A Phase 1b/2 Trial of the Anti-CD47 Antibody Hu5F9-G4 in Combination with Cetuximab in Patients with Solid Tumors and Advanced Colorectal Cancer

Grant Award Details

A Phase 1b/2 Trial of the Anti-CD47 Antibody Hu5F9-G4 in Combination with Cetuximab in Patients with Solid Tumors and Advanced Colorectal Cancer

Grant Type: Clinical Trial Stage Projects

Grant Number: CLIN2-09577

Project Objective: Completion of a Phase 1b/2 trial.

Investigator:

<table>
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<tr>
<th>Name</th>
<th>Mark Chao</th>
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<tbody>
<tr>
<td>Institution</td>
<td>Forty Seven Inc.</td>
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<tr>
<td>Type</td>
<td>PI</td>
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Disease Focus: Cancer, Colon Cancer, Solid Tumors

Human Stem Cell Use: Cancer Stem Cell

Award Value: $10,234,048

Status: Active

Grant Application Details

Application Title: A Phase 1b/2 Trial of the Anti-CD47 Antibody Hu5F9-G4 in Combination with Cetuximab in Patients with Solid Tumors and Advanced Colorectal Cancer
Public Abstract: Therapeutic Candidate or Device

The treatment is two drugs: Hu5F9-G4 and cetuximab. These are antibodies, which are engineered drugs that eliminate cancers using the immune system.

Indication

Patients with advanced colon cancer that have a genetic mutation in the KRAS gene and those without the KRAS genetic mutation.

Therapeutic Mechanism

This treatment targets cancer stem cells, which are cells thought to be responsible for how tumors form. Hu5F9-G4 targets a molecule on cancer cells called CD47, which acts as a cloak that shields the cancer from the immune system. Hu5F9-G4 unmasks this cloak and lets the immune system eliminate the cancer. Cetuximab targets the molecule EGFR, which is on colon cancers, and provides a boost to tumor cell killing. This therapy aims to stop the growth, shrink, or eliminate a patient’s cancer.

Unmet Medical Need

Colon cancer is the 2nd leading cause of US cancer deaths. Only about 10% of patients survive past 5 years. Those who do not respond to initial therapy, and those with a KRAS gene mutation, have very limited treatment options. This treatment has the potential to provide benefit to these patients.

Project Objective

Completion of a Phase 1b/2 trial.

Major Proposed Activities

- Determine the safety and tolerability of Hu5F9-G4 and cetuximab combination treatment in cancer patients
- Determine the optimal dose regimen of Hu5F9-G4 and cetuximab in cancer patients
- Determine the therapeutic efficacy of Hu5F9-G4 and cetuximab treatment in colon cancer patients

Statement of Benefit to California:

Cancer is a leading cause of death in the US accounting for approximately 30% of all mortalities. Furthermore, colorectal cancer is the second leading cause of cancer-related deaths in the US. For the most part, the relative distribution of colorectal cancer in California resembles that of the entire country. This proposal will explore the clinical benefit of Hu5F9-G4 and cetuximab treatment in patients with colorectal cancer and provide a basis to seek regulatory approval of this treatment.

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