

Dear WHO Expert Committee,

I am DR. Hongji Yang. Now, I am working in Sichuan Provincial People's Hospital, Director of hepatobiliary surgery and multi-organ transplant center.

I am delighted to see that the WHO EML has been updated again, which will be more standardized and benefit people around the world. A total of 52 new drugs have submitted applications, and I recommend and support A46 Tislelizumab into WHO EML.

Tislelizumab has been listed in China for over 3 years. So far, 10 indications have been approved, which is the most approved indication among PD-1/PD-L1 listed in China. Nine indications have been included in National Reimbursement Drug List, including NSCLC. In the years following its launch, Tisle conducted multiple clinical trials, which effectively demonstrated the effectiveness and safety of the product. The incidence of adverse reactions was relatively low among similar products. These can be clarified in the submitted application materials. At the same time, it is highly cost-effective and meets the medication needs of patients.

After reviewing the 2021 catalog, I found that medicines indicated for NSCLC which are currently included on the 2021 WHO Model Lists of Essential Medicines are chemotherapy and targeted therapies. Erlotinib (afatinib and gefitinib as alternatives) is used as first-line treatment and maintenance therapy after first-line chemotherapy in advanced NSCLC patients with EGFR mutation, which differs from the target population of tislelizumab. And chemotherapy is widely used in the treatment of NSCLC. So far, no PD-1/PD-L1 drugs indicated for lung cancer are on the 2021 WHO Model Lists of Essential Medicines. Given the lower annual treatment costs and reimbursable, treatment with tislelizumab could largely improve patients' accessibility and affordability.

Tislelizumab has demonstrated prolonged survival, durable clinical responses, and improved quality of life regardless of PD-L1 expression levels with a manageable safety profile. Therefore, I suggested the 24th Expert Committee on the Selection and Use of Essential Medicines to include tislelizumab in the WHO EML.

Yours Sincerely,

Hongji Yang MD.

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