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): January 18, 2023

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

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

c/o Mourant Governance Services (Cayman) Limited
94 Solaris Avenue, Camana Bay
Grand Cayman KY1-1108
Cayman Islands
(Address of Principal Executive Offices) (Zip Code)
+1 (345) 949-4123
(Registrant's telephone number, including area code)
Not Applicable
(Former name or former address, if changed since last report)

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

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

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

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

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

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

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

Item 8.01. Other Events.

On January 18, 2023, BeiGene, Ltd. ("BeiGene") announced that the National Reimbursement Drug List ("NRDL") released by China's National Healthcare Security Administration has been updated to include four new indications for its PD-1 inhibitor tislelizumab. KYPROLIS®, a proteosome inhibitor licensed-in from Amgen, is included for the first time and XGEVA®, a RANKL inhibitor and another Amgen asset, successfully renewed this year. The updated NRDL will officially take effect on March 1, 2023. 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 January 19, 2023, BeiGene announced that the U.S. Food and Drug Administration has approved its Bruton's tyrosine kinase inhibitor BRUKINSA (zanubrutinib) for the treatment of adult patients with chronic lymphocytic leukemia or small lymphocytic lymphoma. The full text of this press release is filed as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	
99.1	Press release titled "BeiGene Announces Expansion of Coverage on China's National Reimbursement Drug List" issued by BeiGene, Ltd. on January 18, 2023
99.2	Press release titled "BRUKINSA® Approved in the U.S. for Chronic Lymphocytic Leukemia" issued by BeiGene, Ltd. on January 19, 2023
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: January 23, 2023

By: /s/ Chan Lee
Name: Chan Lee
Title: Senior Vice President, General Counsel

Exhibit 99.1

BeiGene Announces Expansion of Coverage on China's National Reimbursement Drug List

Four new indications added for tislelizumab and all nine approved indications now included in NRDL

KYPROLIS® included for the first time

XGEVA® successfully renewed

CAMBRIDGE, Mass. & BASEL, Switzerland & BEIJING – January 18, 2023 – BeiGene (NASDAQ: BGNE; HKEX: 06160; SSE: 688235), a global biotechnology company, today announced that the National Reimbursement Drug List (NRDL) released by China's National Healthcare Security Administration (NHSA) has been updated to include four new indications for its PD-1 inhibitor tislelizumab. KYPROLIS® (carfilzomib), a proteosome inhibitor licensed-in from Amgen, is included for the first time and XGEVA® (denosumab), a RANKL inhibitor and another Amgen asset, successfully renewed this year. The updated NRDL will officially take effect on March 1, 2023.

"The expanded coverage of tislelizumab, new inclusion of KYPROLIS, as well as the renewal of XGEVA on the latest NRDL will allow more patients in China to have access to these high-quality medicines at affordable prices," said Xiaobin Wu, Ph.D., President, Chief Operating Officer, and General Manager of China, at BeiGene. "After several years of reform, the NHSA has established a basic medical insurance system with universal coverage. Through the annual updates of the NRDL, it made a leap forward in broadening access to innovative oncology medicines across China. At BeiGene, we share this same vision and endeavor to advance global health by making innovative medicines more accessible and affordable to patients in China and globally."

The following medicines and indications have been included in the updated NRDL:

Tislelizumab is now included in four new indications in NRDL:

- For the treatment of adult patients with locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC) who are negative for epidermal growth factor receptor (EGFR) and anaplastic mesenchymal lymphoma kinase (ALK) mutations and have progressed after or are intolerant of prior chemotherapy with platinum-containing regimens; and adult patients with locally advanced or metastatic squamous NSCLC who are negative or unknown for EGFR and ALK mutations and have progressed after or are intolerant of prior chemotherapy with platinum-containing regimens.
- For the treatment of adult patients with advanced unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumors: patients with advanced colorectal cancer with disease progression after prior treatment with fluoropyrimidines, oxaliplatin and irinotecan; patients with other advanced solid tumors with disease progression after prior treatment and no satisfactory alternative treatment options.
- For the treatment of patients with locally advanced or metastatic esophageal squamous cell carcinoma who have progressed after or are intolerant of prior first-line standard chemotherapy.
- As a first-line treatment for patients with recurrent or metastatic nasopharyngeal cancer.

KYPROLIS is now included in its approved indication:

- For the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least two prior therapies, including a proteasome inhibitor and an immunomodulatory agent.

