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): December 10, 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.

As previously disclosed, BeiGene, Ltd. (the "Company" or "BeiGene") commenced an initial public offering (the "STAR Offering") on the Science and Technology Innovation Board (the "STAR Market") of the Shanghai Stock Exchange in China. The total number of shares being offered in the STAR Offering is 115,055,260 ordinary shares, par value $0.0001 per share (or 132,313,260 ordinary shares if China International Capital Corporation Limited exercises its option to obligate us to issue additional ordinary shares in full). The shares offered in the STAR Offering (the "RMB Shares") are being issued to and subscribed for by permitted investors in the People's Republic of China and listed and traded on the STAR Market in Renminbi. In addition, the Company has granted China International Capital Corporation Limited a 30-day overallotment option for up to 17,258,000 additional RMB Shares. The RMB Shares are expected to be listed and begin trading on the STAR Market on December 15, 2021 under the stock code "688235."

This Current Report on Form 8-K does not constitute an offer to sell or a solicitation of an offer to buy the RMB Shares, nor shall there be any offer or sale of the RMB Shares in any state or jurisdiction in which such offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities laws of any such state or jurisdiction.

On December 10, 2021, the Company issued a press release announcing results from the RATIONALE 309 trial of tislelizumab versus placebo in combination with chemotherapy as a first-line treatment for patients with recurrent or metastatic nasopharyngeal cancer (RM-NPC) at the European Society for Medical Oncology Immuno-Oncology (ESMO I-O) Congress 2021, taking place on December 8-11, 2021. A copy of this press release is attached hereto as Exhibit 99.1, and is incorporated herein by reference.

On December 11, 2021, the Company issued a press release announcing that it presented additional safety and efficacy results from an ongoing Phase 2 trial evaluating BRUKINSA® (zanubrutinib) in patients with previously treated B-cell malignancies who were intolerant to ibrutinib and/or acalabrutinib. These data were reported in a mini-oral presentation at the 63rd American Society for Hematology (ASH) Annual Meeting. A copy of this press release is attached hereto as Exhibit 99.2, and is incorporated herein by reference.

On December 12, 2021, the Company issued a press release announcing results from a planned interim analysis of the Phase 3 SEQUOIA trial in patients with treatment-naïve (TN) chronic lymphocytic leukemia (CLL), including the randomized Cohort 1 comparing BRUKINSA to bendamustine plus rituximab (B+R) and Cohort 3 (Arm D) of BRUKINSA in combination with venetoclax in patients with deletion of chromosome 17p (del[17p]) and/or pathogenic TP53 variants. These data were reported in two oral presentations at the 63rd ASH Annual Meeting. A copy of this press release is attached hereto as Exhibit 99.3, and is incorporated herein by reference.

On December 13, 2021, the Company and Nanjing Leads Biolabs, Inc., a privately-owned clinical stage biotechnology company in China and the U.S., jointly issued a press release announcing entry into a license and collaboration agreement granting BeiGene worldwide research, development and manufacturing rights and exclusive commercialization rights outside of China to LBL-007, a novel investigational antibody targeting the LAG-3 pathway. Data from a Phase 1 clinical trial of LBL-007 in patients with advanced solid tumors were presented at the 2021 annual meeting of the American Society of Clinical Oncology (ASCO). A copy of this press release is attached hereto as Exhibit 99.4, and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release titled "BeiGene Presents Results from Phase 3 Trial of Tislelizumab in Nasopharyngeal Cancer at ESMO Immuno-Oncology Congress 2021", issued by BeiGene, Ltd. on December 10, 2021.
99.2	Press Release titled "BeiGene Presents Updated Safety and Efficacy Findings on BRUKINSA (zanubrutinib) in BTK Inhibitor-Intolerant Patients with Relapsed or Refractory B-Cell Malignancies", issued by BeiGene, Ltd. on December 11, 2021.
99.3	Press Release titled "BeiGene Presents Results from SEQUOIA Trial of BRUKINSA in First-Line Chronic Lymphocytic Leukemia at the 63rd ASH Annual Meeting", issued by BeiGene, Ltd. on December 12, 2021.
99.4	Press Release titled "Nanjing Leads Biolabs and BeiGene Announce Worldwide License and Collaboration Agreement for LBL-007 Anti-LAG-3 Antibody; BeiGene Granted Exclusive Commercialization Rights Outside of China", issued by BeiGene, Ltd. on December 13, 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: December 14, 2021

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

Exhibit 99.1

BeiGene Presents Results from Phase 3 Trial of Tislelizumab in Nasopharyngeal Cancer at ESMO Immuno-Oncology Congress 2021

In RATIONALE 309, tislelizumab in combination with chemotherapy significantly prolonged progression-free survival for patients, with survival benefit observed across patient subgroups

The safety profile of the combination was consistent with known risks of each treatment agent

Following the positive topline at an interim analysis, a supplemental biologics license application in this indication is currently under review in China

CAMBRIDGE, Mass. and BEIJING—December 10, 2021—BeiGene (NASDAQ: BGNE; HKEX: 06160), a global, science-driven biotechnology company focused on developing innovative and affordable medicines to improve treatment outcomes and access for patients worldwide, today announced results from the RATIONALE 309 trial of tislelizumab versus placebo in combination with chemotherapy as a first-line treatment for patients with recurrent or metastatic nasopharyngeal cancer (RM-NPC) at the European Society for Medical Oncology Immuno-Oncology (ESMO I-O) Congress 2021, taking place on December 8-11, 2021.

