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

Form 8-K

CURRENT REPORT

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

Date of Report (Date of earliest event Reported): November 19, 2021

BEIGENE, LTD.

(Exact Name of Registrant as Specified in Charter)

Cayman Islands (State or Other Jurisdiction of Incorporation)	001-37686 (Commission File Number)	98-1209416 (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:

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

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

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

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

Explanatory Note

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

Item 8.01. Other Events.

On November 23, 2021, the Company issued a press release announcing the launch of the STAR Offering. A copy of this press release is attached hereto as Exhibit 99.1, and is incorporated herein by reference.

On November 23, 2021, the Company issued a press release announcing that the European Commission (EC) approved BRUKINSA® (zanubrutinib) 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. The approval is applicable to all 27 European Union (EU) member states, plus Iceland and Norway. A copy of this press release is attached hereto as Exhibit 99.2, and is incorporated herein by reference.

On November 23, 2021, the Company announced that it has purchased a 42-acre site at the Princeton West Innovation Campus in Hopewell, N.J. to house a new state-of-the-art manufacturing campus and clinical R&D center. As a key part of BeiGene’s continued growth, the company is investing in U.S. manufacturing to further expand and diversify its global supply chain and build new manufacturing capabilities for its deep pipeline of biologic and drug candidates. A copy of this press release is attached hereto as Exhibit 99.3, and is incorporated herein by reference.

On November 22, 2021, the Company announced that the first patient has been dosed in a Phase 1 clinical trial of BGB-23339, a potent, allosteric investigational tyrosine kinase 2 (TYK2) inhibitor internally developed by BeiGene scientists. A copy of this press release is attached hereto as Exhibit 99.4, and is incorporated herein by reference.

On November 19, 2021, the China National Medical Products Administration approved POBEVCY® (a biosimilar to bevacizumab injection) for the treatment of patients with advanced, metastatic or recurrent non-small cell lung cancer (NSCLC) and metastatic colorectal cancer. BeiGene has rights to develop, manufacture, and commercialize POBEVCY® in China (including Hong Kong, Macao and Taiwan) under a collaboration agreement with Bio-Thera Solutions, Ltd. entered in August 2020.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other securities laws, including statements regarding the Proposed Issue of RMB Shares under the general mandate to be listed on the STAR Market. Actual results may differ materially from those indicated in the forward-looking statements as a result of various important factors, including the possibility that the conditions, including market conditions and customary closing conditions related to the STAR Offering, will not be met and that BeiGene will be unable to consummate the Proposed Issue of RMB Shares; the possibility that BeiGene will not realize the expected benefits of the transaction; the possibility that the final financial performance data will be different from the preliminary data; BeiGene's ability to demonstrate the efficacy and safety of its drug candidates; the clinical results for its drug candidates, which may not support further development or marketing approval; actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials and marketing approval; BeiGene's ability to achieve commercial success for its marketed medicines and drug candidates, if approved; BeiGene's ability to obtain and maintain protection of intellectual property for its medicines and technology; BeiGene's reliance on third parties to conduct drug development, manufacturing and other services; BeiGene's limited experience in obtaining regulatory approvals and commercializing pharmaceutical products and its ability to obtain additional funding for operations and to complete the development and commercialization of its drug candidates and achieve and maintain profitability; the impact of the COVID-19 pandemic on the BeiGene's clinical development, regulatory, commercial, and other operations, as well as those risks more fully discussed in the section entitled "Risk Factors" in BeiGene's most recent quarterly report on Form 10-Q as well as discussions of potential risks, uncertainties, and other important factors in BeiGene's subsequent filings with the U.S. Securities and Exchange Commission. All information in this Current Report is as of the date of this Current Report, and BeiGene undertakes no duty to update such information unless required by law.

