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): September 13, 2021

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

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

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

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

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

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

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

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

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

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

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

Item 8.01. Other Events.

On September 13, 2021, BeiGene, Ltd. ("BeiGene") announced that the U.S. Food and Drug Administration (FDA) accepted for review a Biologics License Application (BLA) for its anti-PD-1 antibody tislelizumab as a treatment for patients with unresectable recurrent locally advanced or metastatic esophageal squamous cell carcinoma (ESCC) after prior systemic therapy. The Prescription Drug User Fee Act (PDUFA) target action date is July 12, 2022. 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 September 15, 2021, BeiGene announced that BRUKINSA® (zanubrutinib) has received accelerated approval from the U.S. Food and Drug Administration (FDA) for the treatment of adult patients with relapsed or refractory (R/R) marginal zone lymphoma (MZL) who have received at least one anti-CD20-based regimen. 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 U.S. FDA Acceptance of Biologics License Application for Tislelizumab in Esophageal Squamous Cell Carcinoma", issued by BeiGene, Ltd. on September 13, 2021.
99.2	Press Release titled "U.S. FDA Grants BRUKINSA® (Zanubrutinib) Accelerated Approval in Relapsed or Refractory Marginal Zone Lymphoma", issued by BeiGene, Ltd. on September 15, 2021.
104	The cover page from this Current Report on Form 8-K, formatted in Inline XBRL

Exhibit Index

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SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

BEIGENE, LTD.

Date: September 15, 2021

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

Exhibit 99.1

BeiGene Announces U.S. FDA Acceptance of Biologics License Application for Tislelizumab in Esophageal Squamous Cell Carcinoma

This marks the first ex-China regulatory filing for tislelizumab, following approval in five indications in China

The accepted BLA, filed in collaboration with Novartis, is supported by the positive global Phase 3 RATIONALE 302 trial in patients with previously treated, advanced or metastatic ESCC and safety data from tislelizumab's broad clinical program

With its second internally developed medicine filed outside China, BeiGene furthers its commitment to expanding access to innovative treatments for cancer patients worldwide

CAMBRIDGE, Mass. and BEIJING, China, September 13, 2021 -- BeiGene, Ltd. (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 the U.S. Food and Drug Administration (FDA) accepted for review a Biologics License Application (BLA) for its anti-PD-1 antibody tislelizumab as a treatment for patients with unresectable recurrent locally advanced or metastatic esophageal squamous cell carcinoma (ESCC) after prior systemic therapy. The Prescription Drug User Fee Act (PDUFA) target action date is July 12, 2022.

"Our uniquely designed anti-PD-1 antibody tislelizumab has been shown to significantly improve survival compared to chemotherapy for people with a variety of solid tumors and hematologic malignancies. We previously shared the compelling results at ASCO 2021 with tislelizumab significantly prolonging survival and demonstrating a favorable safety profile over chemotherapy in patients with locally advanced or metastatic ESCC, a devastating disease with an average five-year survival rate of just five percent. This BLA acceptance brings us closer to potentially providing tislelizumab as a treatment for these patients in the United States," said Yong (Ben) Ben, M.D., Chief Medical Officer, Immuno-Oncology at BeiGene. "Tislelizumab is already approved in five indications in China and has the potential to become a preferred immunotherapy option there. We look forward to continued collaboration with Novartis to work to bring access to tislelizumab to patients around the world."

The BLA submission is based on results from RATIONALE 302, a randomized, open-label, multicenter global Phase 3 trial (NCT03430843) designed to evaluate the efficacy and safety of tislelizumab when compared to investigator's choice chemotherapy as a second-line treatment for patients with advanced or metastatic ESCC. Results of this trial were presented at the 2021 American Society of Clinical Oncology Annual Meeting (ASCO 2021). The submission also included safety data on 1,972 patients who received tislelizumab as a monotherapy from seven clinical trials.

In addition to the United States, tislelizumab is also under regulatory review in China as a treatment for patients with locally advanced or metastatic ESCC who have disease progression following or are intolerant to first-line standard chemotherapy.