"We are pleased that tislelizumab in combination with chemotherapy demonstrated a statistically significant progression-free survival benefit for patients with RM-NPC over chemotherapy" commented Yong (Ben) Ben, M.D., Chief Medical Officer, Immuno-Oncology at BeiGene. "A filing based on these results is currently under review in China, where NPC as an endemic disease remains a significant unmet medical need. We look forward to continued discussions with the health authority and are working to bring this important immunotherapy to patients in China as soon as we can."

Results from RATIONALE 309: Tislelizumab vs. Placebo in Combination with Chemotherapy in First-Line RM-NPC

Proffered Paper: 121O

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.

"In the RATIONALE 309 trial, the addition of tislelizumab to chemotherapy significantly prolonged PFS for previously untreated patients with RM-NPC, an aggressive head and neck cancer prevalent in Asia, with consistent survival benefit across patient subgroups. Safety results in both arms remained similar to known risks and no new safety signals were identified. The promising results support the potential of tislelizumab in combination with chemotherapy as a new standard of care in China for the first-line treatment of RM-NPC," commented Yunpeng Yang, M.D., Professor at Sun Yat-sen University Cancer Center and principal investigator of the study.

As of March 26, 2021, with a median follow-up time of 10.0 months, RATIONALE 309 achieved the primary endpoint at the interim analysis, with the combination of tislelizumab and chemotherapy demonstrating a statistically significant improvement in PFS, compared to the combination of placebo and chemotherapy, per IRC assessment. Efficacy results included:

- The median PFS was 9.2 months (95% CI: 7.6, 10.1) in Arm A, compared to 7.4 months (95% CI: 5.6, 7.5) in Arm B, with a stratified hazard ratio (HR) of 0.52 (95% CI: 0.38, 0.73) and stratified log-rank $p < 0.0001$, as assessed by IRC;
- The PFS rate at six, nine, and 12 months was 66.1% (95% CI 56.9, 73.8), 51.0% (95% CI: 41.1, 60.1), and 35.7% (95% CI: 25.2, 46.4) in Arm A, compared to 53.0% (95% CI: 43.4, 61.8), 21.6% (95% CI: 13.5, 30.9), and 12.2% (95% CI: 5.6, 21.4) in Arm B, as assessed by IRC;
- The median PFS was 9.8 months (95% CI: 7.8, 11.9) in Arm A, compared to 7.6 months (95% CI: 6.6, 7.8) in Arm B, with a stratified HR of 0.54 (95% CI: 0.38, 0.76), as assessed by investigators;
- Consistent PFS benefit was observed in most subgroups, including disease status, baseline liver metastases, and gender;
- The ORR and complete response (CR) rate were 69.5% and 16.0% in Arm A, compared to 55.3% and 6.8% in Arm B, as assessed by IRC; and
- The median DoR was 8.5 months (95% CI: 6.5, NE), compared to 6.1 months (95% CI: 4.7, 6.2) as assessed by IRC.

The safety profile of tislelizumab and chemotherapy combination was manageable, consistent with known risks of each treatment agent. Safety results included:

- All patients (100%) in Arm A experienced at least one treatment-emergent adverse event (TEAE) of any grade, with the most common (≥20.0%) being anemia, decreased white blood cell count, decreased neutrophil count, nausea, decreased platelet count, decreased appetite, vomiting, constipation, leukopenia, neutropenia, rash, hypothyroidism, increased alanine aminotransferase (ALT), hyponatremia, increased blood creatinine, increased aspartate aminotransferase (AST), malaise, and pyrexia;
- In comparison, 131 patients (99.2%) in Arm B experienced at least one TEAE of any grade, with the most common (≥20.0%) being anemia, nausea, decreased white blood cell count, decreased platelet count, decreased neutrophil count, vomiting, decreased appetite, constipation, leukopenia, neutropenia, hyponatremia, malaise, hypokalemia, rash, increased AST, and hypoalbuminemia;
- Grade ≥3 TEAEs were reported in 106 patients (80.9%) in Arm A, compared to 108 patients (81.8%) in Arm B;
- Serious TEAEs were reported in 36 patients (27.5%) in Arm A, compared to 44 patients (33.3%) in Arm B;
- TEAEs leading to permanent treatment discontinuation and death occurred in 2 patients (1.5%) and 5 patients (3.8%), respectively, in Arm A, compared to 3 patients (2.3%) and 2 patients (1.5%), respectively, in Arm B; and
- In Arm A, 24 patients (18.3%) experienced at least one immune-mediated TEAE of any grade, including 3 patients (2.3%) reporting Grade ≥3 events.

About Nasopharyngeal Cancer

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).[1] There were an estimated 62,555 new cases of NPC in China in 2020, accounting for 46.8 percent of the worldwide incidence.[2] 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.[3] The major risk factors for NPC are genetic predisposition, Epstein-Barr virus (EBV) infection, and consumption of salt-preserved food.[4] The median overall survival rate is about 20 months in advanced NPC;[5] however, progressively worsening prognoses falling to a three-year survival of 7-40% were reported in patients with recurrent or metastatic NPC, indicating a high medical unmet need for more effective treatment.[6,7,8]

About Tislelizumab

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

The China National Medical Products Administration (NMPA) has approved tislelizumab in five indications, including full approval for first-line treatment of patients with advanced squamous non-small cell lung cancer (NSCLC) in combination with chemotherapy and for first-line treatment of patients with advanced non-squamous NSCLC in combination with chemotherapy. NMPA also granted conditional approval for the treatment of patients with classical Hodgkin's lymphoma (cHL) who received at least two prior therapies, for the treatment of patients with locally advanced or metastatic urothelial carcinoma (UC) with PD-L1 high expression whose disease progressed during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy, and for the treatment of patients with hepatocellular carcinoma (HCC) who have received at least one systemic therapy. Full approval for these indications is contingent upon results from ongoing randomized, controlled confirmatory clinical trials.