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

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

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release titled "BeiGene Launches Proposed Initial Public Offering on the STAR Market in China", issued by BeiGene, Ltd. on November 23, 2021.
99.2	Press Release titled "BeiGene Announces Approval of BRUKINSA® (zanubrutinib) in the European Union for Treatment of Adults with Waldenström's Macroglobulinemia", issued by BeiGene, Ltd. on November 23, 2021.
99.3	Press Release titled "BeiGene Closes on Property for New U.S. Manufacturing and Clinical R&D Center", issued by BeiGene, Ltd. on November 23, 2021.
99.4	Press Release titled "BeiGene Initiates First-in-Human Phase 1 Clinical Trial of Investigational TYK2 Inhibitor BGB-23339", issued by BeiGene, Ltd. on November 22, 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: November 23, 2021

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

BeiGene Launches Proposed Initial Public Offering on the STAR Market in China

Cambridge, Mass. and Beijing, China, November 23, 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 the commencement of an initial public offering (STAR Offering) on the Science and Technology Innovation Board (STAR Market) of the Shanghai Stock Exchange (SSE). The total number of shares being offered in the STAR Offering is 115,055,260 ordinary shares, par value \$0.0001 per share, which represents 8.62% of BeiGene's total outstanding ordinary shares as of October 31, 2021, after giving effect to the shares being offered. The shares offered in the STAR Offering (RMB Shares) will be issued to and subscribed for by permitted investors in the People's Republic of China (PRC) and listed and traded on the STAR Market in Renminbi. In addition, BeiGene expects to grant China International Capital Corporation Limited a 30-day overallotment option for up to 17,258,000 additional RMB Shares. The consummation of the STAR Offering is subject to, among other things, market conditions, and there can be no assurance as to whether or when the STAR Offering may be completed, or as to the actual size or terms of the STAR Offering.

China International Capital Corporation Limited and Goldman Sachs Gao Hua Securities Co. Ltd. are acting as joint sponsors and joint bookrunners for the STAR Offering. J.P. Morgan Securities (China) Company Limited, CITIC Securities Co., Ltd. and Guotai Junan Securities Co., Ltd. are acting as joint bookrunners for the STAR Offering.

BeiGene expects to use the net proceeds from the STAR Offering to fund its research and clinical development, construction of its research and development centers and a manufacturing plant in China, sales and marketing force expansion in China, and for working capital and general corporate purposes.

In accordance with applicable PRC laws and regulations, the STAR Offering will be conducted solely within the PRC and only to permitted investors who are eligible to participate in the STAR Offering in accordance with applicable PRC securities laws and regulations, and rules promulgated by the SSE and the China Securities Regulatory Commission (CSRC). The STAR Offering will be conducted pursuant to a prospectus and other offering materials prepared by BeiGene in Chinese language and as approved by and registered with the SSE and the CSRC, which are only permitted to be used within the PRC. **No part of the STAR Offering is intended to involve a public offering or sale of the RMB Shares into or in the United States or any other jurisdiction outside of the PRC.** In addition, although the RMB Shares are of the same class and have the same rights as the Company's existing ordinary shares listed on the Hong Kong Stock Exchange (HKEx), the RMB Shares will not be fungible with the ordinary shares listed on the HKEx or the Company's American Depositary Shares (ADSs) representing its ordinary shares listed on the NASDAQ Global Select Market (NASDAQ), and in no event will any RMB Shares be able to be converted into ordinary shares listed on the HKEx or ADSs listed on NASDAQ, or vice versa.

An automatically effective shelf registration statement on Form S-3 was filed with the Securities and Exchange Commission (SEC) on May 11, 2020. A preliminary prospectus supplement relating to and describing the key terms of the STAR Offering will be filed with the SEC and will be available on the SEC's website at www.sec.gov. The final terms of the STAR Offering will be disclosed in a final prospectus supplement to be filed with the SEC. The purpose of the prospectus supplement is to register all RMB Shares offered in the STAR Offering under the Securities Act of 1933, as amended (Securities Act), to ensure that the offer and sale of the RMB Shares, if any, to permitted investors who are U.S. persons (as defined in Regulation S under the Securities Act) in transactions outside the United States will not violate the registration requirements under Section 5 of the Securities Act.

This press release shall not constitute an offer to sell or a solicitation of an offer to buy these securities, nor shall there be any offer or sale of these securities in any state or jurisdiction in which such offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities laws of any such state or jurisdiction. This press release is being issued pursuant to, and in accordance with, Rule 134 under the Securities Act.

