UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event Reported): January 28, 2022

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 (HKEx)**
RMB Shares, par value $0.0001 per share**	**688235**	**The Science and Technology Innovation Board of the Shanghai Stock Exchange (STAR)**

*Included in connection with the registration of the American Depositary Shares ("ADSs") with the Securities and Exchange Commission. The ordinary shares are not listed for trading in the United States but are listed for trading on the HKEx.

**The RMB shares are ordinary shares of the company issued to permitted investors in the People's Republic of China and listed and traded on the STAR in Renminbi. The RMB shares are not listed for trading in the United States or on the HKEx and are not fungible with the ordinary shares listed on the HKEx or the ADSs representing the ordinary shares listed on NASDAQ, and in no event will any RMB shares be able to be converted into the ordinary shares listed on the HKEx or the ADSs listed on NASDAQ, or vice versa.

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 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

Resignation of Director

On January 31, 2022, Jing-Shyh (Sam) Su resigned from the Board of Directors (the "Board") of BeiGene, Ltd. (the "Company"). In connection with his resignation from the Board, Mr. Su also resigned from the Nominating and Corporate Governance Committee and the Commercial and Medical Affairs Advisory Committee of the Board. Mr. Su served as a member of the Board since 2018. The decision by Mr. Su to resign was not the result of any disagreement with respect to the operations, policies, or practices of the Company.

Appointment of New Directors

On February 1, 2022, the Board enlarged the Board from 11 to 12 members and appointed Margaret Dugan, M.D. and Alessandro Riva, M.D. to fill the two vacancies. Each of Drs. Dugan and Riva will serve as a Class I director until the 2022 Annual General Meeting of Shareholders to be held in June 2022 and until her or his successor is duly elected and qualified, subject to her or his earlier resignation or removal. Dr. Dugan was also appointed to serve as a member of the Scientific Advisory Committee of the Board, while Dr. Riva was also appointed to serve as a member of the Nominating and Corporate Governance Committee and the Scientific Advisory Committee of the Board.

Dr. Dugan, aged 65, is currently Chief Medical Officer at Dracen Pharmaceuticals, Inc., a privately held pharmaceutical company based in New York that leverages immuno-metabolism in oncology. She joined Dracen in 2018 with more than 20 years of experience in oncology. From 1998 to 2018, Dr. Dugan held senior leadership roles at Novartis Oncology, including Senior Vice President and Global Program Head, developing innovative medicines for patients. Prior to that, Dr. Dugan held several development positions at Schering-Plough (now Merck & Co.) and American Cyanamid (now Pfizer). Dr. Dugan received her bachelor of arts and medical degrees and training in hematology and oncology from New York University. We believe that Dr. Dugan's extensive scientific and leadership experience in the healthcare sector qualifies her to serve on, and contributes to the diversity of, the Board.

Dr. Riva, aged 61, is currently Chief Executive Officer of Intima Bioscience, Inc., a privately held clinical stage gene and cell therapy company. From 2019 to 2021, he served as Chief Executive Officer at privately held Ichnos Sciences Inc., where he built a biotechnology company focused on bi- and tri-specific antibodies in oncology and biologics in autoimmune diseases. From 2017 to 2019, he was Executive Vice President and Global Head of Oncology Therapeutics and Cell & Gene Therapy at Gilead Sciences, where he was instrumental in the acquisition of Kite Pharma. Prior to Gilead, from 2005 to 2016, Dr. Riva was Executive Vice President and Global Head of Oncology Development and Medical Affairs at Novartis Pharmaceuticals, where he contributed significantly to the Oncology Business Unit and Gene Therapy Unit. He was also interim President of Novartis Oncology during the acquisition of GSK Oncology. Dr. Riva is currently on the Board of Directors of Century Therapeutics, Inc., a NASDAQ-listed biotechnology company developing innovative iPSC-derived NK and T cell therapies. He previously held roles at Farmitalia Carlo Erba, Rhône-Poulenc Rorer and Aventis and co-founded the Breast Cancer International Research Group (BCIRG) and the Cancer International Research Group (CIRG), where he served as Chief Executive Officer. He received his M.D. in medicine and surgery from the University of Milan and a certificate board in oncology and hematology from the same institution. We believe that Dr. Riva's extensive scientific and management experience in the healthcare sector qualifies him to serve on, and contributes to the diversity of, the Board.

