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): October 6, 2021

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

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

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

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

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

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

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

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

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

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

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

Item 1.02. Termination of a Material Definitive Agreement.

Background

On July 5, 2017, BeiGene, Ltd. ("BeiGene" or the "Company") and Celgene Logistics Sàrl, now a wholly owned subsidiary of Bristol Myers Squibb Company ("BMS-Celgene"), entered into a License and Supply Agreement (the "Agreement") pursuant to which the Company was granted the exclusive right to distribute and promote BMS-Celgene's approved cancer therapies, ABRAXANE®, REVLIMID®, and VIDAZA®, in China, excluding Hong Kong, Macau and Taiwan (the "Territory").

As previously disclosed by the Company, on March 25, 2020, the Chinese National Medical Products Administration (the "NMPA") suspended the importation, sales and use of ABRAXANE® in China supplied to the Company by BMS-Celgene under the Agreement, and BMS-Celgene initiated a voluntary recall of ABRAXANE® in China. This suspension was based on inspection findings at BMS-Celgene's contract manufacturing facility in the United States.

As previously disclosed, the Company is currently engaged in arbitration proceedings at the International Chamber of Commerce ("ICC") against BMS-Celgene asserting that BMS-Celgene breached and continues to breach the terms and conditions of the Agreement and a related quality agreement on the grounds, among other things, that BMS-Celgene has failed to ensure the continuity and adequacy of its supply of ABRAXANE® to the Company in accordance with good manufacturing practices ("GMP"). In the arbitration proceeding, the Company is seeking (i) a declaration that BMS-Celgene was and is in breach of the Agreement, (ii) a declaration that BMS-Celgene acted with gross negligence and/or willful misconduct, (iii) an award of damages, and (iv) such other relief as the arbitrators deem appropriate.

As previously disclosed, the Company has been working with BMS-Celgene to restore ABRAXANE® supply for the China market as soon as possible, including through BMS-Celgene's remediation efforts at its existing manufacturing site in the United States and/or an application to qualify an alternative manufacturing site for China. On August 16, 2021, BMS-Celgene informed the Company that it planned to file a supplementary application in the fourth quarter of 2021 to register a new facility as the manufacturing site for ABRAXANE® for the China market, with an initial projection that the application could be approved by the NMPA in the fourth quarter of 2022.

Notice of Purported Termination

On October 6, 2021, BMS-Celgene delivered a notice to the Company purporting to terminate the Agreement with respect to ABRAXANE® and providing 180-days' notice that it was withdrawing ABRAXANE® from the range of products for sale or distribution in the Territory pursuant to Section 2.6 of the Agreement (the "Notice"). The Notice states:

> "Indeed, as you are aware, due to the National Medical Products Association decision to suspend the importation, sale, or use of Abraxane® in China on March 25, 2020, Celgene has been unable to manufacture Abraxane® for China and, thus, has been unable to manufacture Abraxane® on a global basis as that term is used in § 2.6 of the LSA.
>
> Further, following the suspension by the National Medical Products Administration of the manufacturing in Illinois, the manufacturing facility in Phoenix, Arizona became the primary manufacturing facility for Abraxane®. In July 2021, media fill testing at that facility revealed a failure. Following a root cause investigation, corrective and preventative actions were implemented, but testing resulted in the rejection of additional vials. Celgene is continuing to correct the underlying issue, but all manufacturing production activities with respect to Abraxane® have ceased at the Phoenix facility for the time being and the U.S. Food and Drug Administration has been notified. This further justifies Celgene's exercise of § 2.6 of the LSA.

BMS-Celgene has not advised the Company how long it will be unable to manufacture ABRAXANE® at its Phoenix manufacturing facility or whether it has the ability to manufacture ABRAXANE® at other facilities. The Company would be happy to work with BMS-Celgene to help get the Phoenix manufacturing facility or another facility qualified to restore the supply of ABRAXANE® for patients in China as soon as possible.

