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

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# Form 8-K

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## 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 30, 2021

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

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

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

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

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

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

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

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

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

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

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

**Item 8.01. Other Events.**

On November 30, 2021, BeiGene, Ltd. (the "Company" or "BeiGene") issued a press release announcing the pricing of its initial public offering on the Science and Technology Innovation Board (the "STAR Market") of the Shanghai Stock Exchange in China. A copy of this press release is attached hereto as Exhibit 99.1, and is incorporated herein by reference.

On December 2, 2021, the Company issued a press release announcing that the China National Medical Products Administration (NMPA) has approved SYLVANT® (siltuximab for injection) for the treatment of adult patients with multicentric Castleman disease (MCD) who are human immunodeficiency virus (HIV) negative and human herpes virus-8 (HHV-8) negative, also known as idiopathic MCD (iMCD). A copy of this press release is attached hereto as Exhibit 99.2, and is incorporated herein by reference.

On December 2, 2021, the Company issued a press release announcing that three of its medicines have been added to the most recent National Reimbursement Drug List ("NRDL") in China by the National Healthcare Security Administration. BeiGene-discovered medicines in the updated NRDL include: anti-PD-1 antibody tislelizumab in three new indications, including in lung and liver cancers; BTK inhibitor BRUKINSA® (zanubrutinib) in one new indication; and the initial listing for PARP inhibitor pamiparib. The changes to the NRDL will be effective on January 1, 2022. A copy of this press release is attached hereto as Exhibit 99.3, and is incorporated herein by reference.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits.

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release titled "BeiGene Announces Pricing of its RMB22.2 billion (US$3.5 billion) Initial Public Offering on the STAR Market of the Shanghai Stock Exchange in China", issued by BeiGene, Ltd. on November 30, 2021. |
| 99.2 | Press Release titled "BeiGene and EUSA Pharma Announce NMPA Approval of SYLVANT® (Siltuximab for Injection) in China for Idiopathic Multicentric Castleman Disease", issued by BeiGene, Ltd. on December 2, 2021. |
| 99.3 | Press Release titled "BeiGene Announces Inclusion in the China National Reimbursement Drug List (NRDL) of Tislelizumab in Three New Indications, BRUKINSA® (zanubrutinib) in One New Indication, and the First Listing for Pamiparib", issued by BeiGene, Ltd. on December 2, 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: December 6, 2021

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

**Exhibit 99.1**

**BeiGene Announces Pricing of its RMB22.2 billion (US$3.5 billion) Initial Public Offering on the STAR Market of the Shanghai Stock Exchange in China**

**CAMBRIDGE, Mass. & BEIJING – November 3, 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 pricing of its previously announced 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 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 (RMB Shares).

The public offering price of the RMB Shares is RMB192.60 per ordinary share, which equates to HK$234.89 per ordinary share and US$391.68 per American Depositary Share (ADS), based on an assumed exchange rate of RMB0.81996 to HK$1.00 and RMB6.3924 to US$1.00. Each ADS represents 13 ordinary shares.

The gross proceeds to BeiGene from the STAR Offering, before deducting underwriting commissions and other estimated offering expenses, are expected to be approximately RMB22.2 billion, or approximately US$3.5 billion, based on an assumed exchange rate of RMB6.3924 to US$1.00.

Subject to customary closing conditions, BeiGene expects to deliver the RMB Shares against payment on or about December 9, 2021 and the RMB Shares are expected to begin trading on the STAR Market on or about December 15, 2021 under the stock code "688235."

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 has granted China International Capital Corporation Limited a 30-day overallotment option for up to 17,258,000 additional RMB Shares. If the over-allotment option is fully exercised, the total number of shares being offered in the STAR Offering will be 132,313,260 Shares, which represents 9.79% of BeiGene's total outstanding ordinary shares as of October 31, 2021, after giving effect to the shares being offered.

