAQ Global Select Market**
Ordinary Shares, par value $0.0001 per share*	**06160**	**The Stock Exchange of Hong Kong Limited**

*Included in connection with the registration of the American Depositary Shares with the Securities and Exchange Commission. The ordinary shares are not registered or listed for trading in the United States but are listed for trading on The Stock Exchange of Hong Kong Limited.

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2). Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01. Other Events.

On May 19, 2021, BeiGene, Ltd. ("BeiGene") announced that the U.S. Food and Drug Administration (FDA) has accepted a supplemental new drug application for BRUKINSA® (zanubrutinib) for the treatment of adult patients with marginal zone lymphoma who have received at least one prior anti-CD20-based therapy and granted priority review. The Prescription Drug User Fee Act (PDUFA) target action date is September 19, 2021. 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 May 21, 2021, BeiGene announced that the Phase 3 RATIONALE 309 trial of its anti-PD-1 antibody tislelizumab combined with chemotherapy versus placebo combined with chemotherapy as a first-line treatment for patients with recurrent or metastatic nasopharyngeal cancer met its primary endpoint of progression-free survival (PFS) at the interim analysis, as recommended by an independent data monitoring committee. In the trial results, tislelizumab in combination with chemotherapy demonstrated a statistically significant improvement in PFS in the intention-to-treat population when compared to chemotherapy alone, as assessed by an independent review committee. The safety profile of tislelizumab was consistent with its known risks, with no new safety signals identified with the addition of chemotherapy. 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 U.S. FDA Acceptance and Priority Review of Supplemental New Drug Application for BRUKINSA® (Zanubrutinib) in Marginal Zone Lymphoma", issued by BeiGene, Ltd. on May 19, 2021.
99.2	Press Release titled "BeiGene Announces Positive Topline Results from Phase 3 Trial of Tislelizumab in Combination with Chemotherapy as First-Line Treatment for Recurrent or Metastatic Nasopharyngeal Cancer", issued by BeiGene, Ltd. on May 21, 2021.
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: May 21, 2021

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

Exhibit 99.1

BeiGene Announces U.S. FDA Acceptance and Priority Review of Supplemental New Drug Application for BRUKINSA® (Zanubrutinib) in Marginal Zone Lymphoma

CAMBRIDGE, Mass. & BEIJING, China – May 19, 2021 – BeiGene, Ltd. (NASDAQ: BGNE; HKEX: 06160), a global biotechnology company focused on developing and commercializing innovative medicines worldwide, today announced that the U.S. Food and Drug Administration (FDA) has accepted a supplemental new drug application (sNDA) for BRUKINSA® (zanubrutinib) for the treatment of adult patients with marginal zone lymphoma (MZL) who have received at least one prior anti-CD20-based therapy and granted priority review. The Prescription Drug User Fee Act (PDUFA) target action date is September 19, 2021.

"This is our first regulatory submission in MZL, a serious disease diagnosed in more than 2,000 patients every year in the U.S., with no clear standard of care. In clinical trials, BRUKINSA has demonstrated promising efficacy and tolerability in MZL and presents a potential new option for MZL patients," said Jane Huang, M.D., Chief Medical Officer, Hematology at BeiGene. "We look forward to continuing our communications with the FDA in the coming months as we work on advancing the broad global development program for our potentially best-in-class BTK inhibitor."

Clinical data in the sNDA submission include results from the single-arm, open-label, multicenter, Phase 2 MAGNOLIA trial (NCT03846427) in patients with relapsed or refractory (R/R) MZL as presented at the American Society of Hematology (ASH) Annual Meeting in December 2020, with supportive data from a global Phase 1/2 trial (NCT02343120) in patients with B-cell malignancies. The submission also includes pooled safety data from 847 patients with B-cell malignancies treated with BRUKINSA in seven clinical trials.

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 or small lymphocytic lymphoma (CLL/SLL) in adult patients who have received at least one prior therapy (China, June 2020)**;
- For the treatment of relapsed or refractory MCL (United Arab Emirates, February 2021); and
- For the treatment of Waldenström's macroglobulinemia (WM) in adult patients (Canada, March 2021).

To-date, more than 30 marketing authorization applications in multiple indications have been submitted outside of the United States and China, covering countries in the European Union and more than 20 other countries.

* 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 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.

