



Gyala Therapeutics initiates Phase I/IIa clinical trial of a CAR-T cell therapy in acute leukemias with limited treatment options

Descrizione

COMUNICATO STAMPA - CONTENUTO PROMOZIONALE

BARCELONA, Spain, Feb. 10, 2026 /PRNewswire/ - Gyala Therapeutics, a clinical-stage biotechnology company developing innovative cell therapies for hematologic malignancies, today announced the initiation of a Phase I/IIa clinical trial of GYA01 following authorization from the Spanish Agency of Medicines and Medical Devices (AEMPS).

The study will evaluate GYA01, a first-in-class CAR-T cell therapy targeting the CD84 protein, in patients with relapsed or refractory acute myeloid leukemia (AML) or T-cell acute lymphoblastic leukemia (T-ALL), diseases with poor prognosis and limited treatment options. CD84 is an emerging therapeutic target characterized by high expression in leukemic cells.

The trial is being conducted at Hospital La Fe in Valencia and Hospital Cl n c Barcelona, two internationally recognized reference centers in acute leukemias and advanced cellular therapies. It is an open-label, single-arm, interventional study designed to assess the safety, tolerability, and preliminary efficacy of GYA01 and includes a dose-escalation phase followed by an expansion phase.

Gyala Therapeutics and Hospital La Fe have received ~3.7 million in funding from Spain's Ministry of Science, Innovation and Universities through the CPP 2024 program to conduct the study.

GYA01 has demonstrated strong preclinical activity in models of AML and T-ALL, with results published in *Leukemia* in 2025. There are currently no approved CAR-T therapies for either indication.

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