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SystImmune, Biokin secure first China approval for bispecific ADC iza-bren

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The approval gives recurrent or metastatic nasopharyngeal carcinoma patients a new option after platinum chemotherapy and PD-1/PD-L1 inhibitor therapy.

SystImmune and parent company Sichuan Biokin Pharmaceutical have received regulatory approval in China for iza-bren, also known as BL-B01D1, for the treatment of recurrent or metastatic nasopharyngeal carcinoma.

The approval from the Center for Drug Evaluation of China's National Medical Products Administration covers patients whose disease has progressed after prior platinum-based chemotherapy and PD-1 or PD-L1 inhibitor therapy. It marks the first regulatory approval for iza-bren and an important milestone for SystImmune's bispecific antibody-drug conjugate platform.

This is relevant because recurrent or metastatic nasopharyngeal carcinoma remains difficult to treat after standard therapy failure. Although NPC is uncommon globally, it is endemic in southern China, Southeast Asia and parts of North Africa. Patients who progress after chemotherapy and immunotherapy have limited options and poor outcomes.

SystImmune said the approval is based on the pivotal Phase III BL-B01D1-303 study in China. The trial evaluated iza-bren against physician's choice chemotherapy in patients with recurrent or metastatic NPC who had failed PD-1/PD-L1 monoclonal antibody therapy and at least two lines of chemotherapy, including one platinum-containing line.

In the study, iza-bren achieved a blinded independent central review-assessed confirmed objective response rate of 54.6 per cent, compared with 27.0 per cent for chemotherapy. Median duration of response was 8.5 months with iza-bren versus 4.8 months with chemotherapy.

The therapy also improved progression-free survival. Median PFS was 8.38 months for iza-bren, compared with 4.34 months for chemotherapy. Overall survival data were immature at the time of analysis.

Iza-bren is a first-in-class EGFR x HER3 bispecific antibody-drug conjugate. Its dual targeting mechanism is designed to bind EGFR and HER3, which are expressed in multiple epithelial cancers and linked to cancer cell proliferation and survival. After antibody-mediated internalisation, the ADC releases a Topo1 inhibitor payload to induce cytotoxic stress and cancer cell death.

The approval is significant beyond NPC because it validates SystImmune and Biokin's brengitecan-based ADC platform. Biokin and SystImmune are also developing iza-bren with Bristol Myers Squibb outside China, giving the asset broader global relevance.

The therapeutic need is clear. Recurrent or metastatic NPC patients who progress after platinum chemotherapy and immunotherapy often face limited treatment durability. The reported response and PFS data suggest iza-bren may provide a more active treatment option in this later-line setting.

The development reflects continued momentum in China's ADC sector. Chinese biopharma companies are increasingly moving from platform development into regulatory approvals, global partnerships and competitive oncology indications.

For the broader biopharma industry, the approval reinforces the growing importance of bispecific ADCs as a next-generation modality. The key question is whether dual-target ADC designs can improve tumour selectivity, response depth and durability across multiple epithelial cancers while maintaining a manageable safety profile.