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Trial record **1 of 1** for: STELLAR AND Orbus Therapeutics

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

This study is currently recruiting participants.

See [▶ Contacts and Locations](#)

Verified October 2017 by Orbus Therapeutics, Inc.

Sponsor:

Orbus Therapeutics, Inc.

ClinicalTrials.gov Identifier:

NCT02796261

First Posted: June 10, 2016

Last Update Posted: October 27, 2017

⚠ The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. [Know the risks and potential benefits](#) of clinical studies and talk to your health care provider before participating. Read our [disclaimer](#) for details.

Information provided by (Responsible Party):

Orbus Therapeutics, Inc.

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[▶ Purpose](#)

The purpose of this study is to compare the efficacy and safety of eflornithine in combination with lomustine, compared to lomustine taken alone, in treating patients whose anaplastic astrocytoma has recurred/progressed after radiation and temozolomide chemotherapy.

<u>Condition</u>	<u>Intervention</u>	<u>Phase</u>
Anaplastic Astrocytoma	Drug: Eflornithine	Phase 3
Recurrent Anaplastic Astrocytoma	Drug: Lomustine	

Study Type: Interventional

Study Design: Allocation: Randomized

Intervention Model: Parallel Assignment

Masking: None (Open Label)

Primary Purpose: **Treatment**

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

Resource links provided by NLM:

[Drug Information](#) available for: [Lomustine](#) [Eflornithine hydrochloride](#)

[Genetic and Rare Diseases Information Center](#) resources: [Glioma](#) [Anaplastic Astrocytoma Neuroepithelioma](#)

[U.S. FDA Resources](#)

Further study details as provided by Orbus Therapeutics, Inc.:

Primary Outcome Measures:

- Overall survival [Time Frame: 4 years]

Secondary Outcome Measures:

- Progression-free survival (PFS) [Time Frame: 4 years]
- Objective response rate (ORR) [Time Frame: 4 years]

Other Outcome Measures:

- Clinical benefit response (CBR) based on magnetic resonance imaging (MRI) criteria [Time Frame: 4 years]
- OS rate at 18 months (OS-18) [Time Frame: 18 months]

- Relevance of OS, PFS, ORR, and CBR to commonly used molecular/genetic biomarkers obtained from most recent pre-study tumor samples [Time Frame: 4 years]
- Pharmacokinetic Analysis - Maximum concentrations (Cmax) of eflornithine in plasma will be determined. [Time Frame: 1 Month]
- PK - Area under the curve (AUC) of eflornithine in plasma will be determined. [Time Frame: 1 Month]

Estimated Enrollment: 280
 Study Start Date: July 2016
 Estimated Study Completion Date: August 2019
 Estimated Primary Completion Date: June 2019 (Final data collection date for primary outcome measure)

<u>Arms</u>	<u>Assigned Interventions</u>
<p>Experimental: Eflornithine + Lomustine</p> <p>Eflornithine dosed on a 2 weeks on, 1 week off schedule + Lomustine dosed every 6 weeks</p>	<p>Drug: Eflornithine</p> <p>Eflornithine 2.8 g/m² administered orally every 8 hours on a 2 week on, 1 week off schedule</p> <p>Other Name: DFMO</p> <p>Drug: Lomustine</p> <p>Lomustine 90 mg/m² administered orally once every 6 weeks</p> <p>Other Names:</p> <ul style="list-style-type: none"> • CCNU • CeeNU
<p>Active Comparator: Lomustine</p> <p>Lomustine dosed every 6 weeks</p>	<p>Drug: Lomustine</p> <p>Lomustine 110 mg/m² administered orally once every 6 weeks</p> <p>Other Names:</p> <ul style="list-style-type: none"> • CCNU • CeeNU

Detailed Description:

This study will consist of 4 study periods of up to 50 months in total, consisting of:

Screening Period - A maximum screening duration of 4 weeks.

Treatment Period - Treatment Arm A up to 24 months; Treatment Arm B up to 12 months.

End of Treatment Visit - A minimum of 4 weeks post last treatment for both arms.

Follow-Up Period - Up to 24 months.

A total of approximately 280 patients will be randomized in a 1:1 ratio to receive either eflornithine + lomustine or lomustine alone.

► Eligibility

Information from the National Library of Medicine



Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, [Learn About Clinical Studies](#).

Ages Eligible for Study: 18 Years and older (Adult, Senior)

Sexes Eligible for Study: All

Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

Patients must meet all of the following inclusion criteria to be eligible for participation in this study:

- Surgical or biopsy-proven diagnosis of WHO grade 3 AA.
- Unequivocal evidence of first AA tumor progression or recurrence \leq 3 months prior to randomization based on MRI criteria for tumor progression using enlarging Gd-contrast enhancement and/or T2 hyperintensity. Patients with non-measurable Gd contrast enhancing tumors will only be eligible if there is no necrosis seen on MRI and/or histopathological confirmation of AA per standard of care procedures is obtained.
- First tumor progression or recurrence following surgical resection or biopsy, if resection is not feasible, EBRT and temozolomide chemotherapy.
- Completion of EBRT \geq 6 months prior to randomization.
- A patient whose AA tumor has progressed or recurred and has had another surgical resection prior to randomization will be eligible if a) pathology review confirms AA, and b) post-surgical MRI demonstrates measurable tumor on T2/FLAIR.

- Karnofsky Performance Status (KPS) score of ≥ 70 .

Exclusion Criteria:

Patients who meet any of the following exclusion criteria are not eligible for study participation:

- 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.
- Any other clinical condition or prior therapy that, in the opinion of the Investigator, would make the patient unsuitable for the study.
- Pregnant or breastfeeding.

▶ Contacts and Locations

Information from the National Library of Medicine



To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number):
NCT02796261

Contacts

Contact: Marietta Franco, MS 6504506634 marietta.franco@orbustherapeutics.com

Contact: Kathleen Villamejor, BS 6506569424 kathleen.villamejor@orbustherapeutics.com



[Show 79 Study Locations](#)

Sponsors and Collaborators

Orbus Therapeutics, Inc.

Investigators

Study Director: Marietta Franco, MS **Orbus Therapeutics, Inc.**

▶ More Information

Responsible Party: Orbus Therapeutics, Inc.
ClinicalTrials.gov Identifier: [NCT02796261](#) [History of Changes](#)
Other Study ID Numbers: OT-15-001
First Submitted: June 3, 2016
First Posted: June 10, 2016
Last Update Posted: October 27, 2017
Last Verified: October 2017

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD: No

Keywords provided by Orbus Therapeutics, Inc.:

Anaplastic Astrocytoma	Progressive Anaplastic Astrocytoma
Grade 3 Glioma	Recurrent Anaplastic Astrocytoma
Glioma	Progressive Glioma
Eflornithine	Recurrent Glioma
Brain Cancer	Malignant Glioma
Brain Tumor	Progressive Brain Tumor
Neuro-oncology	Recurrent Brain Tumor

Additional relevant MeSH terms:

Astrocytoma	Antineoplastic Agents, Alkylating
Glioma	Alkylating Agents
Neoplasms, Neuroepithelial	Molecular Mechanisms of Pharmacological Action
Neuroectodermal Tumors	Antineoplastic Agents
Neoplasms, Germ Cell and Embryonal	Trypanocidal Agents
Neoplasms by Histologic Type	Antiprotozoal Agents
Neoplasms	Antiparasitic Agents
Neoplasms, Glandular and Epithelial	Anti-Infective Agents
Neoplasms, Nerve Tissue	Ornithine Decarboxylase Inhibitors
Lomustine	Enzyme Inhibitors
Eflornithine	