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 10, 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**

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

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

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

Item 8.01. Other Events.

On June 10, 2022, BeiGene, Ltd. (“BeiGene”) announced that it was presenting data from its hematology portfolio at the European Hematology Association (EHA) 2022 Hybrid Congress being held June 9-12, 2022, in Vienna, Austria. 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 10, 2022, BeiGene announced that the China National Medical Products Administration (NMPA) approved BeiGene’s anti-PD-1 antibody, tislelizumab, in combination with chemotherapy as a first-line treatment for patients with recurrent or metastatic nasopharyngeal cancer (NPC). 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.

On June 13, 2022, BeiGene announced that the U.S. Food and Drug Administration (FDA) extended the Prescription Drug User Fee Act (PDUFA) goal date by three months to January 20, 2023 for the supplementary new drug application (sNDA) for BRUKINSA as a treatment for adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL). The full text of this press release is filed as Exhibit 99.3 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 Highlights Growing Portfolio and Pipeline Targeting Hematologic Malignancies at European Hematology Association 2022 Congress" issued by BeiGene, Ltd. on June 10, 2022
99.2	Press release titled "China NMPA Approves Tislelizumab for Recurrent or Metastatic Nasopharyngeal Cancer" issued by BeiGene, Ltd. on June 10, 2022
99.3	Press release titled "BeiGene Announces PDUFA Goal Date Extension for U.S. sNDA for BRUKINSA for the Treatment of CLL/SLL" issued by BeiGene, Ltd. on June 13, 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: June 14, 2022

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

Exhibit 99.1

BeiGene Highlights Growing Portfolio and Pipeline Targeting Hematologic Malignancies at European Hematology Association 2022 Congress

- *Clinical data and patient-reported outcomes across extensive clinical development program for zanubrutinib (BRUKINSA®) reinforce its potential across B-cell malignancies*
- *Long-term safety and efficacy results from the Phase 3 ASPEN trial of zanubrutinib versus ibrutinib in patients with Waldenström macroglobulinemia*
- *Oral presentation for the Phase 2 ROSEWOOD trial of zanubrutinib plus obinutuzumab in follicular lymphoma*
- *New results for BGB-11417, a highly selective investigative inhibitor of BCL2 in CLL, non-Hodgkin's lymphoma, and acute myeloid leukemia*

CAMBRIDGE, Mass. & BASEL, Switzerland & BEIJING, China – June 10, 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, presents data from its hematology portfolio at the European Hematology Association (EHA) 2022 Hybrid Congress being held June 9-12, 2022, in Vienna, Austria.

"Our data presentations at EHA build a more complete picture of the potential for our BTK inhibitor zanubrutinib across a number of hematologic malignancies, with positive clinical results from ROSEWOOD in follicular lymphoma, long-term efficacy and safety results from ASPEN, as well as patient-reported outcomes from ALPINE and SEQUOIA," said Lai Wang, Ph.D., Global Head of R&D at BeiGene. "We are seeing our promising early pipeline beginning to mature as a result of our deep expertise in developing treatments for hematologic malignancies, and we're pleased to present positive proof-of-concept data from two studies with our BCL2 inhibitor, BGB-11417, at this important hematology meeting."

Highlights from the broad clinical program for zanubrutinib (BRUKINSA®) presented at EHA include:

- **ASPEN**: Long-term safety and efficacy results from the Phase 3 ASPEN trial of zanubrutinib versus ibrutinib in patients with Waldenström macroglobulinemia (WM) showed that, at a median follow up of 43 months, zanubrutinib continued to demonstrate clinically meaningful efficacy and a tolerable safety profile in patients with WM.
- **ROSEWOOD:** The Phase 2 ROSEWOOD trial of zanubrutinib plus obinutuzumab versus (vs.) obinutuzumab monotherapy in patients with relapsed/refractory (R/R) follicular lymphoma met its primary endpoint of overall response rate (ORR) and was generally well-tolerated, with safety results consistent with previous studies of both medicines.
- **ALPINE:** In the head-to-head ALPINE trial of zanubrutinib versus ibrutinib in patients with R/R chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL), those who received zanubrutinib monotherapy reported improvements in key health-related quality of life (HRQoL) endpoints compared with patients who received ibrutinib monotherapy.
- **SEQUOIA**: In the SEQUOIA trial of zanubrutinib vs. bendamustine plus rituximab (BR), zanubrutinib was associated with significant improvements in HRQoL in patients with treatment-naïve (TN) CLL/SLL without del(17p), as indicated by patient reported outcome (PRO) endpoints.

