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

Form 8-K

CURRENT REPORT

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

Date of Report (Date of earliest event Reported): September 17, 2021

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

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

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

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

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

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

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

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

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

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

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

Item 8.01. Other Events.

On September 17, 2021, BeiGene, Ltd. ("BeiGene") announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion, recommending approval of BRUKINSA (zanubrutinib) for the treatment of adult patients with Waldenström's macroglobulinemia (WM) who have received at least one prior therapy or first-line treatment for patients unsuitable for chemo-immunotherapy. The full text of this press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

On September 20, 2021, BeiGene announced its inclusion in several FTSE Russell indices, including: the FTSE Global Equity Index Large Cap; the FTSE All-World (LM); the FTSE All-Cap (LMS); and the FTSE Total-Cap (LMSμ). In addition, BeiGene has also been included in the FTSE Developed ESG Low Carbon Select Index, and the FTSE Asia ex Japan ESG Low Carbon Select Index, reflecting the company's commitment to sustainability. The company's inclusion on the FTSE indices became effective on Friday, September 17, 2021, after U.S. market close. The full text of this press release is filed as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release titled "BeiGene Receives Positive CHMP Opinion for BRUKINSA® (Zanubrutinib) for the Treatment of Adults with Waldenström's Macroglobulinemia", issued by BeiGene, Ltd. on September 17, 2021.
99.2	Press Release titled "BeiGene Announces Inclusion in FTSE Russell Indices", issued by BeiGene, Ltd. on September 20, 2021.
104	The cover page from this Current Report on Form 8-K, formatted in Inline XBRL

Exhibit Index

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SIGNATURE

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

BEIGENE, LTD.

Date: September 20, 2021

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

Exhibit 99.1

BeiGene Receives Positive CHMP Opinion for BRUKINSA® (Zanubrutinib) for the Treatment of Adults with Waldenström's Macroglobulinemia

BeiGene's European commercial team is preparing to launch BRUKINSA, the company's first medicine submitted for marketing authorization in the EU, upon approval

The CHMP recommendation is based on results from the Phase 3 ASPEN trial, in which BRUKINSA demonstrated a numerically higher very good partial response rate (VGPR) and a favorable safety profile compared to ibrutinib

BASEL, CAMBRIDGE, Mass. & BEIJING—(BUSINESS WIRE)—September 17, 2021—BeiGene (NASDAQ: BGNE; HKEX: 06160) today announced the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion, recommending approval of BRUKINSA (zanubrutinib) for the treatment of adult patients with Waldenström's macroglobulinemia (WM) who have received at least one prior therapy or first-line treatment for patients unsuitable for chemo-immunotherapy.

"Bruton's tyrosine kinase (BTK) inhibitors have emerged as a promising treatment for WM, yet treatment discontinuation due to lack of response or side effects remains a concern," said Prof. Christian Buske, Medical Director at the University Hospital Ulm, Germany, and a trial investigator of the ASPEN study. "The ASPEN trial demonstrated that BRUKINSA provided deep and durable responses and offered substantial improvements in safety and tolerability over standard therapy. Patients in Europe with WM may soon have a new treatment option that can offer improved outcomes."

The positive CHMP opinion is based on results from the randomized, Phase 3 ASPEN clinical trial, evaluating BRUKINSA compared to ibrutinib in patients with relapsed or refractory (R/R) or treatment-naïve (TN) WM who are unsuitable for chemo-immunotherapy. Based on the modified Sixth International Workshop on Waldenström's Macroglobulinemia (IWWM-6) response criteria (Treon 2015), the combined complete response (CR) +VGPR rate in the overall intention-to-treat (ITT) population was 28.4% with BRUKINSA (95% CI: 20, 38), compared to 19.2% 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]

BRUKINSA demonstrated a more favorable safety profile compared to ibrutinib with lower frequency of certain adverse events, including atrial fibrillation or flutter (2.0% vs. 15.3%) minor bleeding (48.5% vs 59.2%) and major hemorrhage (5.9% vs 9.2%).[1] Of the 101 patients with WM treated with BRUKINSA, four percent of patients discontinued due to adverse events, and adverse events leading to dose reduction occurred in 14% of patients.

"The positive CHMP opinion reflects BRUKINSA's potential role in the WM therapeutic landscape as a selective inhibitor designed to deliver sustained and continuous inhibition of BTK, offering patients the potential for reduced frequency of certain cardiovascular events like atrial fibrillation compared to ibrutinib, and underscores our bold approach to R&D," said Jane Huang, M.D., Chief Medical Officer, Hematology, at BeiGene. "We are committed to advancing the global registration of BRUKINSA and, if approved, believe it will become the preferred BTK inhibitor for patients with WM."