XGEVA is successfully renewed in NRDL

- For the treatment of patients with giant cell tumor of the bone (GCTB) that is unresectable or where surgical resection is likely to result in severe morbidity (first included in NRDL in 2020).

About Tislelizumab

Tislelizumab is a humanized IgG4 anti-PD-1 monoclonal antibody specifically designed to minimize binding to Fcγ receptors on macrophages, helping to aid the body's immune cells to detect and fight tumors.

Tislelizumab is the first investigational medicine from BeiGene's immuno-oncology biologics program and is being evaluated in solid tumor and hematologic malignancies, as monotherapy and in combination.

The global tislelizumab clinical development program includes more than 11,500 subjects enrolled to-date in 21 registration-enabling trials, from more than 30 countries and regions.

Biologics License Applications (BLA) for tislelizumab are under review with U.S. and European Union (E.U.) regulators; for unresectable recurrent locally advanced or metastatic esophageal squamous cell carcinoma (ESCC) in the U.S.; for non-small cell lung cancer and unresectable recurrent locally advanced or metastatic ESCC in the E.U.

About KYPROLIS (carfilzomib) for injection

Proteasomes play an important role in cell function and growth by breaking down proteins that are damaged or no longer needed.[1] KYPROLIS has been shown to block proteasomes, leading to an excessive build-up of proteins within cells.[2] In some cells, KYPROLIS can cause cell death, especially in myeloma cells because they are more likely to contain a higher amount of abnormal proteins.[1,2]

Since its first approval in 2012, approximately 200,000 patients worldwide have received KYPROLIS.[3]

KYPROLIS is approved in the U.S. for the following:

- for the treatment of adult patients with relapsed or refractory multiple myeloma who have received one to three lines of therapy in combination with
    - Lenalidomide and dexamethasone; or
    - Dexamethasone; or
    - Daratumumab and dexamethasone; or
    - Daratumumab and hyaluronidase-fihj and dexamethasone
- as a single agent for the treatment of patients with relapsed or refractory multiple myeloma who have received one or more lines of therapy.

KYPROLIS is also approved in more than 40 markets Including Algeria, Argentina, Australia, Bahrain, Belarus, Brazil, Canada, Chile, China, Colombia, Ecuador, Egypt, European Union, India, Israel, Japan, Jordan, Kazakhstan, Kuwait, Lebanon, Malaysia, Mexico, Morocco, New Zealand, Oman, Peru, Philippines, Qatar, Russia, Saudi Arabia, Serbia, Singapore, S. Africa, S. Korea, Switzerland, Thailand, Turkey, United Arab Emirates, and the United Kingdom.

U.S. KYPROLIS® (carfilzomib) Important Safety Information

Cardiac Toxicities

- New onset or worsening of pre-existing cardiac failure (e.g., congestive heart failure, pulmonary edema, decreased ejection fraction), restrictive cardiomyopathy, myocardial ischemia, and myocardial infarction including fatalities have occurred following administration of KYPROLIS. Some events occurred in patients with normal baseline ventricular function. Death due to cardiac arrest has occurred within one day of administration.
- Monitor patients for signs or symptoms of cardiac failure or ischemia. Evaluate promptly if cardiac toxicity is suspected. Withhold KYPROLIS for Grade 3 or 4 cardiac adverse events until recovery, and consider whether to restart at 1 dose level reduction based on a benefit/risk assessment.
- While adequate hydration is required prior to each dose in Cycle 1, monitor all patients for evidence of volume overload, especially patients at risk for cardiac failure. Adjust total fluid intake as clinically appropriate.
- For patients ≥ 75 years, the risk of cardiac failure is increased. Patients with New York Heart Association Class III and IV heart failure, recent myocardial infarction, conduction abnormalities, angina, or arrhythmias may be at greater risk for cardiac complications and should have a comprehensive medical assessment prior to starting treatment with KYPROLIS and remain under close follow-up with fluid management.

Acute Renal Failure

- Cases of acute renal failure, including some fatal renal failure events, and renal insufficiency adverse events (including renal failure) have occurred. Acute renal failure was reported more frequently in patients with advanced relapsed and refractory multiple myeloma who received KYPROLIS monotherapy. Monitor renal function with regular measurement of the serum creatinine and/or estimated creatinine clearance. Reduce or withhold dose as appropriate.