About BeiGene

BeiGene is a global, science-driven biotechnology company focused on developing innovative and affordable medicines to improve treatment outcomes and access for patients worldwide. With a broad portfolio of more than 40 clinical candidates, we are expediting development of our diverse pipeline of novel therapeutics through our own capabilities and collaborations. We are committed to radically improving access to medicines for two billion more people by 2030. BeiGene has a growing global team of over 7,700 colleagues across five continents. To learn more about BeiGene, please visit www.beigene.com and follow us on Twitter at @BeiGeneGlobal.

Note Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 including BeiGene's current intentions, expectations or beliefs regarding the STAR Offering, including its expectations regarding the completion, size or terms of the STAR Offering, its expectations with respect to granting a 30-day overallotment option for up to 17,258,000 additional RMB Shares, and its expectations regarding the use of proceeds. These statements may be preceded by, followed by or include the words "aim," "anticipate," "believe," "estimate," "expect," "forecast," "intend," "likely," "outlook," "plan," "potential," "project," "projection," "seek," "can," "could," "may," "should," "would," "will," the negatives thereof and other words and terms of similar meaning. Actual results or developments may differ materially from those projected or implied in these forward-looking statements. Factors that may cause such a difference include risks and uncertainties related to completion of the STAR Offering on the anticipated terms or at all, market conditions and the satisfaction of customary closing conditions related to the STAR Offering. More information about the risks and uncertainties faced by BeiGene is contained or incorporated by reference in the preliminary prospectus supplement related to the STAR Offering filed with the SEC. Forward-looking statements include all statements that are not historical facts. There is no assurance that any forward-looking statements will materialize. You are cautioned not to place undue reliance on forward-looking statements, which reflect expectations only as of this date. BeiGene does not undertake any obligation to publicly update or review any forward-looking statement, whether as a result of new information, future developments, or otherwise.

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BeiGene Announces Approval of BRUKINSA (zanubrutinib) in the European Union for Treatment of Adults with Waldenström's Macroglobulinemia

EU approval follows recent approvals for BRUKINSA including U.S., China, Brazil, and Canada

The approval is based on Phase 3 ASPEN head-to-head trial comparing BRUKINSA against ibrutinib

BASEL, CAMBRIDGE, Mass. & BEIJING—(BUSINESS WIRE)—November 23, 2021—BeiGene (NASDAQ: BGNE; HKEX: 06160) announced today that the European Commission (EC) approved BRUKINSA[®] (zanubrutinib) 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. The approval is applicable to all 27 European Union (EU) member states, plus Iceland and Norway. BeiGene is working to make this new treatment option available to WM patients in the EU as quickly as possible.

"BTK inhibition is an established mode of treatment for patients with WM, and the approval of BRUKINSA provides an important new option for patients with WM that may offer improved outcomes," said Prof. Christian Buske, Medical Director at the University Hospital Ulm, Germany, and a trial investigator of the ASPEN study. "Patients and their physicians in the EU will soon have access to an innovative medicine that has potential to offer deep and durable responses and improved tolerability, as seen in the ASPEN trial."

The EC approval for BRUKINSA follows a positive opinion granted in September by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA), based on the results of the ASPEN trial. Although the primary endpoint of statistical superiority related to deep response, very good partial response (VGPR) or better, was not met, BRUKINSA demonstrated clinical benefit with advantages in safety compared to ibrutinib.¹ Read more about the positive CHMP opinion and ASPEN trial results here.

"With BRUKINSA now approved in the EU, we continue to execute on our commitment of making this potentially best-in-class BTK inhibitor available for more patients around the world who may benefit," said Jane Huang, M.D., Chief Medical Officer, Haematology at BeiGene. "BRUKINSA was designed to maximize BTK occupancy and minimize off-target effects and has demonstrated efficacy and advantages in safety and tolerability over ibrutinib in the ASPEN trial. We believe BRUKINSA will become the preferred treatment option among patients with WM and their physicians."

