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 6, 2020

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

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

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

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

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

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

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

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

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

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

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

Item 8.01. Other Events.

On December 6, 2020, BeiGene, Ltd. (the "Company" or "BeiGene") announced clinical data on its BTK inhibitor BRUKINSA® (zanubrutinib) at the 62nd American Society for Hematology (ASH) Annual Meeting. These data included an oral presentation on the initial results of the Phase 2 MAGNOLIA trial in patients with relapsed/refractory (R/R) marginal zone lymphoma (MZL) and a poster with follow-up results from Arm C of the Phase 3 SEQUOIA trial in treatment-naïve (TN) patients with chronic lymphocytic leukemia or small lymphocytic lymphoma (CLL/SLL) with del(17p). 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 December 7, 2020, the Company presented clinical data on its BTK inhibitor BRUKINSA® (zanubrutinib) in two posters at the ASH Annual Meeting, including results from a Phase 2 trial in patients with R/R B-cell malignancies who were intolerant to ibrutinib and/or acalabrutinib and the first results from a pivotal Phase 2 trial in patients with R/R Waldenström's Macroglobulinemia (WM) that were included in a supplemental new drug application of BRUKINSA currently under priority review in China. 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 December 7, 2020, the Company announced that the China National Medical Products Administration (NMPA) has approved BLINCYTO® (blinatumomab) for injection for the treatment of adult patients with R/R B-cell precursor acute lymphoblastic leukemia (ALL). The biologics license application (BLA) had been submitted by Amgen and received priority review by the Center for Drug Evaluation (CDE) of the NMPA. Developed by Amgen and licensed to BeiGene in China under a strategic collaboration commenced earlier this year, this is the first approval for BLINCYTO in China and BeiGene's first product licensed from Amgen to be newly approved. With this approval, BLINCYTO has become the first bispecific immunotherapy approved in China. 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 Announces Data on BRUKINSA® (Zanubrutinib) from Phase 2 Trial in Marginal Zone Lymphoma and Phase 3 Trial in Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma at the 62nd ASH Annual Meeting" dated December 6, 2020.
99.2	Press Release titled "BeiGene Presents Clinical Data on BRUKINSA® (Zanubrutinib) in B-Cell Malignancies and Waldenström's Macroglobulinemia at the 62nd ASH Annual Meeting" dated December 7, 2020.
99.3	Press Released titled "BeiGene Announces the Approval in China of BLINCYTO® (Blinatumomab) for Injection for Adult Patients with Relapsed or Refractory B-Cell Precursor Acute Lymphoblastic Leukemia (ALL)" dated December 7, 2020.
104	The cover page from this Current Report on Form 8-K, formatted in Inline XBRL.

Exhibit Index

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99.2	Press Release titled "BeiGene Presents Clinical Data on BRUKINSA® (Zanubrutinib) in B-Cell Malignancies and Waldenström's Macroglobulinemia at the 62nd ASH Annual Meeting" dated December 7, 2020.
99.3	Press Released titled "BeiGene Announces the Approval in China of BLINCYTO® (Blinatumomab) for Injection for Adult Patients with Relapsed or Refractory B-Cell Precursor Acute Lymphoblastic Leukemia (ALL)" dated December 7, 2020.
104	The cover page from this Current Report on Form 8-K, formatted in Inline XBRL.

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 8, 2020

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

Exhibit 99.1

BeiGene Announces Data on BRUKINSA® (Zanubrutinib) from Phase 2 Trial in Marginal Zone Lymphoma and Phase 3 Trial in Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma at the 62nd ASH Annual Meeting

Zanubrutinib was shown to be highly active in patients with relapsed/refractory marginal zone lymphoma in initial results from the Phase 2 MAGNOLIA trial

Zanubrutinib demonstrated an overall response rate of nearly 95 percent and a sustained progression-free survival in treatment-naïve chronic lymphocytic leukemia or small lymphocytic lymphoma patients with del(17p) in Arm C of the Phase 3 SEQUOIA trial

CAMBRIDGE, Mass. and BEIJING, China – December 6, 2020 -- BeiGene, Ltd. (NASDAQ: BGNE; HKEX: 06160), a commercial-stage biotechnology company focused on developing and commercializing innovative medicines worldwide, today announced clinical data on its BTK inhibitor BRUKINSA® (zanubrutinib) at the 62nd American Society for Hematology (ASH) Annual Meeting. These data included an oral presentation on the initial results of the Phase 2 MAGNOLIA trial in patients with relapsed/refractory (R/R) marginal zone lymphoma (MZL) and a poster with follow-up results from Arm C of the Phase 3 SEQUOIA trial in treatment-naïve (TN) patients with chronic lymphocytic leukemia or small lymphocytic lymphoma (CLL/SLL) with del(17p).

"BRUKINSA received accelerated approval from the U.S. FDA last year for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy, and we've since provided additional clinical data on its efficacy and safety across multiple B-cell malignancies. Initial results from the MAGNOLIA trial showed a high response rate, including complete responses, in patients with relapsed/refractory MZL. Activity was seen in patients with high-risk factors, supporting BRUKINSA's robust clinical activity and tolerability," said Jane Huang, M.D., Chief Medical Officer, Hematology at BeiGene. "Additionally, the extended follow-up time in Arm C of the SEQUOIA trial allowed us to further evaluate longer-term responses in previously untreated patients with CLL/SLL with del(17p), and we were excited to observe more complete responses and an adverse event profile consistent with the initial results presented at last year's ASH meeting. The encouraging data presented today support our ongoing global regulatory plans for BRUKINSA as a potentially best-in-class BTK inhibitor."

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.