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 is being 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 is being 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 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 was filed with the SEC and is 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 of the STAR Offering, its expectations with respect to the anticipated share delivery date of the STAR Offering and the anticipated trading date of the RMB Shares on the STAR Market, and its expectations regarding the amount and 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, 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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**Exhibit 99.2**

**BeiGene and EUSA Pharma Announce NMPA Approval of SYLVANT® (Siltuximab for Injection) in China for Idiopathic Multicentric Castleman Disease**

**CAMBRIDGE, Mass., BEIJING, China, and HEMEL HEMPSTEAD, England – December 2, 2021-** BeiGene, Ltd. (NASDAQ: BGNE; HKEX: 06160) and EUSA Pharma (UK), Ltd. today announced that the China National Medical Products Administration (NMPA) has approved SYLVANT® (siltuximab for injection) for the treatment of adult patients with multicentric Castleman disease (MCD) who are human immunodeficiency virus (HIV) negative and human herpes virus-8 (HHV-8) negative, also known as idiopathic MCD (iMCD). This disease is a rare, life-threatening, and debilitating condition of the lymph nodes and related tissues. Siltuximab is a monoclonal antibody approved in the United States, European Union, and other countries and regions around the world.

"Today's approval provides a new treatment for patients in China with this rare systemic disorder," commented Xiaobin Wu, Ph.D., President, Chief Operating Officer, and General Manager of China at BeiGene. "This approval is our second product in our collaboration with EUSA, highlighting the combined expertise of our companies as we work together on behalf of patients. We are excited to have reached this important milestone and we look forward to launching siltuximab in 2022 and to helping patients with iMCD in China."

"We are delighted that siltuximab has been approved in China and that this innovative treatment will soon be made available to patients suffering from this devastating disease," said Carsten Thiel, Ph.D., Chief Executive Officer of EUSA Pharma.

The approval of siltuximab for the treatment of iMCD was supported by clinical results from a multinational, randomized, double blind, placebo-controlled Phase 2 trial (NCT01024036) conducted in 79 patients from 19 countries and regions, including 16 patients from China.

The primary endpoint of the study was durable tumor and symptomatic response, defined as tumor response assessed by independent review and complete resolution or stabilization of prospectively collected iMCD symptoms, for at least 18 weeks without treatment failure. A statistically significant difference in independently reviewed durable tumor and symptomatic response rate in the siltuximab arm compared with the placebo arm (34% vs. 0%, respectively; 95% CI: 11.1, 54.8; $p = 0.0012$) was observed.

Data from all patients treated with siltuximab monotherapy ($n = 370$) form the overall basis of the safety evaluation. Infections (including upper respiratory tract infections), pruritus, rash, arthralgia, and diarrhea were the most common adverse reactions, occurring in > 20% of siltuximab-treated patients in iMCD clinical studies. The most serious adverse reaction associated with the use of siltuximab was anaphylactic reaction.

In the study, a total of 34 Asian patients were enrolled, including 16 from China; 24 of 34 Asian patients were treated in the siltuximab arm and the remaining 10 patients were treated in the placebo arm. The subgroup analyses showed that there was no significant difference in demographic and baseline disease characteristics between Asian patients and the overall patient population; the efficacy data on primary and secondary study endpoints of Asian patients was consistent with those of the overall patient population, and the same for safety data; no other safety signals were found.

An open label, long-term extension Phase 2 trial (NCT01400503) was also conducted in patients with iMCD treated in prior trials. The median duration of siltuximab treatment was 5.52 years (range: 0.8 to 10.8 years); more than 50% of patients received siltuximab treatment for ≥5 years. The rate of serious or Grade ≥3 adverse events did not increase over time as a function of cumulative exposure.