In addition, four supplemental Biologics License Applications for tislelizumab are under review by the Center for Drug Evaluation (CDE) of the NMPA, including as second- or third-line treatment of patients with locally advanced or metastatic NSCLC who progressed on prior platinum-based chemotherapy, for patients with previously treated, locally advanced unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair-deficient (dMMR) solid tumors, for the treatment of patients with locally advanced or metastatic esophageal squamous cell carcinoma (ESCC) who have disease progression following or are intolerant to first-line standard chemotherapy, and for first-line treatment of patients with recurrent or metastatic nasopharyngeal cancer (NPC).

In the U.S., a Biologics License Application for tislelizumab as a treatment for patients with unresectable recurrent locally advanced or metastatic ESCC after prior systemic therapy is currently under review by the U.S. Food and Drug Administration with a PDUFA target action date of July 12, 2022.

BeiGene has initiated or completed 17 potentially registration-enabling clinical trials in China and globally, including 13 Phase 3 trials and four pivotal Phase 2 trials.

In January 2021, BeiGene and Novartis entered into a collaboration and license agreement granting Novartis rights to develop, manufacture, and commercialize tislelizumab in North America, Europe, and Japan.

Tislelizumab is not approved for use outside of China.

About the Tislelizumab Clinical Program

Clinical trials of tislelizumab include:

- Phase 3 trial comparing tislelizumab with docetaxel in the second- or third-line setting in patients with NSCLC (NCT03358875);
- Phase 3 trial comparing tislelizumab to salvage chemotherapy in patients with relapsed or refractory classical Hodgkin Lymphoma (cHL; NCT04486391);
- Phase 3 trial in patients with locally advanced or metastatic urothelial carcinoma (NCT03967977);
- Phase 3 trial of tislelizumab in combination with chemotherapy versus chemotherapy as first-line treatment for patients with advanced squamous NSCLC (NCT03594747);
- Phase 3 trial of tislelizumab in combination with chemotherapy versus chemotherapy as first-line treatment for patients with advanced non-squamous NSCLC (NCT03663205);
- Phase 3 trial of tislelizumab in combination with platinum-based doublet chemotherapy as neoadjuvant treatment for patients with NSCLC (NCT04379635);
- Phase 3 trial of tislelizumab combined with platinum and etoposide versus placebo combined with platinum and etoposide in patients with extensive-stage small cell lung cancer (NCT04005716);

- Phase 3 trial comparing tislelizumab with sorafenib as first-line treatment for patients with hepatocellular carcinoma (HCC; NCT03412773);
- Phase 2 trial in patients with previously treated unresectable HCC (NCT03419897);
- Phase 2 trial in patients with locally advanced or metastatic urothelial bladder cancer (NCT04004221);
- Phase 3 trial comparing tislelizumab with chemotherapy as second-line treatment for patients with advanced esophageal squamous cell carcinoma (ESCC; NCT03430843);
- Phase 3 trial of tislelizumab in combination with chemotherapy as first-line treatment for patients with ESCC (NCT03783442);
- Phase 3 trial of tislelizumab versus placebo in combination with chemoradiotherapy in patients with localized ESCC (NCT03957590);
- Phase 3 trial of tislelizumab combined with chemotherapy versus placebo combined with chemotherapy as first-line treatment for patients with gastric cancer (NCT03777657);
- Phase 2 trial of tislelizumab in patients with relapsed or refractory cHL (NCT03209973);
- Phase 2 trial in patients with MSI-H/dMMR solid tumors (NCT03736889); and
- Phase 3 trial of tislelizumab combined with chemotherapy versus placebo combined with chemotherapy as first-line treatment in patients with nasopharyngeal cancer (NCT03924986).

BeiGene Oncology

BeiGene is committed to advancing best and first-in-class clinical candidates internally or with like-minded partners to develop impactful and affordable medicines to patients across the globe. We have a growing R&D team of approximately 2,750 colleagues dedicated to advancing more than 70 ongoing clinical trials involving more than 14,000 patients and healthy volunteers. Our expansive portfolio is directed by a predominantly internalized clinical development team supporting 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. 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, Bristol Myers Squibb, and EUSA Pharma. We also plan to address greater areas of unmet need globally through our collaborations including with Amgen, Bio-Thera, Mirati Therapeutics, Seagen, and Zymeworks. BeiGene has also entered into a collaboration with Novartis 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 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 7,700 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 plans for the development and potential regulatory approval and commercialization in China of tislelizumab in NPC, the potential of tislelizumab in combination with chemotherapy as a new standard of care in China for the first-line treatment of RM-NPC, ongoing and future clinical development and potential regulatory approvals of tislelizumab in the United States, China and elsewhere, 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 Presents Updated Safety and Efficacy Findings on BRUKINSA (zanubrutinib) in BTK Inhibitor-Intolerant Patients with Relapsed or Refractory B-Cell Malignancies

Follow-up results from Phase 2 trial suggested intolerable adverse events leading to discontinuation of previous BTK inhibitor therapy were unlikely to recur with BRUKINSA

Treatment with BRUKINSA showed continued disease control for 93.8% of trial participants, while response improved for 64.1%

CAMBRIDGE, Mass. and BEIJING—December 11, 2021—BeiGene (NASDAQ: BGNE; HKEX: 06160), a global, science-driven biotechnology company focused on developing innovative and affordable medicines, today presented additional safety and efficacy results from an ongoing Phase 2 trial evaluating BRUKINSA® (zanubrutinib) in patients with previously treated B-cell malignancies who were intolerant to ibrutinib and/or acalabrutinib. These data were reported in a mini-oral presentation today at the 63rd American Society for Hematology (ASH) Annual Meeting.

