

Dear WHO Expert Committee,

I am writing this supporting letter to advise A52 Zanubrutinib inclusion on the WHO Essential Medicine List.

I am Dr. Yuqin Song, deputy director of Beijing Cancer Hospital in China. I am also the leading PI of 206 study, which is the registrational study of Zanubrutinib for the treatment of relapse and refractory Mantle Cell Lymphoma.

Based on 206 study positive results, Zanubrutinib is also the first anti-cancer drug that been recognized by U.S. Food and Drug Administration as “Breakthrough Therapy Designation”, and received ” 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 in 2019.

In 2020, Zanubrutinib received approval for the treatment of MCL in patients who have received at least one prior therapy, and treatment of chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) who have received at least one prior therapy in China. A few months after that, Zanubrutinib was included in China National Reimbursement Drug List (NRDL) to reduce patients ‘economic burden and increase patients’ quality of life.

In January 2023, Zanubrutinib received a Class I priority recommendation and replaced Ibrutinib in the NCCN CLL guidelines in the United States. Meanwhile, based on the average prices of two products worldwide, Zanubrutinib is 20% cheaper than Ibrutinib. In conclusion, Zanubrutinib has better efficacy, safety and pharmacoeconomic advantages in CLL/SLL treatment. It plays a important role in public health care.

The recommendation change based on a crucial global phase III clinical study, the ALPINE study. It recently published on the *New England Journey of Medicine*. It shows Zanubrutinib has a overall better safety profile, and better progression-free survival rate compared with Ibrutinib. Over the years of Zanubrutinib approval around the globe, it has benefits thousands of patients in over 65+ countries and regions around the world.

Thank you in advance for your consideration.

Yours sincerely,

Dr. Yuqin Song

Beijing Cancer Hospital