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): November 14, 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. ☐

Explanatory Note

As previously disclosed, on January 29, 2021, BeiGene, Ltd. (the "Company" or "BeiGene") filed a listing application (as updated from time to time, the "Listing Application") for a proposed public offering of the Company's ordinary shares and initial listing of such shares on the Science and Technology Innovation Board (the "STAR Market") of the Shanghai Stock Exchange (the "STAR Offering"). The STAR Offering will be conducted within the People's Republic of China (the "PRC") and such shares will be issued to and subscribed for by investors in Renminbi ("RMB") in the PRC (the "RMB Shares") and listed and traded on the STAR Market pursuant to the general mandate to issue shares, which was approved by the shareholders at the Company's 2021 annual general meeting of shareholders on June 16, 2021 (the "Proposed Issue of RMB Shares"). The RMB Shares will not be fungible with the ordinary shares of the Company listed on the Hong Kong Stock Exchange or with the American Depositary Shares representing the Company's ordinary shares listed on the NASDAQ Global Select Market. The number of RMB Shares (including the over-allotment option) to be issued will not exceed 132,313,549 ordinary shares, representing no more than 10% of the sum of the total number of issued ordinary shares of the Company as of January 7, 2021 (the day before the date of the board of directors' approval of the STAR Offering) and the total number of RMB Shares to be issued in the STAR Offering. The Listing Application was prepared in accordance with the listing rules of the STAR Market and the applicable securities laws and regulations of the PRC (the "PRC Securities Laws"). On June 28, 2021, the Listing Committee of the STAR Market approved the Company's Listing Application. On July 28, 2021, the Company filed a registration application for the STAR Offering (the "Registration Application") with the China Securities Regulatory Commission ("CSRC"). On November 16, 2021, the CSRC accepted an updated prospectus filed by the Company (the "Prospectus"). The Prospectus is available to the public in Chinese language only on the website maintained by the Shanghai Stock Exchange at www.sse.com.cn. The consummation of the STAR Offering is subject to, among other things, market conditions.

Item 2.02. Results of Operations and Financial Condition.

As required by the PRC Securities Laws, the Prospectus contains historical financial information of the Company that was prepared in accordance with the China Accounting Standards for Business Enterprises – Basic Standard ("CAS") and other applicable PRC accounting rules, guidance and interpretations, including but not limited to the China Securities Regulatory Commission's Compilation Rule for Information Disclosure by Companies Offering Securities to the Public No. 15 – General Rules for Financial Statement (2014 revised), and Compilation Rule for Information Disclosure by Companies Offering Securities to the Public No. 24 – Special Provisions on Information Disclosure in Financial Statements of Pilot Innovative Red-chip Companies on the Sci-Tech Innovation Board (together with CAS, "PRC GAAP") for the years ended December 31, 2018, 2019 and 2020 and the six months ended June 30, 2021, certain historical financial results for the nine months ended September 30, 2021. PRC GAAP are different from the accounting principles generally accepted in the United States ("U.S. GAAP"). The key differences between such financial information prepared in accordance with PRC GAAP and those prepared in accordance with U.S. GAAP, which was previously filed with the U.S. Securities and Exchange Commission (the "SEC"), were summarized in the Company's Current Report on Form 8-K filed with the SEC on June 30, 2021.

As required by the PRC Securities Laws, the Prospectus contains the Company's research and development expenses allocated by key products and other research and development projects ("R&D Expenses") for the years ended December 31, 2018, 2019 and 2020, and the six months ended June 30, 2021 ("Reporting Period") prepared in accordance with PRC GAAP. The R&D Expenses for the Reporting Period prepared in accordance with U.S. GAAP are attached hereto as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

As required by the PRC Securities Laws, the Prospectus contains an estimated forecast of the preliminary range of certain financial results expected for the year ending December 31, 2021, which mainly include the expected total revenue and the net loss attributable to the Company (the "Estimated Range of Financial Results"). The Estimated Range of Financial Results is prepared in accordance with the PRC GAAP and presented in RMB. The Company's independent registered public accountants have not audited, reviewed or performed any procedures with respect to the Estimated Range of Financial Results and accordingly do not express an opinion or any other form of assurance with respect thereto. The Estimated Range of Financial Results could change as a result of further review and the actual results for the year ending December 31, 2021 could differ from the Estimated Range of Financial Results as a result of changes in underlying circumstances or events that cause management's assumptions and estimates to differ from current expectations. The corresponding Estimated Range of Financial Results prepared in accordance with the accounting principles generally accepted in the United States are attached hereto as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

The Prospectus is publicly available in Chinese language only on the website maintained by the Shanghai Stock Exchange at www.sse.com.cn. The Prospectus and the information contained on the Shanghai Stock Exchange's website are not part of this Current Report on Form 8-K and shall not be deemed filed or furnished by the Company with the SEC, nor shall they be deemed incorporated by reference in any filing by the Company under the Securities Act of 1933, as amended (the "Securities Act"), or the Securities Exchange Act of 1934, as amended (the "Exchange Act").