"We are highly encouraged by these results, providing further evidence of BRUKINSA's potential to benefit patients with a variety of advanced B-cell malignancies who experience intolerable adverse events on other BTK inhibitors," said Jane Huang, M.D., Chief Medical Officer, Hematology at BeiGene. "BRUKINSA was purposefully designed by BeiGene scientists to deliver sustained inhibition of the BTK protein and address certain tolerability concerns by optimizing kinase selectivity to reduce off-target effects. The updated results from this trial in patients who discontinued treatment with other BTK inhibitors due to adverse events complements previously reported findings from our two Phase 3 head-to-head trials comparing BRUKINSA to ibrutinib, where BRUKINSA demonstrated certain safety advantages over ibrutinib."

For more information on BeiGene's clinical program and company updates, please visit BeiGene's virtual booth at this year's ASH Annual Meeting at http://www.beigenevirtualexperience.com.

Phase 2 Trial of BRUKINSA in BTK Inhibitor-Intolerant Patients with R/R B-cell Malignancies

Mini Oral Presentation; Abstract #1410

This single-arm, open-label, multicenter Phase 2 trial in the U.S. (NCT04116437) evaluated the safety and efficacy of BRUKINSA in patients with previously treated B-cell malignancies who were intolerant to prior BTK inhibitor therapy, with preliminary results presented at the 62nd ASH Annual Meeting in December 2020. The primary endpoint of safety was assessed by the recurrence and the change in severity of adverse events (AEs) compared to patients' intolerance AE profile to ibrutinib and/or acalabrutinib. Secondary endpoints included investigator-assessed disease control rate (DCR), overall response rate (ORR), investigator-assessed progression-free survival (PFS) and patient-reported outcomes.

A total of 67 patients were enrolled in the trial, with 57 patients intolerant to ibrutinib (Cohort 1) and 10 patients intolerant to acalabrutinib and/or ibrutinib (Cohort 2), including 43 patients with chronic lymphocytic leukemia (CLL; 38 in Cohort 1 and five in Cohort 2), 11 patients with Waldenström's Macroglobulinemia (WM; nine in Cohort 1 and two in Cohort 2), seven patients with small lymphocytic lymphoma (SLL; six in Cohort 1 and one in Cohort 2), three patients with mantle cell lymphoma (MCL; two in Cohort 1 and one in Cohort 2), and three patients with marginal zone lymphoma (MZL; two in Cohort 1 and one in Cohort 2). Patients were considered intolerant if they developed significant or persistent toxicities while on ibrutinib and/or acalabrutinib despite optimal care.

"Tolerability of BTK inhibitors continues to be a significant challenge for patients and their physicians, as treatment disruption or discontinuation may impact clinical outcomes. These data demonstrated that treatment with BRUKINSA was well-tolerated and unlikely to lead to recurrence of intolerant AEs experienced with prior BTK inhibitor therapy," commented Mazyar Shadman, M.D., MPH, Associate Professor of Clinical Research Division at Fred Hutchinson Cancer Research Center and Assistant Professor of Oncology at University of Washington, and a principal investigator of the trial. "Additionally, BRUKINSA was effective in at least maintaining or improving treatment responses from baseline, suggesting BRUKINSA may be a treatment option for patients intolerant to other BTK inhibitor therapy across hematologic malignancies."

At the data cutoff on September 8, 2021, with a median BRUKINSA exposure of 11.1 months (11.6 months in Cohort 1 and 9.8 months in Cohort 2), more than a majority of the ibrutinib and acalabrutinib intolerance events did not recur with BRUKINSA treatment and none of the intolerance events recurred at a higher severity. Safety results included:

- 34 out of 57 patients (59.6%) who took ibrutinib and seven out of 10 patients (70.0%) who took acalabrutinib did not have recurrence of any intolerance event with BRUKINSA treatment;
- Of the 115 ibrutinib intolerance events, 81 (70.4%) did not recur on BRUKINSA; of the 34 recurrent events, 26 (76.5%) recurred at a lower severity, and eight (23.5%) recurred at the same severity;
- Of the 18 acalabrutinib intolerance events, 15 (83.3%) did not recur on BRUKINSA; of the three recurrent events, one (33.3%) recurred at a lower severity, and two (66.6%) recurred at the same severity;
- Of the 38 Grade 3 ibrutinib intolerance events, 25 (65.8%) did not recur on BRUKINSA, 12 (31.6%) recurred at a lower severity, and one (2.6%) recurred at the same severity;
- Of the four Grade 3 acalabrutinib intolerance events, three (75.0%) did not recur on BRUKINSA and one (25.0%) recurred at a lower severity;
- All four Grade 4 intolerance events (neutropenia [n=2], ALT increase [n=1], AST increase [n=1]) did not recur on BRUKINSA; and
- One patient (1.5%) discontinued BRUKINSA due to recurrence of a prior intolerant event (myalgia; acalabrutinib).