Initial Results of the Phase 2 MAGNOLIA Trial in R/R MZL

Oral Presentation; Abstract 339

Initial results from the single-arm, open-label, multicenter, Phase 2 MAGNOLIA trial (NCT03846427) demonstrated that BRUKINSA was highly active and generally well-tolerated in patients with R/R MZL. A total of 68 patients with extranodal, splenic, or nodal subtypes who received at least one prior line of CD20-directed regimen were enrolled in the trial, with identified high-risk features including an elderly population with a median age of 70 years, heavily pre-treated population with a median of two prior lines of therapy, more than 30 percent with refractory disease, and nearly 40 percent with nodal MZL.

"As demonstrated by an ORR of 74.2 percent and a clinical benefit rate of nearly 90 percent in the initial results of the MAGNOLIA trial, zanubrutinib's strong anti-tumor activity could potentially benefit patients with R/R MZL, a disease with limited tolerable and effective therapeutic strategies," commented Stephen Opat, FRACP, FRCPA, MBBS, Director of Clinical Hematology at Monash Health and Head of Department of Hematology at Monash University. "We were particularly excited to see that responses were generally consistent among patients with high-risk features and that zanubrutinib was generally well-tolerated."

At the data cutoff on August 14, 2020, 66 patients were evaluable for efficacy. With a median follow-up time of 10.7 months, results included:

- Across all subtypes in the trial, the investigator-assessed overall response rate (ORR), defined as partial response or better, was 74.2% (95% CI: 62.0, 84.2), including 16 (24.2%) complete responses (CRs) and 33 (50.0%) partial responses (PRs);
- Responses were generally consistent across all subgroups, including the following high-risk subgroups:
  - In patients who were 75 and older (n=18), the ORR was 88.9% (95% CI: 65.3, 98.6);
  - In patients who received at least three lines of prior therapy (n=17), the ORR was 64.7% (95% CI: 38.3, 85.8);
  - In patients with refractory disease (n=21), the ORR was 71.0% (95% CI: 47.8, 88.7);
  - In patients with nodal MZL (n=25), the ORR was 84.0% (95% CI: 63.9, 95.5);
- The median follow-up time for progression free survival (PFS) was 9.13 months, and the PFS rate at six months and nine months was 80.0% and 67.0%, respectively;
- 79.0% of the patients maintained response at six months and overall survival (OS) rate at 12 months was 94.0%
- 95.6% of patients experienced at least one treatment-emergent adverse event (TEAE) of any grade, with the most common (≥10.0%) being diarrhea (20.6%), contusion (19.1%), constipation (13.2%), neutropenia (13.2%), pyrexia (11.8%), upper respiratory tract infection (11.8%), thrombocytopenia (10.3%), and nausea (10.3%);
- 38.2% of patients experienced at least one Grade ≥3 TEAE, with the most common (in at least two patients) being neutropenia (10.3%), diarrhea (2.9%), pyrexia (2.9%), thrombocytopenia (2.9%), anemia (2.9%), and pneumonia (2.9%);
- 32.4% of patients experienced at least one serious TEAE; and
- Two patients discontinued treatment due to TEAEs, both considered unrelated to zanubrutinib, including one patient with pre-existing cardiovascular disease who experienced a fatal TEAE of myocardial infarction.

Follow-up Results from Arm C of the Phase 3 SEQUOIA Trial in TN Patients with CLL/SLL with del(17p)

Abstract 1306

Follow-up results from the non-randomized Arm C in the randomized, open-label, global Phase 3 SEQUOIA trial of zanubrutinib as a monotherapy (NCT03336333) exhibited a high ORR and a sustained PFS in patients with TN CLL/SLL whose tumor exhibited the deletion of chromosome 17p13.1 [del(17p)]. Compared to the initial results presented at the 2019 ASH meeting, with a longer median follow-up time of 21.9 months compared to 10 months, CR rate increased to 6.4% from 1.9%. Zanubrutinib's tolerability profile was generally consistent with previous reports of zanubrutinib treatment in patients with various B-cell malignancies.

"BTK inhibitors have demonstrated positive outcomes in CLL or SLL patients with del(17p), who usually respond poorly to standard chemoimmunotherapy, even in the frontline setting," said Jennifer R. Brown, M.D., Ph.D., Director of the Dana Farber Cancer Institute CLL Center and Professor of Medicine at Harvard Medical School. "With a median follow-up time of close to two years, we were able to observe a high progression-free survival rate of 90.6 percent at 18 months, an overall response rate of 94.5 percent, and a consistent tolerability profile for zanubrutinib."

At the data cutoff on August 10, 2020, all 109 patients enrolled in Arm C were evaluable for efficacy. With a median follow-up time of 21.9 months, results included:

- At 18 months, the PFS rate and OS rate were 90.6% (95% CI: 83.3, 94.9) and 95.4% (95% CI: 89.3, 98.1), respectively;
- At 18 months, the PFS rate among patients with unfavorable characteristics such as unmutated IGHV and complex karyotype status was 88.0% (95% CI: 78, 94) and 94.0% (95% CI: 77, 98), respectively;
- The investigator-assessed ORR was 94.5% (95% CI: 88.4, 98.0), including six (5.5%) CRs, one (0.9%) CR with incomplete bone marrow recovery, one (0.9%) nodular PR, 94 (86.2%) PRs, and one (0.9%) PR with lymphocytosis;
- 93.1% (95% CI: 86, 97) and 87.7% (95% CI: 78, 93) of the patients maintained response at 12 months and 18 months, respectively;
- The most common (≥10.0%) adverse events (AEs) of any grade included contusion (20.2%), upper respiratory tract infection (19.3%), diarrhea (17.4%), nausea (14.7%), back pain (13.8%), constipation (13.8%), rash (13.8%), cough (12.8%), neutropenia (11.9%), arthralgia (11.0%), and pneumonia (10.1%);
- 52.3% of patients experienced at least one Grade ≥3 AE, with the most common (in ≥2.0% of patients) being neutropenia/decreased neutrophil count (15.6%), pneumonia (4.6%), fall (2.8%), and hypertension (2.8%);
- 38.5% of the patients experienced at least one serious AE; and
- Five (4.6%) patients discontinued treatment due to AE, including two (1.8%) patients who experienced a fatal AE, one being pneumonia leading to sepsis and death, which was considered related to zanubrutinib, and the other being renal failure in the context of disease progression, which was considered unrelated to zanubrutinib.

