BeiGene Announces BRUKINSA® (Zanubrutinib) Approved for Treatment of Patients with Mantle Cell Lymphoma

Marks BRUKINSA's second approved indication in Australia, on the heels of its recent initial approval in Waldenström's macroglobulinemia

To date, BRUKINSA is approved in mantle cell lymphoma in nine countries

SYDNEY, CAMBRIDGE, Mass. and BEIJING -- October 10, 2021 -- BeiGene (NASDAQ: BGNE; HKEX: 06160), a global, science-driven biotechnology company focused on developing innovative and affordable medicines to improve treatment outcomes and access for patients worldwide, today announced that BRUKINSA® (zanubrutinib) has been approved in Australia for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy. On October 7, 2021, BRUKINSA received its initial approval in Australia for the treatment of adult patients with Waldenström's macroglobulinemia (WM) who have received at least one prior therapy or in first line treatment for patients unsuitable for chemo-immunotherapy.[1]

Following registration of BRUKINSA with the Therapeutic Goods Administration (TGA) in both approved indications, these patients will have immediate access to BRUKINSA through the BeiGene sponsored post-approval, pre-reimbursement access program.

"Mantle cell lymphoma is an uncommon form of non-Hodgkin lymphoma that is generally considered incurable. While the majority of patients respond well to their initial treatment, virtually all will develop progressive lymphoma over time. Existing therapies for patients with recurrent or refractory MCL are often ineffective or have side effects that can lead to treatment discontinuation," said Professor Stephen Opat, Director of Clinical Haematology at Monash Health and a principal investigator in the zanubrutinib clinical program. "I'm encouraged that zanubrutinib – a highly selective BTK inhibitor with promising clinical results from two trials in relapsed or refractory MCL – will provide a new treatment option for these patients living in Australia."

"Australia has some of the highest rates of non-Hodgkin's lymphoma in the world, and these patients need options for treatment beyond those that exist today," said Sharon Winton, CEO, Lymphoma Australia. "MCL patients will certainly welcome the news that BeiGene is providing access to BRUKINSA by sponsoring a pre-reimbursement program, as new therapies are critical, especially to those diagnosed later in life when it may be challenging to tolerate more aggressive types of treatment."

BeiGene submitted for reimbursement of BRUKINSA to the Pharmaceutical Benefits Advisory Committee (PBAC), with MCL recommended for listing in July 2021.

"BRUKINSA was designed to provide deep and durable responses while reducing off-target side effects compared to first-generation BTK inhibitors," said Jane Huang, M.D., Chief Medical Officer, Hematology at BeiGene. "Our early BRUKINSA clinical trials started in Australia and

coming off the heels of BRUKINSA's TGA registration for the treatment of WM, we are delighted to be able to provide BRUKINSA to more Australians in need of new treatment options."

More than 6,000 people are diagnosed with non-Hodgkin's lymphoma (NHL) in Australia each year, making it the sixth most common cancer in adults.[2] MCL is a B-cell NHL that develops in the outer edge of a lymph node called the mantle zone.[3] MCL usually has a poor prognosis, with a median survival of three to six years, and is often diagnosed at a later stage of disease.[3]

The Australian registration for BRUKINSA in MCL is based on efficacy results from two single-arm clinical trials. Across both trials, as assessed by independent review committee (IRC) per 2014 Lugano Classification, BRUKINSA achieved an overall response rate (ORR) of 83.7%, defined as the combined rate of complete responses (CRs) and partial responses (PRs).

In the multicentre Phase 2 trial of zanubrutinib in patients with relapsed or refractory (R/R) MCL BGB-3111-206 (NCT03206970), with a median follow-up time of 18.4 months, the ORR was 83.7% (95% CI: 74.2, 90.8), including 68.6% CRs (FDG-PET scan required) and 15.1% PRs; the median duration of response (DoR) was 19.5 months (95% CI: 16.6, NE). In the global Phase 1/2 trial BGB-3111-AU-003 (NCT02343120), with a media follow-up time of 14.75 months, the ORR was 84.4% (95% CI: 67.2, 94.7), including 25.0% CRs (FDG-PET scan not required) and 59.4% PRs; the median DoR was 18.5 months (95% CI: 12.6, NE).

