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Efficacy of EpCAM CAR-T IMC001 in advanced gastric cancers.

Authors: Tianhang Luo, Weijia Fang, Zhengmao Lu, Chuchu Tong, Hangyu Zhang, Guoqiang Ai, Suqiong Wang, Ruidong Hao, Minmin Sun

Organizations: Department of Medical Oncology, The First Affiliated Hospital, Zhejiang University School of Medicine, Hangzhou, China, Shanghai Changhai Hospital, Shanghai, China, Suzhou Immunofoco Biotechnology Co., Ltd, Suzhou, China, The First Affiliated Hospital of ZheJiang University, Hangzhou, China

Background: EpCAM is highly expressed in various cancer types of the GI system and serves as a promising prognostic/predictive marker and therapeutic target. IMC001 is an autologous EpCAM-targeting CAR-T cell exhibited promising anti-tumor activity in preclinical studies. The specificity of the extracellular humanized scFv of IMC001 was confirmed by membrane proteome array. Patient derived organoids study and murine GLP study indicated a favorable safety profile of IMC001. Previous IIT data showed promising safety and efficacy. Here we present updated clinical data with longer follow up and more pts treated in the expansion recommended dose of 1 million (M) CAR-T cells/kg. **Methods:** This first-in-human, open-label trial followed a 3+3 design with IMC001 monotherapy dose escalation of 0.3 (n=3), 1 (n=3) or 3 (n=3) M/kg after lymphodepletion chemotherapy, 2 additional pts had been enrolled at dose-expansion (1M/kg). Eligible patients were those with EpCAM-positive (expression ≥1+ staining intensity in ≥10% tumor cells) advanced gastric cancers who had failed or not tolerated at least 2 lines of chemotherapy and were ECOG 0 or 1. The objective was to assess the safety, PK/PD profile and preliminary efficacy of IMC001. **Results:** As of Dec 30, 2023, 11 pts were infused with IMC001, 10 with evaluable efficacy are included in the efficacy analysis. The median time from diagnosis to enroll was 17.0 months (range 6.9-31.2). All pts were in stage IV, with more than 2 lines previous chemotherapy (1 pt failed 1st line and refused a 2nd line treatment), all had metastasis and 72.7% (8/11) had 2 or more metastasis organs. CAR T-cell expansion was observed in most pts; the median Cmax was 547, 500 and 9540 copies/μg gDNA in the 0.3, 1, and 3M/kg dose groups respectively, median Tmax was 7 days (7-28), with a persistence of IMC001 range from 4 to 12 weeks. Significant elevations of serum levels of cytokines were observed in most patients. Three out of 10 evaluable pts achieved PR response and 6 remained SD, with a DCR of 90%. For the recommended dose of 1M/kg, 2 out of 5 pts had PR (ORR 40%), including 1 pt underwent successful radical gastrectomy around W27 after IMC001 infusion and remained survival for more than 81 wks. The other PR pt had a tumor reduction of 48% at W16.

The other 2 SD pts had an OS of 55 wks and 43 wks. Patients were well tolerated with no unexpected safety signals were observed at the recommended dose. **Conclusions:** This phase I study in advanced gastric cancer resulted in durable response with a favorable safety and efficacy profile especially for the recommended dose of 1M/kg, demonstrate a promising of EpCAM CAR-T therapy in advanced GC pts. Further expanding of this dose with larger patient population and longer follow-up shall bring the hope to this unmet medical need. Clinical trial information: ChiCTR2100047129.

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