

To Whom It May Concern,

I am pleased to provide this letter in strong support of including A52 Zanubrutinib (CLL/SLL) in the WHO Model List of Essential Medicines.

I am Jun Ma, the director of Harbin Institute of Hematology and Cancer, steering committee chairman of the Chinese Society of Clinical Oncology.

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

- Zanubrutinib 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; Zanubrutinib also received “Breakthrough Therapy Designation” from the U.S. Food and Drug Administration. (November 2019)
- Zanubrutinib 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)
- Zanubrutinib as the only innovative drug proven to be superior to the first generation of BTKi in the global field of chronic lymphocytic leukemia/small lymphocytic lymphoma, it was approved by U.S. FDA (Jan.20<sup>th</sup>, 2023).
- As of now, Zanubrutinib has been approved for listing in over 65 countries and regions worldwide, including mainstream markets such as Europe and America.

In 2021, Zanubrutinib was included in China’s updated National Reimbursement Drug List (NRDL) by the National Healthcare Security Administration (NHSA). This also a strong recognition of the potential benefit of Zanubrutinib’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.

Zanubrutinib is also the only BTKi recommended by both NCCN and CSCO guidelines as Class I preferred regimens for CLL/SLL patients.

Based on the above, I strongly support the inclusion of Zanubrutinib in the WHO Model List of Essential Medicines. Thank you for your time and consideration.

Yours sincerely,

Dr. Jun Ma

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