"We have a strong team in Europe who are excited for the opportunity to further work with the many investigators who have participated in BRUKINSA trials conducted in Europe to-date. Looking to the future, we have built a team in Europe, and they are poised to help patients access BRUKINSA following its expected approval," said Gerwin Winter, Senior Vice President, Head of Commercial, Europe, at BeiGene. "We look forward to continuing our work with the European health authorities to bring BRUKINSA to patients living with this rare, incurable blood cancer."

Following the CHMP positive opinion, the European Commission will consider BeiGene's marketing application, with a final decision expected within 67 days of receipt of the CHMP opinion. The decision will be applicable to all 27 member states of the EU plus Iceland and Norway.

About Waldenström's Macroglobulinemia

WM is a rare lymphoma representing 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 for everyone million men and four for every one million women.[4]

About the ASPEN trial

The Phase 3 randomized, open-label, multicenter ASPEN clinical trial (NCT03053440) evaluated zanubrutinib versus ibrutinib in people with relapsed or refractory (R/R) or treatment-naïve (TN) WM. The primary objective was to establish superiority of zanubrutinib compared to ibrutinib as demonstrated by the proportion of people achieving complete response (CR) or very good partial response (VGPR). Secondary endpoints included major response rate, duration of response and progression-free survival, 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) and R/R patients (n=164). Exploratory endpoints included quality of life measures.

The study includes two cohorts, a randomized cohort (cohort 1) consisting of 201 patients with a MYD88 mutation ($MYD88^{MUT}$) and a non-randomized cohort (cohort 2) in which 28 patients with MYD88 wild-type ($MYD88^{WT}$) received zanubrutinib because they have historically responded poorly to ibrutinib therapy.

The randomized cohort 1 enrolled 102 patients (including 83 relapsed or refractory (R/R) patients and 19 TN (patients) in the zanubrutinib arm and 99 patients (including 81 R/R patients and 18 TN patients) in the ibrutinib arm. Patients in the zanubrutinib arm were assigned to receive zanubrutinib 160 mg twice daily (BID) and patients in the ibrutinib arm received 420 mg of ibrutinib once daily (QD).

Results of cohort 2 were previously presented at the 24th Congress of European Hematology Association (EHA) and showed an overall response rate (ORR) of 80.8%, a major response rate (MRR; partial response or better) of 53.8% and a VGPR rate of 23.1%.

About BRUKINSA

BRUKINSA is a small molecule inhibitor of Bruton's tyrosine kinase (BTK) discovered by BeiGene scientists that is currently being evaluated globally in a broad clinical program as a monotherapy and in combination with other therapies to treat various B-cell malignancies. Because new BTK is continuously synthesized, BRUKINSA was specifically designed to deliver complete and sustained inhibition of the BTK protein by optimizing bioavailability, half-life, and selectivity. With differentiated pharmacokinetics compared to other approved BTK inhibitors, BRUKINSA has been demonstrated to inhibit the proliferation of malignant B cells within a number of disease relevant tissues.

BRUKINSA is approved in the following indications and regions:

- For the treatment of mantle cell lymphoma (MCL) in adult patients who have received at least one prior therapy (United States, November 2019)*;
- For the treatment of MCL in adult patients who have received at least one prior therapy (China, June 2020)**;
- For the treatment of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) in adult patients who have received at least one prior therapy (China, June 2020)**;
- For the treatment of relapsed or refractory MCL (United Arab Emirates, February 2021);
- For the treatment of Waldenström's macroglobulinemia (WM) in adult patients (Canada, March 2021);

- Registered and reimbursed for the treatment of MCL in patients who have received at least one prior therapy (Israel, April 2021);
- For the treatment of adult patients with WM who have received at least one prior therapy (China, June 2021)**;
- For the treatment of MCL in adult patients who have received at least one prior therapy (Canada, July 2021);
- For the treatment of MCL in adult patients who have received at least one prior therapy (Chile, July 2021);
- For the treatment of adult patients with MCL who have received at least one previous therapy (Brazil, August 2021);
- For the treatment of adult patients with WM (United States, August 2021); and
- For the treatment of adult patients with marginal zone lymphoma (MZL) who have received at least one anti-CD20-based regimen (United States, September 2021)*.

To date, more than 30 marketing authorization applications in multiple indications have been submitted in the United States, China, the European Union, and more than 20 other countries or regions.

* This indication was approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

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

IMPORTANT U.S. SAFETY INFORMATION FOR BRUKINSA (ZANUBRUTINIB)

Warnings and Precautions

Hemorrhage

Fatal and serious hemorrhagic events have occurred in patients with hematological malignancies treated with BRUKINSA monotherapy. Grade 3 or higher hemorrhage including intracranial and gastrointestinal hemorrhage, hematuria and hemothorax have been reported in 3.4% of patients treated with BRUKINSA monotherapy. Hemorrhage events of any grade occurred in 35% of patients treated with BRUKINSA monotherapy.