Tumor Lysis Syndrome

- Cases of Tumor Lysis Syndrome (TLS), including fatal outcomes, have occurred. Patients with a high tumor burden should be considered at greater risk for TLS. Adequate hydration is required prior to each dose in Cycle 1, and in subsequent cycles as needed. Consider uric acid lowering drugs in patients at risk for TLS. Monitor for evidence of TLS during treatment and manage promptly, and withhold until resolved.

Pulmonary Toxicity

- Acute Respiratory Distress Syndrome (ARDS), acute respiratory failure, and acute diffuse infiltrative pulmonary disease such as pneumonitis and interstitial lung disease have occurred. Some events have been fatal. In the event of drug–induced pulmonary toxicity, discontinue KYPROLIS.

Pulmonary Hypertension

- Pulmonary arterial hypertension (PAH) was reported. Evaluate with cardiac imaging and/or other tests as indicated. Withhold KYPROLIS for PAH until resolved or returned to baseline and consider whether to restart based on a benefit/risk assessment.

Dyspnea

- Dyspnea was reported in patients treated with KYPROLIS. Evaluate dyspnea to exclude cardiopulmonary conditions including cardiac failure and pulmonary syndromes. Stop KYPROLIS for Grade 3 or 4 dyspnea until resolved or returned to baseline. Consider whether to restart based on a benefit/risk assessment.

Hypertension

- Hypertension, including hypertensive crisis and hypertensive emergency, has been observed, some fatal. Control hypertension prior to starting KYPROLIS. Monitor blood pressure regularly in all patients. If hypertension cannot be adequately controlled, withhold KYPROLIS and evaluate. Consider whether to restart based on a benefit/risk assessment.

Venous Thrombosis

- Venous thromboembolic events (including deep venous thrombosis and pulmonary embolism) have been observed. Thromboprophylaxis is recommended for patients being treated with the combination of KYPROLIS with dexamethasone or with lenalidomide plus dexamethasone. The thromboprophylaxis regimen should be based on an assessment of the patient's underlying risks.
- Patients using hormonal contraception associated with a risk of thrombosis should consider an alternative method of effective contraception during treatment.

Infusion Reactions

- Infusion reactions, including life–threatening reactions, have occurred. Signs and symptoms include fever, chills, arthralgia, myalgia, facial flushing, facial edema, laryngeal edema, vomiting, weakness, shortness of breath, hypotension, syncope, chest tightness, or angina. These reactions can occur immediately following or up to 24 hours after administration. Premedicate with dexamethasone to reduce the incidence and severity of infusion reactions. Inform patients of the risk and of symptoms and seek immediate medical attention if they occur.

Hemorrhage

- Fatal or serious cases of hemorrhage have been reported. Hemorrhagic events have included gastrointestinal, pulmonary, and intracranial hemorrhage and epistaxis. Promptly evaluate signs and symptoms of blood loss. Reduce or withhold dose as appropriate.

Thrombocytopenia

- KYPROLIS causes thrombocytopenia with recovery to baseline platelet count usually by the start of the next cycle. Monitor platelet counts frequently during treatment. Reduce or withhold dose as appropriate.

Hepatic Toxicity and Hepatic Failure

- Cases of hepatic failure, including fatal cases, have occurred. KYPROLIS can cause increased serum transaminases. Monitor liver enzymes regularly regardless of baseline values. Reduce or withhold dose as appropriate.

Thrombotic Microangiopathy

- Cases of thrombotic microangiopathy, including thrombotic thrombocytopenic purpura/hemolytic uremic syndrome (TTP/HUS), including fatal outcome, have occurred. Monitor for signs and symptoms of TTP/HUS. Discontinue if diagnosis is suspected. If the diagnosis of TTP/HUS is excluded, KYPROLIS may be restarted. The safety of reinitiating KYPROLIS is not known.

Posterior Reversible Encephalopathy Syndrome (PRES)

- Cases of PRES have occurred in patients receiving KYPROLIS. If PRES is suspected, discontinue and evaluate with appropriate imaging. The safety of reinitiating KYPROLIS is not known.

