BeiGene, Ltd.
百濟神州有限公司
(incorporated in the Cayman Islands with limited liability)
(Stock Code: 06160)

VOLUNTARY ANNOUNCEMENT – UPDATE REGARDING RECENT BUSINESS DEVELOPMENTS

BeiGene Announces First Commercial Manufacturing Approval for Its State-of-the-Art Biologics Facility in Guangzhou, China

Commercial supply of tislelizumab for China now expanded with wholly owned manufacturing site

On April 7, 2021 (US Eastern Time), BeiGene, Ltd. ("**BeiGene**" or the "**Company**") announced approval from the China National Medical Products Administration (NMPA) for BeiGene to begin manufacturing commercial supply of its approved anti-PD-1 antibody, tislelizumab, at its state-of-the-art biologics facility in Guangzhou, China. At over one million square feet (100,000 square meters) and 8,000 liters of biologics capacity approved for commercial supply, this wholly owned facility will immediately begin production of commercial supply of tislelizumab for the China market. An additional phase of construction currently in progress to bring total capacity to 64,000 liters is expected to be completed by the end of 2022.

"We started building this large-scale, commercial biologics manufacturing facility in 2017 to meet our expected future demand. Since that time, tislelizumab has been approved in several indications in China, included in the National Reimbursement Drug List (NRDL), and licensed to Novartis in Europe, North America, and Japan," commented Xiaobin Wu, Ph.D., President, Chief Operating Officer, and General Manager of China at BeiGene. "With significantly expanded capacity for tislelizumab and for other biologics in our pipeline, we are continuing our strong commitment to the quality, safety, and compliance of our products."

BeiGene's Guangzhou manufacturing facility has been designed to operate in compliance with current Good Manufacturing Practice (cGMP) standards adopted by the U.S. Food & Drug Administration (FDA), the China National Medical Products Administration (NMPA), and the European Medicines Agency (EMA). The Guangzhou site is expected to be the first paperless biological manufacturing facility in China and integrates new technologies such as 3D modeling, digital twin, augmented interfaces, and artificial intelligence to improve quality and efficiency.

About Tislelizumab

Tislelizumab (BGB-A317) is a 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 from BeiGene's immuno-oncology biologics program and is being developed internationally as a monotherapy and in combination with other therapies for the treatment of a broad array of both solid tumor and hematologic cancers.

The China National Medical Products Administration (NMPA) has granted tislelizumab full approval for first-line treatment of patients with advanced squamous non-small cell lung cancer (NSCLC) in combination with chemotherapy. Tislelizumab has also received conditional approval from the NMPA for the treatment of patients with classical Hodgkin's lymphoma (cHL) who received at least two prior therapies, and for the treatment of patients with locally advanced or metastatic urothelial carcinoma (UC) with PD-L1 high expression whose disease progressed during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. Full approval for these indications is contingent upon results from ongoing randomized, controlled confirmatory clinical trials.

In addition, three supplemental Biologics License Applications for tislelizumab have been accepted by the Center for Drug Evaluation (CDE) of the NMPA and are under review for first-line treatment of patients with advanced non-squamous NSCLC in combination with chemotherapy, for the second- or third-line treatment of patients with locally advanced or metastatic NSCLC who progressed on prior platinum-based chemotherapy, and for previously treated unresectable hepatocellular carcinoma.

Currently, 16 potentially registration-enabling clinical trials are being conducted in China and globally, including 13 Phase 3 trials and three pivotal Phase 2 trials.

In January 2021, BeiGene and Novartis entered into a collaboration and license agreement granting Novartis rights to develop, manufacture, and commercialize tislelizumab in North America, Europe, and Japan.

Tislelizumab is not approved for use outside of China.

About BeiGene

BeiGene is a global, commercial-stage biotechnology company focused on discovering, developing, manufacturing, and commercializing innovative medicines to improve treatment outcomes and access for patients worldwide. Our 5,400+ employees around the world are committed to expediting the development of a diverse pipeline of novel therapeutics. We currently market two internally discovered oncology medicines: BTK inhibitor BRUKINSA® (zanubrutinib) in the United States and China, and anti-PD-1 antibody tislelizumab in China. We also market or plan to market additional oncology products in China licensed from Amgen Inc.; Celgene Logistics Sàrl, a Bristol Myers Squibb (BMS) company; and EUSA Pharma; and have entered a collaboration with Novartis Pharma AG for Novartis to develop, manufacture and commercialize tislelizumab in North America, Europe, and Japan. To learn more about BeiGene, please visit www.beigene.com and follow us on Twitter at @BeiGeneUSA.

Forward-Looking Statements

This announcement 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 expected completion, total capacity, and regulatory approval of the additional phase at BeiGene's Guangzhou biologics manufacturing facility. 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 medicines and drug candidates, if approved; BeiGene's ability to obtain and maintain protection of intellectual property for its medicines and technology; BeiGene's reliance on third parties to conduct drug development, manufacturing and other services; BeiGene's limited experience in obtaining regulatory approvals and commercializing pharmaceutical products and its ability to obtain additional funding for operations and to complete the development of its drug candidates and achieve and maintain profitability; and the impact of the COVID-19 pandemic on BeiGene's clinical development, regulatory, commercial and other operations, as well as those risks more fully discussed in the section entitled "Risk Factors" in BeiGene's most recent annual report on Form 10-K, 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 and The Stock Exchange of Hong Kong Limited. All information in this announcement is as of the date of this announcement, and BeiGene undertakes no duty to update such information unless required by law.

By order of the Board
BeiGene, Ltd.
Mr. John V. Oyler
Chairman

Hong Kong, April 8, 2021

As at the date of this announcement, the Board of Directors of the Company comprises Mr. John V. Oyler as Chairman and Executive Director, Dr. Xiaodong Wang and Mr. Anthony C. Hooper as Non-executive Directors, and Mr. Timothy Chen, Mr. Donald W. Glazer, Mr. Michael Goller, Mr. Ranjeev Krishana, Mr. Thomas Malley, Dr. Corazon (Corsee) D. Sanders, Mr. Jing-Shyh (Sam) Su and Mr. Qingqing Yi as Independent Non-executive Directors.