



Numiera Therapeutics

STALLING THE ENGINES OF CANCER CELLS

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Disease Indication



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- Glioblastoma is an aggressive and fatal brain tumor
- 34,000 newly-diagnosed patients annually in US + EU
- Only one new therapy has benefited GBM patients in 50 years and been integrated into standard-of-care.
- *This drug – temozolomide – only gives patients a few extra months and has serious side effects.*
- *Many patients also take the approved drug bevacizumab, which has no significant survival benefit but reduces brain swelling.*

➤ *Urgent unmet need*

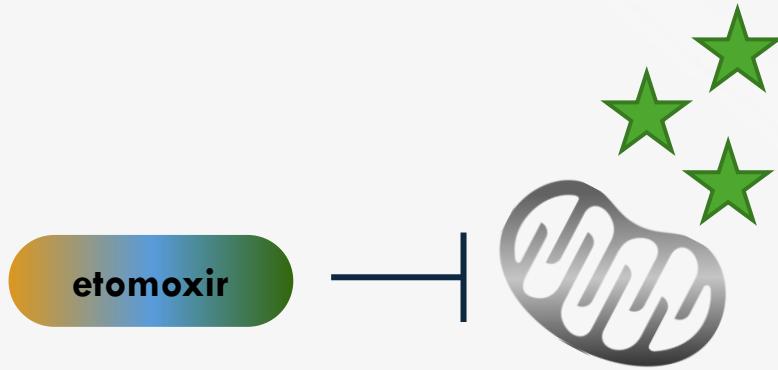




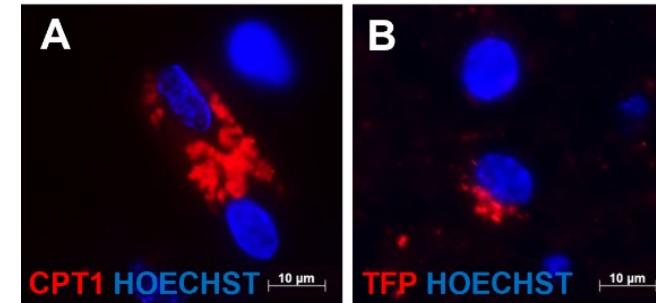
Innovative Solution



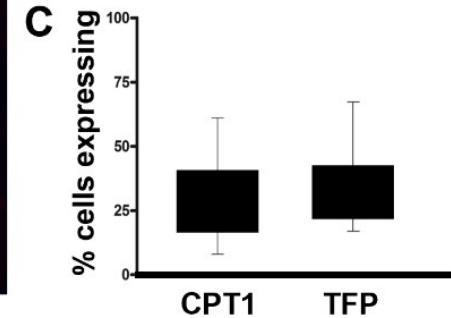
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First-In-Class
Small-Molecule
CPT-1 Inhibitor