About Esophageal Squamous Cell Carcinoma (ESCC)

Esophageal cancer is one of the most common malignant tumors in the digestive tract, with more than 18,400 new cases diagnosed each year in the United States.[1] There are two main types of esophageal cancer, based on the cells where cancer develop: squamous cell carcinoma (ESCC) and adenocarcinoma (EAC).[2] ESCC accounts for up to 30% of esophageal cancer cases in the United States, and is the most common form of esophageal cancer worldwide.[2,3,4] Because many patients are diagnosed at later stages of disease, management of ESCC is challenging and the overall prognosis remains poor.[3,4]

About Tislelizumab

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

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

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

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

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

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

Tislelizumab is not approved for use outside of China.

About the Tislelizumab Clinical Program

Clinical trials of tislelizumab include:

- Phase 3 trial comparing tislelizumab with docetaxel in the second- or third-line setting in patients with NSCLC (NCT03358875);
- Phase 3 trial comparing tislelizumab to salvage chemotherapy in patients with relapsed or refractory classical Hodgkin Lymphoma (cHL; NCT04486391);
- Phase 3 trial in patients with locally advanced or metastatic urothelial carcinoma (NCT03967977);
- Phase 3 trial of tislelizumab in combination with chemotherapy versus chemotherapy as first-line treatment for patients with advanced squamous NSCLC (NCT03594747);
- Phase 3 trial of tislelizumab in combination with chemotherapy versus chemotherapy as first-line treatment for patients with advanced non-squamous NSCLC (NCT03663205);
- Phase 3 trial of tislelizumab in combination with platinum-based doublet chemotherapy as neoadjuvant treatment for patients with NSCLC (NCT04379635);
- Phase 3 trial of tislelizumab combined with platinum and etoposide versus placebo combined with platinum and etoposide in patients with extensive-stage small cell lung cancer (NCT04005716);
- Phase 3 trial comparing tislelizumab with sorafenib as first-line treatment for patients with hepatocellular carcinoma (HCC; NCT03412773);
- Phase 2 trial in patients with previously treated unresectable HCC (NCT03419897);
- Phase 2 trial in patients with locally advanced or metastatic urothelial bladder cancer (NCT04004221);

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

BeiGene Oncology

BeiGene is committed to advancing best and first-in-class clinical candidates internally or with like-minded partners to develop impactful and affordable medicines for 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 volunteers. Our expansive portfolio is directed by a predominantly internalized clinical development team supporting trials in more than 40 countries. Hematology-oncology and solid tumor targeted therapies and immuno-oncology are key focus areas for the Company, with both mono- and combination therapies prioritized in our research and development. 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 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 the filing and potential approval of a BLA for tislelizumab in ESCC in the United States, plans for development and commercialization of tislelizumab in the United States, China and other markets, plans for making tislelizumab accessible to patients in the United States and other markets, the potential for tislelizumab to provide improved clinical benefit 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:

1. Siegel RL et al. CA Cancer J Clin 2020 Jan;70(1):7-30
2. American Cancer Society. What is Esophageal Cancer? Available at https://www.cancer.org/cancer/esophagus-cancer/about/what-is-cancer-of-the-esophagus.html Accessed August 2021.
3. Codipilly DC et al. Gastrointest Endosc. 2018 Sep; 88(3): 413–426.
4. Abnet CC et al. Gastroenterology. 2018 Jan; 154(2): 360–373.

Exhibit 99.2

U.S. FDA Grants BRUKINSA® (Zanubrutinib) Accelerated Approval in Relapsed or Refractory Marginal Zone Lymphoma

This marks the third FDA approval for BRUKINSA and first approval in marginal zone lymphoma

Twenty percent of patients achieved complete remission with single-agent BRUKINSA

BRUKINSA was generally well-tolerated, consistent with its known safety profile

CAMBRIDGE, Mass. & BEIJING, China – September 15, 2021 – BeiGene, Ltd. (NASDAQ: BGNE; HKEX: 06160), a global biotechnology company focused on developing and commercializing innovative medicines worldwide, today announced that BRUKINSA® (zanubrutinib) has received accelerated approval from the U.S. Food and Drug Administration (FDA) for the treatment of adult patients with relapsed or refractory (R/R) marginal zone lymphoma (MZL) who have received at least one anti-CD20-based regimen.