BeiGene Oncology

BeiGene is committed to advancing best and first-in-class clinical candidates internally or with like-minded partners to develop impactful and affordable medicines to patients across the globe. We have a growing R&D team of approximately 2,300 colleagues dedicated to advancing more than 80 clinical trials involving more than 13,000 patients. Our expansive portfolio is directed by a predominantly internalized clinical development team supporting trials in more than 40 countries. Hematology-oncology and solid tumor targeted therapies and immuno-oncology are key focus areas for the Company, with both mono- and combination therapies prioritized in our research and development. The Company currently markets three medicines discovered and developed in our labs: BTK inhibitor BRUKINSA in the United States, China, Canada, and additional international markets; and non-FC-gamma receptor binding anti-PD-1 antibody tislelizumab and PARP inhibitor pamiparib in China.

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

About BeiGene

BeiGene is a global, science-driven biotechnology company focused on developing innovative and affordable medicines to improve treatment outcomes and access for patients worldwide. With a broad portfolio of more than 40 clinical candidates, we are committed to expediting the development of our diverse pipeline of novel therapeutics through collaborations or our own internal capabilities, with the aspirational goal of radically improving access to medicines for two billion more people by 2030. BeiGene is a headquarter-less company by design, with a growing global team of approximately 6,000 colleagues across five continents. To learn more about BeiGene, please visit www.beigene.com and follow us on Twitter at @BeiGeneGlobal.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws, including statements regarding the regulatory filing, timing of review, and potential approval of BRUKINSA as a new treatment option for patients with marginal zone lymphoma 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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Exhibit 99.2

BeiGene Announces Positive Topline Results from Phase 3 Trial of Tislelizumab in Combination with Chemotherapy as First-Line Treatment for Recurrent or Metastatic Nasopharyngeal Cancer

Tislelizumab combined with chemotherapy demonstrated a statistically significant improvement in progression-free survival at the interim analysis

Safety findings of tislelizumab were consistent with known risks

CAMBRIDGE, Mass. and BEIJING, China – May 21, 2021 -- BeiGene, Ltd. (NASDAQ: BGNE; HKEX: 06160), a global biotechnology company focused on developing and commercializing innovative medicines worldwide, today announced that the Phase 3 RATIONALE 309 trial of its anti-PD-1 antibody tislelizumab combined with chemotherapy versus placebo combined with chemotherapy as a first-line treatment for patients with recurrent or metastatic nasopharyngeal cancer (NPC) met its primary endpoint of progression-free survival (PFS) at the interim analysis, as recommended by an independent data monitoring committee. In the trial results, tislelizumab in combination with chemotherapy demonstrated a statistically significant improvement in PFS in the intention-to-treat (ITT) population when compared to chemotherapy alone, as assessed by an independent review committee (IRC). The safety profile of tislelizumab was consistent with its known risks, with no new safety signals identified with the addition of chemotherapy.

"We are excited to see a clinically meaningful improvement in progression-free survival in our Phase 3 trial for tislelizumab plus chemotherapy in patients with NPC. This is our fifth positive Phase 3 readout for tislelizumab, which we are developing broadly as a potentially differentiated anti-PD-1 antibody," said Yong (Ben) Ben, M.D., Chief Medical Officer, Immuno-Oncology, at BeiGene. "We are grateful for the patients and clinicians who participated in this trial and hopeful that they may have a new treatment option in the future."

BeiGene plans to discuss these data with health authorities and present data at an upcoming medical conference.

RATIONALE 309 Trial of Tislelizumab with Chemotherapy Versus Placebo with Chemotherapy in Recurrent or Metastatic NPC

RATIONALE 309 is a randomized, double-blind, placebo-controlled Phase 3 clinical trial (NCT03924986) designed to evaluate the efficacy and safety of tislelizumab combined with gemcitabine and cisplatin versus placebo combined with gemcitabine and cisplatin as a first-line treatment for patients with recurrent or metastatic NPC. The trial's primary endpoint is PFS as assessed by IRC in the ITT population. Key secondary endpoints include overall survival (OS), IRC-assessed objective response rate (ORR) and duration of response (DoR), and investigator-assessed PFS. A total of 263 Asian patients were enrolled and randomized 1:1 to either the tislelizumab plus chemotherapy arm or the placebo plus chemotherapy arm.