"We have built a strong team in Europe that is committed to creating access to BRUKINSA for patients living with WM," said Gerwin Winter, Senior Vice President, Head of Commercial, Europe at BeiGene. "This approval by the European Commission is a significant milestone for BeiGene's expansion in the region, representing another step towards BeiGene's goal of increasing access to innovative oncology medicines globally."

About Waldenström's Macroglobulinemia

Waldenström's macroglobulinemia (WM) is a generally indolent and relatively rare B-cell malignancy characterized by bone marrow infiltration with monoclonal immunoglobulin M (IgM) secreting lymphoplasmacytic cells. WM represents approximately one percent of all non-Hodgkin's lymphomas and typically progresses slowly after diagnosis.² The disease usually affects older adults and is primarily found in the bone marrow, although lymph nodes and the spleen may be involved.³ Throughout Europe, the estimated incidence rate of WM is approximately seven out of every one million men and four out of every one million women.⁴

About the ASPEN trial

The Phase 3 randomized, open-label, multicentre ASPEN clinical trial (NCT03053440) evaluated BRUKINSA (zanubrutinib) versus ibrutinib in patients with relapsed or refractory (R/R) WM or treatment-naïve (TN) WM considered unsuitable for treatment with chemoimmunotherapy. The primary objective was to establish superiority of BRUKINSA compared to ibrutinib as demonstrated by the proportion of patients achieving complete response or very good partial response. Secondary endpoints included major response rate (MRR), duration of response (DoR) and progression-free survival (PFS), and safety, measured by incidence, timing and severity of treatment-emergent adverse events. The pre-specified analysis populations for the trial included the overall population (n=201), of which the majority were R/R patients (n=164). Exploratory endpoints included quality of life measures.

As assessed by an independent review committee (IRC) based on the modified Sixth International Workshop on Waldenström's Macroglobulinemia (IWWM-6) response criteria (Trean 2015), the combined rate of complete response (CR) and VGPR in the overall intention-to-treat (ITT) population was 28% with BRUKINSA (95% CI: 20, 38), compared to 19% with ibrutinib (95% CI: 12, 28). While this difference was not statistically significant, BRUKINSA did achieve numerically higher VGPR rates and trends towards increased response quality.¹

In the ASPEN trial, BRUKINSA demonstrated a more favorable safety profile compared to ibrutinib with lower frequency of adverse reactions that have raised concern with BTK inhibitors, including atrial fibrillation or flutter (2% vs. 15%), minor bleeding (49% vs. 59%) and major hemorrhage (6% vs. 9%). Despite higher rates of grade ≥ 3 neutropenia, patients on BRUKINSA did not demonstrate higher rates of infection as compared to those receiving ibrutinib. Of the 101 patients with WM treated with BRUKINSA, 4% of patients discontinued due to adverse events, and adverse events leading to dose reduction occurred in 14% of patients.¹

The study includes three arms in two cohorts, a randomized cohort (Cohort 1, N=201) consisting of patients with a MYD88 mutation (*MYD88^{MUT}*) and a non-randomized cohort (Cohort 2, N=28) in which patients with MYD88 wild-type (*MYD88^{WT}*) received BRUKINSA because historic data indicated they were unlikely to benefit from ibrutinib. The randomized Cohort 1 enrolled 102 patients (including 83 R/R patients and 19 TN patients) in the BRUKINSA arm and 99 patients (including 81 R/R patients and 18 TN patients) in the ibrutinib arm. Patients in the BRUKINSA arm were assigned to receive BRUKINSA 160 mg twice daily (BID) and patients in the ibrutinib arm received 420 mg of ibrutinib once daily (QD).

About BRUKINSA

BRUKINSA (zanubrutinib) 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 now approved in the United States, China, the European Union and nine other countries and regions. To date, more than 20 marketing authorization applications have been submitted for BRUKINSA for various indications.

Safety Information

The most commonly occurring adverse reactions ($\geq 20\%$) were neutropenia (56.2%), thrombocytopenia (45.1%), upper respiratory tract infection (44.3%), hemorrhage/hematoma (32.2%), rash (29.8%), bruising (29.1%), anemia (28.9%), musculoskeletal pain (24.3%), diarrhea (23.6%), pneumonia (22.1%) and cough (21.7%).

