

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)

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 24th 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 ≥ 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 analyst 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.ⁱ 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

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