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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**Form 8-K/A**

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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): **June 14, 2019**

**BEIGENE, LTD.**

(Exact Name of Registrant as Specified in Charter)

**Cayman Islands**  
(State or Other Jurisdiction of Incorporation)

**001-37686**  
(Commission File Number)

**98-1209416**  
(I.R.S. Employer Identification Number)

**c/o Mourant Governance Services (Cayman) Limited**  
**94 Solaris Avenue, Camana Bay**  
**Grand Cayman KY1-1108**  
**Cayman Islands**

(Address of Principal Executive Offices) (Zip Code)

**+1 (345) 949 4123**

(Registrant's telephone number, including area code)

**Not Applicable**

(Former name or former address, if changed since last report)

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

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

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

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

\*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.

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## Explanatory Note

On June 17, 2019, BeiGene, Ltd. filed a Current Report on Form 8-K (the “Original Form 8-K”) which contained an incorrect Exhibit 99.1. This Form 8-K/A amends the Original Form 8-K to file the correct Exhibit 99.1.

### Item 1.02. Termination of a Material Definitive Agreement.

On June 14, 2019, BeiGene, Ltd. and its wholly-owned subsidiary, BeiGene Switzerland GmbH (collectively, “BeiGene”), and Celgene Corporation and its wholly-owned subsidiary Celgene Switzerland LLC (collectively, “Celgene”) entered into an agreement to mutually terminate their Amended and Restated Exclusive License and Collaboration Agreement, dated August 31, 2017, pursuant to which BeiGene had granted an exclusive license to Celgene to develop and commercialize tislelizumab for solid tumors in the United States, Europe, Japan and the rest of the world other than Asia (the “Collaboration Agreement”). In connection with the termination, Celgene will pay \$150 million to BeiGene and BeiGene will regain full, global development and commercialization rights to tislelizumab.

The License and Supply Agreement entered into as of July 5, 2017 by and among BeiGene and Celgene Logistics Sàrl remains unchanged, and BeiGene retains the right to exclusively distribute and promote ABRAXANE<sup>®</sup>, REVLIMID<sup>®</sup>, and VIDAZA<sup>®</sup> in China, excluding Hong Kong, Macau and Taiwan, pursuant to the terms of the agreement.

### Item 7.01. Regulation FD Disclosure.

BeiGene will host a conference call and webcast of mid-2019 clinical data updates on Thursday, June 20, 2019 at 8:00 a.m. EDT. The information in Item 7.01 of this Current Report on Form 8-K is intended to be furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

### Item 8.01. Other Events.

On June 17, 2019, BeiGene issued a press release announcing the above-described transaction. A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and incorporated by reference herein.

On June 14, 2019, BeiGene issued a press release announcing the first presentation of clinical results from the ASPEN trial, a global randomized Phase 3 open-label trial of its investigational BTK inhibitor zanubrutinib in patients with Waldenström’s Macroglobulinemia (WM). The poster presentation included clinical results from a nonrandomized exploratory cohort of patients with the MYD88<sup>WT</sup> genotype of WM. The Company also announced updated results from the ongoing Phase 1/2 trial of patients with WM; and a pooled safety data analysis of zanubrutinib from six ongoing monotherapy studies in patients with B-cell malignancies. These data were presented in three posters at the 24th European Hematology Association (EHA) Congress, taking place June 13-16, 2019 in Amsterdam. A copy of the press release is filed as Exhibit 99.2 to this Current Report on Form 8-K and incorporated by reference herein.

On June 14, 2019, BeiGene issued a press release announcing updated results from a pivotal Phase 2 study of tislelizumab, an investigational anti-PD-1 antibody, in Chinese patients with relapsed/refractory (R/R) classical Hodgkin lymphoma (cHL) in a poster at the 24th EHA Congress. A copy of the press release is filed as Exhibit 99.3 to this Current Report on Form 8-K and incorporated by reference herein.