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

BRUKINSA was approved by the U.S. FDA in November 2019 to treat adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy. This indication was approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

BRUKINSA was approved in China in June 2020 for the treatment of MCL in adult patients who have received at least one prior therapy and the treatment of CLL/SLL in adult patients who have received at least one prior therapy. A supplemental new drug application (sNDA) of BRUKINSA in patients with relapsed/refractory Waldenström's macroglobulinemia (WM) has been accepted by the Center for Drug Evaluation (CDE) of the NMPA and is currently under priority review.

A marketing authorization application (MAA) for BRUKINSA for the treatment of patients with WM who have received at least one prior therapy or as first-line treatment for patients unsuitable for chemo-immunotherapy has been accepted by the European Medicines Agency (EMA).

In addition, multiple regulatory filings of BRUKINSA have been accepted in other countries and are currently under review.
BRUKINSA is not approved outside of the United States and China.

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

Warnings and Precautions

Hemorrhage

Fatal and serious hemorrhagic events have occurred in patients with hematological malignancies treated with BRUKINSA monotherapy. Grade 3 or higher bleeding events including intracranial and gastrointestinal hemorrhage, hematuria and hemothorax have been reported in 2% of patients treated with BRUKINSA monotherapy. Bleeding events of any grade, including purpura and petechiae, occurred in 50% of patients treated with BRUKINSA monotherapy.

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

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

Infections

Fatal and serious infections (including bacterial, viral, or fungal) and opportunistic infections have occurred in patients with hematological malignancies treated with BRUKINSA monotherapy. Grade 3 or higher infections occurred in 23% of patients treated with BRUKINSA monotherapy. The most common Grade 3 or higher infection was pneumonia. Infections due to hepatitis B virus (HBV) reactivation have occurred.

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

Cytopenias

Grade 3 or 4 cytopenias, including neutropenia (27%), thrombocytopenia (10%), and anemia (8%) based on laboratory measurements, were reported in patients treated with BRUKINSA monotherapy.

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

Second Primary Malignancies

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

Cardiac Arrhythmias

Atrial fibrillation and atrial flutter have occurred in 2% of patients treated with BRUKINSA monotherapy. Patients with cardiac risk factors, hypertension, and acute infections may be at increased risk. Grade 3 or higher events were reported in 0.6% of patients treated with BRUKINSA monotherapy. Monitor signs and symptoms for atrial fibrillation and atrial flutter and manage as appropriate.

Embryo-Fetal Toxicity

Based on findings in animals, BRUKINSA can cause fetal harm when administered to a pregnant woman. Administration of zanubrutinib to pregnant rats during the period of organogenesis caused embryo-fetal toxicity, including malformations at exposures that were 5 times higher than those reported in patients at the recommended dose of 160 mg twice daily. Advise women to avoid becoming pregnant while taking BRUKINSA and for at least 1 week after the last dose. Advise men to avoid fathering a child during treatment and for at least 1 week after the last dose. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus.

Adverse Reactions

The most common adverse reactions in > 10% of patients who received BRUKINSA were neutrophil count decreased (53%), platelet count decreased (39%), upper respiratory tract infection (38%), white blood cell count decreased (30%), hemoglobin decreased (29%), rash (25%), bruising (23%), diarrhea (20%), cough (20%), musculoskeletal pain (19%), pneumonia (18%), urinary tract infection (13%), hematuria (12%), fatigue (11%), constipation (11%), and hemorrhage (10%). The most frequent serious adverse reactions were pneumonia (11%) and hemorrhage (5%).

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

Drug Interactions

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

CYP3A Inducers: Avoid co-administration with moderate or strong CYP3A inducers.

Specific Populations

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

INDICATION

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

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

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

About BeiGene

BeiGene is a global, commercial-stage biotechnology company focused on discovering, developing, manufacturing, and commercializing innovative medicines to improve treatment outcomes and access for patients worldwide. Our 4,700+ employees in China, the United States, Australia, Europe, and elsewhere are committed to expediting the development of a diverse pipeline of novel therapeutics. We currently market two internally discovered oncology products: BTK inhibitor BRUKINSA® (zanubrutinib) in the United States and China, and anti-PD-1 antibody tislelizumab in China. We also market or plan to market in China additional oncology products licensed from Amgen Inc., Celgene Logistics Sàrl, a Bristol Myers Squibb (BMS) company, and EUSA Pharma. To learn more about BeiGene, please visit www.beigene.com and follow us on Twitter at @BeiGeneUSA.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws, including statements regarding promising clinical results from trials of BRUKINSA (zanubrutinib) and BeiGene's further advancement of, and anticipated clinical development, regulatory milestones and commercialization of BRUKINSA (zanubrutinib). Actual results may differ materially from those indicated in the forward-looking statements as a result of various important factors, including BeiGene's ability to demonstrate the efficacy and safety of its drug candidates; the clinical results for its drug candidates, which may not support further development or marketing approval; actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials and marketing approval; BeiGene's ability to achieve commercial success for its marketed products and drug candidates, if approved; BeiGene's ability to obtain and maintain protection of intellectual property for its technology and drugs; BeiGene's reliance on third parties to conduct drug development, manufacturing and other services; BeiGene's limited operating history and BeiGene's ability to obtain additional funding for operations and to complete the development and commercialization of its drug candidates; the impact of the COVID-19 pandemic on the Company's clinical development, commercial and other operations, as well as those risks more fully discussed in the section entitled "Risk Factors" in BeiGene's most recent quarterly report on Form 10-Q, as well as discussions of potential risks, uncertainties, and other important factors in BeiGene's subsequent filings with the U.S. Securities and Exchange Commission. All information in this press release is as of the date of this press release, and BeiGene undertakes no duty to update such information unless required by law.