In 67 patients across both cohorts, BRUKINSA was tolerable with additional safety results including:

- AEs leading to BRUKINSA treatment discontinuation occurred in five patients (7.5%), including four in Cohort 1 and one in Cohort 2);
- 64 patients (95.5%) experienced at least one AE of any grade with BRUKINSA treatment, including 54 in Cohort 1 and 10 in Cohort 2, with the most common (≥10%) being confusion or bruising (22.4%), fatigue (20.9%), myalgia (14.9%), arthralgia (13.4%), diarrhea (13.4%), hypertension (11.9%), dizziness (10.4%), and nausea (10.4%);
- 20 patients (29.9%) experienced at least one Grade ≥3 AE with BRUKINSA treatment, including 17 in Cohort 1 and three in Cohort 2, with the most common (in more than one patient) being neutropenia (7.5%) and decreased neutrophil count (4.5%);
- Eight patients (11.9%) experienced at least one serious AE with BRUKINSA treatment, including six in Cohort 1 and two in Cohort 2; and
- AEs leading to dose interruption, reduction, and death with BRUKINSA treatment occurred in 20 patients (29.9%; 16 in Cohort 1 and four in Cohort 2), six patients (9.0%; five in Cohort 1 and one in Cohort 2), and one patient (1.5%; Cohort 1), respectively.

Efficacy results were assessed by investigators in patients who were on treatment for more than 90 days across both cohorts. BRUKINSA was effective in at least maintaining response in 60 patients (93.8% in all patients, with 94.7% in Cohort 1 and 85.7% in Cohort 2) or improving response from baseline in 41 patients (64.1% in all patients, with 63.2% in Cohort 1 and 71.4% in Cohort 2); the median time to first response was 2.96 months in all patients, with 2.92 months in Cohort 1 and 3.02 months in Cohort 2.

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 received 12 approvals covering 40 countries and regions:

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

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

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

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

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

Warnings and Precautions

Hemorrhage

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

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

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

Infections

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

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

Cytopenias

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

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

Second Primary Malignancies

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

Cardiac Arrhythmias

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

Embryo-Fetal Toxicity

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

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

Adverse reactions

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

Drug Interactions

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

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

Specific Populations

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

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

BeiGene Oncology

BeiGene is committed to advancing best and first-in-class clinical candidates internally or with like-minded partners to develop impactful and affordable medicines for patients across the globe. We have a growing R&D team of approximately 2,750 colleagues dedicated to advancing more than 90 ongoing or planned clinical trials that have involved more than 14,000 patients and healthy volunteers. 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, 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 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 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 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 7,700 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 updated results from the ongoing Phase 2 trial evaluating BRUKINSA (zanubrutinib) in patients with previously treated B-cell malignancies who were intolerant to ibrutinib and/or acalabrutinib, the potential clinical benefits and advantages of BRUKINSA, BeiGene's plans for the advancement, and anticipated clinical development, regulatory milestones and commercialization of BRUKINSA, 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, 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 99.3

BeiGene Presents Results from SEQUOIA Trial of BRUKINSA in First-Line Chronic Lymphocytic Leukemia at the 63rd ASH Annual Meeting

BRUKINSA demonstrated superiority in progression-free survival over chemoimmunotherapy as a first-line treatment for patients with chronic lymphocytic leukemia

Consistent efficacy was observed across high-risk patient subgroups

Safety results were generally consistent with its previously reported profile

Preliminary safety and efficacy data from Cohort 3 of BRUKINSA in combination with venetoclax for patients with del(17p) or TP53 mutations were reviewed at ASH

CAMBRIDGE, Mass. and BEIJING—December 12, 2021—BeiGene (NASDAQ: BGNE; HKEX: 06160), a global, science-driven biotechnology company focused on developing innovative and affordable medicines to improve treatment outcomes and access for patients worldwide, today announced results from a planned interim analysis of the Phase 3 SEQUOIA trial in patients with treatment-naïve (TN) chronic lymphocytic leukemia (CLL), including the randomized Cohort 1 comparing BRUKINSA to bendamustine plus rituximab (B+R) and Cohort 3 (Arm D) of BRUKINSA in combination with venetoclax in patients with deletion of chromosome 17p (del[17p]) and/or pathogenic TP53 variants. These data were reported in two oral presentations at the 63rd American Society for Hematology (ASH) Annual Meeting.

"In the positive SEQUOIA trial, BRUKINSA delivered the therapeutic promise of a selective BTK inhibitor as a frontline treatment for CLL patients, with demonstrated superiority over chemoimmunotherapy. These robust data, along with the results from our previously reported Phase 3 ALPINE trial, strengthen our belief that BRUKINSA could become an important new treatment option for patients with CLL," remarked Jane Huang, M.D., Chief Medical Officer of Hematology at BeiGene. "In addition, BRUKINSA achieved favorable safety advantages in both trials such as lower rates of atrial fibrillation."

"Compared to chemoimmunotherapy, BRUKINSA demonstrated superior PFS benefit for CLL patients receiving frontline treatment, including those harboring high-risk characteristics, such as unmutated IGHV status and del(11q)," said Constantine Tam, MBBS, M.D., Peter MacCallum Cancer Center, and a principal investigator of the study. "Safety findings in SEQUOIA were similar to what has been reported in other BRUKINSA clinical trials, with consistently low rates of atrial fibrillation. Based on these results, BRUKINSA, as a highly selective BTK inhibitor, can potentially provide a chemo-free treatment option for CLL patients."

For more information on BeiGene's clinical program and company updates, please visit BeiGene's virtual booth at this year's ASH Annual Meeting at http://www.beigenevirtualexperience.com.

SEQUOIA Cohort 1: BRUKINSA vs. B+R in TN CLL Patients Without del (17p)

Oral Presentation; Abstract #396; Plain language summary available at https://www.beigene.com/pls/ash2021/sequoia

A total of 479 patients with TN CLL whose tumor did not exhibit del(17p) were enrolled in Cohort 1 of the SEQUOIA trial, with 241 patients randomized to receive BRUKINSA (Arm A) and 238 patients randomized to receive B+R (Arm B). Patient characteristics were balanced between the two arms, with more than 50% with unmutated IGHV gene and 18% with del(11q) in each. Patients with del(17p) typically have poor response to chemoimmunotherapy and were assigned to receive BRUKINSA treatment in Cohort 2. Results from Cohort 2 were previously presented at the 2020 ASH Annual Meeting.