The Company believes that the reasons stated in the Notice do not provide a valid basis for terminating the Agreement with respect to ABRAXANE®, and that the Notice is a tactical maneuver on the part of BMS-Celgene to reduce its damages in the on-going arbitration proceedings described above. The Company intends to contest the purported termination vigorously.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws, including statements regarding BeiGene's plans, objectives and intentions in the arbitration proceeding as well as the projections or plans asserted by BMS-Celgene. 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 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 Current Report is as of the date of this Current Report, and BeiGene undertakes no duty to update such information unless required by law.

Item 8.01. Other Events.

On October 7, 2021, BeiGene announced that BRUKINSA® (zanubrutinib) has been approved in Australia for the treatment of adult patients with Waldenström's macroglobulinemia (WM) who have received at least one prior therapy or in first line treatment for patients unsuitable for chemo-immunotherapy. 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 October 10, 2021, BeiGene announced that BRUKINSA® (zanubrutinib) has been approved in Australia for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy. The full text of this press release is filed as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release titled "BeiGene Announces First Regulatory Approval in Australia for BRUKINSA® (Zanubrutinib) for Treatment of Patients with Waldenström's Macroglobulinemia", issued by BeiGene, Ltd. on October 7, 2021.
99.2	Press Release titled "BeiGene Announces BRUKINSA® (Zanubrutinib) Approved for Treatment of Patients with Mantle Cell Lymphoma", issued by BeiGene, Ltd. on October 10, 2021.
104	The cover page from this Current Report on Form 8-K, formatted in Inline XBRL

Exhibit Index

Exhibit No.	Description
99.1	Press Release titled "BeiGene Announces First Regulatory Approval in Australia for BRUKINSA® (Zanubrutinib) for Treatment of Patients with Waldenström's Macroglobulinemia", issued by BeiGene, Ltd. on October 7, 2021.
99.2	Press Release titled "BeiGene Announces BRUKINSA® (Zanubrutinib) Approved for Treatment of Patients with Mantle Cell Lymphoma", issued by BeiGene, Ltd. on October 10, 2021.
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: October 13, 2021

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

Exhibit 99.1

BeiGene Announces First Regulatory Approval in Australia for BRUKINSA® (Zanubrutinib) for Treatment of Patients with Waldenström's Macroglobulinemia

Represents BRUKINSA's Second Recent Approval in the Asia-Pacific Region, Following October 1 Approval in Singapore for Treatment of Patients with Mantle Cell Lymphoma

The TGA approval is based on results from ASPEN, an Australia-inclusive head-to-head clinical trial evaluating BRUKINSA compared to ibrutinib in patients with Waldenström's macroglobulinemia

CAMBRIDGE, Mass. and BEIJING -- October 7, 2021 -- BeiGene (NASDAQ: BGNE; HKEX: 06160), a global, science-driven biotechnology company focused on developing innovative and affordable medicines to improve treatment outcomes and access for patients worldwide, today announced that BRUKINSA® (zanubrutinib) has been approved in Australia for the treatment of adult patients with Waldenström's macroglobulinemia (WM) who have received at least one prior therapy or in first line treatment for patients unsuitable for chemo-immunotherapy.[1] Following registration of BRUKINSA with the Australia Therapeutic Goods Administration (TGA), these patients will have immediate access to BRUKINSA through a BeiGene sponsored post-approval, pre-reimbursement access program.

In addition, BRUKINSA recently received approval from the Singapore Health Sciences Authority (HSA) for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy.

"BTK inhibition is an established mode of treatment for patients with WM, and the ASPEN trial showed that BRUKINSA is highly effective and has improved tolerability compared to the first-generation BTK inhibitor," said Professor Con Tam, MBBS, M.D., Disease Group Lead for Low Grade Lymphoma and Chronic Lymphocytic Leukemia at the Peter MacCallum Cancer Centre and a principal investigator on the BRUKINSA clinical program. "BeiGene first began clinical trials of BRUKINSA in Australia in 2013, and since that time, many Australians have benefitted from treatment as part of ongoing clinical studies. We hope this therapy will offer new hope for people living with WM in Australia."