The most common Grade 3 or higher adverse reactions ($>5\%$) were neutropenia (28.0%), pneumonia (11.6%), thrombocytopenia (11.4%), and anemia (6.9%).

Of the 779 patients treated with zanubrutinib, 3.6% of patients discontinued treatment due to adverse reactions. The most frequent adverse reaction leading to treatment discontinuation was pneumonia (1.8%). Adverse reaction leading to dose reduction occurred in 4.9% of patients.

The recommended total daily dose of zanubrutinib is 320 mg. The daily dose may be taken either once daily (four 80 mg capsules) or divided into two doses of 160 mg twice daily (two 80 mg capsules).

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 2,750 colleagues dedicated to advancing more than 90 ongoing or planned clinical trials involving more than 14,000 patients and healthy volunteers. Our expansive portfolio is directed predominantly by our internal colleagues supporting clinical trials in more than 45 countries and regions. Haematology-oncology and solid tumour 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, 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 and Bristol Myers Squibb. We also plan to address greater areas of unmet need globally through our collaborations including with Amgen, Bio-Thera, EUSA Pharma, Mirati Therapeutics, Seagen, and Zymeworks. BeiGene has also entered into a collaboration with Novartis granting Novartis rights to develop, manufacture, and commercialize tislelizumab in North America, Europe, and Japan.

About BeiGene

BeiGene is a global, science-driven biotechnology company focused on developing innovative and affordable medicines to improve treatment outcomes and access for patients worldwide. With a broad portfolio of more than 40 clinical candidates, we are expediting development of our diverse pipeline of novel therapeutics through our own capabilities and collaborations. We are committed to radically improving access to medicines for two billion more people by 2030. BeiGene has a growing global team of over 7,700 colleagues across five continents. To learn more about BeiGene, please visit www.beigene.com and follow us on Twitter at @BeiGeneGlobal.

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 be a best-in-class BTK inhibitor, 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 WM and their physicians, 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 products 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 operating history and BeiGene's ability to obtain additional funding for operations and to complete the development and commercialization of its drug candidates; the impact of the COVID-19 pandemic on the Company's clinical development, 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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* 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)^a;
- For the treatment of MCL in adult patients who have received at least one prior therapy (China, June 2020)^b;
- For the treatment of chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL) in adult patients who have received at least one prior therapy (China, June 2020)^b;
- 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)^b;
- For the treatment of MCL in adult patients who have received at least one prior therapy (Canada, July 2021);
- For the treatment of MCL in adult patients who have received at least one prior therapy (Chile, July 2021);
- For the treatment of adult patients with MCL who have received at least one previous therapy (Brazil, August 2021);
- For the treatment of adult patients with WM (United States, August 2021);
- For the treatment of adult patients with marginal zone lymphoma (MZL) who have received at least one anti-CD20-based regimen (United States, September 2021)*;
- For the treatment of adult patients with MCL who have received at least one previous therapy (Singapore, October 2021);
- For the treatment of MCL in patients who have received at least one prior therapy (Israel, October 2021);
- For the treatment of adult patients with WM who have received at least one prior therapy, or in first line treatment for patients unsuitable for chemo-immunotherapy (Australia, October 2021);
- For the treatment of adult patients with MCL who have received at least one prior therapy (Australia, October 2021);
- For the treatment of adult patients with MCL who have received at least one previous therapy (Russia, October 2021);
- For the treatment of mantle cell lymphoma (MCL) in adult patients who have received at least one prior therapy (Saudi Arabia, November 2021); and
- For the treatment of adult patients 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, November 2021).

a. 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.