### Item 9.01 Financial Statements and Exhibits

#### (d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release titled “BeiGene Regains Full Global Rights to Its Investigational Anti-PD-1 Antibody Tislelizumab,” issued on June 17, 2019
99.2	Press Release titled “BeiGene Announces Clinical Results from Three Posters on Zanubrutinib Presented at the 24th Congress of European Hematology Association (EHA),” issued on June 14, 2019
99.3	Press Release titled “BeiGene Announces Updated Results from a Pivotal Phase 2 Study of Tislelizumab in Chinese Patients with Relapsed or Refractory Classical Hodgkin Lymphoma at the 24th Congress of the European Hematology Association (EHA),” issued on June 14, 2019

## Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
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99.3	<a href="#"><u>Press Release titled “BeiGene Announces Updated Results from a Pivotal Phase 2 Study of Tislelizumab in Chinese Patients with Relapsed or Refractory Classical Hodgkin Lymphoma at the 24th Congress of the European Hematology Association (EHA),” issued on June 14, 2019</u></a>

**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: June 18, 2019

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



### **BeiGene Regains Full Global Rights to Its Investigational Anti-PD-1 Antibody Tislelizumab**

CAMBRIDGE, Mass. and BEIJING, China; June 17, 2019 (GLOBE NEWSWIRE) — BeiGene, Ltd. (NASDAQ: BGNE; HKEX: 06160), a commercial-stage biopharmaceutical company focused on developing and commercializing innovative molecularly-targeted and immuno-oncology drugs for the treatment of cancer, today announced that it has entered into a mutual agreement with Celgene Corporation to terminate the parties' global collaboration for tislelizumab, BeiGene's investigational anti-PD-1 antibody, in advance of the pending acquisition of Celgene by Bristol-Myers Squibb. In connection with the termination, Celgene has agreed to pay \$150 million to BeiGene.

"Our collaboration with Celgene was instrumental for the late-stage clinical development of tislelizumab and has provided us with significant resources to continue our broad clinical program," said John V. Oyler, Co-Founder, Chief Executive Officer, and Chairman of BeiGene. "As we have been leading most of the ongoing Phase 3 or potentially registration-enabling trials with a global development organization of over 800 people, we believe that we are well-positioned to continue the development of tislelizumab. I am proud of the work that we have accomplished in collaboration with Celgene and am excited by the tremendous opportunity that we have ahead now that we've regained full global rights to tislelizumab."

Tislelizumab has been dosed in over 2,950 patients globally. With two new drug applications under review in China, BeiGene expects tislelizumab to receive its first regulatory approval later this year.

In July 2017, BeiGene and Celgene announced a global strategic collaboration in which Celgene obtained exclusive rights to develop and commercialize tislelizumab in solid tumor cancers in the United States, Europe, Japan and the rest of world outside of Asia. BeiGene retained rights in hematology indications globally and in solid tumor cancers in Asia (ex-Japan). In connection with that agreement, BeiGene also acquired Celgene's commercial operations in China and an exclusive license to Celgene's cancer commercial portfolio in China (ABRAXANE<sup>®</sup>, REVLIMID<sup>®</sup>, VIDAZA<sup>®</sup>). BeiGene's commercial license from Celgene is not affected by the termination of the tislelizumab agreement. In the almost two years since the transaction, BeiGene has grown its commercial organization in China to more than 600 people.

#### **About Tislelizumab**

Tislelizumab (BGB-A317) is an investigational 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 drug candidate produced from BeiGene's immuno-oncology biologic program, and 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.

Tislelizumab is being studied in a broad clinical program. BeiGene has completed a pivotal Phase 2 clinical trial in patients with relapsed or refractory (R/R) classical Hodgkin's lymphoma (cHL). Ongoing clinical trials of tislelizumab include a Phase 3 clinical trial in patients with second-line or third-line non-small cell lung cancer (NSCLC); a Phase 3 clinical trial in first-line patients with hepatocellular carcinoma (HCC); a Phase 3 clinical trial in second-line patients with esophageal squamous carcinoma (ESCC); a Phase 3 clinical trial in first-line patients with gastric cancer (GC); a Phase 3 clinical trial in first-line patients with ESCC; a Phase 2 clinical trial in second- or third-line patients with HCC; and a Phase 1 clinical trial in patients with R/R NK/T-cell lymphomas. The aforementioned studies are enrolling patients in multiple countries, including the U.S., Europe, and China.

Additionally, BeiGene is conducting a Phase 3 clinical trial in first-line patients with non-squamous NSCLC; a Phase 3 clinical trial in first-line patients with squamous NSCLC; a Phase 3 clinical trial in patients with nasopharyngeal cancer (NPC); a Phase 3 clinical trial in first-line patients with urothelial carcinoma (UC); a pivotal Phase 2 clinical trial in patients with locally advanced or metastatic urothelial cancer; and a pivotal Phase 2 trial in patients with MSI-H or dMMR solid tumors. These studies are enrolling patients in China.

