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China's CARsgen announces approval of Satri-cel, world's first CAR T-cell therapy product for solid tumours

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China-based CARsgen Therapeutics, a company focused on developing innovative CAR T-cell therapies, has announced that as informed by the National Medical Products Administration (NMPA), the New Drug Application (NDA) of satricabtagene autoleucel (satri-cel), the proprietary autologous humanised Claudin18.2 CAR T-cell therapy product, has been approved for the treatment of patients with Claudin18.2-positive, HER2-negative advanced gastric/ gastroesophageal junction adenocarcinoma (G/GEJA) who have failed at least two prior lines of therapy. Satri-cel is the world's first approved CAR T-cell therapy product for the treatment of solid tumours.

Gastric cancer is one of the malignancies with the highest disease burden worldwide, ranking fifth in both incidence and mortality globally, with approximately 970,000 new cases and 660,000 deaths annually.

More than 70% of new and fatal cases occur in Asia, and Chinese patients account for approximately 47% of the global gastric cancer burden.

Claudin18.2 is a highly selective marker protein. Its expression in normal healthy tissues is very limited, occurring only in differentiated gastric mucosal epithelial cells, whereas it is highly expressed in gastric cancer and other malignant tumours.

Satri-cel is an autologous CAR-T cell product targeting Claudin18.2. It is genetically modified to express a CAR construct consisting of a humanised Claudin18.2-specific single-chain monoclonal antibody fragment (hu8E5-2I), a CD8? hinge region, a CD28 transmembrane region, a CD28 intracellular signaling domain (CD28 ICD), and a CD3? intracellular signaling region.

The company claims to be first in the world to successfully identify, validate, and report the solid tumour-associated antigen Claudin18.2 as a valid target for CAR T-cell therapy. To further address the challenges of the tumour microenvironment in treating solid tumours, the company independently developed an innovative, patent-protected preconditioning regimen which is to be administered prior to infusion of satri-cel. This regimen features the addition of low-dose nab-paclitaxel to the conventional lymphodepletion regimen comprising cyclophosphamide and fludarabine to enhance the infiltration and anti-

tumour efficacy of CAR T cells.

The company has implemented global patent layout around satri-cel, covering the target, indications, dosage, and preconditioning regimens, among others.