MT2024-13: First-in Cancer-Type Phase I Study of FT536 for Recurrent WHO Grade 4 Astrocytoma

Status: Recruiting

Eligibility Criteria

Sex: Male or Female
Age Group: 18 years and over
This study is NOT accepting healthy volunteers

Inclusion Criteria:

- 18 to 75 years old - confirmed Grade 4 astrocytoma that has reoccurred or progressed - completed usual antitumor treatment including surgery, radiation therapy, and temozolomide with or without Optune/ Tumor Treatment Fields (TTF) - able to have MRI scans with contrast agent - completely off or on a dose of dexamethasone 2mg daily or less with stable neurological function when starting the study - must use a highly effective form of birth control from the first study visit until at least 3 months after the dose of FT536 - see link to clinicaltrials.gov for complete Inclusion criteria

Exclusion Criteria:

- prior treatment with bevacizumab or any other cellular therapy - prior or current GammaTile, Gliadel wafer use, or other implanted therapeutic agent or photodynamic therapy - women who are pregnant or breastfeeding - history of another cancer in the past 5 years - other significant medical or social conditions that would limit the ability to complete the study requirements - see link to clinicaltrials.gov for complete Exclusion criteria

Conditions & Interventions

Conditions:
Cancer
Keywords:
Clinics and Surgery Center (CSC), Astrocytoma, Brain Cancer

More Information

Description: The upfront treatment for astrocytoma is surgery, radiation therapy, and chemotherapy. There is currently no standard therapy for when the astrocytoma has returned (recurs) or re-grows (progresses). This study uses the investigational drug FT536, a cell therapy that stimulates the immune system into action to treat astrocytoma that has returned or regrown. FT536 is a type of cell therapy made up of “natural killer” or NK cells, a type of immune blood cell that are known to attack cancer cells. The primary purpose of this study is to identify a safe dose of FT536 cells when given as an intratumoral injection and to identify the side effects of treatment with FT536. Another purpose of this study is to understand how FT536 alters the immune system in the brain and body.
Study Contact: Elizabeth Neil - neile@umn.edu
Principal Investigator: Elizabeth Neil
IRB Number: STUDY00027280