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): **December 9, 2017**

BEIGENE, LTD.

(Exact name of registrant as specified in its charter)

Cayman Islands	**001-37686**	**98-1209416**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

c/o Mourant Ozannes Corporate 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 or Rule 12b-2 of the Securities Exchange Act of 1934.

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 December 9, 2017, BeiGene, Ltd. (the "Company") issued a press release announcing updated preliminary clinical data from an ongoing Phase 1b trial of its investigational Bruton's Tyrosine Kinase (BTK) inhibitor zanubrutinib (BGB-3111) in combination with the anti-CD20 antibody GAZYVA® (obinutuzumab) in patients with chronic lymphocytic leukemia / small lymphocytic lymphoma and follicular lymphoma, presented at the 59 th American Society of Hematology Annual Meeting in Atlanta, GA ("ASH"). 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 December 9, 2017, the Company issued a press release announcing preliminary clinical data from an ongoing Phase 1b trial of its investigational BTK inhibitor zanubrutinib (BGB-3111) in patients with non-Hodgkin's lymphoma , presented at ASH. 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.

On December 11, 2017, the Company issued a press release announcing initial data from the ongoing Phase 1b trial of its investigational BTK inhibitor, zanubrutinib (BGB-3111), in combination with its investigational anti-PD-1 antibody, tislelizumab (BGB-A317), in patients with B-cell malignancies, presented at ASH. The full text of this press release is filed as Exhibit 99.3 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 Presents Updated Preliminary Phase 1b Data on BTK Inhibitor Zanubrutinib (BGB-3111) Combined with GAZYVA® (Obinutuzumab) at the 59th American Society of Hematology Annual Meeting, " issued on December 9, 2017
99.2	Press Release titled " BeiGene Presents Preliminary Phase 1b Data on BTK Inhibitor Zanubrutinib (BGB-3111) in Non-Hodgkin's Lymphoma at the 59th American Society of Hematology Annual Meeting, " issued on December 9, 2017
99.3	Press Release titled "BeiGene Presents Initial Phase 1b Data for BTK Inhibitor Zanubrutinib (BGB-3111) Combined with PD-1 Antibody Tislelizumab (BGB-A317) at the 59 th American Society of Hematology Annual Meeting," issued on December 11, 2017

Exhibit Index

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SIGNATURES

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.

Date: December 11, 2017

BEIGENE, LTD.

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

BeiGene, Ltd.

BeiGene Presents Updated Preliminary Phase 1b Data on BTK Inhibitor Zanubrutinib (BGB-3111) Combined with GAZYVA® (Obinutuzumab) at the 59 th American Society of Hematology Annual Meeting

CAMBRIDGE , Mass., and BEIJING, China, December 9, 2017 (GLOBE NEWSWIRE) -- BeiGene, Ltd. (NASDAQ: BGNE), a commercial-stage biopharmaceutical company focused on developing and commercializing innovative molecularly targeted and immuno-oncology drugs for the treatment of cancer, today presented updated preliminary clinical data from an ongoing Phase 1b trial of its investigational Bruton's Tyrosine Kinase (BTK) inhibitor zanubrutinib (BGB-3111) in combination with the anti-CD20 antibody GAZYVA® (obinutuzumab) in patients with chronic lymphocytic leukemia / small lymphocytic lymphoma (CLL/SLL) and follicular lymphoma (FL) at the 59 th American Society of Hematology (ASH) Annual Meeting in Atlanta, GA. The updated preliminary Phase 1b data demonstrated that the combination was generally well tolerated and was highly active in patients with FL and treatment-naïve (TN) or relapsed or refractory (R/R) CLL/SLL.

"These updated Phase 1b data continue to indicate that zanubrutinib in combination with obinutuzumab is well tolerated and highly active in patients with CLL/SLL and FL. Toxicity-related treatment discontinuation has been rare, and the rate and depth of respone in FL, as well as the rate of complete responses in CLL/SLL, is very encouraging," commented Constantine Tam, MD, Disease Group Lead for Low Grade Lymphoma and Chronic Lymphocytic Leukemia at Peter MacCallum Cancer Centre, Director of Haematology at St. Vincent's Hospital, Australia, and lead author of the presentation.