In Australia, more than 6,000 people are diagnosed with non-Hodgkin's lymphoma (NHL) each year, making it the sixth most common cancer in adults.[2] WM is a rare, slow-growing lymphoma that occurs in less than two percent of patients with NHL.[3] The disease usually affects older adults and is primarily found in the bone marrow, although it may also impact lymph nodes and the spleen.[3]

"While WM is a slow-growing lymphoma, not all patients fully respond to existing therapies and many discontinue treatment due to side effects," commented David Young, the National Team Leader at the WMozzies. "We are pleased to hear that people living with WM in Australia will have immediate access to this next-generation BTK inhibitor that has demonstrated clinical benefit with potential to improve treatment outcomes."

BeiGene has submitted for reimbursement of WM to the Australia Pharmaceutical Benefits Advisory Committee (PBAC). In a first for the PBAC, BeiGene expects to enter a facilitated resolution pathway in order to seek a listing date for the WM indication.

"BRUKINSA has been shown to induce deep and durable responses with reduced off-target side effects, suggesting improved clinical benefit compared to standard BTK inhibitor therapy," said Jane Huang, M.D., Chief Medical Officer, Hematology at BeiGene. "We are grateful to the Australian investigators, patients and families who participated in clinical trials contributing to TGA approval. Our ability to offer BRUKINSA to people in Australia impacted by WM is another step toward fulfilling our goal of increasing affordable access to oncology medicines around the world."

"This approval in Australia, and our recent approval in Singapore, represent BRUKINSA's continued expansion in the APAC region," added Adam Roach, Vice President and Head of Commercial for APAC (ex-Greater China) at BeiGene. "We have been building medical and commercial teams in these markets to support our goal of bringing this potential best-in-class BTK inhibitor to patients who need them globally."

The Australian registration for BRUKINSA in WM is based on efficacy results from the ASPEN clinical trial, a Phase 3 randomized, open-label, multicenter trial (NCT03053440) that evaluated BRUKINSA compared to ibrutinib in patients with relapsed or refractory (R/R) or treatment-naïve (TN) WM who harbor a MYD88 mutation (*MYD88*^{MUT}). In the ASPEN trial, BRUKINSA demonstrated a numerically higher very good partial response (VGPR) rate (28.4%, 95% CI: 20, 38) compared to ibrutinib (19.2%, 95% CI: 12, 28), although the primary endpoint of statistical superiority related to deep response (VGPR or better) was not met.

In the ASPEN trial, of the 101 patients with WM randomized and treated with BRUKINSA, 5% of patients discontinued due to adverse events, including cardiomegaly, neutropenia, plasma cell myeloma, and subdural hemorrhage. Adverse events leading to dose reduction occurred in 14.9% of patients, with the most common being neutropenia (3.0%) and diarrhea (2.0%).

The overall safety profile of BRUKINSA is based on pooled data from 779 patients with B-cell malignancies treated with BRUKINSA in clinical trials. The most common adverse reactions (≥20%) with BRUKINSA were neutropenia, thrombocytopenia, upper respiratory tract infection, hemorrhage/hematoma, rash, bruising, anemia, musculoskeletal pain, diarrhea, pneumonia, and cough. The most common Grade 3 or higher adverse reactions (≥5%) were neutropenia, thrombocytopenia, pneumonia, and anemia.

The recommended dose of BRUKINSA is either 160 mg twice daily or 320 mg once daily, taken orally with or without food. The dose may be adjusted for adverse reactions and reduced for patients with severe hepatic impairment and certain drug interactions.

