
**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): **July 22, 2018**

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 Maurant 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 (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 1.01. Entry into a Material Definitive Agreement.

On July 24, 2018, BeiGene, Ltd. (the “Company”) entered into a Consulting Agreement (the “2018 Consulting Agreement”) with Dr. Xiaodong Wang, co-founder of the Company, director and Chairman of the Scientific Advisory Board, to renew the consulting arrangement between the Company and Dr. Wang. Pursuant to the 2018 Consulting Agreement, Dr. Wang will continue to provide certain scientific and strategic advisory services to the Company as requested by the Company from time to time and will continue to receive an annual fee of \$100,000 for such services. In addition to the annual fee, Dr. Wang may receive additional compensation as determined in the sole discretion of the Company. The 2018 Consulting Agreement is effective until December 31, 2020. The Company may terminate the 2018 Consulting Agreement upon 30 days’ prior notice to Dr. Wang, provided that Dr. Wang will be entitled to payment for services performed prior to such date.

The foregoing description of the 2018 Consulting Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the 2018 Consulting Agreement, which the Company intends to file with the U.S. Securities and Exchange Commission as an exhibit to a subsequent periodic report or an amendment to this Current Report on Form 8-K.

Item 8.01. Other Events.

On July 22, 2018, the Company issued a press release announcing that its investigational Bruton’s tyrosine kinase inhibitor zanubrutinib has been granted Fast Track Designation by the U.S. Food and Drug Administration for the treatment of patients with Waldenström macroglobulinemia (“WM”) and that the Company intends to pursue accelerate approval of zanubrutinib for patients with WM based on results from the global Phase 1 clinical trial. 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 July 22, 2018, the Company issued a press release announcing preliminary topline results from the independent review of response data from the pivotal Phase 2 trial of tislelizumab, an investigational anti-programmed cell death protein 1 antibody, in Chinese patients with relapsed/refractory classical Hodgkin’s lymphoma. 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 July 24, 2018, the Company issued a press release announcing that the first patient was dosed in a global Phase 3 clinical trial of pamiparib, an investigational PARP inhibitor, as maintenance therapy in patients with inoperable locally advanced or metastatic gastric cancer who responded to platinum-based first-line chemotherapy. 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.

On July 24, 2018, the Company issued a press release announcing that the first patient was dosed in a Phase 3 pivotal clinical trial of tislelizumab, combined with chemotherapy, in China, as a potential first-line treatment for patients with Stage IIIB or IV non-squamous non-small cell lung cancer. The full text of this press release is filed as Exhibit 99.4 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 issued on July 22, 2018
99.2	Press Release issued on July 22, 2018
99.3	Press Release issued on July 24, 2018
99.4	Press Release issued on July 24, 2018

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release issued on July 22, 2018
99.2	Press Release issued on July 22, 2018
99.3	Press Release issued on July 24, 2018
99.4	Press Release issued on July 24, 2018

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: July 26, 2018

By: /s/ Scott A. Samuels

Scott A. Samuels

Senior Vice President, General Counsel



BeiGene, Ltd.

BeiGene Announces Plan to Pursue Accelerated Approval in the U.S. of BTK Inhibitor Zanubrutinib in Waldenström Macroglobulinemia (WM)

Fast Track Designation Granted by U.S. FDA

Enrollment Complete in Global Phase 3 Clinical Trial in WM

CAMBRIDGE, Mass. and BEIJING, China, July 22, 2018 (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 announced that its investigational BTK inhibitor zanubrutinib has been granted Fast Track Designation by the U.S. Food and Drug Administration (FDA) for the treatment of patients with Waldenström macroglobulinemia (WM). Based on BeiGene's discussions with the FDA, internal review of available data from its global Phase 1 trial of zanubrutinib in patients with WM, and supported by the Fast Track Designation, BeiGene is preparing to submit in the first half of 2019 a New Drug Application (NDA) to pursue an accelerated approval of zanubrutinib for patients with WM based on results from the global Phase 1 study. A final determination to submit the NDA will be made subsequent to the pre-NDA meeting with FDA after obtaining mature data from the study this fall.

"We believe zanubrutinib is a differentiated BTK inhibitor based on the depth and durability of responses observed in our ongoing global Phase 1 trial of zanubrutinib in WM patients. We look forward to working closely with the FDA in the continuing development of zanubrutinib for the treatment of this disease," commented John Oyler, co-founder, CEO and Chairman of BeiGene. "We are hopeful that zanubrutinib, if approved, may represent a valuable and important treatment option for patients with WM."

