

BeiGene Announces Acceptance of a Supplemental New Drug Application in China for Tislelizumab in Urothelial Carcinoma

CAMBRIDGE, Mass. and BEIJING, China; May 30, 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 the China National Medical Products Administration (NMPA, formerly known as CFDA) has accepted a supplemental new drug application (sNDA) for tislelizumab, an investigational anti-PD-1 antibody, for the treatment of patients with previously treated locally advanced or metastatic urothelial carcinoma (UC).

“The development program for tislelizumab is achieving its milestones swiftly with our first solid-tumor filing for patients with previously treated urothelial carcinoma following our initial filing last year for patients with relapsed/refractory classical Hodgkin’s lymphoma. We sincerely hope that this submission, if approved, can bring a meaningful treatment option for patients with UC in China,” said Dr. Xiaobin Wu, General Manager of China and President of BeiGene. “We believe that the broad development program for this anti-PD1 inhibitor, along with manufacturing capabilities that are nearing completion, and non-clinical data presented earlier this year, reinforce tislelizumab as a potentially differentiated immuno-oncology compound. We are excited by its prospects to improve the way people with cancer are treated around the world.”

The sNDA is supported by a clinical, non-clinical, and CMC data package, including the results from a pivotal Phase 2 study of tislelizumab in 113 Chinese and South Korean patients with previously treated PD-L1+ locally advanced or metastatic urothelial carcinoma (chinadrugtrials.org registration number: CTR20170071). A recent independent review of data showed that, with a median follow-up time of 8 months at the data cutoff, overall response rate (ORR) in 104 efficacy-evaluable patients was 23.1 percent, including eight (7.7 percent) confirmed complete responses (CRs) and 16 (15.4 percent) confirmed partial responses (PRs). Frequency and severity of adverse events were generally consistent with the previously reported Phase 1/2 safety and tolerability data for tislelizumab, or, in the case of certain immune-related adverse events, consistent with previous reports of other PD-1 antibodies. Full results of the study are planned to be presented at an upcoming medical conference.

About Urothelial Carcinoma

Urothelial carcinoma (UC), also known as transitional cell carcinoma (TCC), is by far the most common type of bladder cancer.¹ In 2018, there was an estimated 82,270 incidences of bladder cancer in China, accounting for 27.3 percent of all incidences

worldwide.ⁱⁱ Although UC is most common in the bladder, it can occur in other parts of the urinary system.

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.

In addition to the pivotal Phase 2 trial of tislelizumab in locally advanced or metastatic urothelial cancer mentioned in this release, BeiGene has also completed a pivotal Phase 2 clinical trial in patients with relapsed or refractory 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 relapsed/refractory (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); 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.ⁱⁱⁱ

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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ⁱ <https://www.cancer.org/cancer/bladder-cancer/about/what-is-bladder-cancer.html>

ⁱⁱ <https://gco.iarc.fr/>

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