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

References:

1. Tam, et al. A randomized phase 3 trial of zanubrutinib vs ibrutinib in symptomatic Waldenström macroglobulinemia: the ASPEN study. *Blood*. October 2020. 136(18): 2038-2050.
2. Lymphoma Research Foundation. Getting the Facts: Waldenström Macroglobulinemia. Available at https://lymphoma.org/wp-content/uploads/2020/09/LRF-Waldenstrom-Macroglobulinemia_Factsheet.pdf. Updated 2020.
3. Lymphoma Research Foundation. Available at <https://lymphoma.org/aboutlymphoma/nhl/wm/>. Accessed December 2020.
4. Buske, C, et al. Treatment and outcome patterns in European patients with Waldenström's macroglobulinaemia: a large, observational, retrospective chart review. *The Lancet Haematology* 2018; 5: e0299-309.

BeiGene Closes on Property for New U.S. Manufacturing and Clinical R&D Center

BeiGene plans to develop 42-acre site at Princeton West Innovation Park in Hopewell, New Jersey as a manufacturing site for advanced new medicines

HOPEWELL, NJ, CAMBRIDGE, MA, and Beijing, November 23, 2021 – BeiGene, Ltd. (NASDAQ: BGNE; HKEX: 06160), a global biotechnology company focused on developing and commercializing innovative cancer medicines worldwide, announced today that it has purchased a 42-acre site at the Princeton West Innovation Campus in Hopewell, N.J. to house a new state-of-the-art manufacturing campus and clinical R&D center. As a key part of BeiGene’s continued growth, the company is investing in U.S. manufacturing to further expand and diversify its global supply chain and build new manufacturing capabilities for its deep pipeline of biologic and drug candidates.

Subject to finalizing the development plans, BeiGene expects to invest several hundred million dollars in the initial phase of construction, in addition to the acquisition of the property, for the state-of-the-art facility that is expected to include up to approximately 400,000 square feet of dedicated commercial-stage biologic pharmaceutical manufacturing, including up to 16,000 liters of biologics capacity, along with clinical R&D and office space. Construction of the initial phase is expected to commence in 2022 and be completed in late-2023 or in 2024. In addition, the property has more than one million square feet of developable real estate for potential future expansion.

“With this property acquisition, we plan to establish a flagship manufacturing and clinical R&D center in the U.S. to diversify our global supply chain. We are proud to take this next step in our journey to advance impactful treatments and make them more accessible to patients around the world,” said John V. Oyler, Co-Founder, Chairman, and CEO of BeiGene. “We have already begun hiring additional colleagues from the deep talent pool in New Jersey and look forward to serving as a member of the thriving Princeton-Hopewell business community.”

“We are extremely excited that BeiGene has taken the next step in the company’s push to manufacture innovative cancer medicines right here in New Jersey,” said Governor Phil Murphy. “Our goal since day one has been to create an environment in New Jersey that fosters the growth of companies like BeiGene and we are excited to see what’s next as the company expands.”

“With more new companies, like BeiGene, coming into the Princeton West Innovation Campus, Hopewell Township's future as a leader in the biotech base continues to come to fruition. BeiGene's expertise in developing innovative cancer treatments combined with their planned state-of-the-art facility makes this a win-win-win for Hopewell, BeiGene, and the millions of cancer patients whose lives will hopefully improve from BeiGene medicines. We are proud that those medicines will be manufactured right here,” said Hopewell Township Mayor Julie Blake.

BeiGene acquired the Hopewell property from Lincoln Equities Group and has retained DPR Construction as its construction management firm and IPS as its architectural and engineering firm.

About BeiGene

BeiGene is a global, science-driven biotechnology company focused on developing innovative and affordable medicines to improve treatment outcomes and access for patients worldwide. With a broad portfolio of more than 40 clinical candidates, we are expediting development of our diverse pipeline of novel therapeutics through our own capabilities and collaborations. We are committed to radically improving access to medicines for two billion more people by 2030. BeiGene has a growing global team of over 7,700 colleagues across five continents. To learn more about BeiGene, please visit www.beigene.com and follow us on Twitter at [@BeiGeneGlobal](https://twitter.com/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 plans and expectations to establish a new manufacturing and clinical R&D center in New Jersey, to manufacture commercial-stage medicines and drug candidates at the site and to diversify its global supply chain, the expected timing for the initiation and completion of construction, BeiGene's anticipated investment in and recruiting of talent for the new manufacturing and R&D center, and BeiGene's plans, commitments, aspirations and goals under the heading "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; and the impact of the COVID-19 pandemic on BeiGene's clinical development, regulatory, commercial and other operations, as well as those risks more fully discussed in the section entitled "Risk Factors" in BeiGene's most recent quarterly report on Form 10-Q, as well as discussions of potential risks, uncertainties, and other important factors in BeiGene's subsequent filings with the U.S. Securities and Exchange Commission. All information in this 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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BeiGene Initiates First-in-Human Phase 1 Clinical Trial of Investigational TYK2 Inhibitor BGB-23339