The primary endpoint of the SEQUOIA trial is progression-free survival (PFS) per independent review committee (IRC) assessment in the randomized Cohort 1.

At the interim analysis, with a median follow-up of 26.15 months, BRUKINSA demonstrated superiority in PFS over B+R, as assessed by IRC. Results included:

- The 24-month PFS rate was 85.5% (95% CI: 80.1, 89.6) in Arm A, compared to 69.5% (95% CI: 62.4, 75.5) in Arm B, with a hazard ratio (HR) of 0.42 (95% CI: 0.27, 0.63), $p < 0.0001$;
- PFS benefit was consistently observed across key patient subgroups, including patients with del(11q), unmutated IGHV status, Binet stage C, and bulky disease; and

- Overall survival (OS) results were early, and at 24 months, OS probability was similar between two arms, with 94.3% (95% CI: 90.4, 96.7) in Arm A and 94.6% (95% CI: 90.6, 96.9) in Arm B.

Safety analysis was based on 240 patients in Arm A and 227 patients in Arm B who received at least one dose of respective treatment. BRUKINSA was generally well tolerated with a safety profile consistent with its broad clinical program, including a low rate of atrial fibrillation. Results included:

- 224 patients (93.3%) in Arm A experienced at least one adverse event (AE) of any grade, with the most common (≥12%) being contusion (19.2%), upper respiratory tract infection (17.1%), neutropenia (15.4%), diarrhea (13.8%), and arthralgia (13.3%);
- In comparison, 218 patients (96.0%) in Arm B experienced at least one AE of any grade, with the most common (≥12%) being neutropenia (56.8%), nausea (32.6%), pyrexia (26.4%), rash (19.4%), anemia (18.9%), constipation (18.9%), infusion-related reaction (18.9%), fatigue (15.9%), vomiting (14.5%), thrombocytopenia (13.7%), and diarrhea (13.2%);
- 126 patients (52.5%) in Arm A experienced at least one Grade ≥3 AE, compared to 181 patients (79.7%) in Arm B, with the most common in both arms being neutropenia (11.3% in Arm A vs. 51.1% in Arm B) and thrombocytopenia (1.7% in Arm A vs. 7.0% in Arm B);
- 88 patients (36.7%) in Arm A experienced at least one serious AE, compared to 113 patients (49.8%) in Arm B;
- AEs leading to dose reduction, interruption or delay, and discontinuation occurred in 18 patients (7.5%), 111 patients (46.3%), and 20 patients (8.3%), respectively, in Arm A, compared to 84 patients (37.4%), 154 patients (67.8%), and 31 patients (13.7%), respectively, in Arm B;
- Fatal AEs were reported in 11 patients (4.6%) in Arm A, compared to 11 patients (4.8%) in Arm B;
- AEs of interest of any grade included anemia (Arm A vs. Arm B: 4.6% vs. 19.4%), arthralgia (13.3% vs. 8.8%), atrial fibrillation (3.3% vs. 2.6%), bleeding (45.0% vs. 11.0%), diarrhea (13.8% vs. 13.7%), hypertension (14.2% vs. 10.6%), infections (62.1% vs. 55.9%), myalgia (3.8% vs. 1.3%), neutropenia (15.8% vs. 56.8%), other cancers (12.9% vs. 8.8%), and thrombocytopenia (4.6% vs. 17.6%).

In addition, efficacy results with an extended follow-up from Cohort 2 (Arm C) of BRUKINSA as a monotherapy in patients with del(17p) were reported at ASH. With a median follow-up of 30.5 months, the 24-month PFS rate was 88.9% (95% CI: 81.3, 93.6).

Summary of SEQUOIA Cohort 1 Interim Analysis

SEQUOIA Cohort 1 Summary	BRUKINSA (n=241)	Bendamustine + Rituximab (n=238)
Efficacy Results		
IRC-Assessed 24-month PFS (Primary Endpoint)	**85.5% (95% CI: 80.1, 89.6) Hazard Ratio=0.42 (95%CI: 0.27, 0.63) 2-sided *p* <0.0001**	**69.5% (95% CI: 62.4, 75.5)**
Overall Safety Results		
AEs of any grade	93.3%	96.0%
Grade ≥3 AEs	52.5%	79.7%
Serious AEs	36.7%	49.8%
AEs leading to dose reduction	7.5%	37.4%
AEs leading to dose interruption or delay	46.3%	67.8%
AEs leading to treatment discontinuation	8.3%	13.7%
Fatal AEs	4.6%	4.8%
Adverse Events of Interest (Any Grade)		
Anemia	4.6%	19.4%
Neutropenia	15.8%	56.8%
Thrombocytopenia	4.6%	17.6%
Arthralgia	13.3%	8.8%
Atrial fibrillation	3.3%	2.6%
Bleeding	45.0%	11.0%
Diarrhea	13.8%	13.7%
Hypertension	14.2%	10.6%
Infections	62.1%	55.9%
Myalgia	3.8%	1.3%
Other cancers	12.9%	8.8%

SEQUOIA Cohort 3 (Arm D): BRUKINSA + Venetoclax in TN CLL Patients with del(17p) and/or TP53 Mutations

Oral Presentation; Abstract #67

Cohort 3 of SEQUOIA was designed to examine the hypothesis that the addition of venetoclax to BRUKINSA can drive tumors into deeper remission. Building on the demonstrated efficacy and safety of BRUKINSA in Cohort 2, Cohort 3 is planned to enroll approximately 80 patients with TN CLL whose tumor exhibits del(17p) or TP53 mutations, with key endpoints being safety, overall response rate (ORR), PFS, and duration of response (DoR). These patients will receive BRUKINSA treatment at 160 mg twice daily for three months, followed by combination treatment of BRUKINSA at the same dosing and venetoclax with a ramp-up dosing to 400 mg once daily for 12 to 24 cycles until progressive disease, unacceptable toxicity, or confirmed undetectable measurable residual disease (uMRD).