The FDA's Fast Track program is intended to expedite or facilitate the process for reviewing new drugs that are intended to treat a serious or life-threatening disease or condition for which there is no effective treatment and demonstrate the potential to address unmet medical needs for the condition. A drug candidate with a Fast Track Designation may be eligible for more frequent communications with the FDA, for Accelerated Approval and Priority Review (if relevant criteria are met), and rolling review of the NDA.

In addition to the global Phase 1 trial of zanubrutinib, which enrolled 76 WM patients to date, zanubrutinib is also being tested in a global Phase 3 clinical trial in patients with WM comparing zanubrutinib to ibrutinib, a currently approved BTK inhibitor. BeiGene announced today that this global Phase 3 study has completed patient enrollment. In addition, zanubrutinib is being tested in a global Phase 3 clinical trial as a first-line treatment for patients with chronic lymphocytic leukemia (CLL) and a Phase 2 clinical trial in patients with relapsed or refractory follicular lymphoma in combination with GAZYVA[®] (obinutuzumab). In China, BeiGene has completed enrollment in three pivotal Phase 2 clinical trials of zanubrutinib in patients with mantle cell lymphoma (MCL), CLL and WM, and expects to file an NDA in China

for MCL this year. BeiGene is also planning a Phase 3 trial for a head-to-head comparison of zanubrutinib versus ibrutinib in patients with relapsed/refractory CLL/small lymphocytic lymphoma (SLL). As of May 7, 2018, more than 1,200 patients have been enrolled in the zanubrutinib development program.

About Zanubrutinib

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

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 1,300 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.(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 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 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.

Investor Contact

Lucy Li, Ph.D.

+1 781-801-1800

ir@beigene.com

Media Contact

Liza Heapes

+1 857-302-5663

media@beigene.com

(1) ABRAXANE[®], REVLIMID[®], and VIDAZA[®] are registered trademarks of Celgene Corporation. GAZYVA is a registered trademark of Genentech.



BeiGene, Ltd.

BeiGene Announces Preliminary Topline Results of Pivotal Trial in China for Anti-PD-1 Antibody Tislelizumab in Hodgkin's Lymphoma

BEIJING, China and CAMBRIDGE, Mass., July 22, 2018 (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, announced preliminary topline results from the independent review of response data from the pivotal Phase 2 trial of tislelizumab, an investigational anti-PD-1 antibody, in Chinese patients with relapsed/refractory classical Hodgkin's lymphoma (R/R cHL).

"We are excited to announce the preliminary topline results from our first pivotal trial for tislelizumab. Despite short follow-up, we believe there was a demonstration of robust activity, with high overall and complete response rates in addition to a safety profile that is consistent with other PD-1 inhibitors. We believe these strong results will support our first regulatory filing in China for tislelizumab, which is planned for later this year," commented Jane Huang, M.D., Chief Medical Officer, Hematology, at BeiGene.

The single-arm pivotal trial enrolled 70 patients with cHL who either failed autologous stem cell transplantation (ASCT) or who were ineligible for ASCT. The primary endpoint was overall response rate (ORR) as defined by the Lugano 2014 criteria. Secondary endpoints included progression-free survival (PFS), duration of response (DOR), complete response (CR) rate, time to response, safety, and tolerability. As of the data cutoff, the median follow-up time was approximately 6.0 months. A review of responses by an independent review committee, provided in June 2018, demonstrated:

- The ORR was 73 percent, including 50 percent CR, and the median DOR had not been reached.
- Frequency and severity of adverse events were generally consistent with the previously reported Phase 1 safety and tolerability data for tislelizumab, or, in the case of certain immune-related events such as hypothyroidism and fever, consistent with previous reports of other PD-1 antibodies for the treatment of cHL.

These cHL data, along with additional follow-up data from the clinical trial, are expected to be included in BeiGene's Biologics License Application (BLA) planned to be filed with the China Drug Administration (CDA) later this year. Full results of the trial are expected to be presented at an upcoming medical conference.

Tislelizumab is also being studied in global Phase 3 trials in a number of malignancies, including non-small cell lung cancer, hepatocellular carcinoma, and esophageal squamous cell carcinoma; as well as two global Phase 2 trials in patients with previously treated hepatocellular carcinoma or with R/R mature T-and NK-cell lymphomas, and an additional pivotal Phase 2 trial in China in urothelial cancer.

