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NMPA grants priority review to BeiGene's sNDA for tislelizumab

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BeiGene, 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 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.

Urothelial carcinoma (UC), also known as transitional cell carcinoma (TCC), is by far the most common type of bladder cancer. In 2018, there was an estimated 82,270 incidences of bladder cancer in China, accounting for 15.0 percent of all incidences worldwide. Although UC is most common in the bladder, it can occur in other parts of the urinary system.