The information in Item 2.02 of this Current Report on Form 8-K and in Exhibit 99.1 is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 8.01. Other Events.

On November 16, 2021, the Company's application for the registration of the Proposed Issue of RMB Shares was granted by the CSRC. The consummation of the STAR Offering is subject to, among other things, market conditions.

On November 14, 2021, BeiGene and NewBridge Pharmaceuticals, a specialty company in the Middle East and North Africa (MENA) regions established to bridge the access gap by partnering with global pharma and biotech companies, announced that BRUKINSA® (zanubrutinib) has received approval from the Saudi Food and Drug Authority (SFDA) for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy. BeiGene and NewBridge Pharmaceuticals are working together to bring BRUKINSA to healthcare providers and people living with MCL in Saudi Arabia and other MENA markets following regulatory approvals. 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.

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 securities laws, including statements regarding the Proposed Issue of RMB Shares under the general mandate to be listed on the STAR Market and the Estimated Range of Financial Results. Actual results may differ materially from those indicated in the forward-looking statements as a result of various important factors, including the possibility that the conditions, including market conditions, will not be met and that BeiGene will be unable to consummate the Proposed Issue of RMB Shares; the possibility that BeiGene will not realize the expected benefits of the transaction; the possibility that the final financial results will be different from the preliminary Estimated Range of Financial Results; 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 Current Report is as of the date of this Current Report, and BeiGene undertakes no duty to update such information unless required by law.

The Proposed Issue of RMB Shares under the general mandate is subject to, among other things, market conditions, and thus may or may not proceed. Shareholders and potential investors of the Company should be aware that there is no assurance that the Proposed Issue of RMB Shares will materialize or as to when it may materialize. Shareholders and potential investors of the Company should exercise caution when dealing in the securities of the Company.

Further announcement(s) or filings will be made by the Company in accordance with the applicable laws and regulations on any material updates and progress in connection with the Proposed Issue of RMB Shares as and when appropriate. This Current Report is for information purposes only and does not constitute any invitation or offer to acquire, purchase or subscribe for the securities of the Company.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Financial Information, furnished herewith
99.2	Press Release titled "BeiGene and NewBridge Pharmaceuticals Announce Approval in Saudi Arabia of BRUKINSA® (Zanubrutinib) for the Treatment of Patients with Relapsed or Refractory Mantle Cell Lymphoma", issued by BeiGene, Ltd. on November 14, 2021.
104	The cover page from this Current Report on Form 8-K, formatted in Inline XBRL

Exhibit Index

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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: November 16, 2021

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

Exhibit 99.1

Financial Information

BeiGene, Ltd. (the "Company") previously submitted a listing application for a proposed public offering of the Company's ordinary shares and initial listing of such shares on the Science and Technology Innovation Board (the "STAR Market") of the Shanghai Stock Exchange (the "STAR Offering"), which was prepared in accordance with the listing rules of the STAR Market and the applicable securities laws and regulations of the PRC (the "PRC Securities Laws"). On July 28, 2021, the Company filed a registration application for the STAR Offering (the "Registration Application") with the China Securities Regulatory Commission (the "CSRC"). On November 16 2021, the CSRC accepted an updated prospectus filed by the Company (the "Prospectus"). The Prospectus is available to the public in Chinese language only on the website maintained by the Shanghai Stock Exchange at www.sse.com.cn.