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Exhibit 99.2

BeiGene Presents Clinical Data on BRUKINSA® (Zanubrutinib) in B-Cell Malignancies and Waldenström's Macroglobulinemia at the 62nd ASH Annual Meeting

In previously treated patients with B-cell malignancies who were intolerant to other BTK inhibitors, adverse events were unlikely to recur on zanubrutinib with responses maintained or improved compared to prior treatment

Zanubrutinib demonstrated deep and durable responses in relapsed/refractory Waldenström's Macroglobulinemia Patients in a pivotal Phase 2 trial in China; data submitted for regulatory approval in China

CAMBRIDGE, Mass. and BEIJING, China – December 7, 2020 -- BeiGene, Ltd. (NASDAQ: BGNE; HKEX: 06160), a commercial-stage biotechnology company focused on developing and commercializing innovative medicines worldwide, today presented clinical data on its BTK inhibitor BRUKINSA® (zanubrutinib) in two posters at the 62nd American Society for Hematology (ASH) Annual Meeting, including results from a Phase 2 trial in patients with relapsed/refractory (R/R) B-cell malignancies who were intolerant to ibrutinib and/or acalabrutinib and the first results from a pivotal Phase 2 trial in patients with R/R Waldenström's Macroglobulinemia (WM) that were included in a supplemental new drug application of BRUKINSA currently under priority review in China.

"Tolerability of treatments for B-cell malignancies is an important consideration with BTK inhibition, and BRUKINSA was designed with that in mind to maximize BTK occupancy and minimize off-target effects. Following on the results of the Phase 3 ASPEN trial, in which BRUKINSA demonstrated advantages in safety and tolerability compared to ibrutinib in patients with WM, we're excited to learn from the Phase 2 trial that BRUKINSA was tolerable and showed activity in patients who discontinued treatment with ibrutinib and/or acalabrutinib due to adverse events," said Jane Huang, M.D., Chief Medical Officer, Hematology at BeiGene. "Additionally, we reported data from our pivotal Phase 2 trial in China in patients with relapsed/refractory WM, which showed deep responses in a difficult-to-treat patient population. With a growing clinical development team across the globe, we look forward to continuing to advance our clinical program for BRUKINSA."

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 Zanubrutinib in Patients with Previously Treated B-Cell Malignancies Intolerant to Ibrutinib and/or Acalabrutinib

Abstract 2947

This single-arm, open-label, multicenter Phase 2 trial in the U.S. (NCT04116437) was designed to evaluate the safety and efficacy of BRUKINSA in patients with previously treated B-cell malignancies who were intolerant to prior treatment with ibrutinib and/or acalabrutinib. 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 overall response rate (ORR), investigator-assessed progression-free survival (PFS) and patient-reported outcomes. A total of 60 patients with chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL), WM, mantle cell lymphoma (MCL) or marginal zone lymphoma (MZL) intolerant to ibrutinib and/or acalabrutinib were enrolled in this trial.
"BTK inhibitors are an emerging standard of care in B-cell malignancies, but off-target effects have been implicated in adverse events – the most common reason for treatment discontinuation. Data from 32 evaluable patients in this trial demonstrated that some intolerable adverse events that patients experienced on other BTK inhibitors did not recur with zanubrutinib treatment, and that it was generally well-tolerated among these patients," 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.

At the data cutoff on August 28, 2020, with a median zanubrutinib exposure of 3.5 months, safety results from 32 evaluable patients included:

- In 32 patients previously treated with and intolerant to ibrutinib, there were 66 intolerant events, 58 (88%) of which did not recur with zanubrutinib treatment; of the eight intolerant events that recurred, seven recurred at a lower grade in severity and one at the same grade;
- In two patients previously treated with and intolerant to acalabrutinib, there were four intolerant events, two of which did not recur (both arthralgia) with zanubrutinib treatment; of the two intolerant events that recurred, one recurred at a lower grade in severity and one at the same grade;
- Of the 25 Grade 3 intolerant events on ibrutinib and/or acalabrutinib, 23 did not recur with zanubrutinib treatment;
- Of the four Grade 4 intolerant events, which were neutropenia (n=2), increased alanine aminotransferase (ALT) (n=1), and increased aspartate aminotransferase (AST) (n=1), none recurred with zanubrutinib treatment;
- 26 patients experienced at least one AE of any grade on zanubrutinib, with the most common (≥10.0%) being myalgia (21.9%), contusion (18.8%), cough (15.6%), dizziness (15.6%), and fatigue (12.5%);
- Eight patients experienced bleeding events on zanubrutinib, all in low-grade severity;
- Atrial fibrillation did not recur in six patients who were intolerant to ibrutinib due to atrial fibrillation. Atrial fibrillation and flutter recurred in one patient (3.1%) who was previously treated with and intolerant to ibrutinib at a lower severity (Grade 2 on zanubrutinib vs. Grade 3 on ibrutinib) with a shorter duration (3 days on zanubrutinib vs. 14 days on ibrutinib);

- Three patients experienced at least one Grade ≥3 AE, including neutropenia (n=2) and syncope (n=1); and
- No serious adverse events (SAEs) or treatment discontinuation due to AEs were reported.