"Unfavorable prognosis is often seen in CLL patients with del(17p) or pathogenic TP53 variants, even in the front-line setting. While the follow-up in Cohort 3 was relatively short, the high response rate and the deepened responses observed among those treated for longer periods suggested the potential of BRUKINSA in combination with venetoclax in these high-risk CLL patients. The combination treatment also appeared generally well tolerated," commented Alessandra Tedeschi, M.D., Grande Ospedale Metropolitano Niguarda in Italy, a principal investigator on the study. "We look forward to the continued evaluation of BRUKINSA in combination with venetoclax in untreated CLL patients with del(17p) or TP53 mutations."

At the data cutoff on September 7, 2021, 49 patients were enrolled in Cohort 3, including 46 patients (93.9%) with centrally confirmed positive del(17p) status and three patients (6.1%) with a pathogenic TP53 variant alone. Patients enrolled in Cohort 3 also exhibited other markers of high risk, including 87.8% with unmutated IGHV, 91.9% with concurrent TP53 mutation, and 83.3% with complex karyotype (at least three abnormalities).

With a short median follow-up of 12.0 months, a high ORR was observed in the 36 patients who had at least one post-baseline response evaluation by the data cutoff date. Preliminary efficacy results per investigator assessment included:

- Of the 14 patients who received combination treatment for more than 12 months, five patients (36%) achieved a confirmed complete response (CR) or CR with incomplete bone marrow recovery (CRi) in a bone marrow assessment and four additional patients met the criteria for CR or CRi but not confirmed in bone marrow assessment due to COVID-19 restrictions; and

- In all 36 patients evaluable for efficacy, the ORR was 97.2% (95% CI: 85.5, 99.9) and the CR/CRi rate was 13.9% (all CRs or CRis were in patients who received combination treatment for more than 12 months).

With a median follow-up of 7.9 months, safety results in all 49 enrolled patients included:

- 40 patients (81.6%) experienced at least one AE of any grade, with the most common (≥12%) being infections (16.3%), neutropenia (14.3%), bruising (12.2%), diarrhea (12.2%), minor bleeding (12.2%), and nausea (12.2%);

- 16 patients (32.7%) experienced at least one Grade ≥3 AE and four patients (8.2%) experienced at least one serious AE;

- AEs leading to dose interruption, dose reduction, and treatment discontinuation occurred in 10 patients (20.4%), no patients (0.0%), and one patient (2.0%), respectively; and

- One patient (2.0%) experienced a fatal AE.

With a median follow-up of 13.5 months, safety results in the 34 patients who received combination treatment included:

- 29 patients (85.3%) experienced at least one AE of any grade, with the most common (≥12%) being infections (23.5%), neutropenia (20.6%), diarrhea (14.7%), fatigue (14.7%), nausea (14.7%), and bruising (11.8%);

- 13 patients (38.2%) experienced at least one Grade ≥3 AE and three patients (8.8%) experienced at least one serious AE; and

- AEs leading to dose interruption occurred in 10 patients (29.4%), with no AEs leading to dose reduction or treatment discontinuation.

About SEQUOIA

SEQUOIA is a randomized, multicenter, global Phase 3 trial (NCT03336333) designed to evaluate the efficacy and safety of BRUKINSA compared to B+R in patients with TN CLL or SLL. The trial consists of three cohorts:

- Cohort 1 (n=479): randomized 1:1 to receive BRUKINSA (n=241) or B+R (n=238) until disease progression or unacceptable toxicity, in patients not harboring del(17p); data from this group comprise the primary endpoint;
- Cohort 2 (n=110): patients with del(17p) receiving BRUKINSA as a monotherapy; and
- Cohort 3 (enrollment ongoing): patients with del(17p) or pathogenic TP53 variant receiving BRUKINSA in combination with venetoclax.

Patients with del(17p) were not randomized to B+R, as they experience poor clinical outcomes and poor response to chemoimmunotherapy. The primary endpoint of the trial is IRC-assessed PFS. Secondary endpoints include investigator-assessed PFS, IRC- and investigator-assessed overall response rate (ORR), overall survival (OS), PFS and ORR in patients with del(17p), and safety.

Cohort 2 (Arm C), representing high-risk patients treated with BRUKINSA monotherapy, was previously presented at the American Society for Hematology (ASH) Annual Meeting in December 2020. This cohort of patients with del(17p) achieved significant efficacy with an 18-month PFS of 90.6%, as assessed by investigator.