As required by the PRC Securities Laws, the Prospectus contains historical financial information of the Company that was prepared in accordance with the China Accounting Standards for Business Enterprises – Basic Standard ("CAS") and other applicable PRC accounting rules, guidance and interpretations, including but not limited to the China Securities Regulatory Commission's Compilation Rule for Information Disclosure by Companies Offering Securities to the Public No. 15 – General Rules for Financial Statement (2014 revised), and Compilation Rule for Information Disclosure by Companies Offering Securities to the Public No. 24 – Special Provisions on Information Disclosure in Financial Statements of Pilot Innovative Red-chip Companies on the Sci-Tech Innovation Board (together with CAS, "PRC GAAP") for the years ended December 31, 2018, 2019 and 2020 and the six months ended June 30, 2021, certain historical financial results for the nine months ended September 30, 2021, and an estimated forecast of the preliminary range of certain financial results expected for the year ending December 31, 2021, which mainly include the expected total revenue and the net loss attributable to the Company (the "Estimated Range of Financial Results"). The key differences between such financial information prepared in accordance with PRC GAAP and those prepared in accordance with the accounting principles generally accepted in the United States ("U.S. GAAP"), which was previously filed with the U.S. Securities and Exchange Commission (the "SEC"), were summarized in the Company's Current Report on Form 8-K filed with the SEC on June 30, 2021.

Research and Development Expenses Allocated by Key Products and Other R&D Projects

As required by the PRC Securities Laws, the Prospectus contains financial information regarding the research and development ("R&D") expenses allocated by key products and other R&D projects, which was prepared in accordance with PRC GAAP. The corresponding financial information prepared in accordance with U.S. GAAP is presented below. Amounts reported herein are stated in thousands of U.S. dollars.

Pipeline Products/ Projects	Six Months Ended June 30, 2021	Year Ended December 31, 2020	Year Ended December 31, 2019	Year Ended December 31, 2018	Total	Implementation
Zanubrutinib	61,478	155,099	171,112	119,362	**507,051**	Clinical stage
Tislelizumab	92,740	232,369	191,992	127,129	**644,230**	Clinical stage
Pamiparib	6,966	28,156	41,938	38,325	**115,385**	Clinical stage
Other R&D projects	58,249	86,775	84,781	61,960	**291,765**	Clinical / preclinical stage
R&D collaboration projects	108,830	226,505	50,000	89,000	**474,335**	N/A
Subtotal of external R&D expenses	**328,263**	**728,904**	**539,823**	**435,776**	**2,032,766**	
Subtotal of internal R&D expenses	**348,554**	**565,973**	**387,515**	**243,229**	**1,545,271**	
Total	**676,817**	**1,294,877**	**927,338**	**679,005**	**3,578,037**	

Range of Financial Results for the year ending December 31, 2021

As required by the PRC Securities Laws, the Prospectus contains an Estimated Range of Financial Results for the year ending December 31, 2021, which was prepared in accordance with PRC GAAP. The corresponding financial information prepared in accordance with U.S. GAAP is presented below. For the year ending December 31, 2021, the total revenue is estimated to be between $1.059 billion and $1.239 billion, and the net loss attributable to the Company is estimated to be between $1.288 billion and $1.688 billion. The Estimated Range of Financial Results is based on the Company's preliminary calculation. The Company's independent registered public accountants have not audited, reviewed or performed any procedures with respect to the Estimated Range of Financial Results and accordingly do not express an opinion or any other form of assurance with respect thereto. The Estimated Range of Financial Results could change as a result of further review and the actual results for the year ending December 31, 2021 could differ from the Estimated Range of Financial Results as a result of changes in underlying circumstances or events that cause management's assumptions and estimates to differ from current expectations.

Exhibit 99.2

BeiGene and NewBridge Pharmaceuticals Announce Approval in Saudi Arabia of BRUKINSA® (Zanubrutinib) for the Treatment of Patients with Relapsed or Refractory Mantle Cell Lymphoma

BRUKINSA is now approved for the treatment of MCL in 11 countries and regions, including the United States, China, Canada, Australia, Brazil, the United Arab Emirates, and Russia

BeiGene and NewBridge Pharmaceuticals are working together to rapidly advance BRUKINSA in the Middle East and North African (MENA) region

CAMBRIDGE, Mass., BEIJING and DUBAI, United Arab Emirates - November 14, 2021 -- BeiGene (NASDAQ: BGNE; HKEX: 06160), a global, science-driven biotechnology company focused on developing innovative and affordable medicines to improve treatment outcomes and access for patients worldwide, and NewBridge Pharmaceuticals, a specialty company in the Middle East and North Africa (MENA) regions established to bridge the access gap by partnering with global pharma and biotech companies, today announced that BRUKINSA® (zanubrutinib) has received approval from the Saudi Food and Drug Authority (SFDA) for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy. BeiGene and NewBridge Pharmaceuticals are working together to bring BRUKINSA to healthcare providers and people living with MCL in Saudi Arabia and other MENA markets following regulatory approvals.