Increased Fatal and Serious Toxicities in Combination with Melphalan and Prednisone in Newly Diagnosed Transplant-ineligible Patients

- In a clinical trial of transplant-ineligible patients with newly diagnosed multiple myeloma comparing KYPROLIS, melphalan, and prednisone (KMP) vs bortezomib, melphalan, and prednisone (VMP), a higher incidence of serious and fatal adverse events was observed in patients in the KMP arm. KMP is not indicated for transplant-ineligible patients with newly diagnosed multiple myeloma.

Embryo-fetal Toxicity

- KYPROLIS can cause fetal harm when administered to a pregnant woman.
- Females of reproductive potential should be advised to avoid becoming pregnant while being treated with KYPROLIS and for 6 months following the final dose. Males of reproductive potential should be advised to avoid fathering a child while being treated with KYPROLIS and for 3 months following the final dose. If this drug is used during pregnancy, or if pregnancy occurs while taking this drug, the patient should be apprised of the potential hazard to the fetus.

Adverse Reactions

- The most common adverse reactions in the combination therapy trials: anemia, diarrhea, fatigue, hypertension, pyrexia, upper respiratory tract infection thrombocytopenia, cough, dyspnea and insomnia.
- The most common adverse reactions in monotherapy trials: anemia, fatigue, thrombocytopenia, nausea, pyrexia, dyspnea, diarrhea, headache, cough, edema peripheral.

Please see accompanying full Prescribing Information at www.kyprolis.com.

About XGEVA® (denosumab)

XGEVA targets the RANK ligand pathway to prevent the formation, function and survival of osteoclasts, which break down bone. XGEVA is indicated for the prevention of SREs in patients with bone metastases from solid tumors and for treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity. XGEVA is also indicated in the U.S. for the treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy.

XGEVA is indicated for the prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors.

XGEVA U.S. Important Safety Information

Hypocalcemia

Pre-existing hypocalcemia must be corrected prior to initiating therapy with XGEVA®. XGEVA® can cause severe symptomatic hypocalcemia, and fatal cases have been reported. Monitor calcium levels, especially in the first weeks of initiating therapy, and administer calcium, magnesium, and vitamin D as necessary. Concomitant use of calcimimetics and other drugs that can lower calcium levels may worsen hypocalcemia risk and serum calcium should be closely monitored. Advise patients to contact a healthcare professional for symptoms of hypocalcemia.

An increased risk of hypocalcemia has been observed in clinical trials of patients with increasing renal dysfunction, most commonly with severe dysfunction (creatinine clearance less than 30 mL/minute and/or on dialysis), and with inadequate/no calcium supplementation. Monitor calcium levels and calcium and vitamin D intake.

Hypersensitivity

XGEVA® is contraindicated in patients with known clinically significant hypersensitivity to XGEVA®, including anaphylaxis that has been reported with use of XGEVA®. Reactions may include hypotension, dyspnea, upper airway edema, lip swelling, rash, pruritus, and urticaria. If an anaphylactic or other clinically significant allergic reaction occurs, initiate appropriate therapy and discontinue XGEVA® therapy permanently.

Drug Products with Same Active Ingredient

Patients receiving XGEVA® should not take Prolia® (denosumab).

Osteonecrosis of the Jaw

Osteonecrosis of the jaw (ONJ) has been reported in patients receiving XGEVA®, manifesting as jaw pain, osteomyelitis, osteitis, bone erosion, tooth or periodontal infection, toothache, gingival ulceration, or gingival erosion. Persistent pain or slow healing of the mouth or jaw after dental surgery may also be manifestations of ONJ. In clinical trials in patients with cancer, the incidence of ONJ was higher with longer duration of exposure.

Patients with a history of tooth extraction, poor oral hygiene, or use of a dental appliance are at a greater risk to develop ONJ. Other risk factors for the development of ONJ include immunosuppressive therapy, treatment with angiogenesis inhibitors, systemic corticosteroids, diabetes, and gingival infections.

Perform an oral examination and appropriate preventive dentistry prior to the initiation of XGEVA® and periodically during XGEVA® therapy. Advise patients regarding oral hygiene practices. Avoid invasive dental procedures during treatment with XGEVA®. Consider temporarily interrupting XGEVA® therapy if an invasive dental procedure must be performed. Patients who are suspected of having or who develop ONJ while on XGEVA® should receive care by a dentist or an oral surgeon. In these patients, extensive dental surgery to treat ONJ may exacerbate the condition.

