

To Whom It May Concern,

I am writing this letter to recommend the inclusion of A52 Zanubrutinib (CLL/SLL) in the WHO Model List of Essential Medicines.

I am Keshu Zhou, deputy director and chief physician of Henan Cancer Hospital Hematology department. I am also the principal investigator of Zanubrutinib several pivotal clinical trials.

Zanubrutinib is the first Chinese anti-cancer drug that received “Breakthrough Therapy Designation” from the U.S. Food and Drug Administration.

- In 2019, Zanubrutinib was approved by the U.S. for the treatment of mantle cell lymphoma (MCL) in patients who have received at least one prior therapy based on *206 Study* results. As one of the 206 study principal investigators, I have successfully enrolled 14 patients, and I personally saw how Zanubrutinib benefits those patients.
- In 2020, in addition to MCL, Zanubrutinib was approved for the treatment of chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) who have received at least one prior therapy, and Zanubrutinib is the most cost optimal BTKi in China market which benefits thousands of people.
- In 2021, Zanubrutinib was successfully included in China National Reimbursement Drug List (NRDL) to benefit more CLL/SLL, MCL patients in China. This is also a great recognition of Zanubrutinib efficacy and safety profiles, and support to reduce patients burden during the treatment.
- In 2023, based on two Phase III pivotal study positive results, SEQUOIA study and ALPINE study, Zanubrutinib was approved by the U.S. FDA for the treatment of CLL/SLL. It is the only BTKi that shows efficacy superiority comparing with ibrutinib through head-to-head comparison. Now Zanubrutinib has been approved for listing in over 65 markets around the globe.

In Conclusion, Zanubrutinib has been proven it can improve patients' quality of life. It shows a better efficacy and safety comparing with chemo-immune therapy. With the recommendation of WHO Model List of Essential Medicines, I believe Zanubrutinib has the potential to benefit more patients who suffer from hematological malignancies around the globe. Thank you for taking time to consider my recommendation.

Yours sincerely,

Dr. Keshu Zhou

Henan Cancer Hospital