**A Phase I Clinical Trial Combining CAR T-cell Therapy with Autologous Hematopoietic Stem Cells in a Multi-Cultural Patient Population**

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Background: Chimeric Antigen Receptor (CAR) T-Cell therapy is a type of immunotherapy designed to treat relapsed/refractory hematologic malignancies such non-Hodgkin B-Cell Lymphoma, B-Cell Acute Lymphoblastic Leukemia, and Multiple Myeloma. CAR T toxicities such as cytokine release syndrome, immune effector cell-associated neurotoxicity syndrome and post-infusion cytopenias pose major challenges to the regimen. Additionally, CAR T is a complicated and involved therapy. It is critical to explain the risks and benefits to patients, which can be challenging when they are non-native English speakers.

Objectives: The co-primary endpoints of this trial are to determine the feasibility of collecting the target cell dose of autologous hematopoietic stem cells (aHSCs) in 50% of the patients and the safety of combining aHSCs to the planned CAR T treatment. Additionally, we aimed to create educational, multilingual documents to improve patient comprehension of the trial.

Methods: We designed a phase I, single arm clinical trial at Cedars Sinai Medical Center in Los Angeles, California combining aHSCs and any FDA approved CAR T-cell therapy. The aHSC boost should raise blood cell counts, including myeloid cells, which have been shown to work in concert with CAR T-cells in animal models, improving therapeutic efficacy. To address knowledge gaps and language barriers for the local patient population, we created an informed consent form in English and Spanish, created a flow chart describing the procedure in simple terms, and created educational materials for patients explaining the science behind CAR T-cell therapy.

Results: In February of 2023, Cedars Sinai approved the trial with internal funding. It will be activated in the coming months.

Conclusions/Recommendations: We hope our trial will provide meaningful benefit to patients by reducing CAR T related toxicities. Additionally, through our educational content and multilingual consent forms, we aim to increase patient access to and comprehension of this clinical trial.