About BRUKINSA

BRUKINSA is a small molecule inhibitor of Bruton's tyrosine kinase (BTK) discovered by BeiGene scientists that is currently being evaluated globally in a broad clinical program as a monotherapy and in combination with other therapies to treat various B-cell malignancies. Because new BTK is continuously synthesized, BRUKINSA was specifically designed to deliver complete and sustained inhibition of the BTK protein by optimizing bioavailability, half-life, and selectivity. With differentiated pharmacokinetics compared to other approved BTK inhibitors, BRUKINSA has been demonstrated to inhibit the proliferation of malignant B cells within a number of disease relevant tissues.

BRUKINSA is approved in the following indications and regions:

- For the treatment of mantle cell lymphoma (MCL) in adult patients who have received at least one prior therapy (United States, November 2019)*;
- For the treatment of MCL in adult patients who have received at least one prior therapy (China, June 2020)**;
- For the treatment of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) in adult patients who have received at least one prior therapy (China, June 2020)**;
- For the treatment of relapsed or refractory MCL (United Arab Emirates, February 2021);
- For the treatment of Waldenström's macroglobulinemia (WM) in adult patients (Canada, March 2021);
- Registered and reimbursed for the treatment of MCL in patients who have received at least one prior therapy (Israel, April 2021);
- For the treatment of adult patients with WM who have received at least one prior therapy (China, June 2021)**;
- For the treatment of MCL in adult patients who have received at least one prior therapy (Canada, July 2021);
- For the treatment of MCL in adult patients who have received at least one prior therapy (Chile, July 2021);
- For the treatment of adult patients with MCL who have received at least one previous therapy (Brazil, August 2021);
- For the treatment of adult patients with WM (United States, August 2021);
- For the treatment of adult patients with marginal zone lymphoma (MZL) who have received at least one anti-CD20-based regimen (United States, September 2021)*;

- For the treatment of adult patients with MCL who have received at least one previous therapy (Singapore, October 2021); and
- For the treatment of adult patients with WM who have received at least one prior therapy, or in first line treatment for patients unsuitable for chemo-immunotherapy (Australia, October 2021).

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

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

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

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

Warnings and Precautions

Hemorrhage

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

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

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

Infections

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

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

Cytopenias

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

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

Second Primary Malignancies

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

Cardiac Arrhythmias

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

Embryo-Fetal Toxicity

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

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

Adverse reactions

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

Drug Interactions

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

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

Specific Populations

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

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

BeiGene Oncology

BeiGene is committed to advancing hematology, immuno-oncology and targeted therapies in order to bring impactful and affordable medicines to patients across the globe. We have a growing R&D team of approximately 2,300 colleagues dedicated to advancing more than 90 clinical trials involving more than 13,000 patients and healthy subjects. Our expansive portfolio is directed by a predominantly internalized clinical development team supporting trials in more than 40 countries or regions. We currently market three medicines discovered and developed in our labs: BTK inhibitor BRUKINSA in the United States, China, Canada, and additional international markets; and non-FC-gamma receptor binding anti-PD-1 antibody tislelizumab and PARP inhibitor pamiparib in China. BeiGene has a high quality, innovative science and medicine organization and is a leader in China with a large oncology focused commercial team.

