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): February 17, 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)**

*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.

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.

Amended Independent Director Compensation Policy

On February 17, 2022, upon recommendation of the Compensation Committee, the Board of Directors of BeiGene, Ltd. (the "Company" or "BeiGene") approved amendments to the Company's Independent Director Compensation Policy (the "Amended Independent Director Compensation Policy"). Under the Amended Independent Director Compensation Policy, independent directors will be paid an annual cash retainer of $60,000, which reflects no changes from the existing annual retainer adopted in 2021, and additional fees for service as a member or chair of each committee of the Board of Directors on which they serve, ranging from $7,500 to $25,000 per year, as specified in the policy, which reflect increases of $1,500 or $2,500 from the existing fees adopted in 2021 for service as a chairperson of each committee and no changes for service as a member of each committee. The changes for the cash retainers, which are paid quarterly, are effective as of April 1, 2022. There are no changes in the amount or composition of the equity award compared to the policy adopted in 2021. A complete copy of the Amended Independent Director Compensation Policy is filed as Exhibit 10.1 and is incorporated herein by reference. The above summary of the terms of the Amended Independent Director Compensation Policy does not purport to be complete and is qualified in its entirety by reference to such exhibit.

On February 22, 2022, BeiGene issued a press release announcing that the European Medicines Agency has accepted for review two new indication applications for its BTK inhibitor BRUKINSA® (zanubrutinib) for the treatment of patients with chronic lymphocytic leukemia (CLL) and for the treatment of patients with marginal zone lymphoma (MZL). 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 February 22, 2022, BeiGene issued a press release announcing that the U.S. Food and Drug Administration (FDA) has accepted a supplemental new drug application for BRUKINSA® (zanubrutinib) for the treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL). 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
10.1	BeiGene, Ltd. Independent Director Compensation Policy, as amended.
99.1	Press Release titled "BeiGene Announces European Medicines Agency Acceptance of Applications for BRUKINSA (zanubrutinib) in Chronic Lymphocytic Leukemia and Marginal Zone Lymphoma," issued on February 22, 2022.
99.2	Press Release titled "BeiGene Announces U.S. FDA Acceptance of Supplemental New Drug Application for BRUKINSA (zanubrutinib) in Chronic Lymphocytic Leukemia ," issued on February 22, 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 22, 2022

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

Exhibit 10.1

BEIGENE, LTD.

INDEPENDENT DIRECTOR COMPENSATION POLICY

The purpose of this Independent Director Compensation Policy (this "Policy") of BeiGene, Ltd. (the "Company") is to provide a total compensation package that enables the Company to attract and retain, on a long-term basis, high-caliber directors who meet the general independence requirements under NASDAQ Rule 5605(a)(2) and Rule 3.13 of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited. In furtherance of this purpose, all members of the Board of Directors (the "Board") of the Company who are independent directors under NASDAQ Rule 5605(a)(2) shall be paid compensation for services provided to the Company as set forth below:

Cash Retainers

Annual Retainer for Board Membership	
For general availability and participation in meetings and conference calls of the Board. No additional compensation for attending individual Board meetings.	$60,000
Additional Annual Retainers for Committee Membership and Service as Chairperson	
Audit Committee Chairperson:	$25,000
Audit Committee member:	$12,500
Compensation Committee Chairperson:	$20,000
Compensation Committee member:	$10,000
Nominating and Corporate Governance Committee Chairperson:	$15,000
Nominating and Corporate Governance Committee member:	$7,500
Commercial and Medical Affairs Advisory Committee Chairperson:	$18,000
Commercial and Medical Affairs Advisory Committee member:	$9,000
Scientific Advisory Committee Chairperson:	$18,000
Scientific Advisory Committee member:	$9,000
No additional compensation for attending individual committee meetings.	

All cash retainers will be paid quarterly, in arrears, or upon the earlier resignation or removal of the independent director. Cash retainers owing to independent directors shall be annualized, meaning that independent directors who join the Board during the calendar year, such amounts shall be pro-rated based on the number of calendar days served by such director.

Equity Retainers

Upon initial election or appointment to the Board: An initial equity grant (the "Initial Grant") on the date of such election or appointment (the "grant date" for the Initial Grant) with an initial value of $400,000 on the grant date, pro-rated based on the number of calendar days to be served from the grant date until the first anniversary of the most recent Annual Meeting.

Annual equity grants: On the date of the Company's Annual Meeting of Shareholders (the "Annual Meeting"), each continuing independent member of the Board who is eligible to receive awards under this Plan will receive an annual equity grant (the "Annual Grant") with an initial value of $400,000 on the date of grant.