New drug applications (NDA) for tislelizumab in patients with R/R cHL and in patients with locally advanced or metastatic UC have been accepted by the China National Medical Products Administration (NMPA, formerly known as CFDA) and the R/R cHL filing has been granted priority review.

### **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 approximately 2,400 employees in China, the United States, Australia and Europe, 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 BeiGene's advancement of, and anticipated clinical development, regulatory milestones and commercialization of tislelizumab and its commercialization in China of ABRAXANE®, REVLIMID®, VIDAZA®. 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 technology and drugs; 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, 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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(i) ABRAXANE®, REVLIMID®, and VIDAZA® are registered trademarks of Celgene Corporation.



**BeiGene Announces Clinical Results from Three Posters on Zanubrutinib Presented at the 24<sup>th</sup> Congress of European Hematology Association (EHA)**

*First Preliminary Data from Exploratory MYD88<sup>WT</sup> Patient Cohort in Phase 3 Trial in Waldenström's Macroglobulinemia (WM); Updated Phase 1/2 WM Data; and Pooled Safety Data Analysis on Zanubrutinib in B-Cell Malignancies Presented*

*Company to Host Investor Conference Call and Webcast of Mid-2019 Clinical Data Updates on Thursday, June 20, 2019 at 8:00 a.m. EDT*

CAMBRIDGE, Mass. and BEIJING, China, June 14, 2019 (GLOBE NEWSWIRE) — BeiGene, Ltd. (NASDAQ: BGNE; HKEX: 06160), a commercial-stage biopharmaceutical company focused on developing and commercializing innovative molecularly-targeted and immuno-oncology drugs for the treatment of cancer, today announced the first presentation of clinical results from the ASPEN trial, a global randomized Phase 3 open-label trial of its investigational BTK inhibitor zanubrutinib in patients with Waldenström's Macroglobulinemia (WM). The poster presentation included clinical results from a nonrandomized exploratory cohort of patients with the MYD88<sup>WT</sup> genotype of WM. In addition, BeiGene announced updated results from the ongoing Phase 1/2 trial of patients with WM; and a pooled safety data analysis of zanubrutinib from six ongoing monotherapy studies in patients with B-cell malignancies. These data were presented in three posters at the 24<sup>th</sup> European Hematology Association (EHA) Congress, taking place June 13-16 in Amsterdam.

"We are excited to announce new data from ongoing zanubrutinib clinical studies at EHA, including the first results of the Phase 3 ASPEN trial from a non-randomized cohort of patients who have WM with the MYD88<sup>WT</sup> genotype. For these patients, who typically have poorer prognoses with lower response rates, we recognize the real need for a highly potent and selective BTK inhibitor that can sustain BTK inhibition and reduce off-target effects. We are excited that these data have echoed what we saw in earlier trials, with an overall response rate of 81 percent and a major response rate that includes patients with a partial response or better, of 54% including 23% with a very good partial response (VGPR)," said Jane Huang, M.D., Chief Medical Officer, Hematology, at BeiGene. "We will continue to follow these patients to further assess outcomes. Full results from the trial are planned for presentation at a medical congress later this year."

Dr. Huang continued, "In addition, with longer follow-up from the global Phase 1/2 trial of zanubrutinib in patients with WM, we're seeing high rates of CR/VGPR (42%) that are proving to be durable responses. Separately, the pooled safety data analysis of

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zanubrutinib continues to affirm its tolerability as a selective BTK inhibitor, in patients with B-cell malignancies. We believe that these data further support zanubrutinib's potential to become a meaningful treatment option for patients with B-cell malignancies around the world."

### **Major Responses in Patients with MYD88 Wildtype WM Treated with Zanubrutinib**

*Abstract Number: PF487*

The ASPEN trial, a randomized open-label, multicenter Phase 3 trial (clinicaltrials.gov Identifier: NCT03053440) of zanubrutinib vs. ibrutinib in patients with WM, has enrolled 26 patients who were centrally determined at study entry to have the MYD88<sup>WT</sup> genotype. These patients were enrolled in the non-randomized cohort and assigned to receive zanubrutinib 160mg twice daily (BID). Responses were assessed using modified IWWM-6 criteria with endpoints of combined rate of complete response (CR) and very good partial response (VGPR), overall response rate (ORR), major response rate (MRR) and safety.

