

18 May 2021

WHO Expert Committee on the Selection and Use of Essential Medicines

Email: emlsecretariat@who.int

RE: Application for Inclusion of tislelizumab injectable solution for the treatment of locally advanced or metastatic urothelial bladder cancer in the next WHO List of Essential Medicine

Dear WHO Expert Committee,

I am writing this supporting letter regarding to advocate the inclusion of tislelizumab into the WHO Essential Medicines List and I am in full support of the submitted application.

I work as a urologist for more than 30 years. Now, I am working as the Chief of Institute of Urology, Peking University, which is one of the top Urological Center in China.

As a clinician and an investigator of genitourinary cancer, I see the great breakthrough of immunotherapy in the last few years. Tislelizumab, a PD-1 monoclonal antibody, provides an important option for patients with urothelial bladder cancer and upper tract urothelial cancer. Many patients in China benefited from Tislelizumab administration with longer survival and better quality of life.

Tislelizumab was developed independently by Chinese researchers with international quality. As an innovative drug, it was supported by National Science and Technology Major Project. In terms of mechanism, Tislelizumab, as the only successfully modified PD-1 monoclonal antibody in the Fc segment, can effectively avoid binding to FcγR on macrophages, thereby eliminating antibody-dependent cell-mediated phagocytosis Effect (ADCP effect), thus avoiding decrease in the number of activated T cells, also the adverse reactions caused by macrophages at the same time. This unique mechanism of tislelizumab may provide reliable efficacy and safety for patients.

Our center participated in the registered trial of Tislelizumab. Among 104 efficacy-evaluable patients, the confirmed objective response rate was 24%, including 10 patients with complete response and 15 patients with partial response. It is worth to mention that the proportion of patients achieving complete response was nearly 10% with tislelizumab, higher than other PD-1/PD-L1 inhibitors, which may indicate a profound response of tislelizumab.

Based on the evidence above, tislelizumab is recommended by the 2019 Chinese Urological Association (CUA) Guideline of Bladder Cancer, the 2020 Chinese Society of Clinical Oncology (CSCO) Guideline of Urothelial Cancer and the 2021 CSCO Guideline of Immune Checkpoint Inhibitor Clinical Practice. Hence tislelizumab is the only PD-1 inhibitor that was recommended by three authoritative guidelines in China.

Therefore, I urge the 23rd Expert Committee on the Selection and Use of Essential Medicines to include tislelizumab for the treatment of urothelial cancer in the WHO Model List of Essential Medicines and consider if a square box symbol (□) should be added.

Yours Sincerely,

Liqun Zhou

A handwritten signature in black ink, appearing to read 'LQ Zhou', written in a cursive style.

Chairman

The Institute of Urology, Peking University

Dept. of Urology, Peking University First Hospital

National Urological Cancer Center