Personalized Cancer Immunotherapy

T-CURX

Press Release

T-CURX non-viral Siglec-6 lead CAR-T program, TCX-001, was approved for First-in-Human Phase 1 clinical trial in patients with relapsed/refractory AML and CLL

- Clinical Trial approval for TCX-001 is another significant development milestone for T-CURX and marks the transition of T-CURX from a pre-clinical to a clinical-stage biotech company
- TCX-001 targeting Siglec-6 is a first-in-class autologous, non-viral investigational CAR-T therapy for r/r AML as the lead indication and for CLL. This is a testament to T-CURX strategy to develop highly differentiated CAR-T products beyond targets and indications for which CAR-T therapies are already available.
- Siglec-6 is a differentiated target present on AML-blasts and leukemic stem cells, but, unlike most other AML targets, is not expressed on healthy hematopoietic stem or progenitor cells. Siglec-6 CAR-T cell therapy has the potential to be an effective treatment for AML patients, rather than only being a "bridge to transplant".

Würzburg, June 11, 2026. Today, leading European CAR-T biotech company T-CURX announces its first clinical trial approval by Swiss agency Swissmedic for the company's non-viral lead CAR-T program, TCX-001, targeting Siglec-6. The first-in-human Phase 1 study will now be initiated at University Hospital Zürich as the first clinical trial site to treat patients with relapsed/refractory (r/r) Acute Myeloid Leukemia (AML) and Chronic Lymphocytic Leukemia (CLL), including patients that are not eligible for stem cell transplantation. A complementary CTIS application will also be filed at European Medicines Agency (EMA) to extend the trial to four sites in Germany led by University Hospital Würzburg (UKW). The study will enrol up to 23 adult patients with r/r AML or CLL to determine the recommended Phase 2 dose. Primary endpoints are safety, tolerability, and dose-limiting toxicities with key secondary endpoints including overall response rate, duration of response, as well as CAR-T cell expansion and persistence.

Siglec-6 was identified as a leukemia target by T-CURX co-founder Christoph Rader through the natural anti-leukemic immune response of a CLL patient cured by allogeneic stem cell transplantation. It was characterized as a highly promising CAR-T target in AML by Michael Hudecek, co-founder and CMO at T-CURX. In contrast to other AML targets, e.g. CD33 or CD123, Siglec-6 is not expressed on healthy hematopoeitic stem or progenitor cells. This spares the hematopoietic stem cell compartment from destruction by CAR-T cells. Based on this unique aspect, Siglec-6 CAR-T therapy could provide an effective therapy for AML as a stand alone treatment, rather than just a "bridge to transplant".

TCX-001 is a next-generation autologous CAR-T product incorporating several proprietary innovations including virus-free Sleeping Beauty transposon gene transfer and novel CAR-linker ("matchmaker"-) technologies for high scalability and optimal potency. GMP-certified manufacturing has been established at the German Red Cross Blood donation center in Frankfurt, Germany.

Ulf Grawunder, CEO and co-founder of T-CURX said. *"We are excited about the clinical trial approval for our lead CAR-T program TCX-001 leveraging highly innovative non-viral CAR-T technologies. This is an important milestone for T-CURX in our quest to develop first-in-class, transformative CAR-T therapies and to make them accessible for patients with a scalable and economical non-viral CAR-T manufacturing process."*

Michael Hudecek, CMO and co-founder of T-CURX added *"TCX-001 targets Siglec-6 and is manufactured using T-CURX non-viral Sleeping Beauty platform, the same technology validated for clinical use in our prior academic clinical trials, CARAMBA-1 and LION-1, sponsored by University Hospital Würzburg. We have high hopes that TCX-001will ultimately provide meaningful and durable benefit to r/r AML and CLL patients who have exhausted current therapies."*

Upon clinical validation of *ex vivo* manufactured non-viral CAR-T therapy TCX-001, T-CURX will build upon this clinical expertise to also combine it with its *in vivo* CAR-T strategy. This development is accelerated by the recent acquisition of Pantherna Therapeutics and integrating their proprietary LNP-based nucleic acid delivery technologies into T-CURX clinical CAR-T pipeline.

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About T-CURX

T-CURX GmbH is a private, Würzburg & Munich based, German, clinical-stage biotech company with a wholly owned subsidiary, Pantherna Therapeutics in Hennigsdorf & Berlin, Germany, specialized on development of LNP delivery technologies for nucleic acids into cells for therapeutic applications. T-CURX is financially backed by a syndicate of international VC investors and family offices from Germany and Switzerland, led by Swiss BiomedVC, with Bayernkapital (Germany), Highlight Capital (China) and i&iBio Fund (Czech Republic) as institutional co-investors. T-CURX has the vision to bring innovative CAR-T cell therapies based on cost-effective and highly scalable non-viral ex vivo and in vivo CAR-T strategies to more cancer patients in need of these effective cancer therapies. T-CURX was spun out of the laboratory of T-CURX's co-founder Prof. Michael Hudecek at the University of Würzburg and is led by Ulf Grawunder, PhD, a seasoned serial entrepreneur as CEO, who is also one of the co-founders. For more information about T-CURX, visit the company's website at: www.t-curx.com

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