Terms and Conditions of Initial Grant and Annual Grant: Each of the Initial Grant and the Annual Grant (together, the "Equity Awards") shall consist of 50% share options ("Options") and 50% restricted share units ("RSUs"); *provided, however*, that to the extent that a grant of RSUs is subject to shareholder approval pursuant to applicable listing rules, (i) the Initial Grant shall consist of 100% Options and (ii) the Annual Grant shall include RSUs only upon shareholder approval and, in the absence of such shareholder approval, the Annual Grant shall consist of 100% Options. The number of Options awarded will be the applicable grant value divided by the per share option value on the date of grant determined in accordance with the Company's standard option valuation practices, and the number of RSUs awarded will be the applicable grant value divided by the fair market value per share of the Company's shares on the date of grant. The Options will have an exercise price equal to the higher of (i) the fair market value per share of the Company's shares on the date of grant, and (ii) the average fair market value per share of the Company's shares for the five trading days immediately preceding the date of grant. The Equity Awards shall be governed by, and subject to the terms and conditions of, the Company's 2016 Share Option and Incentive Plan (as may be amended from time to time) and standard form of grant agreements in effect on the date of grant. In addition, the Equity Awards shall vest in full (i.e., in a single installment) upon the earlier to occur of the first anniversary of the date of grant or the date of the next Annual Meeting; provided, however, that all vesting shall cease if the director resigns from the Board or otherwise ceases to serve as a director other than as set forth below or the Board determines that the circumstances warrant continuation of vesting. In addition, all Options shall be exercisable for three years following cessation of service, and all Equity Awards shall accelerate in full upon (i) death, (ii) disability, (iii) termination of service in connection with a change of control of the Company, or (iv) upon a change of control of the Company if the director's service continues and the awards are not assumed by the acquiror at the time of the change of control. Subject to specific terms and conditions designed for compliance with applicable tax and other regulations, directors generally may elect to defer settlement of their RSUs until six months following the date that the director ceases to serve as a director.

Limitations on Independent Director Compensation

Cash and equity compensation payable to independent directors under this Policy shall be subject to any limits, terms and conditions set forth in any Company policy or equity incentive plan or as otherwise adopted by the Board from time to time.

Expenses

The Company shall reimburse all reasonable out-of-pocket expenses incurred by independent directors in attending Board and committee meetings.

ADOPTED: November 16, 2016
EFFECTIVE: November 16, 2016
AMENDED: June 6, 2018, June 5, 2019, April 13, 2020, April 5, 2021* and February 17, 2022*

* Changes regarding the cash retainers will become effective on April 1.

Exhibit 99.1

BeiGene Announces European Medicines Agency Acceptance of Applications for BRUKINSA (zanubrutinib) in Chronic Lymphocytic Leukemia and Marginal Zone Lymphoma

The CLL filing is supported by two global Phase 3 trials of BRUKINSA in chronic lymphocytic leukemia covering both treatment-naïve and relapsed or refractory patient populations

BRUKINSA was granted approval by the European Commission for the treatment of Waldenström's macroglobulinemia in November 2021

BASEL, Switzerland, CAMBRIDGE, Mass. and BEIJING—February 22, 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 that the European Medicines Agency (EMA) has accepted for review two new indication applications for its BTK inhibitor BRUKINSA® (zanubrutinib) for the treatment of patients with chronic lymphocytic leukemia (CLL) and for the treatment of patients with marginal zone lymphoma (MZL).

"As a BTK inhibitor designed to maximize BTK occupancy and minimize off-target binding, BRUKINSA demonstrated improvements in ORR and advantages in overall cardiac safety compared to ibrutinib in the ALPINE study in patients with relapsed or refractory CLL. Together with results from the SEQUOIA study in front-line CLL, BRUKINSA has the potential to become a preferred treatment option for patients with CLL and MZL in the European Union," commented Peter Hillmen, MBChB, Ph.D., Professor of Experimental Haematology at University of Leeds, and principal investigator of the ALPINE trial.

In November 2021, BRUKINSA received its first approval in the European Union (EU) for the treatment of adult patients with Waldenström's macroglobulinemia (WM) who have received at least one prior therapy or for the first-line treatment of patients unsuitable for chemo-immunotherapy.

"Following BRUKINSA's recent EU approval in WM, we are pleased that BRUKINSA is now under review for two more indications—CLL and MZL. We are confident in the broad clinical evidence from its global clinical development program and hope to bring this next-generation BTK inhibitor to CLL and MZL patients in the EU," said Jane Huang, M.D., Chief Medical Officer of Hematology at BeiGene.

The application for in CLL is based on data included from two global Phase 3 trials of BRUKINSA in CLL—ALPINE (NCT03734016) comparing BRUKINSA to ibrutinib in relapsed or refractory (R/R) patients and SEQUOIA (NCT03336333) comparing BRUKINSA to bendamustine and rituximab in treatment-naïve (TN) patients. These two studies enrolled patients from a total of 17 countries, including the United States, China, Australia, New Zealand and multiple countries in Europe.

