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

INSIDE INFORMATION
BUSINESS UPDATES

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 "**Listing Rules**") and under Part XIVA of the Securities and Futures Ordinance (Cap. 571).

On August 21, 2019, BeiGene, Ltd. ("**BeiGene**" or the "**Company**") announced that the U.S. Food and Drug Administration (FDA) has accepted the Company's New Drug Application (NDA) for zanubrutinib for the treatment of patients with mantle cell lymphoma (MCL) who have received at least one prior therapy. The FDA granted Priority Review for the NDA and has set a Prescription Drug User Fee Act (PDUFA) target action date of February 27, 2020. This follows the FDA's Breakthrough Therapy designation for zanubrutinib in this setting earlier this year.

Attached hereto as Schedule 1 is the full text of the press release issued by the Company on August 21, 2019 (US time) announcing the above-described business updates.

Cautionary Statement required by Rule 18A.08(3) of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited: BeiGene may not be able to ultimately develop and market zanubrutinib successfully.

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 regulatory review and approval of the company's U.S. NDA for zanubrutinib for patients with MCL who have received at least one prior therapy and the potential for zanubrutinib to treat patients with MCL and various other B-cell malignancies. 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 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, August 22, 2019

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 as Non-executive Director, and Mr. Timothy Chen, Mr. Donald W. Glazer, Mr. Michael Goller, Mr. Ranjeev Krishana, Mr. Thomas Malley, Mr. Jing-Shyh (Sam) Su and Mr. Qingqing Yi as Independent Non-executive Directors.

BeiGene Announces U.S. FDA Acceptance and Grant of Priority Review for its New Drug Application of Zanubrutinib in Patients with Relapsed/Refractory Mantle Cell Lymphoma

CAMBRIDGE, Mass. and BEIJING, China, August 21, 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 U.S. Food and Drug Administration (FDA) has accepted the company's New Drug Application (NDA) for zanubrutinib for the treatment of patients with mantle cell lymphoma (MCL) who have received at least one prior therapy. The FDA granted Priority Review for the NDA and has set a Prescription Drug User Fee Act (PDUFA) target action date of February 27, 2020. This follows the FDA's Breakthrough Therapy designation for zanubrutinib in this setting earlier this year.

"Zanubrutinib, a potent and selective BTK inhibitor designed to maximize BTK occupancy and minimize off-target effects, has shown promise as a potential treatment for a number of B-cell malignancies," said Jane Huang, M.D., Chief Medical Officer, Hematology, at BeiGene. "We are proud to have submitted our first NDA in the U.S., which has now been accepted and designated for Priority Review by the FDA for the treatment of patients with relapsed/refractory mantle cell lymphoma, an aggressive form of lymphoma. We are conducting a broad global clinical development program for zanubrutinib that currently consists of eight Phase 3 or potentially registration-enabling trials, including two head-to-head comparative trials, with approximately 1,500 patients treated across all programs."

The NDA data package includes data from the global Phase 1/2 trial (NCT02343120) in patients with B-cell lymphomas and an aggregate of 123 patients in the multicenter Phase 2 trial of zanubrutinib in patients with relapsed or refractory (R/R) MCL in China (NCT03206970), as well as safety data on 641 patients from five clinical trials, and non-clinical data.

About Priority Review

The U.S. FDA grants Priority Review designation to applications for drugs that, if approved, would provide a significant improvement in safety or effectiveness of the treatment of serious conditions. Under Priority Review, the FDA aims to take action on the marketing application within six months of NDA acceptance, as compared to 10 months under standard review. Priority Review designation does not change the scientific/medical standard for approval or the quality of evidence necessary to support approval.

About Mantle Cell Lymphoma

Lymphoma is a diverse group of malignancies that originates from B-, T- or NK- cells. Mantle cell lymphoma (MCL) is typically an aggressive form of non-Hodgkin lymphoma (NHL) that arises from B-cells originating in the "mantle zone." In the United States, about 70,800 new cases of NHL were estimated in 2014, with MCL representing about six percent (about 4,200 cases) of all new cases of NHL.[i] MCL usually has a poor prognosis, with a median survival of three to four years, although occasionally patients may have an indolent course.[ii] Frequently, MCL is diagnosed at a later stage of disease.

About Zanubrutinib

Zanubrutinib (BGB-3111) is an investigational small molecule inhibitor of Bruton's tyrosine kinase (BTK), discovered by BeiGene scientists, that is currently being evaluated in a broad pivotal clinical program globally as a monotherapy and in combination with other therapies to treat various B-cell malignancies.

Clinical trials of zanubrutinib include the fully-enrolled Phase 3 ASPEN clinical trial in patients with Waldenström macroglobulinemia (WM) comparing zanubrutinib to ibrutinib, currently the only approved BTK inhibitor for WM; the fully-enrolled Phase 3 SEQUOIA trial comparing zanubrutinib with bendamustine plus rituximab in patients with treatment-naive (TN) chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL); a pivotal Phase 2 trial in patients with relapsed/refractory (R/R) follicular lymphoma in combination with GAZYVA® (obinutuzumab); the Phase 3 ALPINE trial comparing zanubrutinib to ibrutinib in patients with R/R CLL/SLL; the Phase 3 trial in patients with untreated mantle cell lymphoma (MCL); the pivotal Phase 2 MAGNOLIA trial in patients with R/R marginal zone lymphoma (MZL); and a Phase 1 trial. BeiGene has completed two pivotal Phase 2 clinical trials of zanubrutinib in patients with R/R MCL and R/R CLL/SLL and the enrollment in the pivotal Phase 2 clinical trials in patients with WM.

The U.S. Food and Drug Administration (FDA) has granted Fast Track designation for the treatment of patients with WM, and Breakthrough Therapy designation for the treatment of adult patients with MCL who have received at least one prior therapy. The New Drug Applications (NDAs) in China for R/R MCL and R/R CLL/SLL have been accepted by the China National Medical Products Administration (NMPA) and granted priority review.

Zanubrutinib is an investigational drug that has not been approved for any use in any country.

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 2,700 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

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[i] https://www.lls.org/sites/default/files/file_assets/mantlecelllymphoma.pdf

[ii] Philip J. Bierman, James O. Armitage, in Goldman's Cecil Medicine (Twenty Fourth Edition), 2012

[iii] ABRAXANE®, REVLIMID®, and VIDAZA® are registered trademarks of Celgene Corporation.