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

"We are excited about the FDA's approval for BRUKINSA in patients with previously treated marginal zone lymphoma, a significant milestone that was made possible by the diligent BeiGene team, the dedicated investigators, and the participating patients and their families. The MAGNOLIA trial results provided additional evidence that the selective design of BRUKINSA can be translated to improved treatment outcomes for these patients," said Jane Huang, M.D., Chief Medical Officer, Hematology at BeiGene. "The ongoing evaluation of BRUKINSA in its broad global clinical program will enable us to further understand this potentially best-in-class BTK inhibitor and its impact on patients. Since the initial FDA approval in November 2019, BRUKINSA has been granted 12 approvals in four indications globally. We will continue to execute on our mission to improve access to innovative and quality treatments for cancer patients worldwide."

"BTK plays a critical role in B-cell receptor signaling, a driver in the development of marginal zone lymphoma. In the MAGNOLIA trial, BRUKINSA demonstrated impressive overall response and complete remission rates, with responses observed in all MZL subtypes. In addition, this next-generation BTK inhibitor was well-tolerated in these patients, with low rate of discontinuation due to adverse reactions. We are optimistic that BRUKINSA will bring clinically meaningful benefit to patients with relapsed or refractory marginal zone lymphoma," said Stephen Opat, FRACP, FRCPA, MBBS, Director of Clinical Hematology at Monash Health, Head of Department of Hematology at Monash University, and lead principal investigator of the MAGNOLIA trial.

"The approval of BRUKINSA offers patients with relapsed and refractory marginal zone lymphoma a new treatment option and new hope for improving patient outcomes," commented Meghan Gutierrez, Chief Executive Officer of the Lymphoma Research Foundation.

The FDA approval of BRUKINSA is based on efficacy results from two single-arm clinical trials, with ORR as assessed by independent review committee (IRC) per 2014 Lugano Classification as the primary endpoint.

In the multicenter, pivotal Phase 2 MAGNOLIA trial (NCT03846427) in patients with R/R MZL who received at least one anti-CD20-based regimen, a total of 66 patients were evaluated, including 26 with extranodal subtype, 26 with nodal subtype, 12 with splenic subtype, and four with unknown subtype. Based on assessment using CT scan, the ORR was 56% (95% CI: 43, 68) with a complete response (CR) rate of 20%; based on assessment prioritizing PET-CT scan, the ORR was 67% (95% CI: 54, 78) with a CR rate of 26%. The median duration of response (DoR) was not reached at the median follow-up time of 8.3 months, with 85% of responders still in remission at 12 months (95% CI: 67, 93). Responses were observed in all MZL subtypes.

In the global Phase 1/2 trial of BGB-3111-AU-003 (NCT02343120), a total of 20 patients were evaluated, including nine with extranodal subtype, five with nodal subtype, and six with splenic subtype. Based on assessment using CT scan, the ORR was 80% (95% CI: 56, 94) with a CR rate of 20%. The median DoR was not reached at the median follow-up time of 31.4 months, with 72% of responders still in remission at 12 months (95% CI: 40, 88).

The most common (≥30%) adverse reactions, including laboratory abnormalities, in the pooled safety population of 847 patients were decreased neutrophil count, upper respiratory tract infection, decreased platelet count, hemorrhage, decreased lymphocyte count, rash, and musculoskeletal pain.

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); and

- 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)*.

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.

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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 BeiGene's plan for the advancement, and anticipated clinical development, regulatory milestones and commercialization of BRUKINSA, the potential for BRUKINSA to provide improved clinical benefit 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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