Of the 118 patients with MCL who received at least one prior therapy and received BRUKINSA treatment, 13.6% of patients discontinued treatment due to adverse events in the trials, with the most frequent being pneumonia (3.4%). Adverse events leading to dose reduction occurred in 3.4% of patients, including hepatitis B, neutropenia, allergic dermatitis, and peripheral sensory neuropathy (in one patient each).

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 most common adverse reactions (≥20%) with BRUKINSA were neutropenia, thrombocytopenia, upper respiratory tract infection, hemorrhage/hematoma, rash, bruising, anemia, musculoskeletal pain, diarrhea, pneumonia, and cough. The most common Grade 3 or higher adverse reactions (≥5%) were neutropenia, thrombocytopenia, pneumonia, and anemia.

The recommended dose of BRUKINSA is either 160 mg twice daily or 320 mg once daily, taken orally with or without food. The dose may be adjusted for adverse reactions and reduced for patients with severe hepatic impairment and certain drug interactions.

About BRUKINSA® (zanubrutinib)

BRUKINSA is a small molecule inhibitor of Bruton's tyrosine kinase (BTK) discovered by BeiGene scientists that is currently being evaluated globally in a broad clinical program as a monotherapy and in combination with other therapies to treat various B-cell malignancies. Because new BTK is continuously synthesised, BRUKINSA was specifically designed to deliver complete and sustained inhibition of the BTK protein by optimising bioavailability, half-life, and

selectivity. With differentiated pharmacokinetics compared to other approved BTK inhibitors, BRUKINSA has been demonstrated to inhibit the proliferation of malignant B cells within a number of disease relevant tissues.

BRUKINSA is approved in the United States, China, Australia, Canada, and other international markets in selected indications and under development for additional approvals globally.

BeiGene Oncology

BeiGene is committed to advancing hematology, immuno-oncology and targeted therapies in order to bring impactful and affordable medicines to patients across the globe. We have a growing R&D team of approximately 2,300 colleagues dedicated to advancing more than 90 clinical trials involving more than 13,000 patients and healthy subjects. Our expansive portfolio is directed by a predominantly internalised clinical development team supporting trials in more than 40 countries or regions. We currently market three medicines discovered and developed in our labs: BTK inhibitor BRUKINSA in the United States, China, Canada, and additional international markets; and non-FC-gamma receptor binding anti-PD-1 antibody tislelizumab and PARP inhibitor pamiparib in China. BeiGene has a high quality, innovative science and medicine organisation and is a leader in China with a large oncology focused commercial team.

BeiGene also partners with innovative companies who share our goal of developing therapies to address global health needs. We commercialise a range of oncology medicines in China licensed from Amgen and Bristol Myers Squibb. We also plan to address greater areas of unmet need globally through our collaborations including with Amgen, Bio-Thera, EUSA Pharma, Mirati Therapeutics, Seagen, and Zymeworks. BeiGene has also entered into a collaboration with Novartis granting Novartis rights to develop, manufacture, and commercialise tislelizumab in North America, Europe, and Japan.

About BeiGene

BeiGene is a global, science-driven biotechnology company focused on developing innovative and affordable medicines to improve treatment outcomes and access for patients worldwide. With a broad portfolio of more than 40 clinical candidates, we are expediting development of our diverse pipeline of novel therapeutics through our own capabilities and collaborations. We are committed to radically improving access to medicines for two billion more people by 2030. BeiGene has a growing global team of over 7,000 colleagues across five continents. To learn more about BeiGene, please visit www.beigene.com.au and follow us on Twitter at @BeiGeneGlobal.

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 development and commercialisation of BRUKINSA in Australia, the APAC region and other markets, the potential commercial opportunity for BRUKINSA, plans for making

BRUKINSA accessible to patients in Australia, the potential for BRUKINSA to provide improved clinical benefits to patients, and BeiGene's plans, commitments, aspirations and goals under the headings "BeiGene Oncology" and "About BeiGene". 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 commercialising pharmaceutical products and its ability to obtain additional funding for operations and to complete the development and commercialisation of its drug candidates and achieve and maintain profitability; the impact of the COVID-19 pandemic on the 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 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 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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