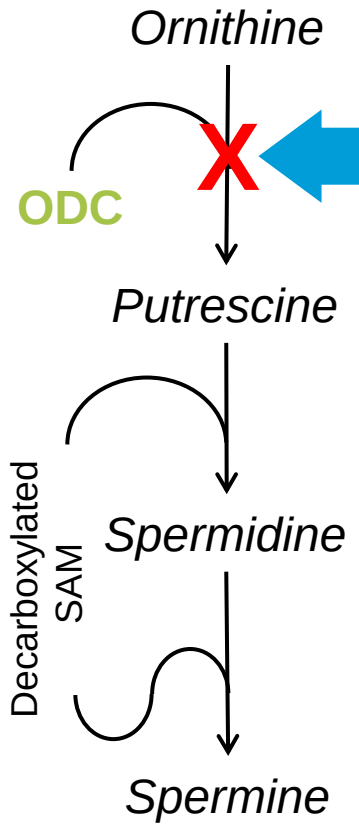
Orbus Therapeutics, Inc.

STELLAR Study

Eflornithine is a Novel Targeted Cancer Therapy that Functions through Metabolic Inhibition

Ornithine decarboxylase (ODC)
- Controls biosynthesis of polyamines
- Essential for cell division and differentiation



Eflornithine:

- Highly selective, irreversible inhibitor of ODC
  - Disrupts DNA & mRNA stabilization
  - Interrupts transcription & translation
  - ***Inhibits cell growth and proliferation***
- Small molecule, orally bioavailable, H_2O soluble
- Not metabolized; cleared through renal elimination

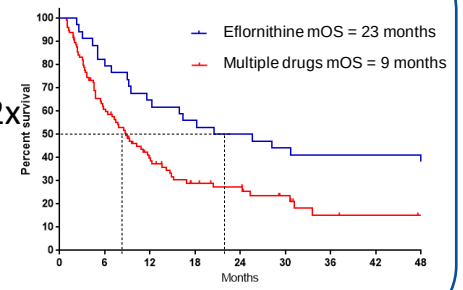
Source(s): C. Kahana, Weizmann Institute of Science; Polyamine Drug Discovery, Ch 11, Bachman & Levin

Eflornithine has Demonstrated Efficacy in Multiple Controlled Clinical Studies in Malignant Glioma

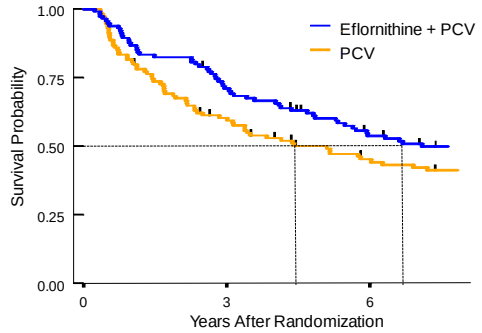
- **Over 390 patient exposures** to date
- **Phase 1, 2 and Phase 3** studies have been completed in high grade glioma
- Eflornithine in malignant glioma tested as single agent and in combination with SOC

Source: Levin, et al., CNS Oncology, 30 Jan 2018

- ✓ 34 rAA patients
- ✓ Improvement in survival (mOS) of 14 months (>2x improvement) over historical controls
- ✓ OS-48 > 40%



- ✓ 228 patients newly diagnosed Grade 3 glioma patients
- ✓ Randomized 1:1 to PCV (SOC chemotherapy) vs. PCV + eflornithine
- ✓ Improved survival > 50% over SOC alone

