

## **BeiGene Announces Preliminary Phase 2 Results of Tislelizumab in Chinese Patients with Nasopharyngeal Cancer at the 2019 ASCO Annual Meeting**

CAMBRIDGE, Mass. and BEIJING, China; June 1, 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 preliminary results of tislelizumab, its investigational anti-PD-1 inhibitor, in Chinese patients with nasopharyngeal cancer (NPC) that were presented in a poster at the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting, being held in Chicago May 31 - June 4, 2019.

“We believe that these data further support the broad development program for tislelizumab, including the global Phase 3 double-blind trial of tislelizumab in combination with chemotherapy in comparison to placebo with chemotherapy as a first-line treatment for patients with recurrent or metastatic NPC,” said Yong (Ben) Ben, M.D., Chief Medical Officer, Immuno-Oncology, at BeiGene. “We see tislelizumab as a potentially differentiated anti-PD1 antibody and are committed to improving outcomes for patients globally.”

“This is the first presentation of tislelizumab data in a population of patients with NPC, and we are encouraged by the objective response rate of 43 percent in Chinese patients with locally advanced or metastatic NPC. Tislelizumab was also generally well-tolerated in these patients,” said Siyang Wang, M.D., Chief Physician, Department of Head and Neck Oncology at The Fifth Affiliated Hospital, Sun Yat-Sen University, in Zhuhai, China, and lead author on the study. “We hope that further study of tislelizumab may lead to a new treatment for the large number of patients with these tumors in need.”

### **Preliminary Results with Tislelizumab in Chinese Patients with NPC**

*Phase 1/2 Poster Data (Abstract number 2556, board number #200)*

The multi-center, open-label Phase 1/2 trial of tislelizumab as monotherapy in advanced solid tumors in China (Chinadrugtrials.org registration number: CTR20160872) consists of a Phase 1 dose verification and pharmacokinetics component and a Phase 2 component of indication expansion in disease-specific cohorts, including patients with NPC solid tumors.

Data presented at ASCO today are from 21 patients with NPC, of whom 20 were enrolled in the Phase 2 indication-expansion portion of the trial. Patients were treated with tislelizumab at a dose of 200 mg every three weeks. Ninety-five percent of the study population received one or more prior regimens of systemic therapy. At the time of the data cutoff on December 1, 2018, median treatment duration was 7.5

months (2.1-15.8 months), median follow-up time was 11.7 months (4.9-15.7 months), and nine patients (43%) remained on treatment.

Adverse events (AEs) assessed by the investigator to be related to treatment occurred in 14 patients. Of those, the most common treatment-related AEs (TRAEs) (occurring in  $\geq 10\%$  of patients) were hypothyroidism (24%), anemia (14%), increased AST (10%), and hemoptysis (10%). There was one grade 4 cutaneous reaction TRAE that led to discontinuation. Of the eight patients (38%) who experienced immune-related AEs (irAEs), two patients experienced three grade  $\geq 3$  irAEs (drug interruption, n=1; rash, n=1; increased  $\gamma$ -glutamyltransferase, n=1). No patients experienced fatal TRAEs.

As of the data cutoff, all 21 patients were evaluable for antitumor activity. A total of nine patients achieved a confirmed partial response and nine patients achieved stable disease. Clinical benefit was observed regardless of PD-L1 expression. The confirmed objective response rate (ORR) was 43 percent. Median duration of response (DOR) was estimated as 8.3 months and median progression-free survival (PFS) was 10.4 months; however, data were not yet mature enough to estimate overall survival (OS).

### **About Nasopharyngeal Cancer**

Nasopharyngeal cancer (NPC) is a type of head and neck cancer, starting in the nasopharynx, the upper part of the throat behind the nose and near the base of skull.<sup>i</sup> The estimated five-year survival rate for people with NPC is 60 percent.<sup>ii</sup> Although NPC is rare in most parts of the world, it is one of the most common malignancies in Asia. There were an estimated 60,558 new cases of NPC in China in 2018, accounting for 46.9 percent of the worldwide incidence.<sup>iii</sup> In addition to geography, sex and age are epidemiological characteristics of NPC that affect incidence and mortality<sup>iv,v</sup>, including Epstein-Barr virus which has also been reported to be strongly linked with NPC in epidemic areas.<sup>vi</sup> The risk of NPC increases slowly throughout life, but it can occur in people of any age, including children.

### **About Tislelizumab**

Tislelizumab (BGB-A317) is an investigational humanized IgG4 anti-PD-1 monoclonal antibody specifically designed to minimize binding to Fc $\gamma$ R on macrophages. In pre-clinical studies, binding to Fc $\gamma$ R 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 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 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<sup>®</sup> (nanoparticle albumin-bound paclitaxel), REVLIMID<sup>®</sup> (lenalidomide), and VIDAZA<sup>®</sup> (azacitidine) in China under a license from Celgene Corporation.<sup>vii</sup>

### **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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<sup>i</sup> <https://www.cancer.org/cancer/nasopharyngeal-cancer/about/what-is-nasopharyngeal-cancer.html>

<sup>ii</sup> <https://www.cancer.net/cancer-types/nasopharyngeal-cancer/statistics>

<sup>iii</sup> <http://gco.iarc.fr>

<sup>iv</sup> Jia WH, Huang QH, Liao J, et al. Trends in incidence and mortality of nasopharyngeal carcinoma over a 20-25 year period (1978/1983-2002) in Sihui and Cangwu counties in southern China. *BMC Cancer*. 2006;6:178

<sup>v</sup> Wei K-R, Zheng R-S, Zhang S-W, Liang Z-H, Li Z-M, Chen W-Q. Nasopharyngeal carcinoma incidence and mortality in China, 2013. *Chin J Can*. 2017;36:90-90.

<sup>vi</sup> Khanna R, Burrows SR, Moss DJ. Immune regulation in Epstein-Barr virus-associated diseases. *Microbiol Rev*. 1995;59:387-405.

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