

## **Priority Review Granted to BeiGene's Supplemental New Drug Application in China for Tislelizumab in Urothelial Carcinoma**

BEIJING, China and CAMBRIDGE, Mass. , July 8, 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 the CFDA) has granted priority review status to the supplemental new drug application (sNDA) for tislelizumab, an investigational Fc-engineered anti-PD-1 antibody, for patients with previously treated locally-advanced or metastatic urothelial carcinoma (UC).

“This is our second priority review granted by the NMPA for tislelizumab, and our first for a solid tumor indication and first in China for a PD-1/PDL1 antibody for bladder cancer,” said Wendy Yan, Senior Vice President, Global Head of Regulatory Affairs, at BeiGene. “Along with the two priority reviews granted for zanubrutinib in China, our regulatory team is working closely with the NMPA as it reviews our applications to treat patients with solid tumors and hematologic cancers. With full global rights to tislelizumab, 13 ongoing pivotal or potentially registration-enabling trials, maturing international clinical and non-clinical data, and advanced manufacturing capabilities, we are excited by the prospects for tislelizumab to help patients in-need around the world.”

The sNDA for tislelizumab as a potential treatment for patients with previously treated locally-advanced or metastatic UC was accepted by the NMPA in May 2019. It is supported by a clinical, non-clinical, and Chemistry, Manufacturing and Controls (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 UC ([chinadrugtrials.org](http://chinadrugtrials.org) registration number: CTR20170071). BeiGene is developing tislelizumab as a monotherapy and in combination with other therapies for the treatment of a broad array of both solid and hematologic cancers. An NDA for tislelizumab as a potential treatment for patients with relapsed / refractory (R/R) classic Hodgkin's lymphoma (cHL) was accepted by the NMPA in August 2018 and granted priority review status in November 2018.

Priority review and approval was established in China to facilitate drug registration management and accelerate the development of new drugs with clinical value. According to the guidance of *Opinions on the Reform of the Review and Approval System for Drugs and Medical Devices* issued by the State Council in August 2015, and *Opinions on Encouraging Pharmaceutical Innovation via Priority Review &*

*Approval* issued by CFDA in December 2017, the regulatory authority will prioritize the review process and evaluation resources for applications under priority review. These applications are expected to have reduced review and approval timelines.

### **About Urothelial Carcinoma**

Urothelial carcinoma (UC), also known as transitional cell carcinoma (TCC), is by far the most common type of bladder cancer.<sup>i</sup> In 2018, there was an estimated 82,270 incidences of bladder cancer in China, accounting for 15.0 percent of all incidences worldwide.<sup>ii</sup> 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.

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 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 trials are enrolling patients in multiple countries, including the United States, Europe, and China.

In addition to a pivotal Phase 2 clinical trial in patients with relapsed or refractory (R/R) classical Hodgkin's lymphoma (cHL) and a pivotal Phase 2 clinical trial in patients with locally advanced or metastatic urothelial cancer, 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 first-line nasopharyngeal cancer (NPC); a Phase 3 clinical trial in first-line patients with urothelial carcinoma (UC); a Phase 3 clinical trial in patients with localized ESCC; and a Phase 2 trial in patients with MSI-H or dMMR solid tumors. These studies have been enrolling patients primarily 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 and granted priority review by the China National Medical Products Administration (NMPA, formerly known as CFDA). BeiGene has full development and commercial rights to tislelizumab worldwide.

### **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 2,500 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>iii</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 mechanism of action of tislelizumab, BeiGene's advancement of, and anticipated clinical development, regulatory milestones and commercialization of tislelizumab, and the expected regulatory review process and timeline in China for drugs with priority review status. 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**

Craig West  
+1 857-302-5189  
ir@beigene.com

**Media Contact**

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

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

<sup>ii</sup> <https://gco.iarc.fr/>

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