Atypical Subtrochanteric and Diaphyseal Femoral Fracture

Atypical femoral fracture has been reported with XGEVA®. These fractures can occur anywhere in the femoral shaft from just below the lesser trochanter to above the supracondylar flare and are transverse or short oblique in orientation without evidence of comminution.

Atypical femoral fractures most commonly occur with minimal or no trauma to the affected area. They may be bilateral and many patients report prodromal pain in the affected area, usually presenting as dull, aching thigh pain, weeks to months before a complete fracture occurs. A number of reports note that patients were also receiving treatment with glucocorticoids (e.g. prednisone) at the time of fracture. During XGEVA® treatment, patients should be advised to report new or unusual thigh, hip, or groin pain. Any patient who presents with thigh or groin pain should be suspected of having an atypical fracture and should be evaluated to rule out an incomplete femur fracture. Patients presenting with an atypical femur fracture should also be assessed for symptoms and signs of fracture in the contralateral limb. Interruption of XGEVA® therapy should be considered, pending a risk/benefit assessment, on an individual basis.

Hypercalcemia Following Treatment Discontinuation in Patients with Giant Cell Tumor of Bone (GCTB) and in Patients with Growing Skeletons

Clinically significant hypercalcemia requiring hospitalization and complicated by acute renal injury has been reported in XGEVA®-treated patients with GCTB and in patients with growing skeletons within one year of treatment discontinuation. Monitor patients for signs and symptoms of hypercalcemia after treatment discontinuation and treat appropriately.

Multiple Vertebral Fractures (MVF) Following Treatment Discontinuation

Multiple vertebral fractures (MVF) have been reported following discontinuation of treatment with denosumab. Patients at higher risk for MVF include those with risk factors for or a history of osteoporosis or prior fractures. When XGEVA® treatment is discontinued, evaluate the individual patient's risk for vertebral fractures.

Embryo-Fetal Toxicity

XGEVA® can cause fetal harm when administered to a pregnant woman. Based on findings in animals, XGEVA® is expected to result in adverse reproductive effects. Advise females of reproductive potential to use effective contraception during therapy, and for at least 5 months after the last dose of XGEVA®. Apprise the patient of the potential hazard to a fetus if XGEVA® is used during pregnancy or if the patient becomes pregnant while patients are exposed to XGEVA®.

Adverse Reactions

The most common adverse reactions in patients receiving XGEVA® with bone metastasis from solid tumors were fatigue/asthenia, hypophosphatemia, and nausea. The most common serious adverse reaction was dyspnea. The most common adverse reactions resulting in discontinuation were osteonecrosis and hypocalcemia.

For multiple myeloma patients receiving XGEVA®, the most common adverse reactions were diarrhea, nausea, anemia, back pain, thrombocytopenia, peripheral edema, hypocalcemia, upper respiratory tract infection, rash, and headache. The most common serious adverse reaction was pneumonia. The most common adverse reaction resulting in discontinuation of XGEVA® was osteonecrosis of the jaw.

Please see accompanying full Prescribing Information at www.XGEVA.com.

About BeiGene

BeiGene is a global biotechnology company that is developing and commercializing innovative and affordable oncology medicines to improve treatment outcomes and access for far more patients worldwide. With a broad portfolio, we are expediting development of our diverse pipeline of novel therapeutics through our internal capabilities and collaborations. We are committed to radically improving access to medicines for far more patients who need them. Our growing global team of more than 9,000 colleagues spans five continents, with administrative offices in Cambridge, U.S. & Basel, Switzerland & Beijing, China. 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 potential for the inclusion in the NRDL of tislelizumab, KYPROLIS and XGEVA to expand patient access and affordability, BeiGene's ability to advance global health by making innovative medicines more accessible and affordable for more patients globally, and BeiGene's plans, commitments, aspirations and goals under the heading "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 of its drug candidates and achieve and maintain profitability; and the impact of the COVID-19 pandemic on BeiGene's clinical development, regulatory, commercial, manufacturing, and other operations, as well as those risks more fully discussed in the section entitled "Risk Factors" in BeiGene's most recent quarterly report on Form 10-Q, as well as discussions of potential risks, uncertainties, and other important factors in BeiGene's subsequent filings with the U.S. Securities and Exchange Commission. All information in this press release is as of the date of this press release, and BeiGene undertakes no duty to update such information unless required by law.