The ROSEWOOD and ASPEN study findings were presented at the American Society of Cancer Oncology (ASCO) Annual Meeting in June 2022.

BeiGene also presented two posters from proof-of-concept studies of BGB-11417, a highly selective investigational BCL2 inhibitor in CLL, non-Hodgkin's lymphoma and acute myeloid leukemia (AML).

- Preliminary data from an ongoing Phase 1/1b dose-escalation and expansion study evaluating the safety, tolerability, maximum tolerated dose (MTD), and recommended Phase 2 dose of oral BGB-11417 as monotherapy or in combination with zanubrutinib, in patients with B-cell malignancies, showed promising efficacy potential for BGB-11417 and an improved safety profile, particularly in combination cohorts.

- Preliminary data from an ongoing Phase 1b/2 global, multi-center dose escalation and expansion study evaluating BGB-11417 plus azacytidine in patients with AML demonstrated the combination to be generally well-tolerated with the majority of complete responses observed by the end of Cycle 1.

Zanubrutinib Plus Obinutuzumab Versus Obinutuzumab Monotherapy in Patients with Relapsed or Refractory Follicular Lymphoma: Primary Analysis of the Phase 2 Randomized ROSEWOOD Trial

Abstract Number: S205

The ROSEWOOD trial met its primary endpoint, with a 68.3% ORR in the zanubrutinib plus obinutuzumab arm versus 45.8% in the obinutuzumab arm (p = 0.0017) and median follow-up of 12.5 months. Zanubrutinib plus obinutuzumab was generally well-tolerated, with safety results consistent with previous studies of both medicines.

- Zanubrutinib plus obinutuzumab was associated with a deep and durable response, with a complete response (CR) rate of 37.2% compared to 19.4% for obinutuzumab alone; 18-month duration of response rate was 70.9% in the zanubrutinib plus obinutuzumab arm versus 54.6% in the obinutuzumab arm.

- Time to next anti-lymphoma treatment was significantly prolonged in the zanubrutinib plus obinutuzumab arm (HR 0.37 [95% CI, 0.23, 0.60].

- Median progression-free survival was 27.4 months in the zanubrutinib plus obinutuzumab arm compared to 11.2 months in the obinutuzumab arm (HR: 0.51 [95% CI, 0.32, -0.81]).

- The most common adverse events in the zanubrutinib plus obinutuzumab arm were thrombocytopenia or platelet count decreased (34.3% any grade; 14% grade ≥ 3) and neutrophil count decreased or neutropenia (27.3% any grade; 22.4% grade ≥ 3); other adverse events were similar between the two arms.

- Infusion-related reactions were more frequent in the obinutuzumab monotherapy arm.

ASPEN: Long-term Follow-up Results of a Phase 3 Randomized Trial of Zanubrutinib vs. Versus Ibrutinib in Patients with Waldenström Macroglobulinemia (WM)

Abstract Number: P1161

With a median follow-up of 43 months, zanubrutinib continued to demonstrate a clinically meaningful efficacy and tolerable safety profile in patients with WM.

- Exploratory analyses showed a consistent trend of deeper, earlier, and more durable responses (CR+VGPR) compared with ibrutinib over time.

- Median time to CR+VGPR was shorter for zanubrutinib: 6.7 months (range, 1.9-42.0) vs ibrutinib: 16.6 months (range, 2.0-49.9).

- Over the follow-up period, patients receiving zanubrutinib had fewer adverse events leading to death, treatment discontinuation, and dose reduction as compared with ibrutinib.

- The prevalence of atrial fibrillation, hypertension, and bleeding were lower in the zanubrutinib arm at all time intervals; neutropenia occurred early, and prevalence decreased over time for patients receiving zanubrutinib.