This exploratory analysis included five patients with treatment-naïve (TN) disease and 21 patients with relapsed/refractory (R/R) WM.

As of February 28, 2019, the median follow-up was 12.2 months (range 2.3 — 21.7 months) and 17 patients remained on study. Results included:

- The ORR was 80.8%. MRR (partial response or better) was 53.8% and the VGPR rate was 23.1%. One patient achieved a complete response by IgM criteria with normal IgM levels and negative immunofixation;
  - Median time to first major response (partial response or better) was 2.9 months;
  - Median progression-free survival (PFS) and overall survival (OS) have not yet been reached;
  - Zanubrutinib tolerability was generally consistent with previous reports. Discontinuation due to adverse events (AEs) occurred in 7.7% of patients (n=2). The primary reason for discontinuation was progressive disease;
  - The most common AEs (in >15% pts) were diarrhea (19%), hypertension (19%), contusion (15%), constipation (15%), muscle spasm (15%), pneumonia (15%), and upper respiratory tract infection (15%);
  - There were no fatal AEs or atrial fibrillation/flutter events reported; and
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- Among adverse events of special interest for BTK inhibitors, bleeding was observed in nine patients (34.6%), hypertension was observed in five patients (19.2%), Grade 3 or 4 cytopenias were observed in four patients (15.4%), Grade 3 or 4 infections were observed in three patients (11.5%), and secondary malignancy in three patients (11.5%). Two patients had major hemorrhage (7.7%).

“Zanubrutinib is a highly potent and selective BTK inhibitor with good bioavailability that was generally well-tolerated in this exploratory cohort from the Phase 3 ASPEN trial, said Meletios A. Dimopoulos, M.D., Professor of Hematology and Medical Oncology, Chairman of the Department of Clinical Therapeutics, Rector of the National and Kapodistrian University of Athens, Greece and first author on the poster. “For the patients with wildtype MYD88 genotype, we are excited by these data that support the results we’ve seen previously from Phase 1/2 studies.”

#### **Summary of Updated Clinical Results From the Global Phase 1/2 Trial**

*Abstract Number PF481*

This global, open-label Phase 1/2 trial (clinicaltrials.gov identifier: NCT02343120) of zanubrutinib as monotherapy in patients with B-cell malignancies, including a cohort of patients with WM, is being conducted in Australia, New Zealand, the United States, Italy, the United Kingdom and South Korea. As of September 16, 2018, 77 patients with TN (n=24) or R/R (n=53) WM without prior BTK exposure have been enrolled in the trial; the median follow-up time was 23.9 months (4.4-45.7). Seventy-three patients including 24 with TN and 49 with R/R WM, were evaluable for efficacy in this analysis, per modified IWWM-6 criteria. At the time of the data cutoff, 61 patients remained on study treatment. Updated results included:

- The ORR by independent review committee (IRC) was 92% (67/73) including MRR of 82% (60/73) and CR / VGPR rate of 42% (31/73).
  - The estimated PFS rate at 12 and 24 months was 90% and 81%, respectively;
  - Zanubrutinib tolerability was generally consistent with previous reports in patients with various B-cell malignancies and AEs were predominantly grade 1 or 2 in severity. The most frequent AEs were upper respiratory tract infection (46%), contusion (30%), cough (20%), headache (18%) and diarrhea (17%);
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- Grade 3-4 AEs occurred in 51.9% of patients. Grade 3-4 AEs of any attribution reported in > 3 patients included neutropenia (10%); anemia (7.8%), basal cell carcinoma (5%) and hypertension (5%); and
- With a median follow up 24 months, discontinuation due to AEs occurred in 10.4% of patients, with five fatal events.

“As we continue to follow the Phase 1/2 trial of zanubrutinib, now for more than four years, we are impressed by the tolerability and efficacy of this BTK inhibitor for patients with WM who had not received prior BTK inhibition therapy,” said Judith Trotman, MBChB, FRACP, FRCPA, Clinical Professor of Medicine at Concord Repatriation General Hospital, Concord, New South Wales, Australia and first author on the poster.