About Nasopharyngeal Cancer (NPC)

Nasopharyngeal cancer (NPC) is a malignant, squamous cell carcinoma which arises from the epithelial cells of the nasopharynx, most commonly originating in the pharyngeal recess (the fossa of Rosenmuller).[i] There were an estimated 60,558 new cases of NPC in China in 2018, accounting for 46.9 percent of the worldwide incidence.[ii] Despite the heavy public health burden of NPC in southern China and other endemic areas, relatively little is known about the etiology and prevention of NPC.[iii] The major risk factors for NPC are genetic predisposition, Epstein-Barr virus (EBV) infection, and consumption of salt-preserved food.[iv] The median overall survival rate is about 20 months in advanced NPC[v], however, progressively worsening prognosis falling to a three-year survival of 7-40% were reported in patients with recurrent or metastatic NPC, indicating a high medical unmet needs for more effective treatment.[vi,vii,viii]

About Tislelizumab

Tislelizumab (BGB-A317) is a humanized IgG4 anti-PD-1 monoclonal antibody specifically designed to minimize binding to FcγR on macrophages. In pre-clinical studies, binding to FcγR on macrophages has been shown to compromise the anti-tumor activity of PD-1 antibodies through activation of antibody-dependent macrophage-mediated killing of T effector cells. Tislelizumab is the first drug from BeiGene's immuno-oncology biologics program and is being developed internationally as a monotherapy and in combination with other therapies for the treatment of a broad array of both solid tumor and hematologic cancers.

The China National Medical Products Administration (NMPA) has granted tislelizumab market authorization in four indications, including full approval for first-line treatment of patients with advanced squamous non-small cell lung cancer

(NSCLC) in combination with chemotherapy; and conditional approval for the treatment of patients with classical Hodgkin's lymphoma (cHL) who received at least two prior therapies and 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. 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 have been accepted by the Center for Drug Evaluation (CDE) of the NMPA and are under review for first-line treatment of patients with advanced non-squamous NSCLC in combination with chemotherapy, for second- or third-line treatment of patients with locally advanced or metastatic NSCLC who progressed on prior platinum-based chemotherapy, and for patients with previously treated unresectable hepatocellular carcinoma.

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).

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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 data from the Phase 3 trial of tislelizumab combined with chemotherapy versus placebo combined with chemotherapy as first-line treatment in patients with NPC, the potential implications of clinical data for patients, BeiGene's plans to present the data at an upcoming medical conference, and BeiGene's advancement, anticipated clinical development, regulatory milestones and commercialization of tislelizumab, and BeiGene's plans, commitments, aspirations and goals under the headings "BeiGene Oncology" and "About BeiGene". Actual results may differ materially from those indicated in the forward-looking statements as a result of various important factors, including BeiGene's ability to demonstrate the efficacy and safety of its drug candidates; the clinical results for its drug candidates, which may not support further development or marketing approval; actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials and marketing approval; BeiGene's ability to achieve commercial success for its marketed medicines and drug candidates, if approved; BeiGene's ability to obtain and maintain protection of intellectual property for its medicines and technology; BeiGene's reliance on third parties to conduct drug development, manufacturing and other services; BeiGene's limited experience in obtaining regulatory approvals and commercializing pharmaceutical products and its ability to obtain additional funding for operations and to complete the development and commercialization of its drug candidates and achieve and maintain profitability; the impact of the COVID-19 pandemic on the BeiGene's clinical development, regulatory, commercial, and other operations, as well as those risks more fully discussed in the section entitled "Risk Factors" in BeiGene's most recent quarterly report on Form 10-Q as well as discussions of potential risks, uncertainties, and other important factors in BeiGene's subsequent filings with the U.S. Securities and Exchange Commission. All information in this press release is as of the date of this press release, and BeiGene undertakes no duty to update such information unless required by law.

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[i] Yu, M. C., & Yuan, J.-M. (2002). Epidemiology of nasopharyngeal carcinoma. Seminars in Cancer Biology, 12(6), 421–429. https://doi.org/10.1016/s1044579x02000858

[ii] Globocan

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[v] Perri, F., (2019). Management of recurrent nasopharyngeal carcinoma: current perspectives. Onco Targets Ther, 12, 1583-1591. doi:10.2147/OTT.S188148

[vi] Li, J.-X., Huang, S.-M., Wen, B.-X., & Lu, T.-X. (2014). Prognostic factors on overall survival of newly diagnosed metastatic nasopharyngeal carcinoma. Asian Pacific Journal of Cancer Prevention: APJCP, 15(7), 3169–3173. https://doi.org/10.7314/apjcp.2014.15.7.3169

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[viii] Xu, Y., Huang, T., Mao, M., Zhai, J., & Chen, J. (2020). Metastatic Patterns and Prognosis of de novo Metastatic Nasopharyngeal Carcinoma in the United States. The Laryngoscope. https://doi.org/10.1002/lary.28983