“Non-Hodgkin’s lymphoma is a leading cause of cancer incidence and mortality in Saudi Arabia, representing a significantly unmet need for those living with diseases, such as MCL. BRUKINSA is a next-generation BTK inhibitor designed to improve tolerability issues often associated with the class and has demonstrated efficacy in clinical trials for patients with relapsed or refractory MCL,” said Dr. Ahmad Absi, Hematology Section Head at the National Guard Health Affairs in Jeddah, Kingdom of Saudi Arabia.

“We are delighted that MCL patients in Saudi Arabia will now have access to BRUKINSA, a potentially best-in-class BTK inhibitor. Driven by our belief —*Cancer has no borders. Neither do we*, BeiGene is committed to expanding access to high-impact medicines for all patients who need them. With approval in Saudi Arabia and in the United Arab Emirates earlier this year, we are working with NewBridge Pharmaceuticals to bring BRUKINSA to more patients in the MENA region,” commented Mohammed Al-Kapany, Senior Director of New Markets in MENA at BeiGene.

“The approval of BRUKINSA in Saudi Arabia represents an important milestone in our ongoing collaboration with BeiGene. With this differentiated BTK inhibitor now approved in two markets in the MENA region, we are one step closer to reaching patients living with MCL with new treatment options,” remarked Joe Henein, President and CEO of NewBridge Pharmaceuticals.

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 Mantle Cell Lymphoma (MCL)

Non-Hodgkin’s lymphoma (NHL) is the third most common cancer in Saudi Arabia,[1] with approximately 1,700 new cases in 2020.[2] MCL is rare form of NHL, accounting for five percent of all cases. It develops in the outer edge of a lymph node called the mantle zone. Mantle cell lymphoma occurs more often in men than in women. It is usually diagnosed in people in their early 60s.[3] MCL has a poor prognosis, with a median survival of three to four years, and is often diagnosed at a later stage of disease.[4]

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);
- For the treatment of adult patients with WM who have received at least one prior therapy (China, June 2021)**;
- For the treatment of MCL in adult patients who have received at least one prior therapy (Canada, July 2021);
- For the treatment of MCL in adult patients who have received at least one prior therapy (Chile, July 2021);
- For the treatment of adult patients with MCL who have received at least one previous therapy (Brazil, August 2021);
- For the treatment of adult patients with WM (United States, August 2021);
- For the treatment of adult patients with marginal zone lymphoma (MZL) who have received at least one anti-CD20-based regimen (United States, September 2021)*;
- For the treatment of adult patients with MCL who have received at least one previous therapy (Singapore, October 2021);
- For the treatment of MCL in patients who have received at least one prior therapy (Israel, October 2021);
- For the treatment of adult patients with WM who have received at least one prior therapy, or in first line treatment for patients unsuitable for chemo-immunotherapy (Australia, October 2021);
- For the treatment of adult patients with MCL who have received at least one prior therapy (Australia, October 2021);
- For the treatment of adult patients with MCL who have received at least one previous therapy (Russia, October 2021); and

- For the treatment of adult patients with MCL who have received at least one previous therapy (Saudi Arabia, November 2021).

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

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

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

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

Warnings and Precautions

Hemorrhage

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

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

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

Infections

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

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

Cytopenias

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

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

Second Primary Malignancies

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

Cardiac Arrhythmias

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

Embryo-Fetal Toxicity

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

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

Adverse reactions

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

Drug Interactions

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

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

Specific Populations

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

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

BeiGene Oncology

BeiGene is committed to advancing 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, Australia 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 7,700 colleagues across five continents. To learn more about BeiGene, please visit www.beigene.com and follow us on Twitter at @BeiGeneGlobal.

About NewBridge Pharmaceuticals

NewBridge Pharmaceuticals is a regional specialty company with a comprehensive pharmaceutical platform of services and expertise, established to bridge the access gap and partner with global pharma and biotech companies to in-license and commercialize U.S. Food and Drug Administration or European Medicines Agency approved innovative therapeutics that address unmet medical needs into the Middle East and North Africa (MENA) regions.

For more information, please visit www.nbpharma.com.

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 Saudi Arabia, MENA and other markets, the potential commercial opportunity for BRUKINSA, plans for making BRUKINSA accessible to patients in Saudi Arabia, MENA and other markets, 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.

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References:

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