Lin et al. (2017) *Neuro Oncol* 19(1):43-54



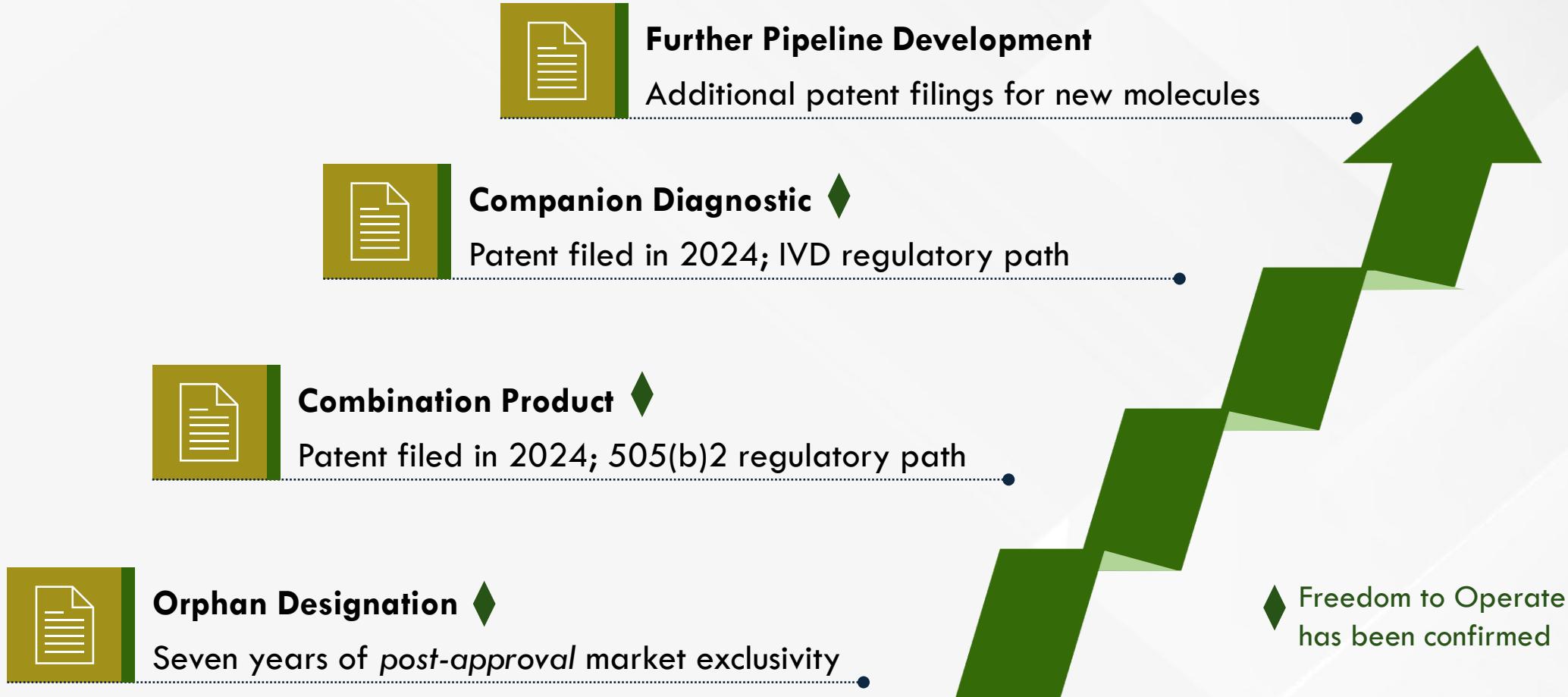
The target protein (CPT1) - and other enzymes involved in mitochondrial fatty acid oxidation - are present in every human GBM sample studied.



Intellectual Property



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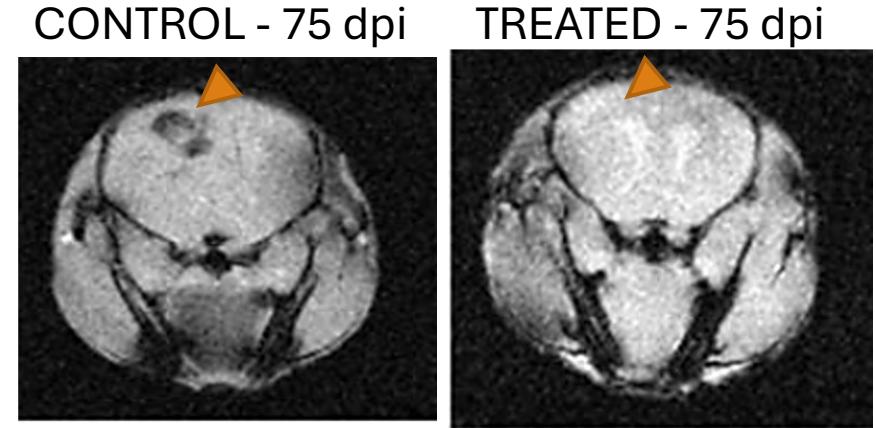
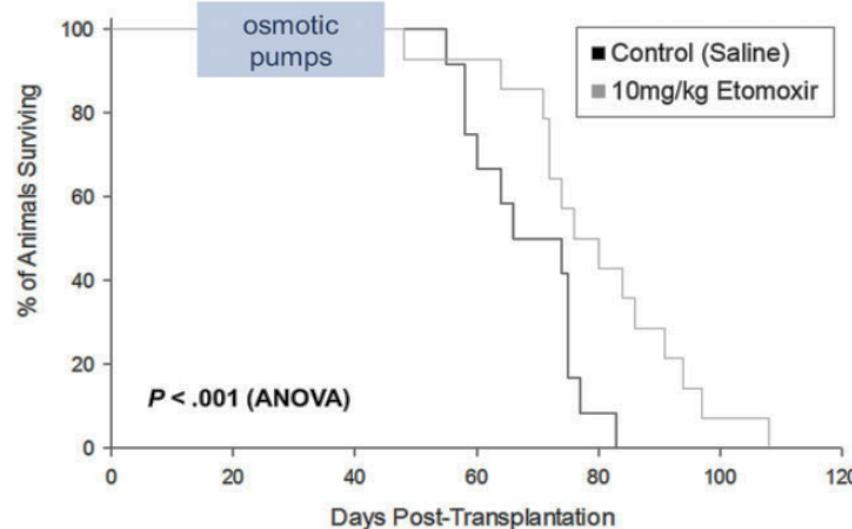
Preclinical Efficacy