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

About BeiGene

BeiGene is a global, science-driven biotechnology company focused on developing innovative and affordable medicines to improve treatment outcomes and access for patients worldwide. With a broad portfolio of more than 40 clinical candidates, we are expediting development of our diverse pipeline of novel therapeutics through our own capabilities and collaborations. We are committed to radically improving access to medicines for two billion more people by 2030. BeiGene has a growing global team of over 7,000 colleagues across five continents. To learn more about BeiGene, please visit www.beigene.com and follow us on Twitter at @BeiGeneGlobal.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws, including statements regarding plans for development and commercialization of BRUKINSA in Australia, Singapore, the APAC region and other markets, the potential commercial opportunity for BRUKINSA, plans for making BRUKINSA accessible to patients in Australia, the potential for BRUKINSA to be a best-in-class BTK inhibitor and to provide improved clinical benefits to patients, and BeiGene’s plans, commitments, aspirations and goals under the headings “BeiGene Oncology” and “About BeiGene”. Actual results may differ materially from those indicated in the forward-looking statements as a result of various important factors, including BeiGene's ability to demonstrate the efficacy and safety of its drug candidates; the clinical results for its drug candidates, which may not support further development or marketing approval; actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials and marketing approval; BeiGene's ability to achieve commercial success for its marketed medicines and drug candidates, if approved; BeiGene's ability to obtain and maintain protection of intellectual property for its medicines and technology; BeiGene's reliance on third parties to conduct drug development, manufacturing and other services; BeiGene’s limited experience in obtaining regulatory approvals and commercializing pharmaceutical products and its ability to obtain additional funding for operations and to complete the development and commercialization of its drug candidates and achieve and maintain profitability; the impact of the COVID-19 pandemic on the BeiGene’s clinical development, regulatory, commercial, and other operations, as well as those risks more fully discussed in the section entitled “Risk Factors” in BeiGene’s most recent quarterly report on Form 10-Q as well as discussions of potential risks, uncertainties, and other important factors in BeiGene's subsequent filings with the U.S. Securities and Exchange Commission. All information in this press release is as of the date of this press release, and BeiGene undertakes no duty to update such information unless required by law.

Investor Contact	Media Contact
Gabrielle Zhou	Emily Collins
+86 10-5895-8058	+1201-201-4570
ir@beigene.com	media@beigene.com

References:

1 BRUKINSA Australia Product Information. Available at https://www.beigene.com.au/PDF/BRUKINSAAUPI.pdf. Accessed October 2021.

2 https://www.lymphoma.org.au/types-of-lymphoma/non-hodgkin-lymphoma. Accessed August 2021.

3 https://www.lls.org/sites/default/files/2021-07/FS20_Waldenstrom_FactSheet_2021.pdf. Accessed August 2021.

Exhibit 99.2

BeiGene Announces BRUKINSA® (Zanubrutinib) Approved for Treatment of Patients with Mantle Cell Lymphoma

Marks BRUKINSA's second approved indication in Australia, on the heels of its recent initial approval in Waldenström's macroglobulinemia

To date, BRUKINSA is approved in mantle cell lymphoma in nine countries

SYDNEY, CAMBRIDGE, Mass. and BEIJING -- October 10, 2021 -- BeiGene (NASDAQ: BGNE; HKEX: 06160), a global, science-driven biotechnology company focused on developing innovative and affordable medicines to improve treatment outcomes and access for patients worldwide, today announced that BRUKINSA® (zanubrutinib) has been approved in Australia for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy. On October 7, 2021, BRUKINSA received its initial approval in Australia for the treatment of adult patients with Waldenström's macroglobulinemia (WM) who have received at least one prior therapy or in first line treatment for patients unsuitable for chemo-immunotherapy.[1]

Following registration of BRUKINSA with the Therapeutic Goods Administration (TGA) in both approved indications, these patients will have immediate access to BRUKINSA through the BeiGene sponsored post-approval, pre-reimbursement access program.

"Mantle cell lymphoma is an uncommon form of non-Hodgkin lymphoma that is generally considered incurable. While the majority of patients respond well to their initial treatment, virtually all will develop progressive lymphoma over time. Existing therapies for patients with recurrent or refractory MCL are often ineffective or have side effects that can lead to treatment discontinuation," said Professor Stephen Opat, Director of Clinical Haematology at Monash Health and a principal investigator in the zanubrutinib clinical program. "I'm encouraged that zanubrutinib – a highly selective BTK inhibitor with promising clinical results from two trials in relapsed or refractory MCL – will provide a new treatment option for these patients living in Australia."