Among the 18 patients who were evaluable for response at the time of data cutoff (13 for CLL, 4 for SLL and 1 for MCL), 17 maintained (n=8) or improved (n=9) responses on zanubrutinib. With the median time to first response being 12.6 weeks, the ORR was 50%, including six (33.3%) PRs and three (16.7%) PRs with lymphocytosis.

Pivotal Phase 2 Trial of Zanubrutinib in Patients with R/R WM in China

Abstract 2940

Data from this single-arm, open-label, multicenter, pivotal Phase 2 trial (NCT03332173) showed that R/R WM patients in China were able to achieve deep, quick, and durable responses on zanubrutinib. A total of 44 patients were enrolled in the trial, including 20 with high risk and 13 with intermediate risk based on WM prognostic scoring, and 43 patients were evaluable for efficacy.

"From the results of the BGB-3111-210 trial, we were encouraged to see a major response rate of nearly 70 percent and a median time to major response under three months, which means zanubrutinib was able to quickly induce deep responses in these WM patients, most of whom were determined to have intermediate to high risks based on the prognostic score," said Lugui Qiu, M.D., Director at Department of Lymphoma in Chinese Academy of Medical Sciences Blood Diseases Hospital and leading Principal Investigator of the trial. "Zanubrutinib also demonstrated a safety profile consistent with previous reports in WM. We hope this BTK inhibitor will become a new effective treatment option for WM patients in China in the near future."

At the data cutoff on August 31, 2019, 27 patients remained on study treatment. With a median follow-up time of 18.58 months, results included:

- Major response rate (MRR), defined as partial response or better, was 69.8% (95% CI: 53.9, 82.8), including 32.6% very good partial responses (VGPRs) and 37.2% partial responses (PRs); ORR, defined as minor response or better, was 79.1% (95% CI: 64.0, 90.0);
- The median time to VGPR and overall response was 2.87 months and 2.76 months, respectively;
- Median progression free survival (PFS) and duration of major response (DOMR) were not reached;
- The most common (≥20.0%) treatment-emergent adverse events (TEAEs) of any grade were decreased neutrophil count (56.8%), decreased platelet count (29.5%), decreased white blood cell count (27.3%), upper respiratory tract infection (27.3%), diarrhea (25.0%), weight increase (20.5%), and arthralgia (20.5%);
- 72.7% of patients experienced at least one Grade ≥3 TEAE, with the most common (≥10.0%) being decreased neutrophil count (31.8%), decreased platelet count (20.5%), lung infection (13.6%), and decreased white blood cell count (11.4%);
- 50.0% of patients experienced at least one serious TEAE and 11.4% of patients discontinued treatment due to TEAEs; and
- 4.5% of patients experienced a fatal TEAE, with one patient caused by multiple organ dysfunction syndrome and acute hepatitis B, and the other one being death with unknown reason, which was considered by investigator to be caused by progression of WM and accompanying respiratory failure.

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

BRUKINSA was approved by the U.S. FDA in November 2019 to treat adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy. This indication was approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

BRUKINSA was approved in China in June 2020 for the treatment of MCL in adult patients who have received at least one prior therapy and the treatment of CLL/SLL in adult patients who have received at least one prior therapy. A supplemental new drug application (sNDA) of BRUKINSA in patients with relapsed/refractory Waldenström's macroglobulinemia (WM) has been accepted by the Center for Drug Evaluation (CDE) of the NMPA and is currently under priority review.

A marketing authorization application (MAA) for BRUKINSA for the treatment of patients with WM who have received at least one prior therapy or as first-line treatment for patients unsuitable for chemo-immunotherapy has been accepted by the European Medicines Agency (EMA).

In addition, multiple regulatory filings of BRUKINSA have been accepted in other countries and are currently under review.

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

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

Warnings and Precautions

Hemorrhage

Fatal and serious hemorrhagic events have occurred in patients with hematological malignancies treated with BRUKINSA monotherapy. Grade 3 or higher bleeding events including intracranial and gastrointestinal hemorrhage, hematuria and hemothorax have been reported in 2% of patients treated with BRUKINSA monotherapy. Bleeding events of any grade, including purpura and petechiae, occurred in 50% of patients treated with BRUKINSA monotherapy.

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

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

Infections

Fatal and serious infections (including bacterial, viral, or fungal) and opportunistic infections have occurred in patients with hematological malignancies treated with BRUKINSA monotherapy. Grade 3 or higher infections occurred in 23% of patients treated with BRUKINSA monotherapy. The most common Grade 3 or higher infection was pneumonia. Infections due to hepatitis B virus (HBV) reactivation have occurred.

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

Cytopenias

Grade 3 or 4 cytopenias, including neutropenia (27%), thrombocytopenia (10%), and anemia (8%) based on laboratory measurements, were reported in patients treated with BRUKINSA monotherapy.

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

Second Primary Malignancies

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

Cardiac Arrhythmias

Atrial fibrillation and atrial flutter have occurred in 2% of patients treated with BRUKINSA monotherapy. Patients with cardiac risk factors, hypertension, and acute infections may be at increased risk. Grade 3 or higher events were reported in 0.6% of patients treated with BRUKINSA monotherapy. Monitor signs and symptoms for atrial fibrillation and atrial flutter and manage as appropriate.

Embryo-Fetal Toxicity
Based on findings in animals, BRUKINSA can cause fetal harm when administered to a pregnant woman. Administration of zanubrutinib to pregnant rats during the period of organogenesis caused embryo-fetal toxicity, including malformations at exposures that were 5 times higher than those reported in patients at the recommended dose of 160 mg twice daily. Advise women to avoid becoming pregnant while taking BRUKINSA and for at least 1 week after the last dose. Advise men to avoid fathering a child during treatment and for at least 1 week after the last dose. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus.