Drs. Dugan and Riva will receive the same compensation and indemnification as the Company's other independent directors, as described in the Company's Proxy Statement on Schedule 14A filed with the Securities and Exchange Commission on April 30, 2021. In accordance with the Company's Amended Independent Director Compensation Policy (the "Policy") and Second Amended and Restated 2016 Share Option and Incentive Plan (as amended, the "2016 Plan"), the Company will grant each of Drs. Dugan and Riva a share option valued at US$400,000, pro-rated in the first year of service, with an exercise price equal to the greater of (i) the fair market value of the Company's ordinary shares on the date of grant and (ii) the average fair market value of the Company's ordinary shares over the five trading days preceding the date of grant, in each case as determined in reference to the closing price of the Company's American Depositary Shares ("ADSs") on the NASDAQ Stock Market. Each ADS represents 13 ordinary shares. The share option will vest in full on the earlier of the first anniversary of date of grant or the date of the next annual meeting of shareholders, and in full upon death, disability or the occurrence of specified events in connection with a change of control of the Company. Dr. Dugan will also receive annual cash compensation of US$60,000 for her service as a director, and annual cash compensation of US$9,000 for her service as a member of the Scientific Advisory Committee, each pro-rated in the first year of service, and reimbursement for reasonable travel and other expenses incurred in connection with attending meetings of the Board and its committees. Dr. Riva will also receive annual cash compensation of US$60,000 for his service as a director, annual cash compensation of US$7,500 for his service as a member of the Nominating and Corporate Governance Committee, and annual cash compensation of US$9,000 for his service as a member of the Scientific Advisory Committee, each pro-rated in the first year of service, and reimbursement for reasonable travel and other expenses incurred in connection with attending meetings of the Board and its committees. Additionally, Drs. Dugan and Riva will be entitled to future cash compensation and annual equity grants in accordance with the Policy and the 2016 Plan.

There are no arrangements or understandings between Dr. Dugan and any other person pursuant to which she was elected as a director, nor are there any transactions between Dr. Dugan and the Company that would be reportable under Item 404(a) of Regulation S-K. There are no arrangements or understandings between Dr. Riva and any other person pursuant to which he was elected as a director, nor are there any transactions between Dr. Riva and the Company that would be reportable under Item 404(a) of Regulation S-K.

A copy of the press release announcing the appointment of Drs. Dugan and Riva to the Board is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 8.01. Other Events.

On January 28, 2022, the Company issued a press release announcing the Center for Drug Evaluation of the China National Medical Products Administration has accepted a supplemental new drug application for BeiGene's BTK inhibitor BRUKINSA (zanubrutinib) as a treatment for adult patients with chronic lymphocytic leukemia or small lymphocytic lymphoma and granted BRUKINSA breakthrough therapy designation. A copy of this press release is attached hereto as Exhibit 99.2, and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release titled "Drs. Margaret Dugan and Alessandro Riva Appointed to BeiGene Board of Directors" issued by BeiGene, Ltd. on February 1, 2022.
99.2	Press Release titled "BeiGene Announces Acceptance of Supplemental New Drug Application in China for BRUKINSA (zanubrutinib) in Chronic Lymphocytic Leukemia with Breakthrough Therapy Designation," issued by BeiGene, Ltd. on January 28, 2022.
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: February 2, 2022

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

Exhibit 99.1

Drs. Margaret Dugan and Alessandro Riva Appointed to BeiGene Board of Directors

Industry Leaders Lend Scientific and Clinical Expertise to Several Board Committees

CAMBRIDGE, Mass. and BEIJING—February 1, 2022—BeiGene (NASDAQ: BGNE; HKEX: 06160; SSE: 688235), a global, science-driven biotechnology company focused on developing innovative and affordable medicines to improve treatment outcomes and access for patients worldwide, today announced the appointment of Margaret Dugan, M.D., and Alessandro Riva, M.D., to its Board of Directors. Dr. Dugan will join the scientific advisory committee and Dr. Riva will join the nominating and corporate governance, and scientific advisory committees of the board. In addition, Jing-Shyh (Sam) Su will be stepping down from BeiGene's board of directors after serving for almost four years.

"Drs. Dugan and Riva both bring significant oncology expertise to BeiGene's Board of Directors during a key period of Company growth as we advance our high-value, late-stage portfolio," commented John V. Oyler, Co-Founder, Chief Executive Officer, and Chairman of BeiGene. They bring complementary medical and commercial experience at both nimble biotechs and global pharmaceutical organizations that will support our efforts to become a leader and transformational agent in the industry. We also want to recognize and thank Sam Su for his support during his tenure on the board."