"Australia has some of the highest rates of non-Hodgkin's lymphoma in the world, and these patients need options for treatment beyond those that exist today," said Sharon Winton, CEO, Lymphoma Australia. "MCL patients will certainly welcome the news that BeiGene is providing access to BRUKINSA by sponsoring a pre-reimbursement program, as new therapies are critical, especially to those diagnosed later in life when it may be challenging to tolerate more aggressive types of treatment."

BeiGene submitted for reimbursement of BRUKINSA to the Pharmaceutical Benefits Advisory Committee (PBAC), with MCL recommended for listing in July 2021.

"BRUKINSA was designed to provide deep and durable responses while reducing off-target side effects compared to first-generation BTK inhibitors," said Jane Huang, M.D., Chief Medical Officer, Hematology at BeiGene. "Our early BRUKINSA clinical trials started in Australia and coming off the heels of BRUKINSA's TGA registration for the treatment of WM, we are delighted to be able to provide BRUKINSA to more Australians in need of new treatment options."

More than 6,000 people are diagnosed with non-Hodgkin's lymphoma (NHL) in Australia each year, making it the sixth most common cancer in adults.[2] MCL is a B-cell NHL that develops in the outer edge of a lymph node called the mantle zone.[3] MCL usually has a poor prognosis, with a median survival of three to six years, and is often diagnosed at a later stage of disease.[3]

The Australian registration for BRUKINSA in MCL is based on efficacy results from two single-arm clinical trials. Across both trials, as assessed by independent review committee (IRC) per 2014 Lugano Classification, BRUKINSA achieved an overall response rate (ORR) of 83.7%, defined as the combined rate of complete responses (CRs) and partial responses (PRs).

In the multicentre Phase 2 trial of zanubrutinib in patients with relapsed or refractory (R/R) MCL BGB-3111-206 (NCT03206970), with a median follow-up time of 18.4 months, the ORR was 83.7% (95% CI: 74.2, 90.8), including 68.6% CRs (FDG-PET scan required) and 15.1% PRs; the median duration of response (DoR) was 19.5 months (95% CI: 16.6, NE). In the global Phase 1/2 trial BGB-3111-AU-003 (NCT02343120), with a media follow-up time of 14.75 months, the ORR was 84.4% (95% CI: 67.2, 94.7), including 25.0% CRs (FDG-PET scan not required) and 59.4% PRs; the median DoR was 18.5 months (95% CI: 12.6, NE).

Of the 118 patients with MCL who received at least one prior therapy and received BRUKINSA treatment, 13.6% of patients discontinued treatment due to adverse events in the trials, with the most frequent being pneumonia (3.4%). Adverse events leading to dose reduction occurred in 3.4% of patients, including hepatitis B, neutropenia, allergic dermatitis, and peripheral sensory neuropathy (in one patient each).

The overall safety profile of BRUKINSA is based on pooled data from 779 patients with B-cell malignancies treated with BRUKINSA in clinical trials. The most common adverse reactions (≥20%) with BRUKINSA were neutropenia, thrombocytopenia, upper respiratory tract infection, hemorrhage/hematoma, rash, bruising, anemia, musculoskeletal pain, diarrhea, pneumonia, and cough. The most common Grade 3 or higher adverse reactions (≥5%) were neutropenia, thrombocytopenia, pneumonia, and anemia.

The recommended dose of BRUKINSA is either 160 mg twice daily or 320 mg once daily, taken orally with or without food. The dose may be adjusted for adverse reactions and reduced for patients with severe hepatic impairment and certain drug interactions.

About BRUKINSA® (zanubrutinib)

BRUKINSA is a small molecule inhibitor of Bruton's tyrosine kinase (BTK) discovered by BeiGene scientists that is currently being evaluated globally in a broad clinical program as a monotherapy and in combination with other therapies to treat various B-cell malignancies. Because new BTK is continuously synthesised, BRUKINSA was specifically designed to deliver complete and sustained inhibition of the BTK protein by optimising bioavailability, half-life, and selectivity. With differentiated pharmacokinetics compared to other approved BTK inhibitors, BRUKINSA has been demonstrated to inhibit the proliferation of malignant B cells within a number of disease relevant tissues.

