JOHN WAYNE CANCER INSTITUTE
at Providence Saint John's Health Center

CLINICAL TRIAL ANNOUNCEMENT

Efficacy, Safety and CNS Exposure of G-202 (Mipsagargin) in Patients with PSMA-Positive Recurrent or Progressive Glioblastoma

Glioblastoma (GBM) comprises about 16% of all malignancies of the nervous system and over 50% of all gliomas. Standard of care for newly-diagnosed GBM is a combination of surgical debulking followed by concurrent radiotherapy and chemotherapy with temozolomide. Efforts to improve second-line therapy in GBM have met with only marginal success and there is a large unmet medical need for new therapies.

Prodrug chemotherapy is an approach to cancer treatment that is being investigated as a means to achieve higher concentrations of cytotoxic or biologically active agents at a tumor location while avoiding systemic toxicity. G-202 is an example of prodrug chemotherapy. It is activated by Prostate Specific Membrane Antigen (PSMA), which is expressed by some cancer cells and in the blood vessels of most solid tumors, including GBM, but not by normal cells or blood vessels in normal tissue. It is believed that activation of the prodrug G-202 will allow the drug to kill cancer cells. This study will evaluate the activity, safety and CNS exposure of G-202 in patients with PSMA-positive recurrent or progressive GBM receiving G-202 by intravenous infusion on three consecutive days of a 28-day cycle.

Inclusion Criteria:

- Written informed consent to participate in this study
- Histological confirmation of glioblastoma with PSMA positivity
- Recurrent or progressive GBM following at least one (1) prior therapeutic regimen including upfront radiation and chemotherapy with temozolomide; up to three additional therapeutic regimens for disease progression prior to enrollment to the study is permitted
- Age > 18 years
- Karnofsky Performance Status (KPS) ≥ 60%
- Life expectancy > 2 months
- Adequate hematologic, renal and hepatic function
- Adequate coagulation profile
- Not pregnant, nursing or planning to become pregnant; willing to use contraception

Please feel free to contact the clinical trial team to learn more about this study.

For more information, please contact the Neuro-Oncology Clinical Trial Team at:
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