Dr. Dugan is currently Chief Medical Officer at Dracen Pharmaceuticals, a privately held pharmaceutical company based in New York that leverages immuno-metabolism in oncology. She joined Dracen in 2018 with more than 20 years of experience in oncology and previously held senior leadership roles at Novartis Oncology, including Senior Vice President and Global Program Head, developing innovative medicines for patients. Dr. Dugan also held several development positions at Schering-Plough (now Merck & Co.) and American Cyanamid (now Pfizer). Dr. Dugan received her B.A. and medical degrees and training in hematology and oncology from New York University.

"Dr. Dugan is widely recognized for her oncology expertise and commitment to bringing important medical breakthroughs to patients around the world," continued Mr. Oyler. "We are very pleased to welcome her to our Board of Directors, and her expertise will be highly valuable as we work to expand our pipeline and make an impact for the greater good of patients."

"I am honored to join BeiGene's board and am excited to work alongside this talented and dedicated team to bring high-quality, innovative therapies to more people around the world who need them. I am impressed by BeiGene's broad internal research and development capabilities as well as its in-licensed portfolio of exciting new assets, and the team's values of putting patients first, having bold ingenuity along with a collaborative spirit, and driving excellence to make a lasting impact in the world," commented Dr. Dugan.

Dr. Riva is currently Chief Executive Officer of Intima Bioscience, a privately held clinical stage gene and cell therapy company. Prior to joining Intima, he served as Chief Executive Officer at privately held Ichnos Sciences, where he built a biotechnology company focused on bi- and tri-specific antibodies in oncology and biologics in autoimmune diseases. Before Ichnos, he was Executive Vice President and Global Head of Oncology Therapeutics and Cell & Gene Therapy at Gilead Sciences, where he was instrumental in the acquisition of Kite Pharma. Prior to Gilead, Dr. Riva was Executive Vice President and Global Head of Oncology Development and Medical Affairs at Novartis Pharmaceuticals, where he contributed significantly to the Oncology Business Unit and the Cell and Gene Therapy Unit. He was also interim President of Novartis Oncology during the acquisition of GSK Oncology. Dr. Riva is currently on the Board of Directors of Century Therapeutics, a NASDAQ-listed biotechnology company developing innovative iPSC-derived NK and T cell therapies. He previously held roles at Farmitalia Carlo Erba, Rhône-Poulenc Rorer and Aventis and co-founded the Breast Cancer International Research Group (BCIRG) and the Cancer International Research Group (CIRG), where he served as CEO. He received his M.D. in medicine and surgery from the University of Milan and a certificate board in oncology and hematology from the same institution.

"Dr. Riva brings key industry insights and depth of experience to our board, having steadfast commitment to the patients we work to help and the values with which we do so," continued Mr. Oyler. "Our team welcomes Dr. Riva to our Board of Directors, and we look forward to incorporating his insights as we deliver on our important mission."

Dr. Riva stated, "BeiGene is building a next-generation global biotech with unique capabilities within our industry. I am honored to join the Board and look forward to joining at such an exciting time, with key catalysts in the near-term, building on the long-term strategy of this fantastic organization."

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 8,000 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 expected contributions of the new board members and BeiGene's future plans and aspirations. 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.

BeiGene Corporate Contacts

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Exhibit 99.2

BeiGene Announces Acceptance of Supplemental New Drug Application in China for BRUKINSA (zanubrutinib) in Chronic Lymphocytic Leukemia with Breakthrough Therapy Designation

BRUKINSA was granted its first breakthrough therapy designation in China with this application

The application is supported by SEQUOIA trial results, which demonstrated BRUKINSA's superiority in efficacy over chemoimmunotherapy

BRUKINSA received the China NMPA conditional approval for the treatment of patients with relapsed or refractory chronic lymphocytic leukemia in June 2020

CAMBRIDGE, Mass., and BEIJING—January 28, 2022—BeiGene (NASDAQ: BGNE; HKEX: 06160; SSE: 688235), a global, science-driven biotechnology company focused on developing innovative and affordable medicines, today announced that the Center for Drug Evaluation (CDE) of the China National Medical Products Administration (NMPA) has accepted a supplemental new drug application (sNDA) for BeiGene's BTK inhibitor BRUKINSA (zanubrutinib) as a treatment for adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) and granted BRUKINSA breakthrough therapy designation (BTD).