**About SYLVANT® (siltuximab for injection)**

Siltuximab is a monoclonal antibody that directly neutralises IL-6, an inflammatory cytokine detected at elevated levels in multiple inflammatory conditions. SYLVANT® is approved in a number of countries and regions and is indicated for the treatment of patients with multicentric Castleman disease (MCD) who are human immunodeficiency virus (HIV) negative and human herpesvirus-8 (HHV-8) negative. iMCD is a rare, life-threatening and debilitating lymphoproliferative disorder, which causes abnormal overgrowth of immune cells and shares many symptomatic and histological features with lymphoma. The Approved EU and U.S. Indications and Usage information are available for additional information at: EMA Summary of Product Characteristics (SmPC) and FDA Prescribing Information .

**About EUSA Pharma**

Founded in March 2015, EUSA Pharma is a world-class biopharmaceutical company focused on oncology and rare disease. The company has extensive commercial operations in the United States and Europe, alongside a direct presence in other select markets across the globe. EUSA Pharma is led by an experienced management team with a strong record of building successful pharmaceutical companies and is supported by significant funding raised from leading life science investor EW Healthcare Partners. For more information please visit www.eusapharma.com.

**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 to 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 (over 70 clinical trials are ongoing) involving more than 14,000 patients and healthy volunteers. Our expansive portfolio is directed by a predominantly internalized clinical development team supporting 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. The Company currently has three approved medicines discovered and developed in our labs: BTK inhibitor BRUKINSA in the United States, China, the European Union, Canada, Australia, and additional international markets; and non-FC-gamma receptor binding anti-PD-1 antibody tislelizumab and PARP inhibitor pamiparib in China.

BeiGene also partners with innovative companies who share our goal of developing therapies to address global health needs. We commercialize a range of oncology medicines in China licensed from Amgen, Bristol Myers Squibb, EUSA Pharma, and Bio-Thera. We also plan to address greater areas of unmet need globally through our collaborations including with Amgen, 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.

**BeiGene 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 launch and opportunity of SYLVANT® in China, the potential benefits of SYLVANT® for patients with iMCD in China, future development and potential commercialization activities of the products under the agreement with EUSA, 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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**Exhibit 99.3**

***BeiGene Announces Inclusion in the China National Reimbursement Drug List (NRDL) of Tislelizumab in Three New Indications, BRUKINSA® (zanubrutinib) in One New Indication, and the First Listing for Pamiparib***

**BEIJING, China & CAMBRIDGE, Mass. – December 2, 2021** - BeiGene (NASDAQ: BGNE; HKEX: 06160), a global science-driven biotechnology company focused on developing innovative and affordable medicines to improve treatment outcomes and access for patients worldwide, today announced that three of its medicines have been added to the most recent National Reimbursement Drug List (NRDL) in China by the National Healthcare Security Administration (NHSA). BeiGene-discovered medicines in the updated NRDL include: anti-PD-1 antibody tislelizumab in three new indications, including in lung and liver cancers; BTK inhibitor BRUKINSA® (zanubrutinib) in one new indication; and the initial listing for PARP inhibitor pamiparib. The changes to the NRDL will be effective on January 1, 2022.

"The inclusion of our three internally-discovered innovative medicines in the latest NRDL will help expand access to these high-quality oncology treatments across China at affordable prices and reduce the financial burden for patients and their families," commented Xiaobin Wu, Ph.D., President of BeiGene, Chief Operating Officer, and General Manager of China. "Since its establishment, the NHSA has accelerated the frequency of adjustment to the NRDL, forming a dynamic mechanism for annual updates. Through the establishment of a comprehensive healthcare system, life-saving innovative oncology medicines are now more quickly included in the NRDL at affordable prices, covering different types of medical care and providing benefits for people living with cancer. As an innovative company with strong R&D capabilities and global reach, BeiGene is working to change the status quo in the field of treatment and fill the gap in clinical treatment options. We look forward to working with the NHSA to fulfill the demand for these treatments across China as soon as possible."