"We are excited to see the frequency and depth of responses in patients with CLL/SLL and R/R FL from this Phase 1b trial. We believe that these updated preliminary data continue to support our ongoing global pivotal Phase 2 trial of this

combination in R/R FL," commented Jane Huang, MD, Chief Medical Officer, Hematology at BeiGene.

Summary of Results from the Ongoing Phase 1b Trial

The open-label, multi-center, Phase 1b trial of zanubrutinib in combination with obinutuzumab in patients with B-cell malignancies is being conducted in Australia, the United States, and South Korea, and consists of a dose-escalation phase and a dose-expansion phase in disease-specific cohorts, which is designed to include TN or R/R CLL/SLL and R/R FL patients. The dose-escalation component is testing zanubrutinib at 320 mg once a day (QD) or 160 mg twice daily (BID) in 28-day cycles, in combination with obinutuzumab; obinutuzumab was administered in line with standard CLL dosing (three loading doses of 1000 mg weekly followed by 1000 mg on day one of cycles 2–6). The ongoing dose-expansion component is testing doses of zanubrutinib at 160 mg BID with the same obinutuzumab schedule. As of September 15, 2017, the date of the most recent data cutoff, 45 patients with CLL/SLL and 26 patients with FL were enrolled in the trial.

At the time of data cutoff, the most common adverse events (AEs) were grade 1-2. The most common AEs in patients with CLL/SLL (occurring in ≥ 20% of patients) of any attribution were petechiae/purpura/contusion (42%), neutropenia (40%), upper respiratory tract infection (URTI) (36%), fatigue (24%), thrombocytopenia (24%), diarrhea (20%), and pyrexia (20%). The most common AEs in patients with FL (occurring in ≥ 20% of patients) of any attribution were URTI (38%), petechia/purpura/contusion (35%), rash (27%), and thrombocytopenia (23%). Grade 3 or 4 AEs of any attribution reported in ≥ 5% of the CLL/SLL patients included neutropenia (24%) and thrombocytopenia (7%). Grade 3 or 4 AEs of any attribution reported in ≥ 5% of the FL patients included neutropenia (12%). There were no cases of serious hemorrhage (≥ grade 3 hemorrhage or central nervous system hemorrhage of any grade), atrial fibrillation, or grade 3 or above diarrhea. Only one

patient with CLL/SLL discontinued treatment due to an AE, a case of squamous cell carcinoma (SCC) in a patient who had a prior history of SCC. This was also the only patient in the study who had a fatal AE .

At the time of data cutoff, 45 patients with CLL/SLL (20 TN and 25 R/R) and 21 patients with R/R FL were evaluable for efficacy. In TN CLL/SLL patients, after a median follow-up of 11.4 months (6.0–17.3 months), the overall response rate (ORR) was 95% with complete responses (CRs) in 35% and partial responses (PRs) in 60% of patients. In R/R CLL/SLL patients, at a median follow-up time of 12.7 months (7.9–19.5 months), the ORR was 92% with CRs in 20% and PRs in 72% of patients. In R/R FL patients, at a median follow-up time of 12.1 months (0.8–19.7 months), the ORR was 76% with CRs in 38% and PRs in 38% of patients. ORR in high-risk CLL/SLL patients with del17p/p53 mutation (n=6), del11q mutation (n=6), and unmutated IGHV (n=19) were 83%, 100%, and 95%, respectively. The majority of patients remained on treatment at the time of data cutoff.

About Zanubrutinib

Zanubrutinib (BGB-3111) is an investigational small molecule inhibitor of BTK that has demonstrated higher selectivity against BTK than ibrutinib (a BTK inhibitor currently approved by the U.S. Food and Drug Administration and the European Medicines Agency) based on biochemical assays, higher exposure than ibrutinib based on their respective Phase 1 experience in separate studies, and sustained 24-hour BTK occupancy in both the peripheral blood and lymph node compartments.

