May 20, 2021

RE: WHO Model List of Essential Medicines

Secretariat Email: emlsecretariat@who.int

Letter of support for BRUKINSA® (Zanubrutinib) application to WHO Model List of Essential Medicines

Dear Esteemed Reviewers:

I am pleased to provide this letter in strong support of including BRUKINSA on the WHO Model List of Essential Medicines.

As the co-founder, Chairman, and Chief Executive Officer of BeiGene, a global science-driven biotech company, I represent more than 6,000 employees dedicated to providing accessible, effective, and affordable medicines to cancer patients all over the world. At BeiGene we say that cancer has no borders; not between countries, or socioeconomic classes, or families. We see tremendous opportunity to benefit patients worldwide as we pursue innovative science and collaborate with the international healthcare community to accomplish our goals.

Improving access to medicines that target lymphomas has the potential to "*ensure healthy lives and support well-being at all ages"*, a key sustainable development goal outlined by the United Nations. BRUKINSA is the first innovative drug accelerated by clinical trials run in China and accepted by the global market. Inclusion on the WHO Essential Medicines List would acknowledge BRUKINSA's value as a novel medicine and underscore the importance of global support for developing more broadly accessible medications.

As the new generation of BTKi, the efficacy of BRUKINSA is widely recognized by the global market, hence its approved status by multiple countries:

- BRUKINSA received accelerated approval in the U.S. for the treatment of mantle cell lymphoma (MCL) in patients who have received at least one prior therapy; BRUKINSA also received "Breakthrough Therapy Designation" from the U.S. Food and Drug Administration. (November 2019)
- BRUKINSA received approval in China for the treatment of adult patients with MCL who have received at least one prior therapy, and treatment of adult patients with chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) who have received at least one prior therapy. (June 2020)
- BRUKINSA was approved in the U.A.E. for the treatment of MCL in patients who have received at least one prior therapy. (February 2021)
- BRUKINSA recently received approval in Canada for the treatment of adult patients with Waldenstrom's macroglobulinemia (WM). (March 2021)

Also of note, BRUKINSA was included in China's updated National Reimbursement Drug List (NRDL) by the National Healthcare Security Administration (NHSA) as of March 2021. We consider this strong

recognition of the potential benefit of BRUKINSA's safety profile and AE occurrence rate, which may improve quality of life for patients and help reduce the burden of long-term patient management on doctors and medical institutions. I believe this has the potential to be remarkably impactful in China in particular, where about one-quarter of the world's new cancer patients are diagnosed every year.

BRUKINSA's advantages across efficacy, safety, and pharmacoeconomics for MCL and CLL treatment position it uniquely to have a positive impact on patients globally and their health systems. I respectfully submit that including BRUKINSA on the WHO Model List of Essential Medicines would reflect favorably on, and support the objectives of, this initiative's goal to identify priority medicines that meet the most important and urgent health needs for patients around the world.

Sincerely,

John V. Oyler

Co-Founder, CEO and Chairman

BeiGene, Ltd.