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Mouse model of malignant glioma



10 mg/kg etomoxir treatment for 28 days

Awarded by **SNO**
The Society for NeuroOncology

Lin et al. (2017)
Neuro Oncol 19(1):43-54.
Syngeneic mouse model
> ETX slows tumor growth

Independently-replicated single-agent efficacy in glioblastoma from four other labs

Kant et al. (2020)
Cell Death Dis 11:253.
Implanted patient cells
> ETX slows tumor growth

Shim et al. (2022)
Cancer Cell Int 22:309.
Implanted patient cells
> ETX slows tumor growth

Jiang et al. (2022)
Nature Comms 13:1511.
Implanted U261 cells
> ETX slows tumor growth

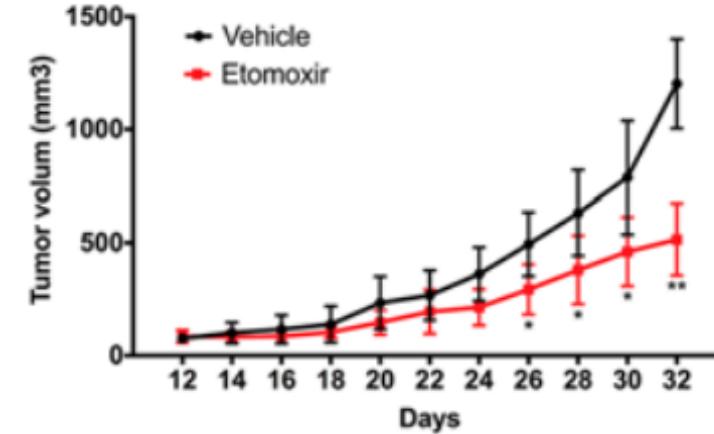
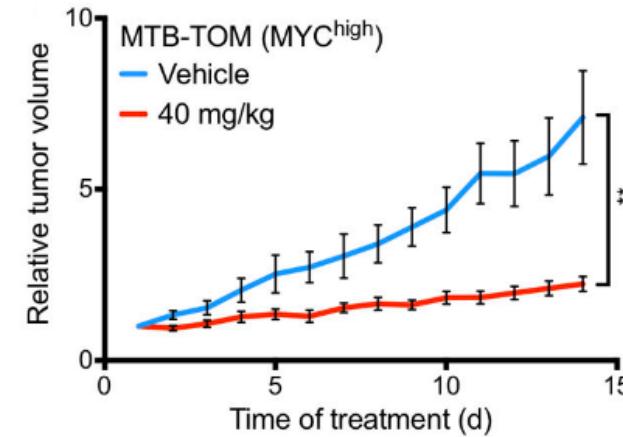
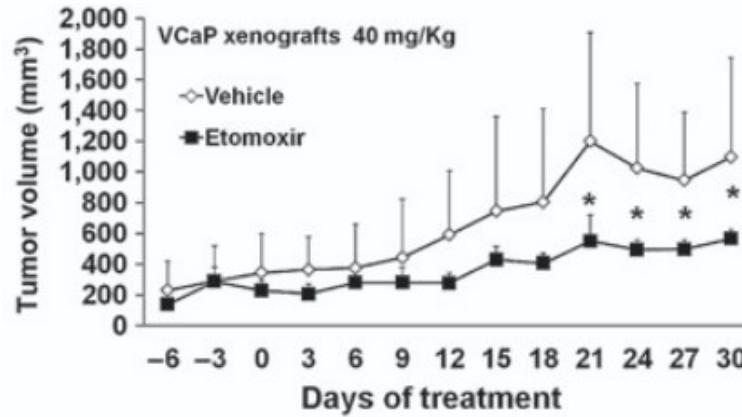
Duman et al. (2023)
Cell Death Dis 14:296.
Implanted NCH421K cells
> ETX slows tumor growth