Results from the ALPINE trial and the SEQUOIA trial were reported at the 26th European Hematology Association (EHA2021) Virtual Congress in June 2021 and at the 63rd American Society for Hematology (ASH) Annual Meeting in December 2021, respectively.

The application for MZL is based on efficacy results from two single-arm clinical trials—MAGNOLIA (NCT03846427), a global pivotal Phase 2 trial in patients with R/R MZL who received at least one anti-CD20-based regimen, and BGB-3111-AU-003 (NCT02343120), a global Phase 1/2 trial. These two studies enrolled patients from a total of nine countries, including sites in the United States, China, Europe, Australia, and New Zealand. Results from the MAGNOLIA trial were reported at the 62nd ASH Annual Meeting in December 2020.

Added Gerwin Winter, Senior Vice President, Head of Commercial, Europe at BeiGene, "We are proud of the progress BeiGene has made in Europe over the past year, with a growing team across the continent. The acceptance of our applications for MZL and CLL bring us a step closer to broadening access to patients."

About Chronic Lymphocytic Leukemia and Small Lymphocytic Lymphoma

Chronic lymphocytic leukemia (CLL) is the most common form of leukemia in the Western countries, accounting for approximately one third of all leukemia cases.[1,2] In 2020, an estimated 30,000 new CLL patients were diagnosed in Europe.[2,3] CLL begins in cells that become certain white blood cells (lymphocytes) in the bone marrow but then go into the blood. 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.[4,5,6] The BTK pathway is a known route that signals malignant B cells and contributes to the onset of CLL.[7] 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.[8]

About Marginal Zone Lymphoma

Marginal Zone lymphoma (MZL) is a group of indolent non-Hodgkin's lymphomas (NHL) that begin in the marginal zones of lymph tissue, representing approximately 5-15 percent of all NHL cases in the Western world.[9] There are three different subtypes of MZL: extranodal marginal zone B-cell lymphoma or mucosa-associated lymphoid tissue (MALT) which is most common; nodal marginal zone B-cell lymphoma which develops in the lymph nodes and is rare; and splenic marginal zone B-cell lymphoma which develops in the spleen, bone marrow, or both and is the rarest form of the disease.[10]

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 supported by a broad clinical program which includes more than 3,900 subjects in 35 trials across 28 markets. In November 2021, the European Commission approved BRUKINSA for the treatment of adult patients with Waldenström's macroglobulinemia (WM) who have received at least one prior therapy or for the first-line treatment of patients unsuitable for chemo-immunotherapy. To date, BRUKINSA has received more than 20 approvals covering more than 40 countries and regions, including the United States, China, the EU and Great Britain, Canada, Australia and additional international markets. Currently, more than 40 additional regulatory submissions are in review around the world.

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.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 planned commercialization and market access of BRUKINSA in the European Union and additional development, regulatory filings and potential approvals in other markets, the potential for BRUKINSA to provide improved clinical benefits with advantages in safety, the potential for BRUKINSA to become the preferred treatment option among patients with CLL and MZL in the European Union, the potential commercial opportunity for BRUKINSA, 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, manufacturing, and other operations, as well as those risks more fully discussed in the section entitled "Risk Factors" in BeiGene's most recent quarterly report on Form 10-Q as well as discussions of potential risks, uncertainties, and other important factors in BeiGene's subsequent filings with the U.S. Securities and Exchange Commission. All information in this press release is as of the date of this press release, and BeiGene undertakes no duty to update such information unless required by law.

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[6] National Cancer Institute. Chronic Lymphocytic Leukemia Treatment (PDQ®)–Patient Version. Available here: Chronic Lymphocytic Leukemia Treatment (PDQ®)–Patient Version.

[7] Haselager MV et al. Proliferative Signals in Chronic Lymphocytic Leukemia; What Are We Missing? Front Oncol. 2020; 10: 592205.

[8] Cancer Support Community. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma. Available at https://www.cancersupportcommunity.org/chronic-lymphocytic-leukemiasmall-lymphocytic-lymphoma.

[9] Annals of Oncology, Marginal Zone Lymphomas: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up, January 6, 2020.

[10] Leukemia & Lymphoma Society, Marginal Zone Lymphoma. Available at: https://www.lls.org/research/marginal-zone-lymphoma-mzl.