About BeiGene

BeiGene is a global, commercial-stage, research-based biotechnology company focused on molecularly targeted and immuno-oncology cancer therapeutics. With a team of over 700 employees in China, the United States, and Australia, BeiGene is advancing a pipeline consisting of novel oral small molecules and monoclonal

antibodies for cancer. BeiGene is also working to create combination solutions aimed to have both a meaningful and lasting impact on cancer patients. BeiGene markets ABRAXANE® (nanoparticle albumin–bound paclitaxel), REVLIMID® (lenalidomide), and VIDAZA® (azacitidine) in China under a license from Celgene Corporation. [i]

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 encouraging clinical data of BGB-3111 and BeiGene's advancement of, and anticipated clinical development and regulatory milestones and plans related to BGB-3111. 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; actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials; BeiGene's ability to achieve market acceptance in the medical community necessary for commercial success; BeiGene's ability to obtain and maintain protection of intellectual property for its technology and drugs; BeiGene's reliance on third parties to conduct preclinical studies and clinical trials; 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, 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, Ltd.

BeiGene Presents Preliminary Phase 1b Data on BTK Inhibitor Zanubrutinib (BGB-3111) in Non-Hodgkin's Lymphoma at the 59 th American Society of Hematology Annual Meeting

CAMBRIDGE , Mass., and BEIJING, China, December 9, 2017 (GLOBE NEWSWIRE) -- BeiGene, Ltd. (NASDAQ: BGNE), a commercial-stage biopharmaceutical company focused on developing and commercializing innovative molecularly targeted and immuno-oncology drugs for the treatment of cancer, today presented preliminary clinical data from an ongoing Phase 1b trial of its investigational Bruton's Tyrosine Kinase (BTK) inhibitor zanubrutinib (BGB-3111) in patients with non-Hodgkin's lymphoma (NHL) in an oral presentation at the 59 th American Society of Hematology (ASH) Annual Meeting in Atlanta, GA. The preliminary data included patients with aggressive NHL subtypes such as diffuse large B-cell lymphoma (DLBCL) and mantle cell lymphoma (MCL) as well as indolent NHL subtypes such as follicular lymphoma (FL) and marginal zone lymphoma (MZL). The Phase 1b data suggest that zanubrutinib was generally well-tolerated and had anti-tumor activity across various NHL subtypes.

"In this Phase 1b trial, zanubrutinib was well-tolerated across multiple NHL subtypes, with very low rates of toxicity-related treatment discontinuation in both indolent and aggressive disease settings. These preliminary data also indicate that zanubrutinib's complete and sustained BTK occupancy translates into high response rates in NHL subtypes beyond Waldenström's macroglobulinemia and chronic lymphocytic leukemia, for which data have previously been reported,"" commented Constantine Tam, MD, Disease Group Lead for Low Grade Lymphoma and Chronic Lymphocytic Leukemia at Peter MacCallum Cancer Centre, Director of Haematology at St. Vincent's Hospital, Australia, and lead author of the presentation.

“Building upon the promising Phase 1b data we have presented for zanubrutinib, we are pleased to report results from additional NHL subtypes enrolled in our Phase 1b trial. We continue to pursue broad development of zanubrutinib with ongoing pivotal trials in a range of NHL subtypes both globally and in China,” commented Jane Huang, MD, Chief Medical Officer, Hematology at BeiGene.

Summary of Results from the Ongoing Phase 1b Trial

The multi-center, open-label Phase 1b trial of zanubrutinib in patients with B-cell malignancies is being conducted in Australia, New Zealand, South Korea, the United States, and Europe, and consists of a dose-escalation phase and a dose-expansion phase in disease-specific cohorts. The ongoing dose-expansion component is testing doses of 160 mg twice daily (BID) or 320 mg once a day (QD). As of September 15, 2017 , the date of the most recent data cutoff, 99 patients with NHL subtypes other than chronic lymphocytic leukemia/small lymphocytic lymphoma and Waldenström's macroglobulinemia were enrolled in the study, including 34 patients in the indolent lymphoma cohort, which consisted of 24 patients with FL and 10 patients with MZL, and 65 patients in the aggressive lymphoma cohort, which consisted of 27 patients with DLBCL and 38 patients with MCL. The median follow-up time was 5.6 months (0.3-22.3 months) and 5.1 months (0.1-31.9) for indolent and aggressive lymphoma, respectively.