Additional Indications



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Prostate Cancer:

Schlaepfer et al. (2019)
Mol Cancer 13(10); 2361-71

Breast Cancer:

Camarda et al. (2016)
Nat Med 22(4): 427-32

Bladder Cancer:

Cheng et al. (2019)
Clin Sci 133: 1745-58

This molecular target is present in multiple aggressive cancers, and etomoxir significantly slows tumor growth.



Clinical Safety



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Etomoxir †		Temodar (Temozolomide) *		Avastin (Bevacizumab) #	
Survival Benefit in Glioblastoma	?	Survival Benefit in Glioblastoma	2.5 months	Survival Benefit in Glioblastoma	2.2 months
Percentage of Patient Population Taking This Drug	?	Percentage of Patient Population Taking This Drug	80%	Percentage of Patient Population Taking This Drug	49%
Serious Side Effects		Serious Side Effects		Serious Side Effects	
High liver enzyme levels	<2%	High liver enzyme levels	12%	High blood pressure	18%
Moderate/Severe		Moderate/Severe		Moderate/Severe	
Cardiac arrhythmia or failure	<2%	Low platelet count	14%	Blood clots, stroke or heart attack	11%
Moderate/Severe		Moderate/Severe		Severe/Can Be Fatal	
		Bone marrow depletion	<10%	Kidney Problems	<7%
		Severe/Can Be Fatal		Severe/Can Be Fatal	
		Induction of other cancers	<2%	Fistula	<2%
		Severe/Can Be Fatal		Severe/Can Be Fatal	
Common Side Effects		Common Side Effects		Common Side Effects	
Increased exercise tolerance		Headache		Headache	
		Nausea		Back Pain	
		Vomiting		Watery Eyes	
		Hair Loss		Inflammation	
		Fatigue		Nosebleed	
Etomoxir †		Temodar (Temozolomide) *		Avastin (Bevacizumab) #	
Lower hepatotoxicity than standard of care Temodar or Avastin. Fewer deaths in treated group (0.9%) than placebo group (3.3%).		Serious adverse effects include liver toxicity, thrombocytopenia, bone marrow depletion and the induction of other cancers.		Serious adverse effects include heart attack, stroke, blood clots, kidney problems, and fistulas which are sometimes fatal.	

† Holubarsch et al. *Clin Sci (Lond)* 2007
226 human subjects treated w/ etomoxir

* Stupp et al. *New Engl J Med* 2005
and GoodRx.com

Gramatzki et al. *Ann Oncol* 2018
and Avastin.com

Our Goal:

Move our
well-characterized
orphan lead asset
to market approval

Build out pipeline
to expand into
additional oncology
indications

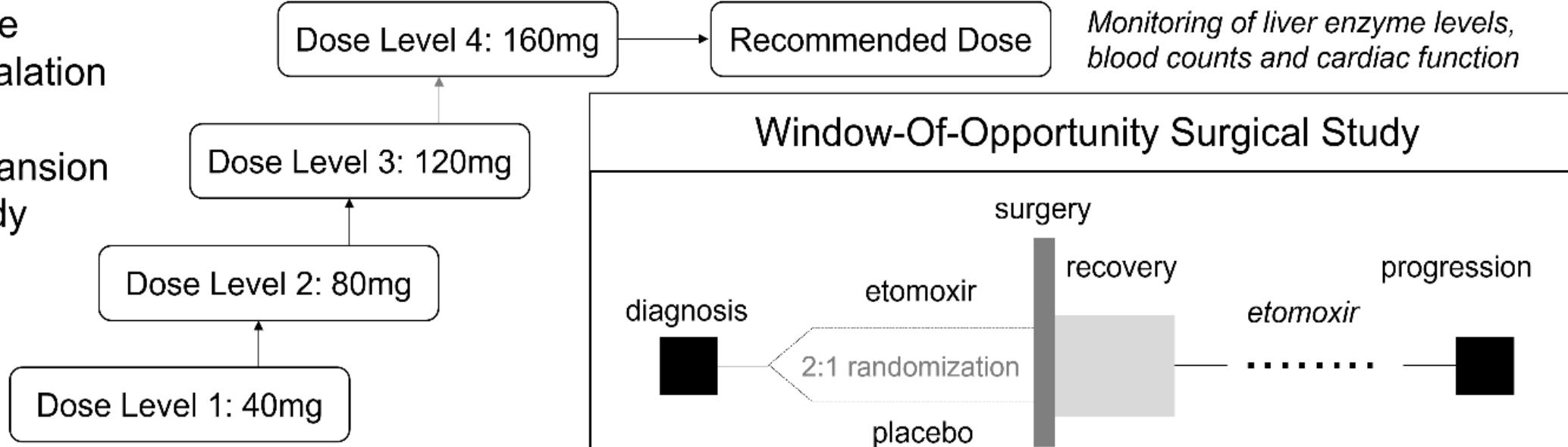


Trial Design



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Dose Escalation And Expansion Study



Open-Label Dose Escalation Study:

Success Indicator: Identification of a daily dose of etomoxir that does not cause Grade 3 or higher adverse events.

Window-of-Opportunity Surgical Study:

Success Indicator: With accrual of 20 patients, 8 patients reaching six-months progression-free survival (PFS6) would be significant, compared with 6 patients under historical control conditions. We will also conduct pharmacological analysis on the resected tissue.

Then: Move into a Combined Phase II/III Clinical Trial with Bayesian Design + Existing Master Protocol



Competitive Advantages



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We have received orphan designation on our lead asset: etomoxir

25% of orphan designated products achieve market authorization.

5.3 years is the average time to market authorization from the date of orphan designation.

Phase I clinical data¹ in 226 human subjects indicates our drug is safer than standard of care.

Four additional labs² have independently replicated our preclinical efficacy data for this drug.

Additional cancer indications represent a \$50B market with further pipeline development.

“I do have the advantage of having seen many, many hundreds of potential new therapies. Numiera Therapeutics’ product is in the top tier of my universe.”

- Tim Cote, First Director of the FDA Office of Orphan Products Development



Market Opportunity



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Treatment-resistant
cancers with this
mitochondrial target
have **TAM of \$50B+**

