BioSpectrum the business of Bio & Health Sciences ASIA EDITION

China approves Gloria Biosciences' drug for cervical cancer treatment

08 September 2023 | News

This is the first and only anti-PD-1 antibody approved for treating cervical cancer in China

Guangzhou Gloria Biosciences (GloriaBio), a commercial stage biopharmaceutical company focusing on the discovery, development and commercialisation of biologics in immuno-oncology, has announced that its fully human anti-PD-1 monoclonal antibody, Zimberelimab injection (YuTuo®, GLS-010) has received marketing approval from the China National Medical Products Administration (NMPA), as monotherapy for the treatment of recurrent or metastatic cervical cancer (R/M CC) patients with positive PD-L1 expression (CPS?1) who progressed on or after platinum-based chemotherapy. Zimberelimab is the first and only immune checkpoint inhibitor (ICI) antibody approved in China for cervical cancer, and third one globally.

The approval of Zimberelimab by NMPA was based on the positive results from a pivotal Phase 2 clinical trial "Efficacy and Safety of Zimberelimab (GLS-010) Monotherapy in Patients with Recurrent or Metastatic Cervical Cancer: A Multicenter, Open-Label, Single-Arm, Phase II Study" (YH-S001-05, NCT03972722), led by Xiaohua Wu, M.D., Professor of Department of Gynecologic Oncology at Fudan University Shanghai Cancer Center, and Director of Oncology and Gynecology at the Cancer Hospital Affiliated to Fudan University.

China has a population of 582.4 million women ages 15 years and older who are at risk of developing cervical cancer. Current estimates indicate that every year 109,741 women are diagnosed with cervical cancer and 59,060 die from the disease. Cervical cancer ranks as the 6th most frequent cancer among women in China and the 3rd most frequent cancer among women between 15 and 44 years of age.