Study of Silevertinib With Temozolomide for the Treatment of Newly Diagnosed GBM With Unmethylated MGMT and EGFRvIII

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Key

Inclusion Criteria:

* Newly diagnosed histologically confirmed glioblastoma that is isocitrate dehydrogenase wild type (IDH-WT). * Positive EGFR status in the brain tumor as determined by a commercially available test or validated laboratory assay (CLIA or comparable certification). * For Part 1 (Safety Lead-in) ONLY: EGFR alterations. * For Part 2 (Randomized, Controlled Trial) ONLY: EGFRvIII. * For Part 2 (Randomized, Controlled Trial) ONLY: Unmethylated MGMT promoter tumor status based on a validated assay. * No treatment for newly diagnosed GBM other than surgery followed by standard-of-care adjuvant postoperative radiation (54 to 60 Gy) and TMZ chemotherapy. * At least 4 weeks since completion of radiation therapy, with a post-radiation MRI showing no progression. Key

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Exclusion Criteria:

* Recurrent multifocal disease, metastatic, leptomeningeal, or extracranial GBM, or gliomatosis cerebri. * Progression of GBM prior to Enrollment, Screening, or Randomization. * Biopsy-only/no resectional surgery. * Prior or concomitant treatment for GBM with an EGFR-targeting agent, including silevertinib, bevacizumab, cytotoxic chemotherapy, immunotherapy, experimental therapies, Gliadel wafers, GammaTile®, or other intratumoral or intracavitary antineoplastic therapy. * Intent to use Optune® (TTF). * Significant other uncontrolled health conditions or other malignancies.

Conditions & Interventions

Interventions:
DRUG: silevertinib in combination with temozolomide, DRUG: temozolomide (TMZ)
Conditions:
Glioma, Brain Cancer, Glioblastoma (GBM), Newly Diagnosed Glioblastoma, GBM, Glioblastoma Multiforme (GBM), Central Nervous System Diseases
Keywords:
EGFR, Glioblastoma, Unmethylated, Unmethylated MGMT promoter, Newly Diagnosed, temozolomide, Temodar, silevertinib, BDTX-1535, EGFR alterations, epidermal growth factor receptor, EGFRvIII, epidermal growth factor receptor (EGFR)

More Information

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