Adverse Reactions

The most common adverse reactions in > 10% of patients who received BRUKINSA were neutrophil count decreased (53%), platelet count decreased (39%), upper respiratory tract infection (38%), white blood cell count decreased (30%), hemoglobin decreased (29%), rash (25%), bruising (23%), diarrhea (20%), cough (20%), musculoskeletal pain (19%), pneumonia (18%), urinary tract infection (13%), hematuria (12%), fatigue (11%), constipation (11%), and hemorrhage (10%). The most frequent serious adverse reactions were pneumonia (11%) and hemorrhage (5%).

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

Drug Interactions

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

CYP3A Inducers: Avoid co-administration with moderate or strong CYP3A inducers.

Specific Populations

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

INDICATION

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

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

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

About BeiGene

BeiGene is a global, commercial-stage biotechnology company focused on discovering, developing, manufacturing, and commercializing innovative medicines to improve treatment outcomes and access for patients worldwide. Our 4,700+ employees in China, the United States, Australia, Europe, and elsewhere are committed to expediting the development of a diverse pipeline of novel therapeutics. We currently market two internally discovered oncology products: BTK inhibitor BRUKINSA® (zanubrutinib) in the United States and China, and anti-PD-1 antibody tislelizumab in China. We also market or plan to market in China additional oncology products licensed from Amgen Inc., Celgene Logistics Sàrl, a Bristol Myers Squibb (BMS) company, and EUSA Pharma. To learn more about BeiGene, please visit www.beigene.com and follow us on Twitter at @BeiGeneUSA.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws, including statements regarding promising clinical results from trials of BRUKINSA (zanubrutinib) and BeiGene's further advancement of, and anticipated clinical development, regulatory milestones and commercialization of BRUKINSA (zanubrutinib). Actual results may differ materially from those indicated in the forward-looking statements as a result of various important factors, including BeiGene's ability to demonstrate the efficacy and safety of its drug candidates; the clinical results for its drug candidates, which may not support further development or marketing approval; actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials and marketing approval; BeiGene's ability to achieve commercial success for its marketed products and drug candidates, if approved; BeiGene's ability to obtain and maintain protection of intellectual property for its technology and drugs; BeiGene's reliance on third parties to conduct drug development, manufacturing and other services; BeiGene's limited operating history and BeiGene's ability to obtain additional funding for operations and to complete the development and commercialization of its drug candidates; the impact of the COVID-19 pandemic on the Company's clinical development, commercial and other operations, as well as those risks more fully discussed in the section entitled "Risk Factors" in BeiGene's most recent quarterly report on Form 10-Q, as well as discussions of potential risks, uncertainties, and other important factors in BeiGene's subsequent filings with the U.S. Securities and Exchange Commission. All information in this press release is as of the date of this press release, and BeiGene undertakes no duty to update such information unless required by law.

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Exhibit 99.3

BeiGene Announces the Approval in China of BLINCYTO® (Blinatumomab) for Injection for Adult Patients with Relapsed or Refractory B-Cell Precursor Acute Lymphoblastic Leukemia (ALL)

BEIJING, China and CAMBRIDGE, Mass., December 7, 2020 -- BeiGene, Ltd. (NASDAQ: BGNE; HKEX: 06160), a commercial-stage biotechnology company focused on developing and commercializing innovative medicines worldwide, today announced that the China National Medical Products Administration (NMPA) has approved BLINCYTO® (blinatumomab) for injection for the treatment of adult patients with relapsed or refractory (R/R) B-cell precursor acute lymphoblastic leukemia (ALL). The biologics license application (BLA) had been submitted by Amgen and received priority review by the Center for Drug Evaluation (CDE) of the NMPA. Developed by Amgen and licensed to BeiGene in China under a strategic collaboration commenced earlier this year, this is the first approval for BLINCYTO in China and BeiGene's first product licensed from Amgen to be newly approved. With this approval, BLINCYTO has become the first bispecific immunotherapy approved in China.

"This approval of BLINCYTO provides us with an opportunity to offer adult patients in China with relapsed or refractory B-cell precursor ALL the first approved immunotherapy treatment for their disease. BLINCYTO is the first immunotherapy to demonstrate superior overall survival versus chemotherapy, more than doubling patients' chances for survival, when used in first salvage R/R ALL in studies outside of China," commented Xiaobin Wu, Ph.D., General Manager of China and President of BeiGene. "We are working to ensure BLINCYTO is available to patients in China as soon as possible. Our commercial organization of more than 1,500 people in China is excited to add BLINCYTO to our product portfolio, which now includes six approved cancer treatments."

The approval of BLINCYTO was based on results from the Phase 3 trial (NCT03476239) in China evaluating the efficacy and safety of BLINCYTO in adult patients with Philadelphia-negative R/R B-cell precursor ALL. Results of the interim analysis of 67 patients showed that the efficacy results in Chinese subjects were generally consistent with those in the global and Japan studies in subjects with Philadelphia-negative R/R ALL. The complete response/complete response with partial recovery of blood cells (CR/CRh) rate within two cycles of BLINCYTO treatment (the primary endpoint) was 47.8% (32 of 67 subjects; 95% CI: 35.4, 60.3). The median overall survival time was 9.6 months (95% CI: 6.4, not estimable). The safety profile observed for Chinese subjects in this study was consistent with that observed in the global studies evaluating BLINCYTO in R/R ALL. No new safety risks were identified based on these interim analyses of adverse events in Chinese subjects.

