

Phase 1/1b study of T-allo10 infusion after HLA-partially matched abdepleted-HSCT in children and young adults with hematologic malignancies.

Grant Award Details

Phase 1/1b study of T-allo10 infusion after HLA-partially matched abdepleted-HSCT in children and young adults with hematologic malignancies.

Grant Type: Clinical Trial Stage Projects

Grant Number: CLIN2-12563

Project Objective: To assess the feasibility and safety of T-Allo10 drug product in the absence of immune suppression , determine the recommended Phase 2 dose (RP2D) and evaluate potential efficacy endpoints for the Phase 2 clinical trial.

Investigator:

Name: Maria Grazia Roncarolo

Institution: Stanford University

Type: PI

Disease Focus: Acute Myeloid Leukemia , B cell cancers, Blood Cancer, Cancer, Leukemia

Human Stem Cell Use: Adult Stem Cell

Award Value: \$10,563,822

Status: Active

Grant Application Details

Application Title: Phase 1/1b study of T-allo10 infusion after HLA-partially matched abdepleted-HSCT in children and young adults with hematologic malignancies.

Public Abstract: **Therapeutic Candidate or Device**

An immunotherapy cell product, T-allo10, that is enriched for specialized immune cells called type I regulatory T (Tr1) cells

Indication

Children and young adults with relapse/refractory acute leukemia receiving a specialized stem cell transplant, $\alpha\beta$ depleted-HSCT

Therapeutic Mechanism

$\alpha\beta$ depleted-HSCT has increased the number of patients who can safely receive transplants, however this strategy cannot provide a fast reconstitution of the immune system which is critical for infection fighting functions and prevention of leukemia relapse. The proposed therapy, T-allo10, when given after $\alpha\beta$ depleted-HSCT has the potential to accelerate recovery of immune responses without graft versus host disease, thus improving cancer-free outcomes for children with leukemia.

Unmet Medical Need

Hematologic malignancies are the most common cancer in children and young adults, and current treatment options do not offer long-term cure. We propose that post- $\alpha\beta$ depleted HSCT infusion of T-allo10 will improve the probability of being alive and disease free, thus addressing an unmet medical need.

Project Objective

Phase 1/1b to select dose, safety & pilot efficacy

Major Proposed Activities

- Determine recommended Phase 2 dose (RP2D) of T-allo10 cell product for high risk patients with hematologic malignancies receiving $\alpha\beta$ depleted-HSCT
- Evaluate the safety, and explore the potential for clinical efficacy of infusion of T-allo10 at the RP2D (or highest dose) after $\alpha\beta$ depleted-HSCT
- Perform immune monitoring to establish immune criteria that predict successful patient outcomes.

Statement of Benefit to California:

Almost 500 children/year receive stem cell transplants in California. A durable cure for these children can provide a great economic benefit to the state. A successful outcome of our trial will significantly reduce the length of hospitalization, thus reducing patient care costs, as well as the risk of the need for a second transplant. Thus, the benefit to California is the improved lives of its citizens (both patients and family members) while simultaneously decreasing the societal costs.

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