Investor Contacts
ir@beigene.com
Kevin Mannix
+1 240-410-0129
Gabrielle Zhou
+86 010 5895 8058

Media Contacts
media@beigene.com
Kyle Blankenship
+1 667 3515176
Dana Yu
+86 010 6844 5311

REFERENCES

[1]Moreau P, Richardson PG, Cavo M, et al. Proteasome inhibitors in multiple myeloma: 10 years later. *Blood*. 2012 Aug 2;120(5):947-59.

[2]Kortuem KM and Stewart AK. Carfilzomib. *Blood*. 2013 Feb 7;121(6):893-7.

[3]Amgen Data on File.

Exhibit 99.2

BRUKINSA® Approved in the U.S. for Chronic Lymphocytic Leukemia

Two global Phase 3 trials in adult CLL patients demonstrated superior efficacy for BRUKINSA (zanubrutinib) in first-line and relapsed/refractory treatment settings

BRUKINSA is the only BTKi to demonstrate superior PFS vs IMBRUVICA® (ibrutinib)

BASEL & BEIJING & CAMBRIDGE, Mass. – January 19, 2023 – BeiGene (NASDAQ: BGNE; HKEX: 06160; SSE: 688235), a global biotechnology company, today announced that the U.S. Food and Drug Administration (FDA) has approved its Bruton's tyrosine kinase inhibitor (BTKi) BRUKINSA (zanubrutinib) for the treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).

"With four US approvals in just over three years and demonstrated superiority versus ibrutinib in the final progression-free survival (PFS) analysis of the ALPINE trial, we believe BRUKINSA is well-positioned to become the BTKi of choice across multiple indications," said Mehrdad Mobasher, M.D., M.P.H., Chief Medical Officer, Hematology at BeiGene. "We're grateful to the patients who participated in the ALPINE and SEQUOIA studies; and with this new approval, we're excited to expand our impact to even more patients."

The U.S. approval is based on two global Phase 3 clinical trials demonstrating superior efficacy and a favorable safety profile for BRUKINSA in CLL:

- With a median follow-up of 26.2 months in the SEQUOIA trial, BRUKINSA demonstrated a significant PFS benefit versus bendamustine plus rituximab, (HR 0.42, [95% CI: 0.28, 0.63], P<0.0001), as assessed by an Independent Review Committee (IRC) in the first-line treatment setting.[1]
- BRUKINSA achieved a superior overall response rate versus ibrutinib in the relapsed/refractory (R/R) treatment setting (ORR 80.4% vs 72.9%, P=0.0264), as assessed by an IRC in the ALPINE trial.[2]
- The overall safety profile of BRUKINSA in the ALPINE and SEQUOIA trials was consistent with prior studies.

In the pooled safety population of CLL patients who received BRUKINSA across the clinical development program (N=1,550), the most common adverse reactions (≥30%), were decreased neutrophil count (42%), upper respiratory tract infection (39%), decreased platelet count (34%), hemorrhage (30%), and musculoskeletal pain (30%).[3]

The pre-defined final PFS analysis of the ALPINE study demonstrating superior efficacy and a favorable cardiac safety profile for BRUKINSA versus IMBRUVICA in patients with R/R CLL, was presented in a late-breaking session at the 64th Annual American Society for Hematology (ASH) Meeting and published simultaneously in The New England Journal of Medicine. With a median follow-up of 29.6 months, BRUKINSA demonstrated superior PFS compared with ibrutinib in patients with R/R CLL (HR: 0.65 [95% CI, 0.49-0.86] P=.0024, for both investigator and IRC). Additionally, BRUKINSA demonstrated a favorable cardiac safety profile, with significantly lower rates of atrial fibrillation/flutter (5.2% vs 13.3%) and zero deaths due to cardiac disorders with BRUKINSA vs. six with ibrutinib (0% vs 1.9%).[4,5]

Jennifer R. Brown, M.D., Ph.D., Director of the CLL Center of the Division of Hematologic Malignancies at Dana-Farber Cancer Institute, commented "We have seen striking data from the BRUKINSA development program demonstrating significant and consistent efficacy across CLL patient sub-types, including the high-risk del17p/*TP53* mutated population, and regardless of treatment setting. With extensive follow-up across the CLL development program and the combined results from the SEQUOIA and ALPINE trials, BRUKINSA is established as a new standard of care for CLL."