About Chronic Lymphocytic Leukemia and Small Lymphocytic Lymphoma

Chronic lymphocytic leukemia (CLL) is the most common form of leukemia in adults, with a global incidence of approximately 114,000 new cases in 2017.[1,2] CLL affects white blood cells or lymphocytes in the bone marrow.[1] Proliferation of cancer cells (leukemia) in the marrow result in reduced ability to fight infection and spread into the blood, which affects other parts of the body including the lymph nodes, liver and spleen.[1,3] The BTK pathway is a known route that signals malignant B cells and contributes to the onset of CLL.[4] Small lymphocytic lymphoma (SLL) is a non-Hodgkin's lymphoma affecting the B-lymphocytes of the immune system, which shares many similarities to CLL but with cancer cells found mostly in lymph nodes.[5]

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 received 12 approvals covering 40 countries and regions:

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

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

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

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

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

Warnings and Precautions

Hemorrhage

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

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

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

Infections

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

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

Cytopenias

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

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

Second Primary Malignancies

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

Cardiac Arrhythmias

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

Embryo-Fetal Toxicity

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

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

Adverse reactions

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

Drug Interactions

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

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

Specific Populations

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

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

BeiGene Oncology

BeiGene is committed to advancing best and first-in-class clinical candidates internally or with like-minded partners to develop impactful and affordable medicines for patients across the globe. We have a growing R&D team of approximately 2,750 colleagues dedicated to advancing more than 90 ongoing or planned clinical trials that have involved more than 14,000 patients and healthy volunteers. 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, 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 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 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 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 7,700 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 results from the interim analysis of the Phase 3 SEQUOIA trial, the potential clinical benefits and advantages of BRUKINSA, BeiGene's plans for the advancement, and anticipated clinical development, regulatory milestones and commercialization of BRUKINSA, 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, 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 99.4

Nanjing Leads Biolabs and BeiGene Announce Worldwide License and Collaboration Agreement for LBL-007 Anti-LAG-3 Antibody; BeiGene Granted Exclusive Commercialization Rights Outside of China

CAMBRIDGE, Mass. and BEIJING, China – December 13, 2021 - BeiGene (NASDAQ: BGNE; HKEX: 06160), a global science-driven biotechnology company focused on developing innovative and affordable medicines to improve treatment outcomes and access for patients worldwide, and Nanjing Leads Biolabs, Inc. (Leads Biolabs), a privately-owned clinical stage biotechnology company in China and the U.S., today announced entry into a license and collaboration agreement granting BeiGene worldwide research, development and manufacturing rights and exclusive commercialization rights outside of China to LBL-007, a novel investigational antibody targeting the LAG-3 pathway. Data from a Phase 1 clinical trial of LBL-007 in patients with advanced solid tumors were presented at the 2021 annual meeting of the American Society of Clinical Oncology (ASCO).

"We are excited about the strategic opportunity of adding an anti-LAG-3 agent to our portfolio and the potential to expedite the clinical development and scientific understanding of both LBL-007 and the anti-LAG-3 pathway as monotherapy and in combination with other immuno-oncology assets in BeiGene's portfolio, including our anti-PD-1 inhibitor tislelizumab, where we see exciting combination potential for improved anti-tumor activity," said Lai Wang, Ph.D., Global Head of R&D at BeiGene. "Nanjing Leads Biolabs has developed a promising clinical candidate, which complements our I/O program and supports our strategic imperatives of global clinical excellence and opportunities to address unmet medical needs around the world."

Under the terms of the agreement, Leads Biolabs will receive $30 million upfront and is eligible to receive up to $742 million in clinical development, regulatory approval, and sales milestones, plus tiered double-digit royalties on sales in the licensed territory.

"Securing a collaboration to further develop LBL-007 has been a key strategic priority, and we are excited to begin working with BeiGene, a global leader in oncology," said Xiaoqiang Kang, M.D., Ph.D., CEO and Chairman of Leads Biolabs. "BeiGene is the ideal partner for Leads Biolabs given its extensive experience in the development of oncology medicines worldwide and the compelling immuno-oncology combination opportunity in its pipeline. By collaborating with BeiGene, Leads Biolabs expects to significantly accelerate the development and commercialization of LBL-007."

About LBL-007

LAG-3 is an immune checkpoint receptor expressed on activated T cells to negatively regulate these cells, resulting in tumor immune escape. LBL-007, a novel investigational anti-LAG-3 antibody, was developed by screening of a human antibody phage display library and demonstrated specific binding to human LAG-3, stimulation of IL-2 release and blockage of LAG-3 binding to MHC II and other known LAG-3 ligands. LBL-007 monotherapy was shown in pre-clinical studies to significantly inhibit tumor growth, with more pronounced tumor inhibition when combined with an anti-PD-1 antibody. LBL-007 has obtained IND clearance in both the U.S. and China, as well as completed a Phase 1a clinical trial, and is currently in Phase 1b/2 clinical trials in China.

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 team of approximately 2,750 colleagues dedicated to advancing more than 90 ongoing or planned clinical trials (over 70 clinical trials are ongoing) involving more than 14,000 patients and healthy volunteers. 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, 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 collaborations including with Amgen, Mirati Therapeutics, Seagen, and Zymeworks. BeiGene has also entered into a collaboration with Novartis granting Novartis rights to develop, manufacture, and commercialize tislelizumab in North America, Europe, and Japan.

About Nanjing Leads Biolabs

Nanjing Leads Biolabs (Leads Biolabs) is a clinical-stage US-Sino joint venture company, focusing on development and commercialization of second-generation immuno-oncology therapeutics. As an innovation-driven biopharmaceutical company, Leads Biolabs has established a rich portfolio of more than 10 novel mono- or bispecific antibody drug projects to fulfill unmet medical needs, Leads Biolabs will continue and expand its innovative R&D to provide patients with safe, effective, accessible and affordable new drugs. To learn more about Leads Biolabs, please visit www.leadsbiolabs.com.

About BeiGene

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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 future development of LBL-007 and plans to accelerate the development and commercialization of LBL-007; the potential of the licensed technology as monotherapy and in combination with other immuno-oncology assets, including tislelizumab; potential payments to Nanjing Leads Biolabs; the parties' commitments and the potential benefits of the collaboration; 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 products 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 Company'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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