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

CLINICAL TRIAL ANNOUNCEMENT

Study to Evaluate Eflornithine + Lomustine vs Lomustine in Recurrent Anaplastic Astrocytoma (AA) Patients (STELLAR)

Official Title: A Randomized Phase 3 Open-Label Study To Evaluate the Efficacy and Safety of Eflornithine With Lomustine Compared to Lomustine Alone in Patients With AA That Progress/Recur After Irradiation and Adjuvant Temozolomide Chemotherapy

Eflornithine (DFMO, difluromethylornithine) is a potent, enzyme-activated, irreversible inhibitor of the enzyme ornithine decarboxylase (ODC), the first and rate limiting enzyme in the biosynthesis of polyamines. Polyamines play critical roles in differentiation and proliferation of mammalian cells. Polyamines are also essential for neoplastic transformation, making inhibition of ODC activity an attractive target for a chemotherapeutic agent. Inhibition of polyamine synthesis by **eflornithine** results in growth arrest of a number of malignant and nonmalignant mammalian cells and has been shown to inhibit the promotion and progression phases of carcinogenesis.

Key Inclusion Criteria:

- Surgical or biopsy-proven diagnosis of WHO grade 3 AA.
- Unequivocal evidence of first AA tumor progression or recurrence ≤ 3 months prior to randomization based on MRI criteria for tumor progression using enlarging Gd-contrast enhancement and/or T2 hypersensitivity .
- First tumor progression or recurrence following surgical resection or biopsy, if resection is not feasible, EBRT and temozolomide chemotherapy.
- Completion of EBRT ≥ 6 months prior to randomization.

Exclusion Criteria:

- MRI defining progression is consistent with a diagnosis of glioblastoma or radiation necrosis.
- Patients who are considered to be refractory to EBRT and temozolomide but who have not progressed.
- Prior systemic therapy for recurrence of AA.
- Presence of extracranial or leptomeningeal disease.
- Prior lomustine use.

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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Sponsor

Orbus Therapeutics , Inc.

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