Health-related Quality of Life Outcomes Associated with Zanubrutinib vs Ibrutinib Monotherapy in Patients with Relapsed/Refractory (R/R) CLL/SLL: Results from The Randomized Phase 3 ALPINE Trial

Abstract Number: P663

In the Phase 3 open-label ALPINE trial, HRQoL was examined at key cycles (7 and 13; corresponding to 6 and 12 months of treatment, respectively). PRO endpoints included global health status (GHS), physical and role functions, and fatigue, pain, diarrhea, and nausea/vomiting.

- Adjusted completion rates for PROs were high (>85%) in both arms at Cycles 7 and 13.

- Estimated mean treatment differences and 95% CI in key PRO endpoints demonstrated treatment differences, in favor of zanubrutinib, in GHS, physical functioning, and fatigue in Cycle 7, and diarrhea in Cycle 13.

- Mean change from baseline showed greater improvement with zanubrutinib compared with ibrutinib at both Cycle 7 and Cycle 13.

Patient-Reported Outcomes from a Phase 3 Randomized Study of Zanubrutinib Versus Bendamustine Plus Rituximab (BR) in Patients with Treatment-naïve (TN) CLL/SLL

Abstract Number: P662

PROs were secondary endpoints in the Phase 3, open-label,SEQUOIA trial of zanubrutinib (n=241) versus bendamustine plus BR (n=238) in adult patients with TN CLL/SLL without del(17p) and were assessed using the EORTC QLQ-C30, and EQ-5D-5L VAS. The PRO endpoints included GHS, physical and role functions, and symptoms of fatigue, pain, diarrhea, and nausea/vomiting measured at critical clinical cycles of Weeks 12 and 24.

- Across all patients, adjusted completion rates for PROs were high (80%) at Weeks 12 and 24.
- Patients treated with zanubrutinib experienced greater improvements in HRQoL at Weeks 12 and 24 compared with patients who received BR.
- By Week 24, improvements were observed with zanubrutinib vs. BR in GHS, physical functioning, role functioning as well as greater reductions in diarrhea, fatigue, and nausea/vomiting.
- Comparable improvements from baseline between zanubrutinib and BR in the health status were observed at Weeks 12 and 24, respectively.

A Phase 1 Study with the Novel B-Cell Lymphoma 2 Inhibitor BGB-11417 as Monotherapy or in Combination with Zanubrutinib in Patients with B-cell Malignancies: Preliminary Data

Abstract Number: P687

This ongoing first-in-human Phase 1/1b dose-escalation and expansion study evaluated the safety, tolerability, maximum tolerated dose (MTD), and recommended Phase 2 dose of oral BGB-11417, a highly selective investigational inhibitor of BCL2, as monotherapy (n=34) or in combination with zanubrutinib (n=44), in patients with B-cell malignancies.

Early phase 1 results suggested that BGB-11417 monotherapy and combination with zanubrutinib is generally well-tolerated in patients with CLL or NHL at the dose levels tested:

- Dose escalation concluded for monotherapy patients with NHL, with 1 dose limiting toxicity (DLT) seen and no MTD reached at doses as high as 640mg; 1 DLT was seen in monotherapy patients with CLL.
- Transient neutropenia was the most frequent grade ≥3 AE; risk of TLS appears limited and manageable.

Dose escalation was completed for Cohort 1A, with no MTD reached through 640mg and only 1 DLT of grade 3 febrile neutropenia was seen at 160 mg Although dose escalation has not yet been completed for the other cohorts and the follow up is limited, responses were observed at the preliminary dose levels:

- A reduction in ALC was noted among all patients with CLL during ramp-up, with reduction in lymphocytes noted at dose levels as low as 1 mg. Four of six R/R CLL/SLL patients receiving BGB-11417 and zanubrutinib achieved PR-L or better across dose levels ranging from 40 – 320 mg.