BRUKINSA is approved in the United States, China, Australia, Canada, and other international markets in selected indications and under development for additional approvals globally.

BeiGene Oncology

BeiGene is committed to advancing hematology, immuno-oncology and targeted therapies in order to bring impactful and affordable medicines to patients across the globe. We have a growing R&D team of approximately 2,300 colleagues dedicated to advancing more than 90 clinical trials involving more than 13,000 patients and healthy subjects. Our expansive portfolio is directed by a predominantly internalised clinical development team supporting trials in more than 40 countries or regions. We currently market three medicines discovered and developed in our labs: BTK inhibitor BRUKINSA in the United States, China, Canada, and additional international markets; and non-FC-gamma receptor binding anti-PD-1 antibody tislelizumab and PARP inhibitor pamiparib in China. BeiGene has a high quality, innovative science and medicine organisation and is a leader in China with a large oncology focused commercial team.

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

About BeiGene

BeiGene is a global, science-driven biotechnology company focused on developing innovative and affordable medicines to improve treatment outcomes and access for patients worldwide. With a broad portfolio of more than 40 clinical candidates, we are expediting development of our diverse pipeline of novel therapeutics through our own capabilities and collaborations. We are committed to radically improving access to medicines for two billion more people by 2030. BeiGene has a growing global team of over 7,000 colleagues across five continents. To learn more about BeiGene, please visit www.beigene.com.au 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 plans for development and commercialisation of BRUKINSA in Australia, the APAC region and other markets, the potential commercial opportunity for BRUKINSA, plans for making BRUKINSA accessible to patients in Australia, the potential for BRUKINSA to provide improved clinical benefits to patients, and BeiGene's plans, commitments, aspirations and goals under the headings "BeiGene Oncology" and "About BeiGene". Actual results may differ materially from those indicated in the forward-looking statements as a result of various important factors, including BeiGene's ability to demonstrate the efficacy and safety of its drug candidates; the clinical results for its drug candidates, which may not support further development or marketing approval; actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials and marketing approval; BeiGene's ability to achieve commercial success for its marketed medicines and drug candidates, if approved; BeiGene's ability to obtain and maintain protection of intellectual property for its medicines and technology; BeiGene's reliance on third parties to conduct drug development, manufacturing and other services; BeiGene's limited experience in obtaining regulatory approvals and commercialising pharmaceutical products and its ability to obtain additional funding for operations and to complete the development and commercialisation of its drug candidates and achieve and maintain profitability; the impact of the COVID-19 pandemic on the BeiGene's clinical development, regulatory, commercial, and other operations, as well as those risks more fully discussed in the section entitled "Risk Factors" in BeiGene's most recent quarterly report on Form 10-Q as well as discussions of potential risks, uncertainties, and other important factors in BeiGene's subsequent filings with the U.S. Securities and Exchange Commission. All information in this press release is as of the date of this press release, and BeiGene undertakes no duty to update such information unless required by law.

BeiGene Corporate Contacts

Investor Contact	**Media Contact**	**Australia Media Contact**
Gabrielle Zhou	Vivian Ni	Jenny Westdorp
+86 10-5895-8058	+1 857-302-7596	+61 0413 334 425
ir@beigene.com	media@beigene.com	jenny@healthythinkinggroup.com

References:

1 BRUKINSA Australia Product Information. Available at https://www.beigene.com.au/PDF/BRUKINSAAUPI.pdf. Accessed October 2021.

2 https://www.lymphoma.org.au/types-of-lymphoma/non-hodgkin-lymphoma. Accessed August 2021.

3 https://www.lls.org/sites/default/files/2021-05/FS4_MCL_Facts_Rev.pdf. Accessed August 2021.