#### **Pooled Analysis of Safety Data from Monotherapy Studies of Zanubrutinib in B-cell Malignancies**

*Abstract Number PS1159*

Safety results from six ongoing, Phase 1 and Phase 2 clinical trials of zanubrutinib monotherapy, including collectively 682 patients with non-Hodgkin’s lymphoma (NHL), WM, or chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SL), were included in this comprehensive analysis. The majority of patients had R/R disease; almost all patients received zanubrutinib at a dose of 320mg once daily or 160mg twice daily. The median duration of zanubrutinib exposure was 13.4 months (0.1-49.7).

This analysis included an evaluation of the frequency and severity of AEs, AEs of Special Interest (AESIs), and AEs leading to death, dose reduction or treatment discontinuation (d/c).

Ninety-seven percent of patients reported at least one AE, which were primarily grade 1 or 2. The most common AEs of all grades included upper respiratory tract infection (32.4%), neutrophil count decreased (25.2%), diarrhea (19.4%), cough (19.1%), contusion (18.6%), and rash (18%). The most common grade  $\geq 3$  AEs included neutrophil count decreased (14.4%), anemia (7.6%), neutropenia (6.6%), pneumonia (4.5%), platelet count decreased (4.3%), and lung infection (4.1%). Serious AEs (SAEs) consisting primarily of infectious complications such as pneumonia/lung infection were reported in 36% of patients.

AESIs such as atrial fibrillation/flutter (1.9%), major hemorrhage (2.5%), and grade  $\geq 3$  hypertension (3.4%) were infrequent, and treatment discontinuation due to AEs was uncommon (9.1% overall, including 3.5% for whom the event(s) were treatment-

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related).

“Zanubrutinib was generally well-tolerated, with less than five percent discontinuation for treatment-related adverse events. These data also demonstrated low safety-related treatment failure rates at doses of zanubrutinib associated with complete and sustained BTK inhibition,” commented Constantine S. Tam, M.D., Disease Group Lead for Low Grade Lymphoma and Chronic Lymphocytic Leukemia at Peter MacCallum Cancer Center and Director of Hematology at St. Vincent’s Hospital, Australia, and lead author of the poster presentation.

**Mid-2019 Clinical Data Update Conference Call and Webcast Information:**

BeiGene will host a conference call and webcast on Thursday, June 20 at 8:00 a.m. EDT. Investors and analysts are invited to join the conference call using the following dial-in information:

U.S. Toll-Free: +1 (844) 461-9930  
U.S. Toll: +1 (478) 219-0535  
Hong Kong Toll-Free: +852 800 279 19250  
China Toll-Free: +86 800 914 686  
Conference ID: 1790069

A live webcast of the conference call can be accessed from the investors section of BeiGene’s website at <http://ir.beigene.com/> or <http://hkexir.beigene.com>. An archived replay will be available two hours after the event for 90 days.

**About Zanubrutinib**

Zanubrutinib (BGB-3111) is an investigational small molecule inhibitor of Bruton’s tyrosine kinase (BTK) discovered by BeiGene scientists that is currently being evaluated in a broad pivotal clinical program globally as a monotherapy and in combination with other therapies to treat various B-cell malignancies.

Clinical trials of zanubrutinib include a fully-enrolled, global Phase 3 clinical trial in patients with Waldenström macroglobulinemia (WM) comparing zanubrutinib to ibrutinib, currently the only approved BTK inhibitor for WM; a global Phase 3 clinical trial in patients with previously untreated chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL); a pivotal Phase 2 trial in patients with relapsed/refractory (R/R) follicular lymphoma in combination with GAZYVA® (obinutuzumab); a Phase 3 trial comparing zanubrutinib to ibrutinib in patients with R/R CLL/SLL; and a global Phase 1 trial. In China, BeiGene has completed two pivotal Phase 2 clinical trials of

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zanubrutinib in patients with MCL and CLL/SLL and the enrollment in the pivotal Phase 2 clinical trials in patients with WM.

Zanubrutinib has been granted by the U.S. Food and Drug Administration (FDA) Fast Track designation for the treatment of patients with WM, and Breakthrough Therapy designation for the treatment of adult patients with MCL who have received at least one prior therapy. The New Drug Applications (NDAs) in China for R/R MCL and R/R CLL/SLL have been accepted by the China National Medical Products Administration (NMPA) and granted priority review. BeiGene plans to submit its first NDA in the U.S. for zanubrutinib in 2019 or early 2020.