“Thanks to research that has delivered innovative and effective medicines, people with CLL can remain on therapy for years so tolerability is an important consideration. I’m pleased that the approval of zanubrutinib provides a new BTKi option for people with CLL/SLL, with demonstrated efficacy as well as being very well tolerated long-term,” said Brian Koffman, M.D., Chief Medical Officer and Executive Vice-President at CLL Society.

About ALPINE

ALPINE is a randomized, global Phase 3 trial (NCT03734016) comparing BRUKINSA against ibrutinib in previously treated patients with relapsed or refractory chronic lymphocytic leukemia CLL or SLL. In the trial, a total of 652 patients across Europe (60%), the United States (17%), China (14%), and New Zealand and Australia (9%) were randomized into two arms, with the first arm receiving BRUKINSA (160 mg orally twice daily) and the second arm receiving ibrutinib (420 mg orally once daily) until disease progression or unacceptable toxicity.

The primary endpoint of ORR, defined by pre-specified non-inferiority of BRUKINSA versus ibrutinib, was assessed by investigator and IRC using the modified 2008 iwCLL guidelines, with modification for treatment-related lymphocytosis for patients with CLL, and per Lugano Classification for non-Hodgkin’s lymphoma for patients with SLL. There was pre-specified hierarchical testing of non-inferiority followed by superiority in ORR as assessed by investigator and IRC. Key secondary endpoints include PFS and event rate of atrial fibrillation or flutter; other secondary endpoints include duration of response, overall survival, and incidence of adverse events.

Interim study results from ALPINE were published online in the Journal of Clinical Oncology in November 2022 and the final pre-defined PFS analysis was presented in a late-breaking session at the 64th Annual American Society for Hematology (ASH) Meeting and published simultaneously in The New England Journal of Medicine.[4,5]

About SEQUOIA

SEQUOIA is a randomized, multicenter, global Phase 3 trial (NCT03336333) designed to evaluate the efficacy and safety of BRUKINSA compared to bendamustine + rituximab (B+R) in patients with treatment-naïve 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 Cohort 1, 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 ORR, overall survival, PFS and ORR in patients with del(17p), and safety.

Results for Cohort 2 (Arm C), representing high-risk patients treated with BRUKINSA monotherapy, were presented at the 62nd ASH Annual Meeting in December 2020.[6] This cohort of patients with del(17p) achieved significant efficacy, with an 18-month PFS of 90.6%, as assessed by investigator. Full study results were published in Lancet Oncology.[1]

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IMPORTANT SAFETY INFORMATION

Warnings and Precautions

Hemorrhage

Fatal and serious hemorrhage has 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 3.6% of patients treated with BRUKINSA monotherapy in clinical trials, with fatalities occurring in 0.3% of patients. Bleeding of any grade, excluding purpura and petechiae, occurred in 30% of patients.

Bleeding has occurred in patients with and without concomitant antiplatelet or anticoagulation therapy. Coadministration 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 infections) and opportunistic infections have occurred in patients with hematological malignancies treated with BRUKINSA monotherapy. Grade 3 or higher infections occurred in 24% of patients, most commonly pneumonia (11%), with fatal infections occurring in 2.9% of patients. Infections due to hepatitis B virus (HBV) reactivation have occurred.

Consider prophylaxis for herpes simplex virus, pneumocystis jirovecii 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 (22%), thrombocytopenia (8%) and anemia (7%) based on laboratory measurements, developed in patients treated with BRUKINSA monotherapy. Grade 4 neutropenia occurred in 11% of patients, and Grade 4 thrombocytopenia occurred in 2.8% 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 13% of patients treated with BRUKINSA monotherapy. The most frequent second primary malignancy was non-melanoma skin cancer reported in 7% of patients. Other second primary malignancies included malignant solid tumors (5%), melanoma (1.2%), and hematologic malignancies (0.5%). Advise patients to use sun protection and monitor patients for the development of second primary malignancies.

Cardiac Arrhythmias

Serious cardiac arrhythmias have occurred in patients treated with BRUKINSA. Atrial fibrillation and atrial flutter were reported in 3.7% of 1550 patients treated with BRUKINSA monotherapy, including Grade 3 or higher cases in 1.7% of patients. Patients with cardiac risk factors, hypertension, and acute infections may be at increased risk. Grade 3 or higher ventricular arrhythmias were reported in 0.2% of patients.