Preliminary Safety and Efficacy of BGB-11417, a Potent and Selective B-Cell Lymphoma 2 (BCL2) Inhibitor, in Patients with Acute Myeloid Leukemia

Abstract Number: P590

This ongoing Phase 1b/2, global, multi-center, dose-escalation and expansion study evaluated the combination of BGB-11417 and azacitidine in patients (n=31) with acute myeloid leukemia (TN unfit for intensive chemotherapy or R/R). Preliminary results showed that the 10-day regimen of BGB-11417 in 28-day cycle plus 7-day azacytidine was generally well-tolerated and active across the three dose levels tested (40, 80, 160 mg):

- 58% TN and 55% R/R patients with AML met CR+CRh criteria.
- Most CRs (7 of 11) were achieved by the end of cycle 1.

- Five of 13 evaluable CR/CRi achieved minimal residual disease negativity.
- Neutropenia was the most common grade ≥3 AE (54.8%) and was manageable with growth factor support and dose modification.
- DLTs of grade 4 neutropenia/thrombocytopenia occurred in two patients; safety stopping criteria were not met.
- Higher dose and different dosing scheduling are being explored.

About ASPEN

ASPEN is a randomized, open-label, multi-center Phase 3 study comparing BRUKINSA to ibrutinib in patients with relapsed or refractory (R/R) or treatment-naïve WM. The primary endpoint was proportion of patients achieving complete response or very good partial response (CR+VGPR). Patients with MYD88 mutations were assigned to cohort 1 and randomized 1:1 to receive BRUKINSA 160 mg twice daily or ibrutinib 420 mg once daily. Patients without MYD88 mutations were assigned to cohort 2 and received BRUKINSA160 mg twice daily. A total of 229 patients were enrolled in the trial, with 130 patients receiving BRUKINSA and 99 patients receiving ibrutinib.

As assessed by an independent review committee (IRC) based on the modified Sixth International Workshop on Waldenström 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.

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.

About ROSEWOOD

ROSEWOOD is a randomized, open-label, Phase 2 study comparing BRUKINSA plus obinutuzumab to obinutuzumab alone in patients with R/R FL who have received two or more lines of therapy. The primary endpoint was overall response rate (ORR) assessed by independent central review (ICR) according to Lugano classification. Select secondary endpoints include investigator-assessed ORR, ICR-reviewed and investigator-assessed duration of response (DOR) and progression-free survival (PFS), overall survival (OS), ICR- and investigator-assessed CR and complete metabolic response (CMR) rate. A total of 217 patients were enrolled in the trial, with 145 patients receiving BRUKINSA plus obinutuzumab and 72 patients receiving obinutuzumab.

About BRUKINSA (zanubrutinib)

BRUKINSA (zanubrutinib) 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 supported by a broad clinical program which includes more than 3,900 subjects in 35 trials across 28 markets. To date, BRUKINSA has received more than 20 approvals covering nearly 50 countries and regions, including the United States, China, the EU, Great Britain, Canada, Australia, and additional international markets. Currently, more than 40 additional regulatory submissions are in review around the world.

U.S. INDICATIONS and IMPORTANT SAFETY INFORMATION

INDICATIONS

- 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.

- BRUKINSA is indicated for the treatment of adult patients with Waldenström's macroglobulinemia (WM).
- BRUKINSA is indicated for the treatment of adult patients with relapsed or refractory marginal zone lymphoma (MZL) who have received at least one anti-CD20-based regimen.

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 Prescribing Information including Patient Information.

IMPORTANT SAFETY INFORMATION

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 events 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, were reported 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.

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 16,000 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 U.S., China, the European Union, Great Britain, Canada, Australia, and additional international markets; and the non-FC-gamma receptor binding anti-PD-1 antibody tislelizumab as well as the PARP inhibitor pamiparib in China.

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 BeiGene's advancement, anticipated clinical development, regulatory milestones and commercialization of BGB-11417 and zanubrutinib, 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 BeiGene's clinical development, regulatory, commercial, manufacturing, and other operations, as well as those risks more fully discussed in the section entitled "Risk Factors" in BeiGene's most recent 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.

Investor
Kevin Mannix
+1 240-410-0129
ir@beigene.com

Media
Maryline Iva
+41 616 852 090
Kyle Blankenship
+1 667 351 5176
media@beigene.com

Exhibit 99.2

China NMPA Approves Tislelizumab for Recurrent or Metastatic Nasopharyngeal Cancer

Tislelizumab is now approved in nine indications in China

CAMBRIDGE, Mass. & BASEL, Switzerland & BEIJING, China – June 10, 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 China National Medical Products Administration (NMPA) has approved BeiGene's anti-PD-1 antibody, tislelizumab, in combination with chemotherapy as a first-line treatment for patients with recurrent or metastatic nasopharyngeal cancer (NPC).

