

广州中医药大学

Guangzhou University of Chinese Medicine

Recommendation Letter for Zanubrutinib

April 7, 2023

Dear WHO Expert Committee,

My name is Yunfeng Lai, from School of Public Health and Management, Guangzhou University of Chinese Medicine, Guangzhou, China.

I have reviewed this application to add Zanubrutinib to WHO Model List of Essential Medicines as a medicine for treatment of chronic lymphocytic leukaemia from item by item based on the basic drug selection principles. The first is safety and efficacy. Since Ibrutinib has been added into WHO Model List of Essential Medicines – 22nd List (2021) with the indication of relapsed/refractory chronic lymphocytic leukaemia, adding zanubrutinib proven to have better efficacy and safety profile in head-to-head multinational clinical trials with lower cost, to the WHO essential list of medications might help to benefit more patients around the globe. And it also might help to promote mechanisms that may enhance its accessibility and affordability. The second is relative cost-effectiveness advantage. Zanubrutinib has a relative cost-effectiveness advantage in the same class of drugs. Regarding the availability of facilities for manufacture or storage, BeiGene has strong production and storage capabilities. It can ensure the long-term stable supply of drugs. Zanubrutinib has the advantages of pharmacokinetics, good drug quality and bioavailability. Moreover, Zanubrutinib is single compound.

Furthermore, Zanubrutinib was included in China's updated National Reimbursement Drug List (NRDL) by the National Healthcare Security Administration (NHSA) in 2021. This is also recognition of the safety, efficacy, and cost-effectiveness of Zanubrutinib.

Therefore, to reduce the global disease burden on chronic lymphocytic leukaemia patients, I suggest including Zanubrutinib to WHO Model List of Essential Medicines.

Yours sincerely,

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