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3615RO

First-in-human phase I study of UCL70802, a LACO-Stim armored anti-CD70 CAR T-cell therapy, in patients with metastatic clear cell renal cell carcinoma (mccRCC)

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Background

UCL70802 is a novel autologous T-cell product engineered to co-express anti-CD70 CAR and LACO-Stim. It exerts antitumor effects via dual mechanisms: direct CAR-mediated lysis of CD70-positive tumors and LACO-Stim-driven systemic immune activation. Via CD40/CD28 co-stimulation, LACO-Stim enhances immune cell activity, remodels the tumor microenvironment, and sustains durable antitumor immunity.

Methods

Eligible patients with CD70-positive mccRCC who failed standard therapies were enrolled. Primary endpoints included safety, dose-limiting toxicities (DLTs), and maximum tolerated dose. Secondary endpoints covered pharmacokinetics and antitumor response per RECIST v1.1.

Results

As of May 8, 2026, 9 patients were treated with UCL70802. All CRS events were manageable: 5 patients had Grade 1–2 CRS and 4 had Grade 3 CRS, resolving to Grade 2 within one day. Common TRAEs included lymphopenia (100%), erythema (100%) and edema (88.9%). Grade ≥3 non-CRS TRAEs were lymphodepletion-related hematological toxicities, with no DLTs observed. Antitumor activity was observed across all dose cohorts except DL1 (0.6×10^6 cells/kg). In 9 evaluable patients, the ORR was 33.3% (3/9) and DCR was 88.9% (8/9). At DL3 (2×10^6 cells/kg), 50% (2/4) patients achieved confirmed PRs (85% tumor reduction at M8 and 34.6% shrinkage at M6). At DL4 (3×10^6 cells/kg), one patient achieved a confirmed PR at M3, the other patient achieve SD at M1. Notably, 4 patients had undetectable peripheral CAR copies at M1/M2 but sustained durable tumor regression (>8 months in 1 patient; >6 months in2 patients; >3 months in 1 patient). This indicates LACO-Stim-driven innate immune activation sustains long-term efficacy post CAR-T-mediated tumor clearance.Table: 3615RO

Patients no.	Age/Gender	Prior therapies	ECOG	Lymphodepletion	Dose level	C_{max} (copies/μg DNA)	Response	Grade of CRS
1	54/M	1	1	YES	0.6×10^6/kg	12486	PD	G1
2	70/F	2	1	NO	1.2×10^6/kg	209	SD	G1
3	54/M	5	1	YES	1.2×10^6/kg	1368	SD	G2
4	61/M	2	1	YES	2.0×10^6/kg	37750	SD	G2
5	59/M	3	0	YES	2.0×10^6/kg	61565	PR	G1
6	62/M	2	0	YES	2.0×10^6/kg	19565	PR	G3
7	73/F	2	1	YES	2.0×10^6/kg	107135	SD	G3
8	66/M	1	1	YES	3.0×10^6/kg	115067	PR	G3
9	58/M	2	0	YES	3.0×10^6/kg	32655	SD	G3

Conclusions

UCL70802 demonstrated a manageable safety profile and promising preliminary antitumor activity in mccRCC patients. Dose escalation continues to further assess efficacy and safety.

Clinical trial identification

NCT05990621.

Legal entity responsible for the study

The authors.

Funding

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Disclosure

X. Gan: Non-Financial Interests, Institutional, Local PI: UTC therapeutics(Shanghai) Co., LTD). W. Li: Financial Interests, Institutional, Project Lead: UTC therapeutics(Shanghai) Co., LTD). W. Zhang: Non-Financial Interests, Institutional, Local PI: UTC therapeutics(Shanghai) Co., LTD). J. Ding: Non-Financial Interests, Institutional, Local PI: UTC therapeutics(Shanghai) Co., LTD). J. Hu: Non-Financial Interests, Institutional, Local PI: UTC therapeutics(Shanghai) Co., LTD). C. Wu: Financial Interests, Institutional, Full or part-time Employment: UTC therapeutics(Shanghai) Co., LTD). L. Lu: Financial Interests, Institutional, Full or part-time Employment: UTC therapeutics(Shanghai) Co., LTD). C. Han: Financial Interests, Institutional, Full or part-time Employment: UTC therapeutics(Shanghai) Co., LTD). X. Liu: Financial Interests, Institutional, Member of Board of Directors: UTC therapeutics(Shanghai) Co., LTD). Y. Zhao: Financial Interests, Institutional, Member of Board of Directors: UTC therapeutics(Shanghai) Co., LTD). L. Wang: Non-Financial Interests, Institutional, Principal Investigator: UTC therapeutics(Shanghai) Co., LTD).

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