BeiGene Launches BRUKINSA® (Zanubrutinib) in Canada for Patients with Waldenström's Macroglobulinemia

- *BRUKINSA is now commercially available in Canada following approval in March.*
- *Canadian patients now have access to the myBeiGene® patient support program.*

Mississauga, Ont.,—(BUSINESS WIRE)—April 8, 2021-- BeiGene, Ltd. (NASDAQ: BGNE; HKEX: 06160), a commercial-stage biotechnology company focused on developing and commercializing innovative medicines worldwide, today announced the official launch of BRUKINSA® (zanubrutinib) in Canada for the treatment of adult patients with Waldenström's macroglobulinemia (WM). BRUKINSA was authorized for sale by Health Canada in this indication on March 1, 2021, following the previous grant of priority review in September 2020.

In tandem with the commercial launch of BRUKINSA, the myBeiGene® patient support program is available in Canada to support patients, caregivers, and healthcare providers with access to BRUKINSA.

"We are thrilled to officially launch BRUKINSA in Canada, making this potentially best-in-class BTK inhibitor available to Canadian WM patients. Since the approval in Canada five weeks ago, our team has been working to set up distribution channels across the country for a speedy launch," said Peter Brenders, General Manager of Canada at BeiGene. "Together with the myBeiGene patient support program with comprehensive financial assistance, disease education, and emotional support, we are striving to ensure access for patients in Canada."

"On behalf of the Waldenström's Macroglobulinemia Foundation of Canada (WMFC), we are pleased to see BeiGene's launch of BRUKINSA as a WM treatment in Canada following the approval last month. We hope this will help expand access to an important treatment option for Canadian WM patients," commented Paul Kitchen, Chair of the Board at WMFC.

The approval in Canada for BRUKINSA was based on efficacy results from the Phase 3 ASPEN clinical trial, a randomized, open-label, multicenter trial (NCT03053440) that evaluated BRUKINSA compared to ibrutinib in patients with relapsed/refractory (R/R) or treatment-naïve (TN) WM who harbor a MYD88 mutation (*MYD88*^{MUT}). In the ASPEN trial, BRUKINSA demonstrated a numerically higher very good partial response (VGPR) rate and a favorable safety profile over ibrutinib, although the primary endpoint of statistical superiority related to deep response (VGPR or better) was not met.

The overall safety profile of BRUKINSA is based on pooled data from 779 patients with B-cell malignancies treated with BRUKINSA in clinical trials.

The recommended total daily dose of BRUKINSA is 320mg.

"Zanubrutinib is a newly approved treatment in Canada. We are glad to learn that this second-generation BTK inhibitor is now available for Canadian patients," said Christine Chen, M.D., Med, FRCPC, Associate Professor at the University of Toronto and Clinical Investigator at Princess Margaret Cancer Centre.

About myBeiGene® Patient Support Program

The myBeiGene® patient support program is designed to support patients, caregivers, and healthcare providers with access to BRUKINSA®. It goes beyond financial assistance support to provide patients and caregivers with education about their disease and treatment with BRUKINSA, as well provide practical and emotional support by connecting them to third-party resources that can address their individual needs. Oncology Nurse Advocates are available Monday through Friday from 8 a.m. to 5 p.m. Eastern Time at 1-833-234-4366.

About Waldenström's Macroglobulinemia

Waldenström's macroglobulinemia (WM) is a rare indolent B-cell lymphoma that occurs in less than two percent of patients with non-Hodgkin's lymphoma (NHL). The disease usually affects older adults and is primarily found in the bone marrow, although lymph nodes and the spleen may be involved.[1] In Canada and the United States, the incidence rate of WM is about five cases per million people per year.[2]

About BRUKINSA® (zanubrutinib)

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

BRUKINSA is approved in the following indications and regions:

- For the treatment of mantle cell lymphoma (MCL) in adult patients who have received at least one prior therapy (United States, November 2019)*;
- For the treatment of MCL in adult patients who have received at least one prior therapy (China, June 2020)**;
- For the treatment of chronic lymphocytic leukemia or small lymphocytic lymphoma (CLL/SLL) in adult patients who have received at least one prior therapy (China, June 2020)**;
- For the treatment of relapsed or refractory MCL (United Arab Emirates, February 2021); and
- For the treatment of Waldenström's macroglobulinemia (WM) in adult patients (Canada, March 2021).

In Canada, a new drug submission for BRUKINSA for the treatment of patients with MCL who have received at least one prior therapy has been accepted and is currently under review. Currently, more than 20 marketing applications for BRUKINSA have been submitted, covering more than 40 countries and regions globally, including the United States, China, and European Union.

* This indication was approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

** This indication was approved under conditional approval. Complete approval for this indication may be contingent upon results from one or more ongoing randomized, controlled confirmatory clinical trials.

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 in China additional oncology products 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.ca and follow us on Twitter at @BeiGeneUSA.

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 plans for setting up distribution channels in Canada for the commercialization of BRUKINSA, the potential for BRUKINSA to be a best-in-class BTK inhibitor and plans for making BRUKINSA accessible to patients, caregivers, and healthcare providers in Canada. 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; 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. 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.

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[1] Lymphoma Research Foundation. Available at https://lymphoma.org/aboutlymphoma/nhl/wm/. Accessed December 2020.
[2] Waldenström's Macroglobulinemia Foundation of Canada. https://wmfc.ca/what-we-do/what-is-wm/.