About Classical Hodgkin's Lymphoma

Classical 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. Hodgkin's lymphoma is characterized by the presence of very large cells called Reed-Sternberg cells, although other abnormal cell types may be present. According to the Lymphoma Research Foundation, Hodgkin's lymphoma is less common than non-Hodgkin's lymphoma. There were approximately 2,100 diagnosed cases of Hodgkin's lymphoma in China in 2012.(1) 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 monoclonal antibody that belongs to a class of immuno-oncology agents known as immune checkpoint inhibitors. Discovered by BeiGene scientists in Beijing, tislelizumab 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 demonstrated high affinity and specificity for PD-1. It is potentially 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, based on preclinical data. 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 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 over 1,300 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.(2)

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. 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.

Investor Contact

Lucy Li, Ph.D.
+1 781-801-1800
ir@beigene.com

Media Contact

Liza Heapes
+ 1 857-302-5663
media@beigene.com

(1) http://globocan.iarc.fr/Pages/fact_sheets_population.aspx

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



BeiGene, Ltd .

BeiGene Initiates Global Phase 3 Trial of PARP Inhibitor Pamiparib in Patients with Advanced Gastric Cancer

BEIJING, China and CAMBRIDGE, Mass., July 24, 2018 (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 announced that the first patient was dosed in a global Phase 3 clinical trial of pamiparib, an investigational PARP inhibitor, as maintenance therapy in patients with inoperable locally advanced or metastatic gastric cancer who responded to platinum-based first-line chemotherapy.

“We are pleased to announce the initiation of the first global Phase 3 trial of pamiparib, an important compound in our clinical pipeline. With our recently announced Phase 3 clinical trial of pamiparib in China for patients with platinum-sensitive recurrent ovarian cancer and now with this global Phase 3 trial in gastric cancer, we are striving to maximize opportunities for patients with a broad range of cancer diagnoses to be treated with and potentially benefit from pamiparib,” commented John V. Oyler, Founder, Chief Executive Officer, and Chairman of BeiGene.

“Our focus at BeiGene is on developing treatments for patients who often have limited options. We are excited about this opportunity to evaluate our PARP inhibitor as maintenance therapy for patients with platinum-sensitive gastric cancer, especially considering more than 50 percent of these patients worldwide live in Eastern Asia, mainly China(1),” commented Amy Peterson, M.D., Chief Medical Officer for Immuno-Oncology at BeiGene.

The global Phase 3, randomized, double-blind, placebo-controlled trial in China, the U.S., Europe, Japan, Australia, and Singapore, is designed to compare the efficacy and safety of pamiparib to placebo as maintenance therapy in approximately 540 patients with advanced gastric cancer who have responded to first-line platinum-based

chemotherapy. The primary endpoint of the trial is progression-free survival (PFS) by blinded independent review committee assessment. Overall survival (OS) is a key secondary endpoint as are progression after the next line of therapy (PFS2) and safety and tolerability.

“Inoperable, locally advanced and metastatic gastric cancer has limited treatment options. While first-line platinum-based therapy can result in initial responses, platinum-based chemotherapies are associated with significant toxicities. We are currently studying pamiparib, a PARP inhibitor, as a maintenance therapy to understand if a response to chemotherapy can be maintained without the associated toxicities,” said Johanna Bendell, M.D., Chief Development Officer at Sarah Cannon, Nashville, Tenn., and co-chair of the steering committee for this trial.

About Pamiparib

Pamiparib (BGB-290) is an investigational inhibitor of PARP1 and PARP2 which has demonstrated pharmacological properties such as brain penetration and PARP-DNA complex trapping in preclinical models. Pamiparib is currently in global clinical development as a monotherapy and in combination with other agents for a variety of solid tumor malignancies.

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 1,300 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.(2)

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 and regulatory milestones and plans related to pamiparib. 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.

Investor Contact

Lucy Li, Ph.D.
+1 781-801-1800
ir@beigene.com

Media Contact

Liza Heapes
+1 857-302-5663
media@beigene.com

(1) GLOBOCAN 2012: China (2012) Estimated Cancer Incidence, All Ages: Both Sexes. <http://globocan.iarc.fr/old/FactSheets/cancers/stomach-new.asp>, Accessed July 23, 2018.

