

April 6, 2023

To Whom It May Concern,

It is my pleasure to recommend including A52 Zanubrutinib (CLL/SLL) in the WHO Model List of Essential Medicines.

I am Lugui Qiu, director of Lymphoma & Myeloma Center at the Institute of Hematology & Blood disease Hospital in China, Chinese Academy of Medical Sciences.

Zanubrutinib is the next generation BTK inhibitor, approved in over 65 market global-wide to treat multiple lymphoma subtypes, the efficacy and safety are well-recognized around the world:

- In June 2020, Zanubrutinib was approved by China National Medical Products Administration (NMPA) 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, and benefits thousands of patients in China until now.
- In Dec. 2022, ALPINE study release positive results and published on *The New England Journal of Medicine*. In patients with relapsed or refractory CLL or SLL, progression-free survival was significantly longer among patients who received Zanubrutinib than among those who received Ibrutinib, and Zanubrutinib was associated with fewer cardiac adverse events. As ALPINE study leading PI in China, I am very pleased to see our win in this head-to-head phase III clinical trial.
- Based on ALPINE study superiority, in Jan 2023, Zanubrutinib was approved by EU and U.S. FDA to treat adult patients with CLL/SLL.

In 2023 V1 NCCN CLL/SLL guideline in the United States, Zanubrutinib received recommendation as preferred regimens to treat all CLL/SLL patients regardless of patients with/without del(17p)/TP53 mutation.

In addition, Zanubrutinib was also received “Class I priority recommendation” in Chinese CSCO and Chinese Medical Association Guidelines to treat CLL/SLL patients.

Based on the achievements listed above, I highly suggest including Zanubrutinib in the WHO Model List of Essential Medicines.

Thank you for your consideration.

Yours sincerely,

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