BeiGene

BeiGene, Ltd.

(incorporated in the Cayman Islands with limited liability and trading as "百濟神州" or "百濟神州有限公司")

(Stock Code: 06160)

VOLUNTARY ANNOUNCEMENT — UPDATE REGARDING RECENT BUSINESS DEVELOPMENTS

BEIGENE ANNOUNCES UPDATED PHASE 1A/1B DATA ON TISLELIZUMAB PRESENTED AT THE EUROPEAN SOCIETY FOR MEDICAL ONCOLOGY IMMUNO-ONCOLOGY CONGRESS

On December 15, 2018, BeiGene, Ltd. ("BeiGene" or the "Company"), a commercial-stage biopharmaceutical company focused on developing and commercializing innovative molecularly-targeted and immuno-oncology drugs for the treatment of cancer, announced that updated clinical data from an ongoing Phase 1A/1B trial of tislelizumab, an investigational anti-PD-1 antibody, were presented in an oral session and a poster at the European Society for Medical Oncology Immuno-Oncology (ESMO-IO) Congress, being held December 13-16 in Geneva, Switzerland.

"We continue to be pleased with the results of tislelizumab in solid tumors," commented Amy Peterson, M.D., Chief Medical Officer, Immuno-Oncology, at BeiGene. "We believe that these updated results provide support for the continued development of tislelizumab in patients with bladder, esophageal, stomach, liver and non-small cell lung cancers, and we have registration-enabling studies ongoing or planned to start soon in each of these indications."

Summary of ESMO-IO Presentations from the Ongoing Phase 1A/1B Trial

The multi-center, open-label Phase 1A/1B trial (NCT02407990) of tislelizumab as monotherapy in advanced solid tumors is being conducted in Australia, New Zealand, the United States, Taiwan and South Korea and consists of dose-escalation and dose-expansion phases in disease-specific cohorts.

Updated Results in Patients with Urothelial Carcinoma (UC)

Data presented at ESMO-IO included updated results from an analysis of tislelizumab in 17 patients with UC. At the time of the data cutoff on August 31, 2018, median treatment duration was 4.1 months (0.7-30.4 months), with two patients still on treatment.

Treatment-related adverse events (TRAEs) as assessed by the investigator occurred in 15 patients (88.2%). Of those, fatigue (n=5), infusion-related reactions (n=3), rash (n=3), nausea (n=2), pain in extremity (n=2), peripheral adema (n=2), and proteinuria (n=2) occurred in two or more patients. Three treatment-related Grade 3 or 4 AEs occurred in two patients, fatigue (n=1), and hyperglycemia and latent autoimmune diabetes (n=1). One patient discontinued treatment due to recurrent infusion-related reactions considered related to tislelizumab.

At the time of the data cutoff, all 17 patients were evaluable for response, defined as having a baseline tumor assessment with at least one post-baseline tumor response assessment, or progression or death. The confirmed response rate was 29.4 percent, with one complete response (CR) and four partial responses (PR). Three additional patients achieved stable disease (SD) as their best response. There was one CR, one PR and one SD among the eight patients with PD-L1 high tumors and two PRs and two SDs among the eight patients with PD-L1 low or negative tumors (one tumor was not-evaluable for PD-L1 expression). The median duration of response was 18.7 months (6.2-18.7 months).

Updated Results in Patients with Esophogeal, Gastric, Hepatocellular and Non-Small Cell Lung Cancers

In an oral presentation at ESMO-IO, data on patients with esophageal (EC, n=54), gastric (GC, n=54), hepatocellular (HC, n=50) and non-small cell lung cancers (NSCLC, n=49) were reported.

TRAEs occurring in at least five percent of patients across all cohorts included fatigue (8.7%), pruritis (7.7%), hypothyroidism (7.2%), decreased appetite (6.8%), rash (6.8%) and nausea (6.3%). Ten patients experienced one or more serious adverse events considered related to tislelizumab, including pneumonitis (n=3) and one case each of acute hepatitis, dermatitis, diarrhea, increased ALT, increased AST, infusion-related reaction, pyrexia and vomiting. Grade 3 or 4 TRAEs occurring in more than one patient included increased AST (n=4), increased ALT (n=3) and pneumonitis (n=2). There were two fatal TRAEs reported, including acute hepatitis in a patient with HCC confounded by rapidly progressive disease, and pneumonitis in a patient with NSCLC with compromised pulmonary capacity at baseline.

Confirmed response rates and disease control rates in patients with EC were 11.1 percent and 37.0 percent, respectively; 13.0 percent and 29.6 percent in patients with GC, respectively; 12.2 percent and 51.0 percent in patients with HCC, respectively, and 13.0 percent and 63.0 percent in patients with NSCLC, respectively. For patients with EC and NSCLC, the median duration of response (mDOR) had not been reached. The mDOR in patients with GC was 8.5 months and for patients with HCC it was 15.7 months.

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.

