

Dear WHO Expert Committee,

This letter is to advocate the inclusion of A52 Zanubrutinib on the WHO Essential Medicine List.

I am Dr. Jian-Qing Mi, professor from Ruijin Hospital, Shanghai Jiaotong University School of Medicine in China.

Zanubrutinib is a more selective Bruton's tyrosine kinase inhibitor to treat multiple lymphoma subtypes including adult patients with chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL). Zanubrutinib efficacy and safety is widely recognized around the globe. It has been approved for listing in over 65 countries/regions worldwide. On January of this year, Zanubrutinib was approved for the treatment of CLL/SLL patients in the United States, and European Union.

Zanubrutinib development program cover more than 4,700 subjects in more than 25 countries and regions, including the United States, China, the European Union (EU), Great Britain, Canada, Australia, South Korea, Switzerland, and additional international markets. Those clinical studies illustrate Zanubrutinib is an anti-cancer drug with sufficient evidence and safety profiles for patients all around the world. Zanubrutinib has also been proved in a multinational head-to-head phase III clinical trial to have superior efficacy and better safety profile than Ibrutinib in patients with refractory/relapse CLL setting. This clinical study was recently published on *The New England Journal of Medicine*.

In CLL/SLL frontline treatment, Zanubrutinib also demonstrates better progression free survival rate compared with bendamustine-rituximab. This was proven through another global head-to-head clinical study, the SEQUOIA study, published on *The Lancet Oncology* last year. In additional, Zanubrutinib received "preferred

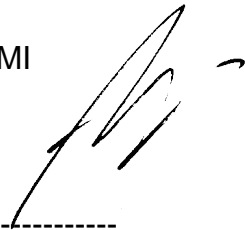
regimen” recommendation by 2023 V1 NCCN CLL/SLL Guideline for both front-line and second line CLL/SLL regardless patients high risk factors.

In terms of price, Zanubrutinib is cheaper comparing with Ibrutinib, and this could reduce patients’ economic burden during the treatment.

Based on the evidence above I strongly recommend the inclusion of Zanubrutinib in the WHO Model List of Essential Medicines.

Thank you for your consideration.

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