Doctor's Note — Clinical Trial Summary

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TRIAL

C7R-GD2.CART Cells for Patients With Relapsed or Refractory Neuroblastoma and Other GD2 Positive Cancers (GAIL-N)

NCT ID: NCT03635632 Phase: PHASE1 Sponsor: Baylor College of Medicine Status: Active Not Recruiting

SUMMARY

This study is for patients with neuroblastoma, sarcoma, uveal melanoma, breast cancer, or another cancer that expresses a substance on the cancer cells called GD2. The cancer has either come back after treatment or did not respond to treatment. Because there is no standard treatment at this time, patients are asked to volunteer in a gene transfer research study using special immune cells called T cells. T cells are a type of white blood cell that helps the body fight infection.

The body has different ways of fighting infection and disease. No single way seems perfect for fighting cancers. This research study combines two different ways of fighting cancer: antibodies and T cells. Both antibodies and T cells have been used to treat patients with cancers. They have shown promise but have not been strong enough to cure most patients.

We have found from previous research that we can put a new gene into T cells that will make them recognize cancer cells and kill them. In our last clinical trial we made a gene called a chimeric antigen receptor (CAR) from an antibody that recognizes GD2, a substance found on almost all neuroblastoma cells (GD2-CAR). We put this gene into the patients' own T cells and gave them back to 11 neuroblastoma patients. We saw that the cells did grow for a while, but started to disappear from the blood after 2 weeks. We think that if T cells are able to last longer they may have a better chance of killing GD2 positive tumor cells.

Therefore, in this study we will add a new gene to the GD2 T cells that can cause the cells to live longer. T cells need substances called cytokines to survive and the cells may not get enough cytokines after infusion. We have added the gene C7R that gives the cells a constant supply of cytokine and helps them to survive for a longer period of time.

In other studies using T cells, investigators found that giving chemotherapy before the T cell infusion can improve the amount of time the T cells stay in the body and therefore the effect the T cells can have. This is called lymphodepletion and we think that it will allow the T cells to expand and stay longer in the body, and potentially kill cancer cells more effectively.

The GD2-C7R T cells are an investigational product not approved by the Food and Drug Administration.

The purpose of this study is to find the largest safe dose of GD2-C7R T cells, and also to evaluate how long they can be detected in the blood and what affect they have on cancer.

KEY ELIGIBILITY CRITERIA

- Procurement Inclusion Criteria:

• 1. Evaluable neuroblastoma with persistent or relapsed disease

• 1. Recurrent disease following completion of aggressive multi-drug frontline therapy.

• 2. Progressive disease during aggressive multi-drug frontline therapy.

• 3. Primary resistant/refractory disease (less than partial response by INRC) detected at the conclusion of at least 4 cycles of aggressive multi-drug induction chemotherapy on or according to a standard high-risk treatment protocol

• OR Relapsed or refractory osteosarcoma not responsive to standard treatment

• OR Patients diagnosed with GD2 positive metastatic uveal melanoma and progressed after at least one prior systemic treatment

• OR GD2 positive breast cancer with metastatic or locally recurrent unresectable breast cancer currently progressive after at least two prior lines of therapy in the advanced setting. Patients with HER2+ disease must have failed two or more different anti-HER2 agents.

• OR Patients with other relapsed or refractory solid tumors not responsive to standard treatment with confirmed expression of GD2 by immunohistochemistry testing.

• 2. Life expectancy of at least 12 weeks

Total sites: 2 | 0 currently recruiting