"NPC is one of the most common head and neck cancers in China and many parts of Asia. Treatment options have been limited, with chemotherapy primarily provided for front-line care. On behalf of these patients, today's approval of tislelizumab, a potentially differentiated checkpoint inhibitor, for patients with recurrent or metastatic NPC could provide new hope," commented Mark Lanasa, M.D., Ph.D., Chief Medical Officer, Solid Tumors at BeiGene. "We look forward to bringing this important immunotherapy to the underserved patient community in China."

"With nine approved indications in China, our 3,100+ science-based commercial team is working to make tislelizumab more broadly available to those who may benefit from this important immunotherapy," commented Xiaobin Wu, Ph.D., President, Chief Operating Officer, and General Manager of China, at BeiGene. "Today's approval is a great step for patients in China with NPC."

"In the pivotal Phase 3 RATIONALE-309 trial, comparing two arms of patients receiving either tislelizumab in combination with standard chemotherapy, or a placebo with standard chemotherapy, we observed statistical and clinically meaningful improvement in progression-free survival in the tislelizumab arm as assessed by both independent review committee and clinical investigators, and a positive trend in overall survival. These results were consistent with the updated survival data with a follow up time of 15 months, and tislelizumab was generally well tolerated," said Li Zhang, M.D., professor at the Collaborative Innovation Center for Cancer Medicine, State Key Laboratory of Oncology in South China and Sun Yat-sen University Cancer, and the principal investigator of the trial. "The NMPA's approval of tislelizumab in NPC is welcoming news to these many patients with the disease."

This approval was supported by clinical results from the randomized, double-blind, Phase 3 clinical trial RATIONALE 309 (NCT03924986) 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.

As announced in May 2021, RATIONALE 309 met the primary endpoint of PFS at the planned interim analysis. Updated efficacy analyses at a median follow-up of 15.5 months, tislelizumab in combination with chemotherapy continued to demonstrate a clinically significant progression-free survival (PFS) benefit over chemotherapy and placebo for patients with RM-NPC. Meanwhile, the tislelizumab arm continued to demonstrate a positive trend in overall survival (OS) and improvement in time to disease progression or death after next-line therapy (PFS2). The safety profile of the tislelizumab and chemotherapy combination was generally manageable and consistent with safety profiles of each treatment agent. These data were presented at an ASCO Virtual Plenary session in April and at the ASCO Annual Meeting in June 2022.

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 Rosenmüller).[i] There were an estimated 62,555 new cases of NPC in China in 2020, accounting for 46.8 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] with progressively worsening prognoses falling to a three-year survival of 7-40% reported in patients with recurrent or metastatic NPC, indicating a high medical unmet need with more effective treatment urgently needed.[vi,vii,viii]

About RATIONALE-309

RATIONALE-309 is a multicenter, randomized, double-blind, placebo-controlled Phase 3 clinical trial (NCT03924986) designed to evaluate the efficacy and safety of tislelizumab combined with gemcitabine and

cisplatin (Arm A) versus placebo combined with gemcitabine and cisplatin (Arm B) as a first-line treatment for patients with RM-NPC.

The primary endpoint of the trial is progression-free survival (PFS) in the intent-to-treat (ITT) population as assessed by an independent review committee (IRC) per RECIST v1.1 criteria; secondary endpoints include IRC-assessed overall response rate (ORR), IRC-assessed duration of response (DoR), overall survival (OS), investigator-assessed PFS, time to second objective disease progression (PFS2), and safety.

A total of 263 patients were enrolled in the trial, with 131 and 132 randomized to Arm A and Arm B, respectively, with balanced baseline characteristics between both arms. Interim results from the trial were presented in December at the European Society for Medical Oncology Immuno-Oncology (ESMO I-O) Congress. Those data showed that at a media follow-up time of 10 months, tislelizumab demonstrated a statistically significant improvement in terms of extending progression-free survival (PFS) as well as clinically meaningful benefit on other survival endpoints compared with chemotherapy and placebo and a generally manageable safety profile.