At the time of data cutoff, the most frequent adverse events (AEs) (occurring in ≥15% of patients) of any attribution among 34 patients with indolent lymphoma were petechiae/purpura/contusion (24%), upper respiratory tract infection (URTI) (21%), nausea (18%) and pyrexia (15%). The most frequently reported grade 3 or greater AEs (occurring in ≥5% of patients) of any attribution were anemia (9%), neutropenia (9%), urinary tract infection (6%), and abdominal pain (6%). Serious AEs were reported in 11 patients (32%). Of those, four patients had serious AEs that were considered possibly related to zanubrutinib, including one case each of nausea,

urinary tract infection, diarrhea, and creatinine increase.

The most frequent AEs (occurring in ≥15% of patients) of any attribution among 65 patients with aggressive lymphoma were petechiae/purpura/contusion (25%), diarrhea (23%), constipation (22%), fatigue (18%), URTI (18%), anemia (17%), cough (15%), pyrexia (15%), and thrombocytopenia (15%). The most frequently reported grade 3 or greater AEs (occurring in ≥5% of patients) of any attribution were anemia (11%), neutropenia (9%), thrombocytopenia (9%), and pneumonia (6%). Serious AEs were reported in 26 patients (40%). Of those, three patients had serious AEs that were considered possibly related to zanubrutinib, including one case each of peripheral edema and joint effusion (occurring in the same patient), pneumonia, and pneumonitis.

At the time of data cutoff, 26 patients with indolent lymphoma including 17 patients with FL and nine patients with MZL were evaluable for efficacy. In patients with FL, the overall response rate (ORR) was 41% with complete responses (CRs) in 18% and partial responses (PRs) in 24% of patients. Stable disease (SD) was observed in 41% of patients. Progressive disease (PD) was observed in one patient. In patients with MZL, the ORR was 78% with no CR, and PRs in 78% of patients. SD was observed in 22% of patients. No PD was observed.

Fifty-eight patients with aggressive lymphoma including 26 patients with DLBCL and 32 patients with MCL were evaluable for efficacy. In patients with DLBCL, the ORR was 31% with CRs in 15% and PRs in 15% of patients. In patients with MCL, the ORR was 88% with CRs in 25% and PRs in 63% of patients.

About Zanubrutinib

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Agency) based on biochemical assays, higher exposure than ibrutinib based on their respective Phase 1 experience in separate studies, and sustained 24-hour BTK occupancy in both the peripheral blood and lymph node compartments.

About BeiGene

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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 encouraging clinical data of zanubrutinib and BeiGene’s advancement of, and anticipated clinical development and regulatory milestones and plans related to zanubrutinib. 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; actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials; BeiGene's ability to achieve market acceptance in the medical community necessary for commercial success; BeiGene's ability to obtain and maintain protection of intellectual property for its technology and drugs; BeiGene's reliance on third parties to conduct preclinical studies and clinical trials; 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, 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, Ltd.

BeiGene Presents Initial Phase 1b Data for BTK Inhibitor Zanubrutinib (BGB-3111) Combined with PD-1 Antibody Tislelizumab (BGB-A317) at the 59 th American Society of Hematology Annual Meeting

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"The initial data from this Phase 1b trial indicate that the combination of zanubrutinib and tislelizumab is tolerable with adverse events generally consistent with each therapeutic class. With only a short follow-up time, we have observed objective responses across different malignancy types in this heavily pre-treated population," commented Constantine Tam, MD, Disease Group Lead for Low Grade Lymphoma and Chronic Lymphocytic Leukemia at Peter MacCallum Cancer Centre, Director of Haematology at St. Vincent's Hospital, Australia, and lead author of the presentation.

"Based on pre-clinical data suggesting the synergy of this combination, we are hopeful that this clinical trial will help to characterize the combination's potential in treating patients with B-cell malignancies, particularly aggressive lymphomas," commented Jane Huang, MD, Chief Medical Officer, Hematology at BeiGene.

Summary of Results from the Ongoing Phase 1b Trial

The open-label, multi-center Phase 1b trial of zanubrutinib in combination with tislelizumab consists of a dose escalation portion to be followed by a dose expansion portion. Data presented at ASH include patients enrolled at the first two dose levels of the dose escalation phase: dose 1 cohort of zanubrutinib at 320 mg once a day (QD) with tislelizumab at 2 mg/kg every three weeks (Q3W), and dose 2 cohort of zanubrutinib at 320 mg QD with tislelizumab at 5 mg/kg Q3W. Patients in the third dose cohort will receive zanubrutinib at 160 mg twice daily with tislelizumab at 200 mg Q3W.

