A Phase 1b Trial of Hu5F9-G4 Monotherapy or Hu5F9-G4 in Combination with Azacitidine in Patients with Acute Myeloid Leukemia

Grant Award Details

A Phase 1b Trial of Hu5F9-G4 Monotherapy or Hu5F9-G4 in Combination with Azacitidine in Patients with Acute Myeloid Leukemia

Grant Type: Clinical Trial Stage Projects

Grant Number: CLIN2-10144

Project Objective: Cancer is a leading cause of death in the US accounting for approximately 30% of all mortalities. Acute myeloid leukemia (AML) is one of the deadliest blood cancers, and generally the relative distribution of AML in California resembles that of the entire country. This proposal will explore the clinical benefit of Hu5F9-G4 treatment in patients with AML with treatment of patients in California and provide a basis to enable a follow-on trial seeking regulatory approval in AML.

Investigator:

Name:	Mark Chao
Institution:	Forty Seven Inc.
Type:	PI

Disease Focus: Acute Myeloid Leukemia, Blood Cancer, Cancer

Human Stem Cell Use: Cancer Stem Cell

Award Value: $5,000,000

Status: Active

Grant Application Details

Application Title: A Phase 1b Trial of Hu5F9-G4 Monotherapy or Hu5F9-G4 in Combination with Azacitidine in Patients with Acute Myeloid Leukemia

Public Abstract:

Therapeutic Candidate or Device

Hu5F9-G4 is a drug called an antibody that is designed to mobilize the body's immune system to eliminate cancer and cancer stem cells.

Indication

Patients with relapsed and/or refractory AML or newly diagnosed AML who cannot receive standard high dose chemotherapy.

Therapeutic Mechanism

This treatment targets cancer stem cells, which are cells thought to be responsible for how AML forms. Hu5F9-G4 targets a molecule on cancer cells called CD47, which acts as a "don't eat me" signal that cancer cells commandeer to avoid being ingested by the immune system. Hu5F9-G4 covers up this signal, allowing for the immune system to kill the cancer cells.

Unmet Medical Need

Acute myeloid leukemia (AML) affects over 13,000 adults annually and is one of the deadliest blood cancers in the United States. New therapies are needed as none available have been approved in over 40 years. Hu5F9-G4 alone or in combination has promising potential to benefit to AML patients.

Project Objective

Phase 1b trials completed.

Major Proposed Activities

- Investigating how safe and well tolerated Hu5F9-G4 alone or in combination with azacitidine is in AML patients
- Investigating how effective Hu5F9-G4 alone or in combination with azacitidine in eliminating leukemic disease in AML patients
- Investigating the optimal dosing regimen of Hu5F9-G4 for the treatment of AML patients

Statement of Benefit to California:

Cancer is a leading cause of death in the US accounting for approximately 30% of all mortalities. Acute myeloid leukemia (AML) is one of the deadliest blood cancers, and generally the relative distribution of AML in California resembles that of the entire country. This proposal will explore the clinical benefit of Hu5F9-G4 treatment in patients with AML with treatment of patients in California and provide a basis to enable a follow-on trial seeking regulatory approval in AML.
