

NMPA approves Kylimei, the first CAR T-cell therapy for gastric / GEJ adenocarcinoma

Market Event Summary

Kylimei is a first in solid tumor CAR T-cell therapy

Background and study design

- On June 22, 2026, the NMPA approved satricabtagene autoleucel (CARsgen Therapeutics' Kylimei) for the treatment of claudin18.2-positive, HER2-negative advanced gastric / gastroesophageal junction adenocarcinoma following two lines of therapy.
- Kyverni is an autologous CLDN18.2-targeted CAR T-cell therapy that recognizes CLDN18.2-expressing tumor cells and induces targeted tumor cell killing through antigen-specific cytotoxic T-cell activation
- Kylimei's approval was based on the Phase 1/2 CT041-ST-01 study (initiated in October 2020), an open-label, multicenter trial in mainland China that randomized 156 patients to receive Kylimei or physician's choice chemotherapy (paclitaxel, irinotecan, apatinib, or an anti-PD-1 antibody).

Key endpoints

Endpoint	Kylimei (n=104)	Physician's choice treatment (n=52)
Median progression-free survival (mPFS)	3.25 months (95% CI, 2.86-4.53)	1.77 months (95% CI, 1.61-2.04)
Median overall survival (mOS)	7.92 months (95% CI, 5.78-10.02)	5.49 months (95% CI, 3.94-6.93)
Objective response rate (ORR)	22% (95% CI, 15-31%)	4% (95% CI, 0-13%)
Disease control rate (DCR)	63% (95% CI, 52-72%)	25% (95% CI, 14-39%)

Clarivate's takeaways



CAR-T therapy breakthrough in solid tumors

Kylimei's approval represents the first successful translation of a CAR T-cell therapy into solid tumors, an area historically limited by challenges such as tumor heterogeneity and an immunosuppressive microenvironment. However, its clinical impact is limited to CLDN18.2-positive ≥ 3 L gastric / GEJ cancer, with no validation yet in broader or earlier-line populations.



Commercial implications in 3L GEJ

Significant unmet need remains in gastric / GEJ cancer after two prior therapies, but Kylimei uptake may be limited by manufacturing complexity, cost, and competition from existing treatments (apatinib, tislelizumab, and chemotherapy) and emerging CLDN18.2-targeted antibodies (CMG901 [AstraZeneca]) and ADCs (JS-107 [NingBo Junyuan Hongshi Biosciences] and tecotabart vedotin [LaNova Medicines]).



Early-line expansion driven by investigator interest

Kylimei is also being evaluated in postadjuvant consolidation (NCT06857786) and post-1L sequential settings (NCT07179484) in gastric / GEJ cancer. While these investigator-led studies reflect interest in moving the CAR T-cell therapy to earlier lines, adoption will depend on demonstrating a meaningful survival benefit and manageable safety compared with current perioperative and 1L standards, including sintilimab, tislelizumab, and chemotherapy.

About the author



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Hardik Patel, B.Tech., is a healthcare research & data analyst on the China In-Depth team. He is involved in primary and secondary market research to create syndicated landscape and forecast content and provide market insights into various therapy areas in China, such as oncology and immunology. He has expertise in market sizing, market forecasting, competitive intelligence, and conducting primary market research across multiple disease areas. He holds a bachelor's degree in biotechnology from Lovely Professional University, Jalandhar, India.

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