As of September 15, 2017, the date of the most recent data cutoff, 25 patients, including 15 patients in the dose 1 cohort and 10 patients in the dose 2 cohort, had been enrolled. There were 13 patients with indolent lymphoma, including chronic lymphocytic leukemia (CLL), follicular lymphoma (FL), marginal zone lymphoma (MZL), and Waldenström's macroglobulinemia (WM), and 12 patients with aggressive lymphoma, including diffuse large B-cell lymphoma (DLBCL), mantle cell lymphoma (MCL), and transformed lymphoma. The median follow-up time was 5.1 months (0.4-14.1 months). Two cases of autoimmune hemolysis occurred in patients with WM in the dose 2 cohort, and one qualified as a dose-limiting toxicity (DLT). These events were not associated with a positive direct antiglobulin test and resolved with immunosuppressive therapy, but resulted in the decision to exclude further enrollment of WM patients in the trial. No further DLTs were observed after WM patients were excluded.

Among patients with indolent lymphoma, the most common adverse events (AEs) (occurring in ≥ 20% of patients) of any attribution were petechiae/purpura/contusion (31%) and thrombocytopenia (23%). Grade 3-4 AEs of any attribution reported in at least two patients included thrombocytopenia, anemia, and hemolysis (15% each). Besides the two cases of autoimmune hemolysis, there was one more immune-

related event, a grade 4 autoimmune encephalitis. The patient was treated with aggressive immunosuppressive therapy and gradually improved over time.

Among patients with aggressive lymphoma, the most common AEs (occurring in ≥ 20% of patients) of any attribution were diarrhea, fatigue, pyrexia, upper respiratory tract infection (33% each), cough (25%), and nausea (25%). Grade 3-4 AEs of any attribution reported in at least two patients included pyrexia (17%). There was one patient with multiple occurrences of grade 2 and 3 pneumonitis.

At the time of data cutoff, the efficacy-evaluable population consisted of 25 patients. The median follow-up time was 5.1 months (0.4-14.1 months). Objective responses were observed in 10 patients (40%). By tumor type, two partial responses (PRs) were observed out of five patients with CLL, one complete response (CR) and one PR were observed out of five patients with FL, one very good partial response and one minor response were observed out of two patients with WM, one CR was observed out of five patients with DLBCL, and three PRs were observed out of five patients with transformed lymphoma.

About Zanubrutinib

Zanubrutinib (BGB-3111) is an investigational small molecule inhibitor of BTK that has demonstrated higher selectivity against BTK than ibrutinib (a BTK inhibitor currently approved by the U.S. Food and Drug Administration and the European Medicines Agency) based on biochemical assays, higher exposure than ibrutinib based on their respective Phase 1 experience in separate studies, and sustained 24-hour BTK occupancy in both the peripheral blood and lymph node compartments.

About Tislelizumab

Tislelizumab (BGB-A317) is an investigational humanized monoclonal antibody that belongs to a class of immuno-oncology agents known as immune checkpoint inhibitors. It is designed to bind to PD-1, a cell surface receptor that plays an

important role in downregulating the immune system by preventing the activation of T-cells. Tislelizumab has high affinity and specificity for PD-1. It is differentiated from the currently approved PD-1 antibodies in an engineered Fc region, which is believed to minimize potentially negative interactions with other immune cells. Tislelizumab is being developed as a monotherapy and in combination with other therapies for the treatment of a broad array of both solid tumor and hematologic cancers. BeiGene and Celgene Corporation have a global strategic collaboration for tislelizumab for solid tumors.

About BeiGene

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Forward-Looking Statements

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affect the initiation, timing and progress of clinical trials; BeiGene's ability to achieve market acceptance in the medical community necessary for commercial success; BeiGene's ability to obtain and maintain protection of intellectual property for its technology and drugs; BeiGene's reliance on third parties to conduct preclinical studies and clinical trials and manufacturing; 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, 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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