Monitor for signs and symptoms of cardiac arrhythmias (e.g., palpitations, dizziness, syncope, dyspnea, chest discomfort), manage appropriately, and consider the risks and benefits of continued BRUKINSA treatment.

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

In this pooled safety population, the most common adverse reactions, including laboratory abnormalities, in ≥30% of patients who received BRUKINSA (N=1550) included decreased neutrophil count (42%), upper respiratory tract infection (39%), decreased platelet count (34%), hemorrhage (30%), 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 strong or moderate CYP3A inducers. Dose adjustment may be recommended with moderate CYP3A inducers.

Specific Populations

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

INDICATIONS

BRUKINSA is a kinase inhibitor indicated for the treatment of adult patients with:

- Chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)
- Waldenström's macroglobulinemia (WM)
- Mantle cell lymphoma (MCL) who have received at least one prior therapy
- Relapsed or refractory marginal zone lymphoma (MZL) who have received at least one anti-CD20-based regimen

The MCL and MZL indications are approved under accelerated approval based on overall response rate. Continued approval for these indications may be contingent upon verification and description of clinical benefit in confirmatory trials.

Please see full 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 biotechnology company that is developing and commercializing innovative and affordable oncology medicines to improve treatment outcomes and access for far more patients worldwide. With a broad portfolio, we are expediting development of our diverse pipeline of novel therapeutics through our internal capabilities and collaborations. We are committed to radically improving access to medicines for far more patients who need them. Our growing global team of more than 9,000 colleagues spans five continents, with administrative offices in Beijing, China; Cambridge, U.S.; and Basel, Switzerland. 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 potential for BRUKINSA to provide clinical benefit to patients with CLL/SLL, the future development, regulatory filing and approval, commercialization, and market access of BRUKINSA in the U.S. and other markets, and BeiGene's plans, commitments, aspirations, and goals under the heading "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; and the impact of the COVID-19 pandemic on BeiGene's clinical development, regulatory, commercial, manufacturing, and other operations, as well as those risks more fully discussed in the section entitled "Risk Factors" in BeiGene's most recent quarterly report on Form 10-Q, as well as discussions of potential risks, uncertainties, and other important factors in BeiGene's subsequent filings with the U.S. Securities and Exchange Commission. All information in this press release is as of the date of this press release, and BeiGene undertakes no duty to update such information unless required by law.

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

Media Contact
Kyle Blankenship
+1 667 3515176
media@beigene.com

REFERENCES

[1] Tam CS, Brown JR, Kahl BS, et al. Zanubrutinib versus bendamustine and rituximab in untreated chronic lymphocytic leukaemia and small lymphocytic lymphoma (SEQUOIA): a randomised, controlled, phase 3 trial. *Lancet Oncology.* 2022;23(8):1031-1043. doi:10.1016/S1470-2045(22)00293-5

[2] Hillmen P, Eichorst B, Brown JR, et al. Zanubrutinib Versus Ibrutinib in Relapsed/Refractory Chronic Lymphocytic Leukemia and Small Lymphocytic Lymphoma: Interim Analysis of a Randomized Phase III Trial. *Journal of Clinical Oncology.* doi:10.1200/JCO.22.00510

[3] US Prescribing Information www.beigene.com/PDF/BRUKINSAUSPI.pdf

[4] Brown JR, Eichhorst, B, Hillmen, P., et al.. (2022). Zanubrutinib or Ibrutinib in Relapsed or Refractory Chronic Lymphocytic Leukemia. *New England Journal of Medicine*. doi:10.1056/NEJMoa2211582

[5] Brown JR, Eichhorst B, Hillmen P, et al.; Zanubrutinib Demonstrates Superior Progression-Free Survival (PFS) Compared with Ibrutinib for Treatment of Relapsed/Refractory Chronic Lymphocytic Leukemia and Small Lymphocytic Lymphoma (R/R CLL/SLL): Results from Final Analysis of ALPINE Randomized Phase 3 Study. *Blood.* 2022;140 (Supplement 2): LBA–6. doi:10.11.82/blood-2022-171538

[6] Tam CS, Giannopoulos K, Jurczak W, et al. SEQUOIA: Results of a Phase 3 Randomized Study of Zanubrutinib versus Bendamustine + Rituximab (BR) in Patients with Treatment-Naïve (TN) Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL), *Blood.* 2021;138(Supplement 1, p396) doi:10.1182/blood-2021-148457