"Our collaboration with BeiGene is advancing Amgen's oncology pipeline for patients with significant unmet medical needs. We are confident the approval of BLINCYTO in China has the potential to make a meaningful difference to adult patients with R/R B-cell precursor acute lymphoblastic leukemia," said My Linh Kha, Vice President & General Manager, Amgen Japan Asia-Pacific (JAPAC). "We are deeply committed to continuing to bring therapeutic options to treat debilitating cancers for patients in China, while also actively supporting the Government's focus on healthy aging through innovative products and initiatives designed to prevent chronic diseases, such as cardiovascular disease and fragility fracture."

About Acute Lymphoblastic Leukemia (ALL)

Acute lymphoblastic leukemia (ALL), also known as acute lymphocytic leukemia, is a rapidly progressing cancer of the blood and bone marrow that occurs in both adults and children[i]. ALL accounts for approximately 20% of all adult leukemia, and in China there were an estimated 82,607 new cases of leukemia in 2018[ii,iii]. In children, the relapse rate of ALL is nearly 10%, while in adults the relapse rate is closer to 50%[iv].

About BLINCYTO® (blinatumomab)

BLINCYTO is a bispecific CD19-directed CD3 T cell engager (BiTE®) immuno-oncology molecule that binds specifically to CD19 expressed on the surface of cells of B-lineage origin and CD3 expressed on the surface of T cells.

BiTE molecules are a type of immuno-oncology therapy being investigated for fighting cancer by helping the body's immune system to detect and target malignant cells. The modified molecules are designed to engage two different targets simultaneously, thereby juxtaposing T cells (a type of white blood cell capable of killing other cells perceived as threats) to cancer cells. BiTE immuno-oncology molecules help place the T cells within reach of the targeted cell, with the intent of allowing T cells to inject toxins and trigger the cancer cell to die (apoptosis). BiTE immuno-oncology therapies are currently being investigated for their potential to treat a wide variety of cancers.

BLINCYTO was granted breakthrough therapy and priority review designations by the U.S. Food and Drug Administration and is approved in the U.S. for the treatment of:

- relapsed or refractory B-cell precursor ALL in adults and children.
- B-cell precursor ALL in first or second complete remission with minimal residual disease (MRD) greater than or equal to 0.1% in adults and children. This indication is approved under accelerated approval based on MRD response rate and hematological relapse-free survival. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

In the European Union (EU), BLINCYTO is indicated as monotherapy for the treatment of:

- adults with Philadelphia chromosome negative CD19-positive relapsed or refractory B-precursor acute lymphoblastic leukemia (ALL).
- adults with Philadelphia chromosome negative CD19-positive B-precursor ALL in first or second complete remission with minimal residual disease (MRD) greater than or equal to 0.1%.
- pediatric patients age 1 year or older with Philadelphia chromosome-negative CD19-positive B-precursor ALL which is refractory or in relapse after receiving at least two prior therapies or in relapse after receiving prior allogeneic hematopoietic stem cell transplantation.

In China, BLINCYTO is indicated for the treatment of adult patients with relapsed or refractory B-cell precursor ALL.

Important U.S. Safety Information

WARNING: CYTOKINE RELEASE SYNDROME and NEUROLOGICAL TOXICITIES

- **Cytokine Release Syndrome (CRS), which may be life-threatening or fatal, occurred in patients receiving BLINCYTO®. Interrupt or discontinue BLINCYTO® and treat with corticosteroids as recommended.**
- **Neurological toxicities, which may be severe, life-threatening or fatal, occurred in patients receiving BLINCYTO®. Interrupt or discontinue BLINCYTO® as recommended.**

Contraindications

BLINCYTO® is contraindicated in patients with a known hypersensitivity to blinatumomab or to any component of the product formulation.

Warnings and Precautions

- Cytokine Release Syndrome (CRS): CRS, which may be life-threatening or fatal, occurred in 15% of patients with R/R ALL and in 7% of patients with MRD-positive ALL. The median time to onset of CRS is 2 days after the start of infusion and the median time to resolution of CRS was 5 days among cases that resolved. Closely monitor and advise patients to contact their healthcare professional for signs and symptoms of serious adverse events such as fever, headache, nausea, asthenia, hypotension, increased alanine aminotransferase (ALT), increased aspartate aminotransferase (AST), increased total bilirubin (TBILI), and disseminated intravascular coagulation (DIC). The manifestations of CRS after treatment with BLINCYTO® overlap with those of infusion reactions, capillary leak syndrome, and hemophagocytic histiocytosis/macrophage activation syndrome. If severe CRS occurs, interrupt BLINCYTO® until CRS resolves. Discontinue BLINCYTO® permanently if life-threatening CRS occurs. Administer corticosteroids for severe or life-threatening CRS.

- Neurological Toxicities: Approximately 65% of patients receiving BLINCYTO® in clinical trials experienced neurological toxicities. The median time to the first event was within the first 2 weeks of BLINCYTO® treatment and the majority of events resolved. The most common (≥ 10%) manifestations of neurological toxicity were headache and tremor. Severe, life-threatening, or fatal neurological toxicities occurred in approximately 13% of patients, including encephalopathy, convulsions, speech disorders, disturbances in consciousness, confusion and disorientation, and coordination and balance disorders. Manifestations of neurological toxicity included cranial nerve disorders. Monitor patients for signs or symptoms and interrupt or discontinue BLINCYTO® as outlined in the PI.

- Infections: Approximately 25% of patients receiving BLINCYTO® in clinical trials experienced serious infections such as sepsis, pneumonia, bacteremia, opportunistic infections, and catheter-site infections, some of which were life-threatening or fatal. Administer prophylactic antibiotics and employ surveillance testing as appropriate during treatment. Monitor patients for signs or symptoms of infection and treat appropriately, including interruption or discontinuation of BLINCYTO® as needed.

