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

INSIDE INFORMATION

COLLABORATION WITH NOVARTIS TO DEVELOP AND COMMERCIALIZE ANTI-PD-1 ANTIBODY TISLELIZUMAB

This announcement is issued pursuant to Rule 13.09 of the Rules Governing the Listing of the Securities on The Stock Exchange of Hong Kong Limited (the "**Hong Kong Listing Rules**") and under Part XIVA of the Securities and Futures Ordinance (Cap. 571).

On January 11, 2021 (U.S. Eastern Time), BeiGene, Ltd. announced that BeiGene Switzerland GmbH, a wholly-owned indirect subsidiary of BeiGene, Ltd. (collectively, "**BeiGene**" or the "**Company**"), entered into a Collaboration and License Agreement (the "**Collaboration and License Agreement**") with Novartis Pharma AG ("**Novartis**"), pursuant to which BeiGene will grant Novartis the right to develop, manufacture and commercialize BeiGene's anti-PD-1 antibody tislelizumab in the United States, Canada, Mexico, member countries of the European Union, United Kingdom, Norway, Switzerland, Iceland, Liechtenstein, Russia, and Japan (the "**Licensed Territory**").

Under the Collaboration and License Agreement, BeiGene will receive an upfront cash payment of US$650 million from Novartis. Additionally, BeiGene is eligible to receive up to US$1.3 billion upon the achievement of regulatory milestones, US$250 million upon the achievement of sales milestones, and tiered royalties based on percentages of annual net sales of tislelizumab in the Licensed Territory ranging from the high-teens to high-twenties, with customary reductions in specified circumstances. Royalties are payable on a country-by-country basis from the time of the first commercial sale until the latest of the expiration of the last valid patent claim, the expiration of regulatory exclusivity, or 10 years after the first commercial sale of tislelizumab in the country of sale.

Under the Collaboration and License Agreement, BeiGene and Novartis have agreed to jointly develop tislelizumab in the Licensed Territory, with Novartis responsible for regulatory submissions after a transition period and for commercialization upon regulatory approvals. In addition, both companies may conduct clinical trials globally to explore combinations of tislelizumab with other cancer treatments. BeiGene will be responsible for funding the ongoing clinical trials of tislelizumab, and Novartis has agreed to fund any new registrational, bridging, or post-marketing studies in the Licensed Territory. Subject to specified conditions, BeiGene and Novartis have agreed to jointly fund other new clinical trials in the Licensed Territory agreed by the parties, provided that each party will be responsible for funding clinical trials evaluating tislelizumab in combination with its own or third-party cancer treatments. BeiGene will initially be responsible for supplying tislelizumab to Novartis, with Novartis having the right to conduct manufacturing for its use in the Licensed Territory after successful transfer of the manufacturing process. In addition, BeiGene has an option to co-detail the product in the United States, Canada and Mexico, on an indication-by-indication basis, funded in part by Novartis. Each party retains the worldwide right to commercialize its propriety products in combination with tislelizumab.

The Collaboration and License Agreement contains customary representations, warranties and covenants by BeiGene and Novartis. Unless earlier terminated, the agreement will expire on a country-by-country basis upon the expiration of the royalty term in such country. The Collaboration and License Agreement will expire in its entirety upon the expiration of all applicable royalty terms under the agreement in all countries in the Licensed Territory. BeiGene may terminate the agreement in its entirety upon written notice (i) if Novartis challenges the licensed BeiGene patents, or (ii) if Novartis files a biologics license application for its anti-PD-1 antibody, spartalizumab, in the Licensed Territory, and BeiGene does not elect to include spartalizumab as a licensed product under the Collaboration and License Agreement or Novartis does not divest the product candidate, in which case Novartis would pay BeiGene a specified termination fee. The agreement may be terminated by Novartis upon 120 days' prior written notice if delivered before first commercial sale or 180 days' prior written notice if delivered following first commercial sale of tislelizumab in the Licensed Territory, or by either party upon the other party's bankruptcy or uncured material breach.

The transaction contemplated under the Collaboration and License Agreement is expected to close in the first quarter of 2021, subject to expiration or early termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act.

BeiGene Presentation at J.P. Morgan Healthcare Conference

The Company will present at the 39th Annual J.P. Morgan Healthcare Conference on Thursday, January 14 at 5:20 p.m. ET.

A live webcast of the conference call can be accessed from the investors section of BeiGene's website at http://ir.beigene.com or http://hkexir.beigene.com. An archived replay will be available after the event for 90 days.