The following indications have been included in the updated NRDL:

- **Tislelizumab is now included in the NRDL in all five of its approved indications** – three new indications in November 2021 and two indications included last year:
    - For use in combination with pemetrexed and platinum chemotherapy as a first-line treatment in patients with unresectable, locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC), with EGFR genomic tumor aberrations negative and ALK genomic tumor negative (approved in June 2021 and included in the NRDL in November 2021);
    - For the treatment of patients with hepatocellular carcinoma (HCC) who have been previously treated with at least one systemic therapy (conditionally approved in June 2021 and included in the NRDL in November 2021);
    - For use in combination with paclitaxel and carboplatin as a first-line treatment in patients with unresectable, locally advanced or metastatic squamous NSCLC (approved in January 2021 and included in the NRDL in November 2021);
    - For the treatment of patients with locally advanced or metastatic urothelial carcinoma (UC) with PD-L1 high expression whose disease progressed during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy (conditionally approved in April 2020 and included in NRDL in 2020); and
    - For the treatment of patients with classical Hodgkin's lymphoma (cHL) who have received at least two prior therapies (conditionally approved in December 2019 and included in the NRDL in 2020).
- **BRUKINSA is now included in the NRDL in all three of its approved indications** – one new indication in November 2021 and two indications included last year:
    - For the treatment of adult patients with Waldenström's macroglobulinemia (WM) who have received at least one prior therapy (conditionally approved in June 2021 and included in the NRDL in November 2021);
    - For the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy (conditionally approved in June 2020 and included in the NRDL in 2020); and

- For the treatment of adult patients with chronic lymphocytic leukemia (CLL) /small lymphocytic lymphoma (SLL) who have received at least one prior therapy (conditionally approved in June 2020 and included in the NRDL in 2020).

- **Pamiparib is initially included in the NRDL in its approved indication:**

  - For the treatment of patients with germline BRCA (gBRCA) mutation-associated recurrent advanced ovarian, fallopian tube, or primary peritoneal cancer who have been treated with two or more lines of chemotherapy (conditionally approved in May and included in the NRDL in November 2021).

**About Tislelizumab**

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

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

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

In the United States, a Biologics License Application for tislelizumab as a treatment for patients with unresectable recurrent locally advanced or metastatic ESCC after prior systemic therapy is currently under review by the U.S. Food and Drug Administration with a PDUFA target action date of July 12, 2022. BeiGene has initiated or completed 17 potentially registration-enabling clinical trials in China and globally, including 13 Phase 3 trials and four pivotal Phase 2 trials. In January 2021, BeiGene and Novartis entered into a collaboration and license agreement granting Novartis rights to develop, manufacture, and commercialize tislelizumab in North America, Europe, and Japan. Tislelizumab is not approved for use outside of China.

**About BRUKINSA® (zanubrutinib)**

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 approved in one or more indications in a total of 40 countries and regions, including the United States, China, the European Union, Australia and Canada. To date, more than 20 marketing authorization applications have been submitted for BRUKINSA for various indications.

**About Pamiparib**

Pamiparib is an inhibitor of PARP1 and PARP2 which has demonstrated pharmacological properties such as brain penetration and PARP-DNA complex trapping in preclinical models. Discovered by BeiGene scientists, pamiparib was the first PARP inhibitor approved in both platinum-sensitive and platinum-resistant relapsed ovarian cancer in China. Pamiparib is currently being evaluated globally as a monotherapy or in combination with other agents for a variety of solid tumor malignancies.

In China, pamiparib received conditional approval for the treatment of patients with germline BRCA (gBRCA) mutation-associated recurrent advanced ovarian, fallopian tube, or primary peritoneal cancer who have been treated with two or more lines of chemotherapy in May 2021. Full approval for this indication is contingent upon results from ongoing corroborative trials confirming the clinical benefit of pamiparib in this population.

**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 (over 70 clinical trials are ongoing) 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. 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, 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 collaborations including with Amgen, 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.

**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 for the inclusion in the NRDL of tislelizumab, BRUKINSA® and pamiparib to expand access and reduce the financial burden for patients and families, BeiGene's efforts to change the status quo in the field of treatment and fill the gap in clinical treatment options, BeiGene's plans to work with the NHSA to provide access to BeiGene's medicines across China as soon as possible, 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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