Gastrointestinal Cancers Symposium

Abstract #: 398 Poster Session

Phase I trial of efficacy and safety of IMC002, a VHH-based anti-CLDN18.2 CAR-T therapy, for gastroesophageal cancers.

Authors: Chao Li, Tianhang Luo, Weijia Fang, Hongfeng Gou, Jiayi Li, Jianwei Yang, Ziwen Fan, Yueying Peng, Shuangshuang Zhang, Zhuoan Cheng, Ruidong Hao, Zhenggang Jiang, Minmin Sun, Jianming Xu

Organizations: Senior Department of Oncology, Chinese PLA General Hospital, Beijing, China, Department of General Surgery, Changhai Hospital, Second Military Medical University, Shanghai, China, The First Affiliated Hospital, Zhejiang University School of Medicine, Hangzhou, China, Department of Medical Oncology, Gastric Cancer Center, West China Hospital, West China School of Clinical Medicine, Sichuan University, Chengdu, Sichuan, China, Oncology Dept. The First Affiliated Hospital of Xiamen University, Xiamen, China, Department of Medical Oncology, Fujian Provincial Cancer Hospital, Fuzhou, China, Medical Department, Suzhou Immunofoco Biotechnology Co., Ltd, Shanghai, China, Medical Department, Suzhou Immunofoco Biotechnology Co., Ltd, Suzhou, China, Suzhou Immunofoco Biotechnology Co., Ltd, Shanghai, China, Suzhou Immunofoco Biotechnology Co., Ltd., Suzhou, China

Background:
Advanced gastric and gastroesophageal junction (GC/GEJ) cancers are highly aggressive with limited late-line treatment options. Novel strategies are therefore urgently needed. Preclinical studies demonstrated that IMC002, a VHH-based anti-CLDN18.2 CAR-T, exhibited lower toxicity and reduced T-cell exhaustion compared with scFv-based constructs. In an IIT study, 1 of 6 GC patients achieved CR, which persisted for >2 years post-infusion.

Methods:
IMC002-RT01 is a single-arm, open-label, multi-center study evaluating the safety and efficacy of IMC002 in late-line CLDN18.2+ (≥2+ in ≥40%) GC/GEJ or pancreatic cancer (PC) patients. Three dose levels (1.0×10^8, 2.5×10^8, and 5.0×10^8 CAR-T cells) were evaluated using a 3+3 design. Primary endpoint was safety while secondary endpoint was mainly efficacy. Here we report results from the GC/GEJ cohort. Data cutoff: August 8, 2025.

Results:
Between August 2023 and April 2025, 16 GC/GEJ patients received IMC002 (2.5×10^8, n=11; 5.0×10^8, n=5). Median follow-up was 7.0 months (range: 5.5–10.4). Baseline characteristics of all 16 patients: 50.0% ≥3 prior lines, 37.5% liver metastases, all PD-1/PD-L1 exposed.

No DLTs, treatment-related deaths, ICANS or grade ≥3 liver toxicity occurred. Grade ≥3 TRAEs were mainly hematologic and lymphodepletion-related. All patients experienced CRS, with 75% grade 1 and 25% grade 2.
In 15 evaluable patients, the objective response rate (ORR) and disease control rate (DCR) were 66.7% and 93.3%. The CR rate was 6.7%. PFS and OS data were not mature with the current median PFS of 7.0 months (95% CI: 3.9–NR) and OS of 10.3 (95% CI: 6.1–NR) months. Notably, this represents a significantly improved PFS (7.0 months) in late-line GC, compared to historical benchmarks. One patient with liver metastases achieved a deep and durable response, converting from PR to CR and maintained through 48 weeks, while another patient maintained a PR for 60 weeks without progression, demonstrating durable anti-tumor activity. These results align with preclinical and IIT study data indicating sustained activity and low CAR-T cell exhaustion.

Conclusions:
IMC002 exhibited favorable tolerability and durable anti-tumor efficacy in GC/GEJ patients of the Phase I trial (n=16), including one durable CR. When combined with the IIT (n=6) data, the overall CR rate reached 9.1% (2/22) in late-line GC patients. IMC002 has the potential to be evaluated in earlier-line settings and achieve higher CR rates. Based on these findings, a phase III RCT of IMC002 in late-line GC/GEJ patients has been initiated.

Research Funding:
Suzhou Immunofoco Biotechnology Co., Ltd.

Track:
Esophageal and Gastric Cancer, Other GI Cancer

Clinical Trial Registration Number:
NCT05946226

Citation:
J Clin Oncol 44, 2026 (suppl 2; abstr 398)

DOI:
10.1200/JCO.2026.44.2_suppl.398

Abstract Disclosures:
https://coi.asco.org/Report/ViewAbstractCOI?id=519080