(2) ABRAXANE[®], REVLIMID[®], and VIDAZA[®] are registered trademarks of Celgene Corporation.



BeiGene, Ltd .

BeiGene Initiates Phase 3 Pivotal Trial of Anti-PD-1 Antibody Tislelizumab Combined with Chemotherapy as First-Line Treatment for Patients with Advanced Non-Squamous Non-Small Cell Lung Cancer in China

BEIJING, China, and CAMBRIDGE, Mass., July 24, 2018 (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, announced today that the first patient was dosed in a Phase 3 clinical trial of tislelizumab, an investigational anti-PD-1 antibody, combined with chemotherapy, as a potential first-line treatment in Chinese patients with Stage IIIB or IV non-squamous non-small cell lung cancer (NSCLC). Tislelizumab is also being studied in global Phase 3 trials in solid tumors, including second-line non-small cell lung cancer, first-line hepatocellular carcinoma, and second-line esophageal squamous cell carcinoma; two global Phase 2 trials in previously treated advanced hepatocellular carcinoma and relapsed/refractory mature T- and natural killer-cell lymphomas; and two pivotal Phase 2 trials in China in relapsed/refractory classical Hodgkin's lymphoma and second-line urothelial cancer.

"We are pleased to be enrolling patients in this important trial evaluating the potential impact of adding tislelizumab, an investigational immuno-oncology therapy, to platinum plus pemetrexed chemotherapy, the current global standard of care in first-line treatment of patients with advanced stage non-squamous NSCLC," commented Amy Peterson, M.D., Chief Medical Officer for Immuno-Oncology at BeiGene.

"As shown by the most recent data from other checkpoint inhibitors, combining immunotherapy and chemotherapy can improve anti-tumor activity and significantly improve outcomes for patients. Our Phase 3 study will assess whether the addition of tislelizumab to standard-of-care chemotherapy will improve outcomes in Chinese patients with advanced lung cancer, a disease known for its poor prognoses even with

chemotherapy treatment,” commented Lai Wang, Ph.D., Senior Vice President and Head of China Development at BeiGene.

The Phase 3, open-label, multi-center trial is expected to enroll approximately 320 chemotherapy naïve patients who have Stage IIIB or IV non-squamous NSCLC in mainland China. The trial is designed to compare progression-free survival (PFS) as assessed by the Independent Review Committee (IRC) per RECIST v1.1. Key secondary endpoints include overall survival, overall response rate, PFS by investigator, and safety and tolerability.

“We look forward to building upon our clinical experience with tislelizumab to date by testing the efficacy and safety of this investigational agent in an area of great unmet need, where patients currently have poor outcomes. We are hopeful that patients with Stage IIIB/IV NSCLC will see benefit through enrollment in this trial,” said Prof. Shun Lu, M.D, Director of Shanghai Lung Cancer Center, Shanghai Chest Hospital of Shanghai Jiao Tong University, and the Principal Investigator of this pivotal study.

For more information about the trial, patients and physicians should email BeiGene at clinicaltrials@beigene.com.

About Non-Small Cell Lung Cancer

In China, there were an estimated 733,300 new cases of lung cancer in 2015.(1) Lung cancer is the leading cause of cancer-related death in both men and women, with an estimated 610,200 deaths in China in 2015. (1) According to the American Cancer Society, about 80 to 85 percent of lung cancers are non-small cell lung cancer (NSCLC) and there are three main subtypes: adenocarcinoma, squamous cell (epidermoid) carcinoma and large cell (undifferentiated). For patients with advanced NSCLC, five-year survival rates are approximately 26 percent for Stage IIIB, 10 percent for Stage IVA, and 1 percent for Stage IVB.(2)

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. Discovered by BeiGene scientists in Beijing, tislelizumab 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 demonstrated high affinity and specificity for PD-1. It is potentially 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, based on preclinical data. 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 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 over 1,300 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.(3)

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. 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.

Investor Contact

Lucy Li, Ph.D.
+1 781-801-1800
ir@beigene.com

Media Contact

Liza Heapes
+ 1 857-302-5663
media@beigene.com

(1) Chen et al 2016.

(2) American Cancer Society. Non-Small Cell Lung Cancer. <https://www.cancer.org/cancer/nonsmall-cell-lung-cancer.html>. Accessed 07 February 2017.

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