Overall brain tumor
SAM of \$8B+ by
expected market
approval date

US/EU glioblastoma
SOM of \$2B+ by
expected market
approval date

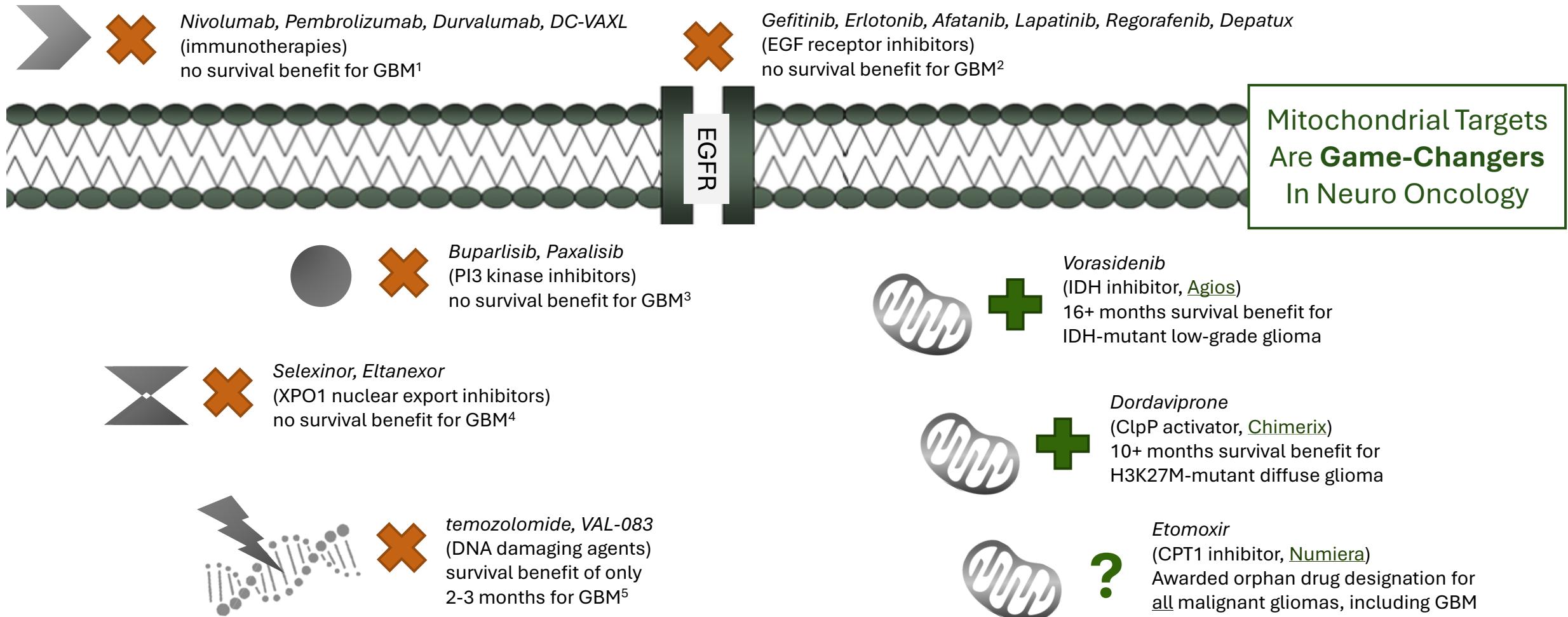




Competitive Landscape



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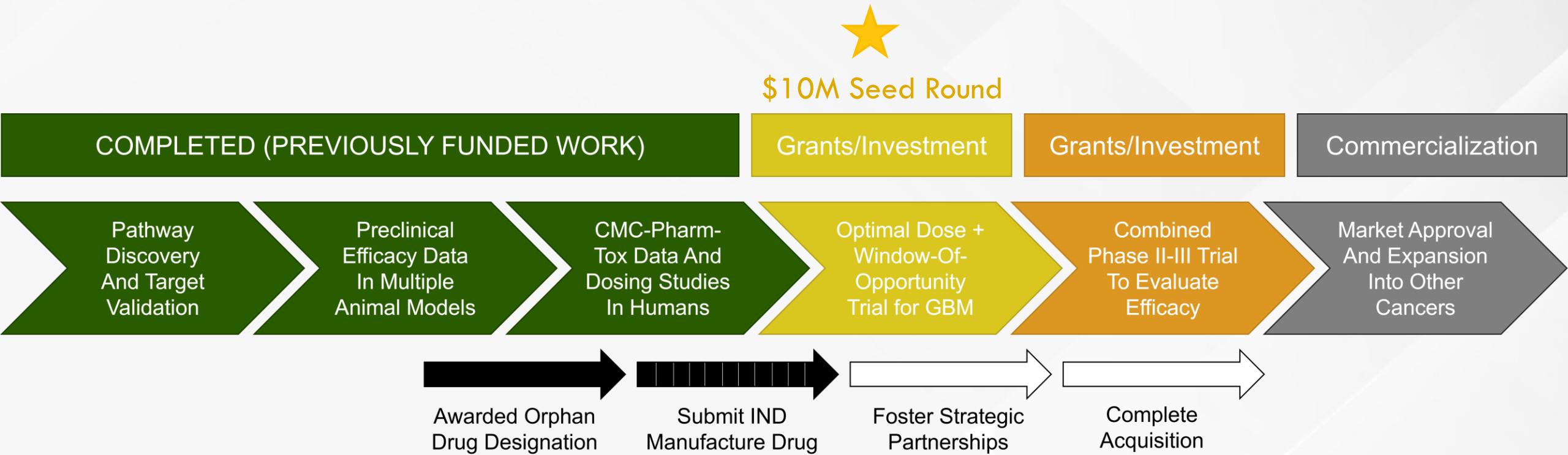




