Phase 1 Study of CD19/CD22 Chimeric Antigen Receptor (CAR) T Cells in Adults with Recurrent or Refractory B Cell Malignancies

Grant Award Details

Grant Type: Clinical Trial Stage Projects
Grant Number: CLIN2-10846

Project Objective: To complete a Phase 1 Study of CD19/CD22 Chimeric Antigen Receptor (CAR) T Cells in Adults with Recurrent or Refractory B Cell Malignancies.

Investigator:

<table>
<thead>
<tr>
<th>Name:</th>
<th>Crystal Mackall</th>
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<tr>
<td>Institution:</td>
<td>Stanford University</td>
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<td>Type:</td>
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Disease Focus: B cell cancers, Blood Cancer, Cancer, Leukemia

Human Stem Cell Use: Adult Stem Cell

Cell Line Generation: Adult Stem Cell

Award Value: $11,034,982

Status: Active

Grant Application Details

Application Title: Phase 1 Study of CD19/CD22 Chimeric Antigen Receptor (CAR) T Cells in Adults with Recurrent or Refractory B Cell Malignancies
Public Abstract:

**Therapeutic Candidate or Device**

T cells genetically engineered to express as bispecific Chimeric Antigen Receptor (CAR) targeting CD19 and/or CD22

**Indication**

Patients with relapsed and refractory B cell malignancies

**Therapeutic Mechanism**

T cells expressing the bispecific CAR will recognize cancer cells expressing one of both of the target antigens. Upon recognition, the T cells will become activated, divide, and then kill the cancer cells. Progenitor T cells contained within the larger population will form memory stem cells that will persist and continue to survey the body and kill residual cancer. These cancer killing T cells are designed to persist for years following one treatment with CD19/22-CAR T cells.

**Unmet Medical Need**

50% or less of patients with diffuse large B cell lymphoma and B cell leukemia are cured with standard regimens, that rely on chemotherapy for benefit. CD19/22-CAR T cells effectively kill chemotherapy resistant lymphoma and leukemia and thus could improve cure rates for these aggressive cancers.

**Project Objective**

Phase 1 trial completed

**Major Proposed Activities**

- Demonstrate feasibility of producing CD19/22-CAR T cells
- Assess toxicity of CD19/22-CAR T cells
- Assess clinical activity of CD19/22-CAR T cells in adults with B-ALL and DLBCL.

**Statement of Benefit to California:**

In California, approximately 2000 adults are diagnosed annually with DLBCL and 600 with B-ALL. At least one third will not respond to chemotherapy based treatment and most will die of their disease within one year. The CD19/22-CAR provides a new, potentially effective therapy for these patients. It could demonstrate both a higher response rate and greater long-term effectiveness than the CD19-CAR that has recently received FDA approval for these patients.

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