Expanding portfolio with first internally discovered asset in Inflammation and Immunology with internally discovered asset

A highly selective, allosteric TYK2 inhibitor that has shown potent inhibition against pro-inflammatory cytokines in preclinical studies

CAMBRIDGE, Mass. and BEIJING – November 22, 2021 -- BeiGene (NASDAQ: BGNE; HKEX: 06160), a global, science-driven biotechnology company focused on developing innovative and affordable medicines, today announced that the first patient has been dosed in a Phase 1 clinical trial of BGB-23339, a potent, allosteric investigational tyrosine kinase 2 (TYK2) inhibitor internally developed by BeiGene scientists.

TYK2 is a member of the JAK family and functions as a critical mediator in cytokine signaling pathways implicated in multiple immune-mediated disorders, such as psoriasis and inflammatory bowel disease. BGB-23339 is a potent, highly selective, investigational TYK2 inhibitor targeting the regulatory pseudokinase (JH2) domain.

“Discovered and developed by BeiGene, BGB-23339 is a highly selective, potent, allosteric TYK2 inhibitor that has shown promising activity in preclinical evaluation,” commented Lai Wang, Ph.D., Global Head of R&D at BeiGene. “Building on our proven track record in oncology, BeiGene is expanding its clinical focus to discover new modalities and platforms in areas of high unmet need, including inflammation and immunology, to bring innovative, impactful medicines to patients.”

The first-in-human Phase 1 trial (NCT05093270) is designed to evaluate the safety, tolerability, pharmacokinetics, and preliminary activity of BGB-23339. The trial is expected to enroll up to 115 healthy volunteers in Australia and/or China.

In addition to its broad portfolio focused on hematological malignancies and solid tumors, BeiGene is applying its research excellence and clinical expertise to address inflammation and immunology, an area of high unmet medical need. BeiGene’s internally developed, highly selective next-generation BTK inhibitor BRUKINSA[®] (zanubrutinib) is currently being evaluated in a Phase 2 trial in patients with active proliferative lupus nephritis.

About BGB-23339

BGB-23339 is a potent, highly selective, allosteric investigational tyrosine kinase 2 (TYK2) inhibitor discovered and being developed by BeiGene. TYK2 is a member of the JAK family and functions as a critical mediator in cytokine signaling pathways implicated in multiple immune-mediated disorders. Designed to target the regulatory pseudokinase (JH2) domain on TYK2, BGB-23339 has demonstrated strong selectivity in preclinical studies with potent inhibition of interleukin (IL)-12, IL-23, and Type 1 interferons (IFNs)—pro-inflammatory cytokines that play a determinant role in the induction of inflammation. BGB-23339 is currently being evaluated in a Phase 1 clinical study.

About BeiGene

BeiGene is a global, science-driven biotechnology company focused on developing innovative and affordable medicines to improve treatment outcomes and access for patients worldwide. With a broad portfolio of more than 40 clinical candidates, we are expediting development of our diverse pipeline of novel therapeutics through our own capabilities and collaborations. We are committed to radically improving access to medicines for two billion more people by 2030. BeiGene has a growing global team of over 7,700 colleagues across five continents. To learn more about BeiGene, please visit www.beigene.com and follow us on Twitter at @BeiGeneGlobal.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws, including statements regarding plans for the Phase 1 trial and development of BGB-23339, the potential for BGB-23339 to address unmet medical needs, BeiGene's plan to expand its clinical focus to discover new modalities and platforms in areas of high unmet need, including inflammation and immunology, and BeiGene's plans, commitments, aspirations and goals under "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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