- Tumor Lysis Syndrome (TLS), which may be life-threatening or fatal, has been observed. Preventive measures, including pretreatment nontoxic cytoreduction and on-treatment hydration, should be used during BLINCYTO® treatment. Monitor patients for signs and symptoms of TLS and interrupt or discontinue BLINCYTO® as needed to manage these events.

- Neutropenia and Febrile Neutropenia, including life-threatening cases, have been observed. Monitor appropriate laboratory parameters (including, but not limited to, white blood cell count and absolute neutrophil count) during BLINCYTO® infusion and interrupt BLINCYTO® if prolonged neutropenia occurs.

- Effects on Ability to Drive and Use Machines: Due to the possibility of neurological events, including seizures, patients receiving BLINCYTO® are at risk for loss of consciousness, and should be advised against driving and engaging in hazardous occupations or activities such as operating heavy or potentially dangerous machinery while BLINCYTO® is being administered.

- Elevated Liver Enzymes: Transient elevations in liver enzymes have been associated with BLINCYTO® treatment with a median time to onset of 3 days. In patients receiving BLINCYTO®, although the majority of these events were observed in the setting of CRS, some cases of elevated liver enzymes were observed outside the setting of CRS, with a median time to onset of 19 days. Grade 3 or greater elevations in liver enzymes occurred in approximately 7% of patients outside the setting of CRS and resulted in treatment discontinuation in less than 1% of patients. Monitor ALT, AST, gamma-glutamyl transferase, and TBILI prior to the start of and during BLINCYTO® treatment. BLINCYTO® treatment should be interrupted if transaminases rise to > 5 times the upper limit of normal (ULN) or if TBILI rises to > 3 times ULN.

- Pancreatitis: Fatal pancreatitis has been reported in patients receiving BLINCYTO® in combination with dexamethasone in clinical trials and the post-marketing setting. Evaluate patients who develop signs and symptoms of pancreatitis and interrupt or discontinue BLINCYTO® and dexamethasone as needed.

- Leukoencephalopathy: Although the clinical significance is unknown, cranial magnetic resonance imaging (MRI) changes showing leukoencephalopathy have been observed in patients receiving BLINCYTO®, especially in patients previously treated with cranial irradiation and antileukemic chemotherapy.

- Preparation and administration errors have occurred with BLINCYTO® treatment. Follow instructions for preparation (including admixing) and administration in the PI strictly to minimize medication errors (including underdose and overdose).

- Immunization: Vaccination with live virus vaccines is not recommended for at least 2 weeks prior to the start of BLINCYTO® treatment, during treatment, and until immune recovery following last cycle of BLINCYTO®.

- Risk of Serious Adverse Reactions in Pediatric Patients due to Benzyl Alcohol Preservative: Serious and fatal adverse reactions including "gasping syndrome," which is characterized by central nervous system depression, metabolic acidosis, and gasping respirations, can occur in neonates and infants treated with benzyl alcohol-preserved drugs including BLINCYTO® (with preservative). When prescribing BLINCYTO® (with preservative) for pediatric patients, consider the combined daily metabolic load of benzyl alcohol from all sources including BLINCYTO® (with preservative) and other drugs containing benzyl alcohol. The minimum amount of benzyl alcohol at which serious adverse reactions may occur is not known. Due to the addition of bacteriostatic saline, 7-day bags of BLINCYTO® solution for infusion with preservative contain benzyl alcohol and are not recommended for use in any patients weighing < 22 kg.

Adverse Reactions

- The most common adverse reactions (≥ 20%) in clinical trial experience of patients with MRD-positive B-cell precursor ALL (BLAST Study) treated with BLINCYTO® were pyrexia (91%), infusion-related reactions (77%), headache (39%), infections (pathogen unspecified [39%]), tremor (31%), and chills (28%). Serious adverse reactions were reported in 61% of patients. The most common serious adverse reactions (≥ 2%) included pyrexia, tremor, encephalopathy, aphasia, lymphopenia, neutropenia, overdose, device related infection, seizure, and staphylococcal infection.

- The most common adverse reactions (≥ 20%) in clinical trial experience of patients with Philadelphia chromosome-negative relapsed or refractory B-cell precursor ALL (TOWER Study) treated with BLINCYTO® were infections (bacterial and pathogen unspecified), pyrexia, headache, infusion-related reactions, anemia, febrile neutropenia, thrombocytopenia, and neutropenia. Serious adverse reactions were reported in 62% of patients. The most common serious adverse reactions (≥ 2%) included febrile neutropenia, pyrexia, sepsis, pneumonia, overdose, septic shock, CRS, bacterial sepsis, device related infection, and bacteremia.

- Adverse reactions that were observed more frequently (≥ 10%) in the pediatric population compared to the adults with relapsed or refractory B-cell precursor ALL were pyrexia (80% vs. 61%), hypertension (26% vs. 8%), anemia (41% vs. 24%), infusion-related reaction (49% vs. 34%), thrombocytopenia (34% vs. 21%), leukopenia (24% vs. 11%), and weight increased (17% vs. 6%).

- In pediatric patients less than 2 years old (infants), the incidence of neurologic toxicities was not significantly different than for the other age groups, but its manifestations were different; the only event terms reported were agitation, headache, insomnia, somnolence, and irritability. Infants also had an increased incidence of hypokalemia (50%) compared to other pediatric age cohorts (15-20%) or adults (17%).

Dosage and Administration Guidelines

- BLINCYTO® is administered as a continuous intravenous infusion at a constant flow rate using an infusion pump which should be programmable, lockable, non-elastomeric, and have an alarm.

- It is very important that the instructions for preparation (including admixing) and administration provided in the full Prescribing Information are strictly followed to minimize medication errors (including underdose and overdose).

Please see full Prescribing Information and medication guide for BLINCYTO at www.BLINCYTO.com.

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

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