About Tislelizumab

Tislelizumab is an anti-programmed death receptor-1 (PD-1) inhibitor designed to help aid the body's immune cells to detect and fight tumors. Tislelizumab, a humanized monoclonal antibody, is 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. BeiGene has initiated or completed more than 20 potentially registration-enabling clinical trials in 35 countries and regions, including 17 Phase 3 trials and four pivotal Phase 2 trials.

Tislelizumab is approved by the China National Medical Products Administration (NMPA) as a treatment for nine indications, including multiple approvals in non-small cell lung cancer (NSCLC). Tislelizumab has been submitted for regulatory review as a potential treatment for unresectable recurrent locally advanced or metastatic esophageal squamous cell carcinoma (ESCC) after prior systemic therapy in the U.S., and in NSCLC and second-line ESCC in Europe. In January 2021, BeiGene partnered with Novartis to accelerate the clinical development and marketing of tislelizumab in North America, Europe and Japan.

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 16,000 subjects. Our expansive portfolio is directed predominantly by our internal colleagues supporting clinical trials in more than 45 countries and regions. Hematology-oncology and solid tumor targeted therapies and immuno-oncology are key focus areas for the Company, with both mono- and combination therapies prioritized in our research and development. BeiGene currently has three approved medicines discovered and developed in our own labs: BTK inhibitor BRUKINSA in the United States, China, the EU and U.K., Canada, Australia and additional international markets; and the non-FC-gamma receptor binding anti-PD-1 antibody tislelizumab as well as the PARP inhibitor pamiparib in China.

BeiGene also partners with innovative companies who share our goal of developing therapies to address global health needs. We commercialize a range of oncology medicines in China licensed from Amgen, Bristol Myers Squibb, EUSA Pharma and Bio-Thera. We also plan to address greater areas of unmet need globally through our other collaborations including with Mirati Therapeutics, Seagen, and Zymeworks.

In January 2021 BeiGene and Novartis announced a collaboration granting Novartis rights to co-develop, manufacture, and commercialize BeiGene's anti-PD1 antibody tislelizumab in North America, Europe, and Japan. Building upon this productive collaboration, including a biologics license application (BLA) under FDA review, BeiGene and Novartis announced an option, collaboration and license agreement in December 2021 for BeiGene's TIGIT inhibitor, ociperlimab, that is in Phase 3 development. Novartis and BeiGene also entered into a strategic commercial agreement through which BeiGene is promoting 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 data from the Phase 3 clinical trial RATIONALE 309, BeiGene's efforts to make tislelizumab more broadly available in China, the potential for tislelizumab to treat patients with NPC, 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." BeiGene's ability to demonstrate the efficacy and safety of its drug candidates; the clinical results for its drug candidates, which may not support further development or marketing approval; actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials and marketing approval; BeiGene's ability to achieve commercial success for its marketed medicines and drug candidates, if approved; BeiGene's ability to obtain and maintain protection of intellectual property for its medicines and technology; BeiGene's reliance on third parties to conduct drug development, manufacturing and other services; BeiGene's limited experience in obtaining regulatory approvals and commercializing pharmaceutical products and its ability to obtain additional funding for operations and to complete the development of its drug candidates and achieve and maintain profitability; and the impact of the COVID-19 pandemic on BeiGene's clinical development, regulatory, commercial, manufacturing, and other operations, as well as those risks more fully discussed in the section entitled "Risk Factors" in BeiGene's most recent 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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Investor
Kevin Mannix
+1 240-410-0129
ir@beigene.com

Media
Kyle Blankenship
+1 667-351-5176
media@beigene.com

Exhibit 99.3

BeiGene Announces PDUFA Goal Date Extension for U.S. sNDA for BRUKINSA for the Treatment of CLL/SLL

Following Additional Data Submission to FDA Demonstrating ORR Superiority Over Ibrutinib As Determined by IRC, PDUFA Goal Date Extended to January 20, 2023 to Allow Time for Review

CAMBRIDGE, Mass., BASEL, Switzerland and BEIJING, China – June 13, 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 U.S. Food and Drug Administration (FDA) has extended the Prescription Drug User Fee Act (PDUFA) goal date by three months to January 20, 2023 for the supplementary new drug application (sNDA) for BRUKINSA as a treatment for adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).