#### **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 approximately 2,400 employees in China, the United States, Australia and Europe, 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<sup>®</sup> (nanoparticle albumin-bound paclitaxel), REVLIMID<sup>®</sup> (lenalidomide), and VIDAZA<sup>®</sup> (azacitidine) in China under a license from Celgene Corporation.(1)

#### **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 from clinical trials of zanubrutinib and BeiGene's advancement of, and anticipated clinical development, regulatory milestones and commercialization of 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 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 technology and drugs; 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

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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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(1) ABRAXANE®, REVLIMID®, and VIDAZA® are registered trademarks of Celgene Corporation.

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**BeiGene Announces Updated Results from a Pivotal Phase 2 Study of Tislelizumab in Chinese Patients with Relapsed or Refractory Classical Hodgkin Lymphoma at the 24<sup>th</sup> Congress of the European Hematology Association (EHA)**

*Company to Host Investor Conference Call and Webcast of Mid-2019 Clinical Data Updates on Thursday, June 20 at 8:00 a.m. EDT*

CAMBRIDGE, Mass. and BEIJING, China; June 14, 2019 (GLOBE NEWSWIRE) — BeiGene, Ltd. (NASDAQ: BGNE; HKEX: 06160), a commercial-stage biopharmaceutical company focused on developing and commercializing innovative molecularly-targeted and immuno-oncology drugs for the treatment of cancer, today announced updated results from a pivotal Phase 2 study of tislelizumab, an investigational anti-PD-1 antibody, in Chinese patients with relapsed/refractory (R/R) classical Hodgkin lymphoma (cHL) in a poster at the 24<sup>th</sup> Congress of the European Hematology Association (EHA), taking place June 13-16, 2019 in Amsterdam.

“The encouraging clinical results from this study further support our new drug application for tislelizumab in patients with R/R cHL that is currently under priority review in China,” said Jane Huang, M.D., Chief Medical Officer, Hematology, at BeiGene. “We hope that this potentially differentiated anti-PD-1 antibody could become a new treatment option for cancer patients in China and across the world.”

“Tislelizumab demonstrated high anti-tumor activity in patients with R/R cHL — evidenced by an overall response rate of 87% and a complete response rate of 63%, and was generally well tolerated in these patients,” said Yuqin Song, M.D., Ph.D., Associate Professor of Medical Oncology, Deputy Director of the Lymphoma Department at Peking University Cancer Hospital in China, and the presenting author of the study.

**Summary of Clinical Results**

*Abstract Number: PF469*

This single-arm, multi-center, pivotal Phase 2 study of tislelizumab as a monotherapy in Chinese patients with R/R cHL (clinicaltrials.gov identifier: NCT03209973) enrolled 70 patients who were either R/R to autologous stem cell transplantation (ASCT), or received at least two prior lines of systemic therapy for cHL and were not candidates for ASCT. Patients were treated with tislelizumab, dosed at 200 mg intravenously

every three weeks. The primary endpoint of the trial is overall response rate (ORR) assessed by independent review committee (IRC) according to the Lugano Classification 2014.

As of November 26, 2018, 70 patients with R/R cHL were evaluable for efficacy. Thirteen patients received prior ASCT, and the remaining 57 patients were ineligible for ASCT. Patients had a median of three prior lines of systemic therapy (2-11). Results included:

- With a minimum of 23.8 weeks of follow-up and a median follow-up time of 13.9 months at the data cutoff, the ORR by IRC was 87.1% (61/70); 44 patients (62.9%) achieved a complete response (CR), and 17 patients (24.3%) achieved a partial response (PR);
- The median duration of response (DOR) has not been reached;
- Twelve-month progression-free survival (PFS) was estimated at 73.8% and median PFS has not been reached;
- The majority of adverse events (AEs) were grade 1 or 2 in severity. The most frequently reported treatment-emergent adverse events (TEAEs) of any grade include pyrexia (57.1%), weight increase (34.3%), upper respiratory tract infection and hypothyroidism (32.9% each), pruritus, white blood cell (WBC) count decreased, and cough (18.6%, each);
- Grade  $\geq 3$  TEAEs occurred in 30% of patients, with the most frequently reported being hypertension, pneumonitis, neutrophil count decrease, upper respiratory tract infection, and weight increase (2.9%, each); only 2.9% of patients reported grade 4 TEAEs and there were no fatal TEAEs.
- Four patients (5.7%) discontinued treatment due to TEAEs, including pneumonitis (n=2), focal segmental glomerulosclerosis (n=1), and organizing pneumonia (n=1); and
- Immune-related (ir) TEAEs reported in more than 5% of patients included thyroid disorder (22.9%), skin adverse reactions (8.6%)\*, and pneumonitis (7.1%).



