(PB2602) TRIAL IN PROGRESS: T-RREX - A PIVOTAL PHASE 2 STUDY OF WU-CART-007 (SOFI-CEL), CD7-DIRECTED ALLOGENEIC CAR-T CELL THERAPY, IN PATIENTS WITH R/R T-CELL ACUTE LYMPHOBLASTIC LEUKEMIA/LYMPHOMA

Topic: 02. Acute lymphoblastic leukemia - Clinical

Elias Jabbour*[1], Ibrahim Aldoss[2], Shannon Maude[3], Ashish Bajel[4], Seong L. Khaw[5], Rawan Faramand[6], Jeremy Rubinstein[7], Adam Lamble[8], Priti Tewari[1], Deepa Bhojwani[9], Jacqueline Blem[10], Alexander S. Hamil[10], Cherry T. Thomas[10], Armin Ghobadi[11]

[1]University of Texas MD Anderson Cancer Center, Houston, United States of America;[2]City of Hope Hospital, Duarte, United States of America; [3]Children's Hospital of Philadelphia, Philadelphia, United States of America;[4]Peter McCallum Cancer Centre and The Royal Melbourne Hospital, Melbourne, Australia; [5]Royal Children's Hospital, Parkville, Australia;[6]Moffitt Cancer Center, Tampa, United States of America; [7]Cincinnati Children's Hospital Medical Center, Cincinnati, United States of America;[8]Seattle Children's Hospital, Seattle, United States of America; [9]Children's Hospital Los Angeles and Keck School of Medicine, Los Angeles, United States of America; [10]Wugen, Inc, St. Louis, United States of America;[11]Washington University, St. Louis, United States of America;

Background

T-cell acute lymphoblastic leukemia/lymphoblastic lymphoma (T-ALL/LBL) are aggressive hematologic cancers with high rates of mortality in both children and adults in the relapsed setting. Once relapsed, the disease is resistant to most therapies. CD7 is expressed on leukemic blasts in over 95% of patients with T-ALL/LBL. WU-CART-007 (soficabtagene geleucel "sofi-cel") is an allogeneic, CD7-targeted CAR-T cell therapy with a CD7 deletion to mitigate fratricide and a T-cell receptor alpha constant deletion to minimize graft-versus-host disease. In a global first-in-human, Phase 1 study, 26 adult and adolescent patients with relapsed/refractory (R/R) T-ALL/LBL were treated with sofi-cel (Ghobadi, *et al,* Blood 2025).

The recommended Phase 2 dose (RP2D) was $900x10^6$ sofi-cel cells administered following lymphodepletion (LD). At the RP2D, sofi-cel demonstrated acceptable safety and anti-tumor activity. The overall response rate was 91%, with a composite complete remission (CRc) rate of 73%. The median duration of response was not reached (95% CI: 0.5 to not estimable; range, 0.3-10.7 months). CAR-T cell expansion peaked on Day 10 and was detectable through Day 90.

Aims

To describe the design of T-RRex, a pivotal Phase 2 single-arm, open-label, multicenter study evaluating the efficacy of sofi-cel in patients with R/R T-ALL/LBL. The study also includes a planned exploratory cohort of patients with minimal residual disease (MRD)-positive T-ALL.

Methods

Adult and pediatric patients ≥6 months old with R/R T-ALL/LBL, as defined by the World Health Organization classification, are eligible. R/R disease is defined as ≥5% bone marrow blasts or the presence of extramedullary disease after frontline induction and consolidation or in first or subsequent relapse. Patients receive sofi-cel at the target dose following LD.

The primary objective is to evaluate the CRc rate following administration of sofi-cel therapy. The CRc rate is defined as the proportion of patients achieving complete remission (CR), CR with partial hematologic recovery (CRh), or CR with incomplete hematologic recovery (CRi). Secondary endpoints include assessment of safety, duration of response, best overall response rate, and overall survival.

Response assessments are performed on Day 28, and at Months 3, 6, 9, 12, and 24. These evaluations include bone marrow aspirate and biopsy, with PET-CT imaging when clinically indicated.

An exploratory cohort is planned for pediatric and adult patients with MRD-positive T-ALL. MRD-positive status is defined as patients in CR with detectable MRD (0.1 to <5% bone marrow blasts).

Results

The study is currently open and enrolling (NCT06514794) at 10 sites in the U.S. and Australia.

Summary/Conclusion

This pivotal study is designed to generate evidence supporting the potential of sofi-cel to address a significant unmet medical need in patients with R/R T-ALL/LBL.