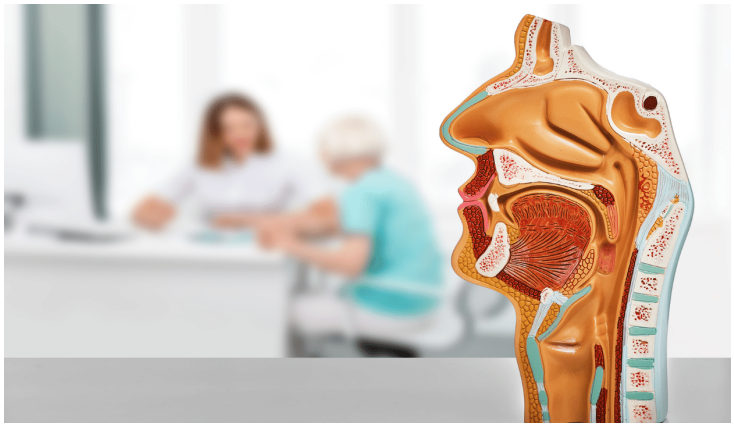
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ASIA EDITION

Junshi Biosciences announces Toripalimab's approval in Australia for cancer treatment

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Toripalimab has become the first and only immuno-onocology treatment for nasopharyngeal carcinoma in Australia



Shanghai Junshi Biosciences Co., and its wholly-owned subsidiary, TopAlliance Biosciences Inc. have announced that toripalimab, the anti-PD-1 monoclonal antibody self-developed by the company, has obtained the marketing authorisation issued by the Therapeutic Goods Administration (TGA) of the Australian Government Department of Health and Aged Care. The New Chemical Entity (NCE) application for toripalimab in combination with cisplatin and gemcitabine, for the first-line treatment of adults with metastatic or recurrent, locally advanced nasopharyngeal carcinoma (NPC) and 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 has been approved by TGA. Toripalimab has become the first and only immuno-onocology treatment for NPC in Australia.

NPC is a malignant tumour that occurs in the epithelium mucosae of the nasopharynx and is one of the most common types of head and neck cancers. According to GLOBOCAN 2022 statistics, the number of newly diagnosed NPC cases in 2022 exceeded 120,000 worldwide.

Toripalimab is an anti-PD-1 monoclonal antibody developed for its ability to block PD-1 interactions with its ligands, PD-L1 and PD-L2, and to induce PD-1 receptor internalisation (endocytosis function). Blocking PD-1 interactions with PD-L1 and PD-L2 promotes the immune system’s ability to attack and kill tumor cells.

More than forty company-sponsored toripalimab clinical studies covering more than fifteen indications have been conducted globally by Junshi Biosciences, including in China, the United States, Europe and Southeast Asia. Ongoing or completed pivotal clinical trials evaluating the safety and efficacy of toripalimab cover a broad range of tumor types, including cancers of the lung, nasopharynx, esophagus, stomach, bladder, breast, liver, kidney, and skin.