**Mid-2019 Clinical Data Update Conference Call and Webcast Information:**

BeiGene will host a conference call and webcast on Thursday, June 20 at 8:00 a.m. EDT. Investors and analysts are invited to join the conference call using the following dial-in information:

U.S. Toll-Free: +1 (844) 461-9930  
U.S. Toll: +1 (478) 219-0535  
Hong Kong Toll-Free: +852 800 279 19250  
China Toll-Free: +86 800 914 686  
Conference ID: 1790069

A live webcast of the conference call can be accessed from the investors section of BeiGene's website at <http://ir.beigene.com/> or <http://hkexir.beigene.com>. An archived replay will be available two hours after the event for 90 days.

**About Classical Hodgkin Lymphoma**

Hodgkin's lymphoma is one of the two major types of lymphoma that begin in the lymph nodes and tissues of the lymphatic system. All other lymphomas are classified as non-Hodgkin's lymphomas. Classical Hodgkin lymphoma, the most common form representing about 95% of patients with Hodgkin's lymphoma, is characterized by the presence of very large cells called Reed-Sternberg cells. There were approximately 2,100 diagnosed cases of Hodgkin's lymphoma in China in 2012.<sup>(i)</sup> Although the cancer can occur in both children and adults, it is most commonly diagnosed in young adults between the ages of 15 and 35 and in older adults over age 50.

**About Tislelizumab**

Tislelizumab (BGB-A317) is an investigational 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 drug candidate produced from BeiGene's immuno-oncology biologic program, and 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.

Tislelizumab is being studied in a broad clinical program. BeiGene has completed a pivotal Phase 2 clinical trial in patients with relapsed or refractory (R/R) classical Hodgkin's lymphoma (cHL). Ongoing clinical trials of tislelizumab include a Phase 3

clinical trial in patients with second-line or third-line non-small cell lung cancer (NSCLC); a Phase 3 clinical trial in first-line patients with hepatocellular carcinoma (HCC); a Phase 3 clinical trial in second-line patients with esophageal squamous carcinoma (ESCC); a Phase 3 clinical trial in first-line patients with gastric cancer (GC); a Phase 3 clinical trial in first-line patients with ESCC; a Phase 3 trial in patients with Stage III NSCLC; a Phase 2 clinical trial in second- or third-line patients with HCC; and a Phase 2 clinical trial in patients with R/R NK/T-cell lymphomas. The aforementioned studies are enrolling patients in multiple countries, including the U.S., Europe, and China.

Additionally, BeiGene is conducting a Phase 3 clinical trial in first-line patients with non-squamous NSCLC; a Phase 3 clinical trial in first-line patients with squamous NSCLC; a Phase 3 clinical trial in patients with nasopharyngeal cancer (NPC); a Phase 3 clinical trial in first-line patients with urothelial carcinoma (UC); a pivotal Phase 2 clinical trial in patients with locally advanced or metastatic UC; and a pivotal Phase 2 trial in patients with MSI-H or dMMR solid tumors. These studies are enrolling patients in China.

New drug applications (NDA) for tislelizumab in patients with R/R cHL and in patients with previously treated locally advanced or metastatic UC have been accepted by the China National Medical Products Administration (NMPA, formerly known as CFDA) and the R/R cHL filing has been granted priority review. BeiGene and Celgene Corporation have a global strategic collaboration for the development of tislelizumab in solid tumor cancers outside of Asia (except Japan).

#### **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 approximately 2,400 employees in China, the United States, Australia and Europe, 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.(ii)

## 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 from clinical trials of tislelizumab, the mechanism of action of tislelizumab, and BeiGene's advancement of, and anticipated clinical development, regulatory milestones and commercialization of tislelizumab. 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 technology and drugs; 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, 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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\* Skin ir TEAEs included dermatitis, erythema nodosum, pruritis (3), vitiligo

(i) [http://globocan.iarc.fr/Pages/fact\\_sheets\\_population.aspx](http://globocan.iarc.fr/Pages/fact_sheets_population.aspx)

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