"This is BRUKINSA's first filing in treatment-naïve CLL supported by the positive global Phase 3 SEQUOIA trial, a remarkable step forward in its global registration program. As presented at ASH, BRUKINSA significantly prolonged progression-free survival and was generally well-tolerated in these patients, with demonstrated superiority over chemoimmunotherapy in the SEQUOIA trial," commented Jane Huang, M.D., Chief Medical Officer of Hematology at BeiGene. "Together with the filing in Waldenström's macroglobulinemia, we are hoping to expand the clinical use of this potential best-in-class BTK inhibitor from relapsed or refractory setting to frontline care for the blood cancer community in China."

The sNDA is supported by clinical results from the randomized, multicenter, global Phase 3 SEQUOIA trial (NCT03336333) comparing BRUKINSA to bendamustine in combination with rituximab (B+R) in patients with treatment-naïve CLL.

As assessed by an independent review committee (IRC), BRUKINSA demonstrated superiority in progression-free survival (PFS) over B+R. With a median follow-up of 26.15 months, the 24-month PFS was 85.5% (95% CI: 80.1, 89.6) with BRUKINSA, compared to 69.5% (95% CI: 62.4, 75.5) with B+R, and the hazard ratio (HR) was 0.42 (95% CI: 0.27, 0.63), $p<0.0001$. BRUKINSA was generally well tolerated with a safety profile consistent with its broad clinical program, including a low rate of atrial fibrillation.

About Chronic Lymphocytic Leukemia

Chronic lymphocytic leukemia (CLL) is the most common form of leukemia in adults, with a global incidence of approximately 114,000 new cases in 2017.CLL affects white blood cells or lymphocytes in the bone marrow, Proliferation of cancer cells (leukemia) in the marrow result in reduced ability to fight infection and spread into the blood, which affects other parts of the body including the lymph nodes, liver and spleen.[i,ii,iii] The BTK pathway is a known route that signals malignant B cells and contributes to the onset of CLL.[iv] Small lymphocytic lymphoma (SLL) is a non-Hodgkin's lymphoma affecting the B-lymphocytes of the immune system, which shares many similarities to CLL but with cancer cells found mostly in lymph nodes.[v]

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 has received 20 approvals covering 43 countries 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 MCL in patients who have received at least one prior therapy (Israel, January 2021);
- 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 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);
- For the treatment of adult patients with MCL who have received at least one previous therapy (Saudi Arabia, November 2021);
- For the treatment of adult patients with WM who have received at least one prior therapy or first-line treatment of patients unsuitable for chemo-immunotherapy (European Union plus Iceland, Lichtenstein, and Norway, November 2021);
- For the treatment of eligible adult patients with Waldenström's macroglobulinemia (WM) who have received at least one prior therapy or for the first-line treatment of eligible patients unsuitable for chemo-immunotherapy (Great Britain, December 2021); and
- For the treatment of adult patients with MCL who have received at least one previous therapy (Ecuador, December 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 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 and medical affairs team of approximately 2,900 colleagues dedicated to advancing more than 100 clinical trials that have involved more than 14,500 subjects. Our expansive portfolio is directed predominantly by our internal colleagues supporting clinical trials in more than 45 countries and regions. 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. BeiGene currently has three approved medicines discovered and developed in our own labs: BTK inhibitor BRUKINSA in the United States, China, the EU and U.K., Canada, Australia and additional international markets; and the non-FC-gamma receptor binding anti-PD-1 antibody tislelizumab as well as the 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, Bristol Myers Squibb, EUSA Pharma and Bio-Thera. We also plan to address greater areas of unmet need globally through our other collaborations including with Mirati Therapeutics, Seagen, and Zymeworks.

In January 2021 BeiGene and Novartis announced a collaboration granting Novartis rights to co-develop, manufacture, and commercialize BeiGene's anti-PD1 antibody tislelizumab in North America, Europe, and Japan. Building upon this productive collaboration, including a biologics license application (BLA) under FDA review, BeiGene and Novartis announced an option, collaboration and license agreement in December 2021 for BeiGene's TIGIT inhibitor ociperlimab that is in Phase 3 development. Novartis and BeiGene also entered into a strategic commercial agreement through which BeiGene will promote five approved Novartis Oncology products across designated regions of China.

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 8,000 colleagues across five continents. To learn more about BeiGene, please visit www.beigene.ca and follow us on Twitter at @BeiGeneGlobal.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws, including statements regarding the potential clinical benefits and advantages of BRUKINSA, BeiGene's plans for the advancement, and anticipated clinical development, regulatory milestones and commercialization of BRUKINSA, the potential commercial opportunity for BRUKINSA, plans for making BRUKINSA accessible to patients in China, 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 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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