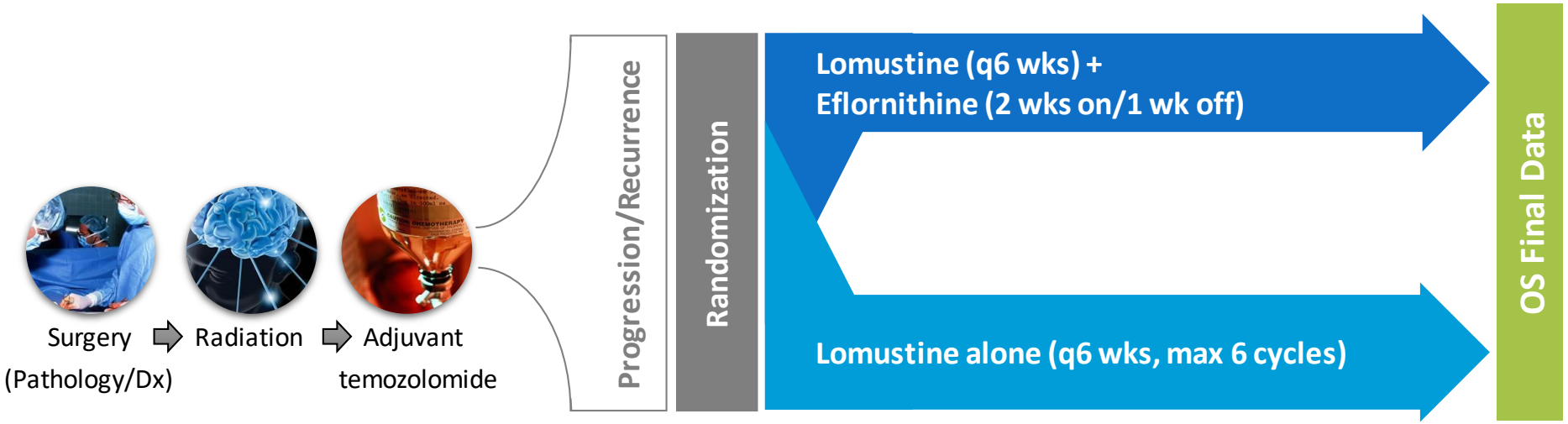


NCI IND
NIH funded
CTEP audited

Multi-center studies
Collaboratively run in US
by CCOP

Study Design and Overview

Phase 3, Randomized, Open-Label **S**tudy **T**o Evaluate the **E**fficacy and Safety of Eflornithine with **L**omustine Compared to **L**omustine Alone in Patients with Anaplastic **A**strocytoma That Progress/**R**ecur After Irradiation and Adjuvant Temozolomide Chemotherapy



Primary objective is to show an improvement in overall survival in recurrent anaplastic astrocytoma patients treated with lomustine + eflornithine compared to lomustine alone

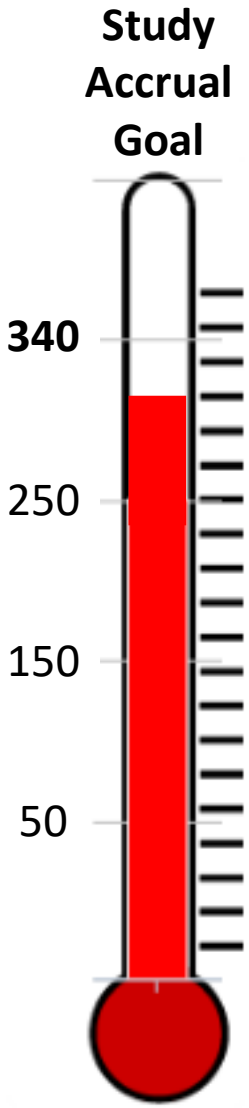
Eligibility Criteria

✓ Inclusion Criteria

- Surgical or biopsy-proven diagnosis of WHO grade 3 AA
- 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
- Karnofsky Performance Status score of > 70

✗ Exclusion Criteria

- MRI defining progression is consistent with a diagnosis of glioblastoma or radiation necrosis
- Prior systemic therapy for recurrence of AA
- Prior lomustine use
- Unable to undergo an MRI with contrast



Study Resources

Study website:
www.stellarstudy.com

Facebook page and ad campaign:
https://www.facebook.com/STELLARstudy/

Stellar study Twitter page (@StellarStudy):
https://twitter.com/stellarstudy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