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ASIA EDITION

Junshi Biosciences' oncology drug Toripalimab obtains marketing approval in India and Hong Kong SAR

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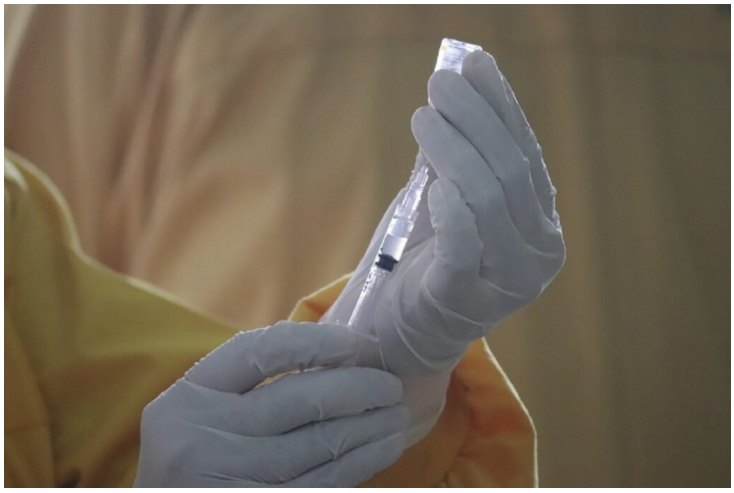
Toripalimab is the first and only treatment for nasopharyngeal carcinoma approved in India and China's Hong Kong SAR



Shanghai Junshi Biosciences Co. and its wholly-owned subsidiary, TopAlliance Biosciences Inc., has announced that toripalimab (Indian trade name: ZYTORVI, Hong Kong trade name: LOQTORZI) has been approved for marketing in India and China's Hong Kong Special Administrative Region (SAR), for treatment of recurrent or metastatic nasopharyngeal carcinoma (NPC).

The approved indications are: 1) toripalimab in combination with cisplatin and gemcitabine, for first line treatment of adults with metastatic or with recurrent, locally advanced NPC; 2) toripalimab as a single agent, for the treatment of adults with recurrent unresectable or metastatic NPC with disease progression on or after a platinum-containing chemotherapy. Zytorvi shall be imported and commercialised in India by Dr. Reddy's Laboratories Ltd.

NPC is a malignant tumour that occurs in the epithelium of the nasopharynx. According to GLOBOCAN 2022 statistics, the number of newly diagnosed NPC cases in 2022 exceeded 120,000 worldwide. Due to the location of the primary tumour, surgery is rarely an option. Toripalimab is the first and only treatment for NPC approved in India and China's Hong Kong SAR.

In Asia, toripalimab obtained import license from the National Regulatory Authority (NRA) of India in September 2024, and marketing approval from Pharmacy and Poisons Board of China's Hong Kong SAR in October 2024, for the treatment of recurrent or metastatic NPC. In Singapore, the new drug application (NDA) was accepted by the Singapore Health Sciences Authority (HSA) in January 2024. The HSA has also granted priority review designation for the NDA.