Bleeding events have occurred in patients with and without concomitant antiplatelet or anticoagulation therapy. Co-administration of BRUKINSA with antiplatelet or anticoagulant medications may further increase the risk of hemorrhage.

Monitor for signs and symptoms of bleeding. Discontinue BRUKINSA if intracranial hemorrhage of any grade occurs. Consider the benefit-risk of withholding BRUKINSA for 3-7 days pre- and post-surgery depending upon the type of surgery and the risk of bleeding.

Infections

Fatal and serious infections (including bacterial, viral, or fungal) and opportunistic infections have occurred in patients with hematological malignancies treated with BRUKINSA monotherapy. Grade 3 or higher infections occurred in 27% of patients, most commonly pneumonia. Infections due to hepatitis B virus (HBV) reactivation have occurred.

Consider prophylaxis for herpes simplex virus, pneumocystis jiroveci pneumonia and other infections according to standard of care in patients who are at increased risk for infections. Monitor and evaluate patients for fever or other signs and symptoms of infection and treat appropriately.

Cytopenias

Grade 3 or 4 cytopenias, including neutropenia (26%), thrombocytopenia (11%) and anemia (8%) based on laboratory measurements, developed in patients treated with BRUKINSA monotherapy. Grade 4 neutropenia occurred in 13% of patients, and Grade 4 thrombocytopenia occurred in 3.6% of patients.

Monitor complete blood counts regularly during treatment and interrupt treatment, reduce the dose, or discontinue treatment as warranted. Treat using growth factor or transfusions, as needed.

Second Primary Malignancies

Second primary malignancies, including non-skin carcinoma, have occurred in 14% of patients treated with BRUKINSA monotherapy. The most frequent second primary malignancy was non-melanoma skin cancer, reported in 8% of patients. Other second primary malignancies included malignant solid tumors (4.0%), melanoma (1.7%) and hematologic malignancies (1.2%). Advise patients to use sun protection and monitor patients for the development of second primary malignancies.

Cardiac Arrhythmias

Atrial fibrillation and atrial flutter were reported in 3.2% of patients treated with BRUKINSA monotherapy. Patients with cardiac risk factors, hypertension, and acute infections may be at increased risk. Grade 3 or higher events were reported in 1.1% of patients treated with BRUKINSA monotherapy. Monitor signs and symptoms for atrial fibrillation and atrial flutter and manage as appropriate.

Embryo-Fetal Toxicity

Based on findings in animals, BRUKINSA can cause fetal harm when administered to a pregnant woman. Administration of zanubrutinib to pregnant rats during the period of organogenesis caused embryo-fetal toxicity including malformations at exposures that were 5 times higher than those reported in patients at the recommended dose of 160 mg twice daily. Advise women to avoid becoming pregnant while taking BRUKINSA and for 1 week after the last dose. Advise men to avoid fathering a child during treatment and for 1 week after the last dose.

If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus.

Adverse reactions

The most common adverse reactions, including laboratory abnormalities, in ≥ 30% of patients who received BRUKINSA (N = 847) included decreased neutrophil count (54%), upper respiratory tract infection (47%), decreased platelet count (41%), hemorrhage (35%), decreased lymphocyte count (31%), rash (31%) and musculoskeletal pain (30%).

Drug Interactions

CYP3A Inhibitors: When BRUKINSA is co-administered with a strong CYP3A inhibitor, reduce BRUKINSA dose to 80 mg once daily. For coadministration with a moderate CYP3A inhibitor, reduce BRUKINSA dose to 80 mg twice daily.

CYP3A Inducers: Avoid coadministration with moderate or strong CYP3A inducers.

Specific Populations

Hepatic Impairment: The recommended dose of BRUKINSA for patients with severe hepatic impairment is 80 mg orally twice daily.

Please see full U.S. Prescribing Information at www.beigene.com/PDF/BRUKINSAUSPI.pdf and Patient Information at www.beigene.com/PDF/BRUKINSAUSPPI.pdf.

BeiGene Oncology

BeiGene is committed to advancing best and first-in-class clinical candidates internally or with like-minded partners to develop impactful and affordable medicines for patients across the globe. We have a growing R&D team of approximately 2,300 colleagues dedicated to advancing more than 90 clinical trials involving more than 13,000 patients and healthy volunteers. Our expansive portfolio is directed by a predominantly internalized clinical development team supporting trials in more than 40 countries. Hematology-oncology and solid tumor targeted therapies and immuno-oncology are key focus areas for the Company, with both mono- and combination therapies prioritized in our research and development. We currently market three medicines discovered and developed in our labs: BTK inhibitor BRUKINSA in the United States, China, Canada, and additional international markets; and non-FC-gamma receptor binding anti-PD-1 antibody tislelizumab and PARP inhibitor pamiparib in China.