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 globally as a monotherapy and in combination with other therapies for the treatment of a broad array of both solid tumor and hematologic cancers.

Tislelizumab received conditional approval from the China National Medical Products Administration (NMPA) as a treatment for patients with classical Hodgkin's lymphoma (cHL) who received at least two prior therapies and for 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. Complete approval for these indications may be contingent upon results from ongoing randomized, controlled confirmatory clinical trials.

In addition, three supplemental new drug applications for tislelizumab have been accepted by the Center for Drug Evaluation (CDE) of the NMPA and are under review. These indications are first-line treatment of patients with advanced squamous NSCLC in combination with chemotherapy, for first-line treatment of patients with advanced non-squamous NSCLC in combination with chemotherapy, and previously treated unresectable hepatocellular carcinoma (HCC).

Currently, 15 potentially registration-enabling clinical trials are being conducted in China and globally, including 13 Phase 3 trials and two pivotal Phase 2 trials.

Tislelizumab is not approved for use outside of China.

About Tislelizumab Clinical Program

Clinical trials of tislelizumab include:

- Phase 3 trial comparing tislelizumab to salvage chemotherapy in patients with relapsed/refractory classical Hodgkin Lymphoma (NCT04486391);
- Phase 3 trial in patients with locally advanced or metastatic urothelial carcinoma (NCT03967977);
- Phase 3 trial comparing tislelizumab with docetaxel in the second- or third-line setting in patients with NSCLC (NCT03358875);
- Phase 3 trial of tislelizumab in combination with chemotherapy versus chemotherapy as first-line treatment for patients with advanced squamous NSCLC (NCT03594747);

- Phase 3 trial of tislelizumab in combination with chemotherapy versus chemotherapy as first-line treatment for patients with advanced non-squamous NSCLC (NCT03663205);

- Phase 3 trial of tislelizumab in combination with platinum-based doublet chemotherapy as neoadjuvant treatment for patients with NSCLC (NCT04379635);

- Phase 3 trial of tislelizumab combined with platinum and etoposide versus placebo combined with platinum and etoposide in patients with extensive-stage small cell lung cancer (NCT04005716);

- Phase 3 trial comparing tislelizumab with sorafenib as first-line treatment for patients with hepatocellular carcinoma (HCC; NCT03412773);

- Phase 2 trial in patients with previously treated unresectable HCC (NCT03419897);

- Phase 3 trial comparing tislelizumab with chemotherapy as second-line treatment for patients with advanced esophageal squamous cell carcinoma (ESCC; NCT03430843);

- Phase 3 trial of tislelizumab in combination with chemotherapy as first-line treatment for patients with ESCC (NCT03783442);

- Phase 3 trial of tislelizumab versus placebo in combination with chemoradiotherapy in patients with localized ESCC (NCT03957590);

- Phase 3 trial of tislelizumab combined with chemotherapy versus placebo combined with chemotherapy as first-line treatment for patients with gastric cancer (NCT03777657);

- Phase 2 trial in patients with MSI-H/dMMR solid tumors (NCT03736889); and

- Phase 3 trial of tislelizumab combined with chemotherapy versus placebo combined with chemotherapy as first-line treatment in patients with nasopharyngeal cancer (NCT03924986).

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 5,000+ employees in China, the United States, Australia, Europe, and elsewhere are committed to expediting the development of a diverse pipeline of novel therapeutics. We currently market two internally discovered oncology products: 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 in China additional oncology products licensed from Amgen Inc., Celgene Logistics Sàrl, a Bristol Myers Squibb (BMS) company, and EUSA Pharma. 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 further advancement of, and anticipated clinical development, regulatory milestones, and commercialization of tislelizumab; the parties' commitments and the potential benefits of the collaboration, and the conditions to closing and expected timing for the closing of the transaction. Actual results may differ materially from those indicated in the forward-looking statements as a result of various important factors, including the possibility that the closing conditions set forth in the Collaboration and License Agreement, including, those related to antitrust clearance, will not be met and that the parties will be unable to consummate the proposed transaction; the possibility that BeiGene will not realize the expected benefits of the transaction; the possibility that BeiGene or Novartis will fail to fully perform their respective obligations under the Collaboration and License Agreement; 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; and the impact of the COVID-19 pandemic on the Company's clinical development, commercial and other operations, 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 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.

The Company's shareholders and potential investors are advised not to place undue reliance on this announcement and to exercise caution in dealing in securities in the Company.

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

Hong Kong, January 12, 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.