Commercialization Pathway

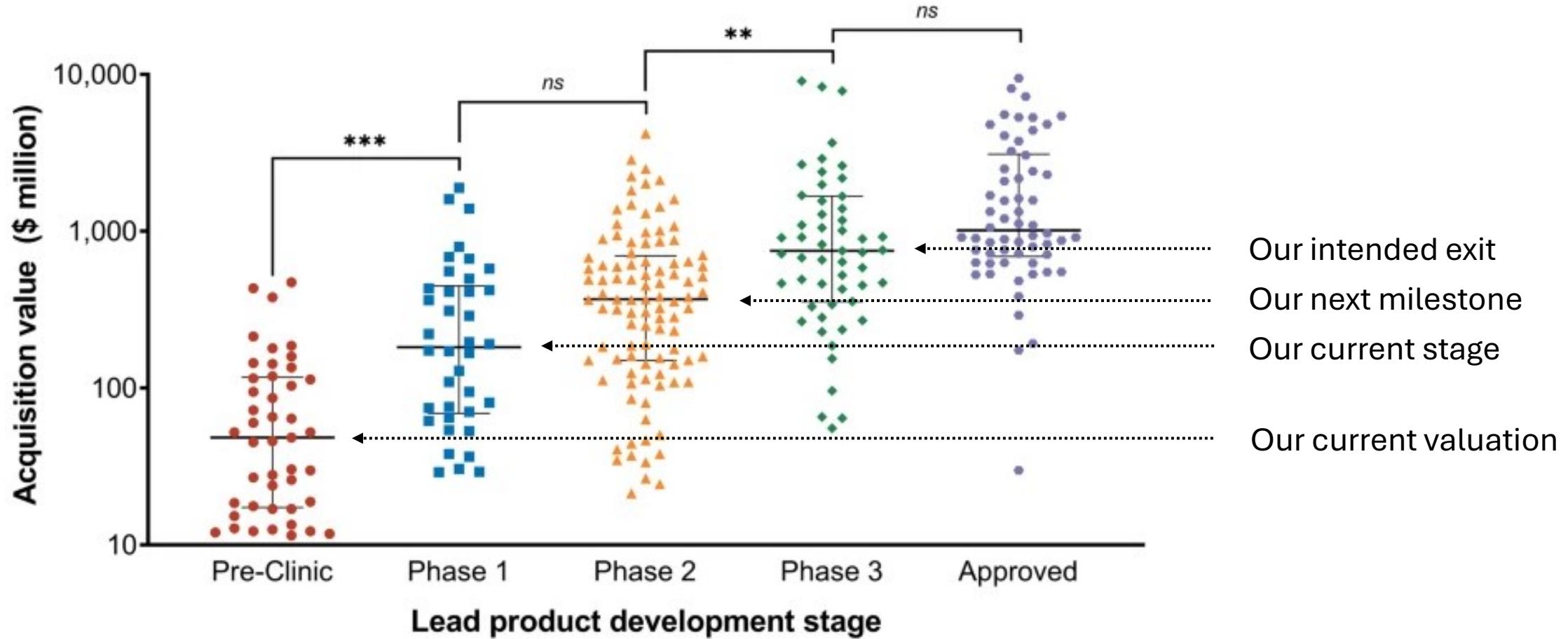


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Exit Comps





Leadership Team

Izi Stoll, PhD
CEO/Founder



WESTERN INSTITUTE
FOR
ADVANCED STUDY

Karl Nicholls, CPA
Financial Operations



Gordon Beck, PhD
Corporate Strategy



Dustin Key, MS
Data Management



Vicky Abbas, RN
Clinical Operations



Patrick Wen, MD
Neuro Oncologist



Key Partners



TECH.
SCIENCE.
ACCELERATED.



SHERIDAN ROSS pc
attorneys at
innovation

Morgan Lewis



TIE
GLOBAL
FOSTERING
ENTREPRENEURSHIP



Thank You!



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Let's talk more:
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