BeiGene also partners with innovative companies who share our goal of developing therapies to address global health needs. We commercialize a range of oncology medicines in China licensed from Amgen and Bristol Myers Squibb. We also plan to address greater areas of unmet need globally through our collaborations including with Amgen, Bio-Thera, EUSA Pharma, Mirati Therapeutics, Seagen, and Zymeworks. BeiGene has also entered into a collaboration with Novartis granting Novartis rights to develop, manufacture, and commercialize tislelizumab in North America, Europe, and Japan.

About BeiGene

BeiGene is a global, science-driven biotechnology company focused on developing innovative and affordable medicines to improve treatment outcomes and access for patients worldwide. With a broad portfolio of more than 40 clinical candidates, we are expediting development of our diverse pipeline of novel therapeutics through our own capabilities and collaborations. We are committed to radically improving access to medicines for two billion more people by 2030. BeiGene has a growing global team of over 7,000 colleagues across five continents. To learn more about BeiGene, please visit www.beigene.com and follow us on Twitter at @BeiGeneGlobal.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws, including statements regarding future development and potential commercialization of BRUKINSA in the European Union and other markets, the potential for BRUKINSA to be a best-in-class BTK inhibitor, the potential for zanubrutinib to provide improved clinical benefit with advantages in safety, and the potential commercial opportunity for BRUKINSA. 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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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_Factsheet_Waldenstro%CC%88m-Macroglobulinemia_090920.pdf. Accessed April 2021.

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.

Exhibit 99.2

BeiGene Announces Inclusion in FTSE Russell Indices

BeiGene added to FTSE Global Equity Index Large Cap, All-World (LM), All-Cap (LMS), Total-Cap (LMSμ); as well as the Developed ESG Low Carbon Select Index and Asia ex Japan ESG Low Carbon Select Index

CAMBRIDGE, Mass. & BEIJING, China – September 20, 2021 – BeiGene, Ltd. (NASDAQ: BGNE; HKEX: 06160), a global biotechnology company focused on developing and commercializing innovative medicines worldwide, has announced its inclusion in several FTSE Russell indices, including: the FTSE Global Equity Index Large Cap; the FTSE All-World (LM); the FTSE All-Cap (LMS); and the FTSE Total-Cap (LMSμ). In addition, BeiGene has also been included in the FTSE Developed ESG Low Carbon Select Index, and the FTSE Asia ex Japan ESG Low Carbon Select Index, reflecting the company's commitment to sustainability. The company's inclusion on the FTSE indices became effective on Friday, September 17, 2021, after U.S. market close.

FTSE Russell is a global index leader that provides innovative benchmarking, analytics, and data solutions for investors worldwide. FTSE Russell calculates thousands of indexes that measure and benchmark markets and asset classes in more than 70 countries, covering 98 percent of the investable market globally. According to FTSE Russell, a core set of universal principles guides FTSE Russell index design and management: a transparent rules-based methodology is informed by independent committees of leading market participants.

"BeiGene's inclusion on these indices has the potential to elevate our visibility among the global investment community and diversify our overall investor base," said John V. Oyler, Co-Founder, Chairman and CEO of BeiGene. "Our more than 7,000 colleagues on five continents share a commitment to operating with urgency to change how cancer is treated globally, while operating with the highest integrity."

BeiGene's environmental, social and governance (ESG) approach centers on its ambition to expand affordable access to treatments for more patients around the world; to provide meaningful growth and development opportunities for its employees; and to operate its business responsibly and sustainably.

Added Christine Riley Miller, Reputation & ESG Lead at BeiGene, "We are determined to not only create world-class therapies for all, but also to do our part in creating a more inclusive, equitable, and sustained world. Our ESG framework reflects our aspiration to increase access and affordability of cancer treatments for all who need them."

More information about BeiGene's ESG efforts can be found in the company's inaugural global ESG report.

For more information, please refer to the Index page on FTSE's website at https://www.ftserussell.com/products/indices/esg.

About BeiGene

BeiGene is a global, science-driven biotechnology company focused on developing innovative and affordable medicines to improve treatment outcomes and access for patients worldwide. With a broad portfolio of more than 40 clinical candidates, we are expediting development of our diverse pipeline of novel therapeutics through our own capabilities and collaborations. We are committed to radically improving access to medicines for two billion more people by 2030. BeiGene has a growing global team of over 7,000 colleagues across five continents. To learn more about BeiGene, please visit www.beigene.com and follow us on Twitter at @BeiGeneGlobal.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws, including statements regarding BeiGene's plans, commitments, aspirations, and goals, such as the aspiration to increase access and affordability of cancer treatment for patients worldwide. 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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