Discovered by BeiGene scientists, 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. The new drug application (NDA) for tislelizumab in China for patients with relapsed/refractory (R/R) classical Hodgkin's lymphoma (cHL) has been accepted by the China National Medical Products Administration (NMPA, formerly known as CFDA) and granted priority review status. BeiGene and Celgene Corporation have a global strategic collaboration for the development of tislelizumab in solid tumors in the United States, Europe, Japan and the rest of world outside Asia.

BEIGENE INITIATES TWO GLOBAL PHASE 3 FRONT-LINE CLINCIAL TRIALS OF TISLELIZUMAB, FOR PATIENTS WITH GASTRIC CANCER AND FOR PATIENTS WITH ESOPHAGEAL CANCER

On December 17, 2018, BeiGene, Ltd. ("BeiGene" or the "Company"), a commercial-stage biopharmaceutical company focused on developing and commercializing innovative molecularly-targeted and immuno-oncology drugs for the treatment of cancer, announced that the first patients have been enrolled in two global Phase 3 clinical trials of its investigational anti-PD-1 antibody, tislelizumab. These trials are evaluating tislelizumab combined with chemotherapy as potential first-line treatments in patients with locally advanced unresectable or metastatic gastric or gastroesophageal junction adenocarcinoma, and in patients with unresectable, locally advanced recurrent or metastatic esophageal squamous cell carcinoma (ESCC).

"Available data have shown promise for anti-PD-1 antibodies in patients with advanced gastric or gastroesophageal adenocarcinoma and in patients with advanced esophageal carcinoma. We are looking forward to investigating tislelizumab globally in these Phase 3 trials," said Amy Peterson, M.D., Chief Medical Officer, Immuno-Oncology, at BeiGene. "Gastric and esophageal cancers are among the most common malignancies in Asia and collectively are responsible for over 800,000 deaths annually in China[i] alone. We are hopeful that these global studies of tislelizumab may ultimately lead to improved treatment options for patients diagnosed with these malignancies."

Global Phase 3 Trial of Tislelizumab in Advanced Gastric or Gastroesophageal Adenocarcinoma

The global, randomized, double-blind, placebo-controlled Phase 3 trial is designed to enroll 720 patients with locally advanced unresectable or metastatic gastric or gastroesophageal junction adenocarcinoma. Patients will either receive 200 mg of tislelizumab or placebo combined with platinum- and fluoropyrimidine-based chemotherapy, the standard chemotherapy treatment, intravenously once every three weeks.

The co-primary endpoints will be progression-free survival (PFS) and overall survival (OS). Secondary endpoints include overall response rate (ORR), duration of response (DOR) and quality of life (QoL), as well as safety and tolerability.

Global Phase 3 Trial of Tislelizumab in Advanced Esophageal Squamous Cell Carcinoma

The global, randomized, double-blind, placebo-controlled Phase 3 trial is designed to enroll 480 patients with unresectable, locally advanced recurrent, or metastatic esophageal squamous cell carcinoma. Patients will either receive 200 mg of tislelizumab or placebo combined with platinum- and fluoropyrimidine-based chemotherapy, intravenously once every three weeks.

The co-primary endpoints will be PFS and OS. Secondary endpoints include ORR, DOR, and QoL, as well as safety and tolerability.

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

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Discovered by BeiGene scientists, 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. The new drug application (NDA) for tislelizumab in China for patients with R/R cHL has been accepted by the China National Medical Products Administration (NMPA, formerly known as CFDA) and granted priority review status. BeiGene and Celgene Corporation have a global strategic collaboration for the development of tislelizumab in solid tumors in the United States, Europe, Japan, and the rest of world outside Asia.

TERMINATION OF MERCK KGAA LICENSE AGREEMENT

On December 17, 2018, BeiGene, Ltd. (the "Company") and Merck KGaA ("Merck KGaA") entered into a letter agreement for the Company to buy back the commercialization option it had granted to Merck KGaA under the parties' License Agreement (the "License Agreement") dated October 28, 2013, as amended, for the Company's investigational PARP inhibitor pamiparib (BGB-290) in the People's Republic of China, for an undisclosed payment by the Company to Merck KGaA. As a result of the letter agreement, as of December 31, 2018, the License Agreement will be terminated and Merck KGaA will be relieved of any future milestone obligations to the Company under the License Agreement.

Cautionary Statement required by Rule 18A.05 of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited: BeiGene may not be able to ultimately develop and market tislelizumab or pamiparib successfully.

Forward-Looking Statements

This announcement 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 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 announcement is as of the date of this announcement, and BeiGene undertakes no duty to update such information unless required by law.

By order of the Board
BeiGene, Ltd.
Mr. John V. Oyler
Chairman

Hong Kong, December 21, 2018

As at the date of this announcement, the Board of Directors of the Company comprises Mr. John V. Oyler as Chairman and Executive Director, Dr. Xiaodong Wang as Non-executive Director, and Mr. Timothy Chen, Mr. Donald W. Glazer, Mr. Michael Goller, Mr. Ranjeev Krishana, Mr. Thomas Malley, Mr. Jing-Shyh (Sam) Su and Mr. Qingqing Yi as Independent Non-executive Directors.

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[i] Chen, W. e. (2016). Cancer statistics in China, 2015. CA Cancer J Clin, 66(2), 115-32.