The FDA extended the PDUFA goal date to allow time to review additional clinical data submitted by BeiGene, which was deemed a major amendment to the sNDA. The submission included final response analysis from the global ALPINE clinical trial showing BRUKINSA demonstrated superiority versus ibrutinib in overall response rate (ORR) as assessed by an Independent Review Committee (IRC) in adult patients with relapsed or refractory (R/R) CLL or SLL. This final response analysis was announced by the company on April 11, 2022.

“We will continue to work closely with the FDA to facilitate the review of our sNDA for BRUKINSA in CLL/SLL,” said John V. Oyler, Co-Founder, Chairman and CEO of BeiGene. “We are confident that the data in our filing demonstrate BRUKINSA’s potential in the treatment of CLL/SLL and are committed to bringing this important medicine to CLL/SLL patients in the U.S. as soon as possible following regulatory approval.”

The sNDA filing in CLL/SLL includes data from two pivotal randomized Phase 3 studies and eight supportive studies in B-cell malignancies. The two global Phase 3 trials of BRUKINSA in CLL/SLL are: SEQUOIA (NCT03336333) comparing BRUKINSA to bendamustine and rituximab in treatment-naïve (TN) patients and ALPINE (NCT03734016) comparing BRUKINSA to ibrutinib in relapsed or refractory (R/R) patients. Additionally, the SEQUOIA study enrolled patients with deletion 17p in a non-randomized arm evaluating BRUKINSA monotherapy in this high-risk population. ALPINE and SEQUOIA enrolled patients from a total of 17 countries, including the United States, multiple countries in Europe, China, Australia, and New Zealand. Interim results from the ALPINE trial and the SEQUOIA trial were reported at the 26th European Hematology Association (EHA2021) Virtual Congress in June 2021 and at the 63rd American Society for Hematology (ASH) Annual Meeting in December 2021, respectively.

About ALPINE

ALPINE is a randomized, global Phase 3 trial (NCT03734016) comparing BRUKINSA against ibrutinib in previously treated patients with relapsed or refractory chronic lymphocytic leukemia CLL or SLL. In the trial, a total of 652 patients were randomized into two arms, with the first receiving BRUKINSA (160 mg orally twice daily) and the second receiving ibrutinib (420 mg orally once daily) until disease progression or unacceptable toxicity. The primary analysis of overall response rate (ORR), defined by pre-specified non-inferiority of BRUKINSA versus ibrutinib, was assessed by investigator and independent review committee (IRC) using the modified 2008 iwCLL guidelines, with modification for treatment-related lymphocytosis for patients with CLL, and per Lugano Classification for non-Hodgkin’s lymphoma for patients with SLL. There was hierarchical testing of non-inferiority followed by superiority in ORR as assessed by investigator and IRC. Key secondary endpoints include progression-free survival (PFS) and event rate of atrial fibrillation or flutter; other secondary endpoints include duration of response, overall survival, and incidence of adverse events. The study is ongoing with a planned formal analysis of PFS when the target number of events is reached.

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 has previously been approved for three indications in the United States: for the treatment of mantle cell lymphoma (MCL) in adult patients who have received at least one prior therapy (Nov. 2019)*; for the treatment of adult patients with Waldenström's macroglobulinemia (WM) (Aug. 2021); and for the treatment of adult patients with relapsed or refractory marginal zone lymphoma (MZL) who have received at least one anti-CD20-based regimen (Sept. 2021)*.

BRUKINSA is supported by a broad clinical program which includes more than 3,900 subjects in 35 trials across 28 markets. To date, BRUKINSA has received approvals covering 50 countries and regions, including the United States, China, the EU and Great Britain, Canada, Australia, South Korea, Switzerland and additional international markets.

*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.

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.

About BeiGene

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Forward-Looking Statements

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Investor Contact:
Kevin Mannix
+1 240-410-0129
ir@beigene.com

Media Contact:
Emily Collins
+ 1 201-201-4570
media@beigene.com