Exhibit 99.2

BeiGene Announces U.S. FDA Acceptance of Supplemental New Drug Application for BRUKINSA (zanubrutinib) in Chronic Lymphocytic Leukemia

The filing is supported by two global Phase 3 trials of BRUKINSA in chronic lymphocytic leukemia covering both treatment-naïve and relapsed or refractory patient populations

The Prescription Drug User Fee Act target action date is October 22, 2022

CAMBRIDGE, Mass. and BEIJING—February 22, 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 that the U.S. Food and Drug Administration (FDA) has accepted a supplemental new drug application (sNDA) for BRUKINSA® (zanubrutinib) for the treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL). CLL is the most common form of adult leukemia. The Prescription Drug User Fee Act (PDUFA) target action date is October 22, 2022.

"We are pleased with the FDA's acceptance of BRUKINSA's filing in CLL. This is an important milestone in BRUKINSA's global registration program. With superiority in investigator-assessed ORR over ibrutinib in ALPINE for relapsed or refractory patients and in PFS over chemoimmunotherapy in the SEQUOIA study for treatment-naïve patients, BRUKINSA has demonstrated its potential to improve treatment outcomes for CLL patients," commented Jane Huang, M.D., Chief Medical Officer of Hematology at BeiGene. "We look forward to furthering our discussions with the FDA on this filing and the potential to bring this important treatment option to the CLL community in the U.S."

The sNDA filing in CLL/SLL includes data from two pivotal randomized Phase 3 studies and eight supportive studies in B cell malignancies. The two global Phase 3 trials of BRUKINSA in CLL/SLL are: ALPINE (NCT03734016) comparing BRUKINSA to ibrutinib in relapsed or refractory (R/R) patients and SEQUOIA (NCT03336333) comparing BRUKINSA to bendamustine and rituximab in treatment-naïve (TN) patients. Additionally, the SEQUOIA study enrolled patients with deletion 17p in a non-randomized arm evaluating BRUKINSA monotherapy in this high risk population. ALPINE and SEQUOIA enrolled patients from a total of 17 countries, including the United States, China, Australia, New Zealand and multiple countries in Europe. Results from the ALPINE trial and the SEQUOIA trial were reported at the 26th European Hematology Association (EHA2021) Virtual Congress in June 2021 and at the 63rd American Society for Hematology (ASH) Annual Meeting in December 2021, respectively.

"While previously approved BTK inhibitors have been transformational for some patients with CLL, there continues to be unmet need as not all patients achieve a favorable clinical response while others are unable to tolerate currently approved BTKi therapies," said Jennifer R. Brown, MD, PhD, Director of the CLL Center of the Division of Hematologic Malignancies at Dana-Farber Cancer Institute, and a principal investigator in the two studies. "As demonstrated in both the ALPINE AND SEQUOIA studies, BRUKINSA was generally well-tolerated in CLL patients with low rates of atrial fibrillation and showed strong efficacy compared to ibrutinib and chemoimmunotherapy, respectively."

About Chronic Lymphocytic Leukemia

Chronic lymphocytic leukemia (CLL) is the most common form of leukemia in adults. CLL accounts for about one quarter of new cases of leukemia, and in 2021 there were more than 21,000 new cases diagnosed in the U.S.[1] In 2018, there were an estimated 195,129 people living with chronic lymphocytic leukemia in the United States.[1] CLL begins in cells that become certain white blood cells (lymphocytes) in the bone marrow but then go into the blood. 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.[2,3,4] The BTK pathway is a known route that signals malignant B cells and contributes to the onset of CLL.[5] 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.[6]

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 previously been approved for three indications in the United States: for the treatment of mantle cell lymphoma (MCL) in adult patients who have received at least one prior therapy (Nov. 2019)*; for the treatment of adult patients with Waldenström's macroglobulinemia (WM) (Aug. 2021); and for the treatment of adult patients with relapsed or refractory marginal zone lymphoma (MZL) who have received at least one anti-CD20-based regimen (Sept. 2021)*.

BRUKINSA is supported by a broad clinical program which includes more than 3,900 subjects in 35 trials across 28 markets. To date, BRUKINSA has received more than 20 approvals covering more than 40 countries and regions, including the United States, China, the EU and Great Britain, Canada, Australia and additional international markets. Currently, more than 40 additional regulatory submissions are in review around the world.

* 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.

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.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 future development, regulatory filings and potential commercialization of BRUKINSA in the United States and other markets, the potential for BRUKINSA to provide improved clinical benefits with advantages in safety, the potential commercial opportunity for BRUKINSA, 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, manufacturing, and other operations, as well as those risks more fully discussed in the section entitled "Risk Factors" in BeiGene's most recent quarterly report on Form 10-Q as well as discussions of potential risks, uncertainties, and other important factors in BeiGene's subsequent filings with the U.S. Securities and Exchange Commission. All information in this press release is as of the date of this press release, and BeiGene undertakes no duty to update such information unless required by law.

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