A Natural Nanoparticle Platform for Drug Delivery to the Brain

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TEAM

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Associate Professor of Neurosurgery and of Biomedical Engineering

Preclinical characterization (Nature Materials, 2012; PNAS, 2007, 2012)

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Associate Professor of Neurology and of Neurosurgery; Associate Chair of Clinical Research

Clinical translation (Lancet Neurology, 2016; Global PI of CHARM phase III glyburide trial)

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BACKGROUND

- Stroke as a major public health disease: ~700,000 diagnosis in the US, 8 billion market
- A unique delivery system selected for efficiently penetrates the blood brain barrier
- Strong preliminary data in gold standard animal model of stroke
- Lead nanoparticle carries an exciting small molecule that has been tested in phase II stroke trials by our team

OUR BREAKTHROUGH

Library of natural compounds that form nanoparticles (NPs) for drug delivery

	Brain penetration	Oral bioavailable	Antioxidant	Commercially available	Tested in human
Betulinic acid (BA)	*****	*****	******	**Y**	**Y**
Sumaresinolic acid (SA)	*	***	***	Y	
Stigmasterol (ST)	*	**	***	Y	
Dehydrotrametenolic acid (DHA)	****	****	N	N	N
Poricoic acid A (PAA)	-	***	-	N	
Others…					

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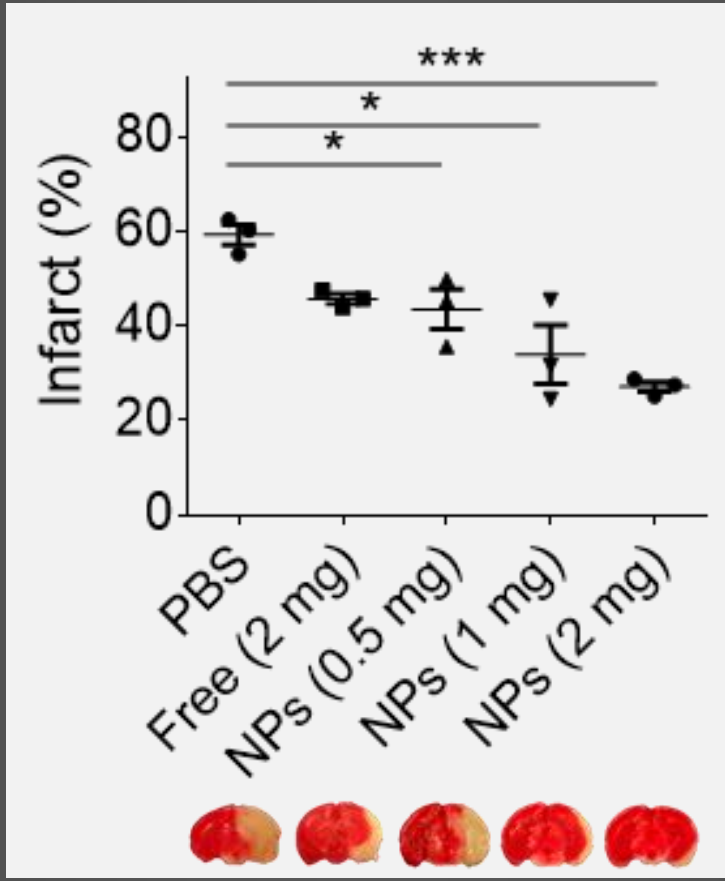
BETULINIC ACID NANOPARTICLES (BA NPS) ALONE IMPROVE STROKE OUTCOME



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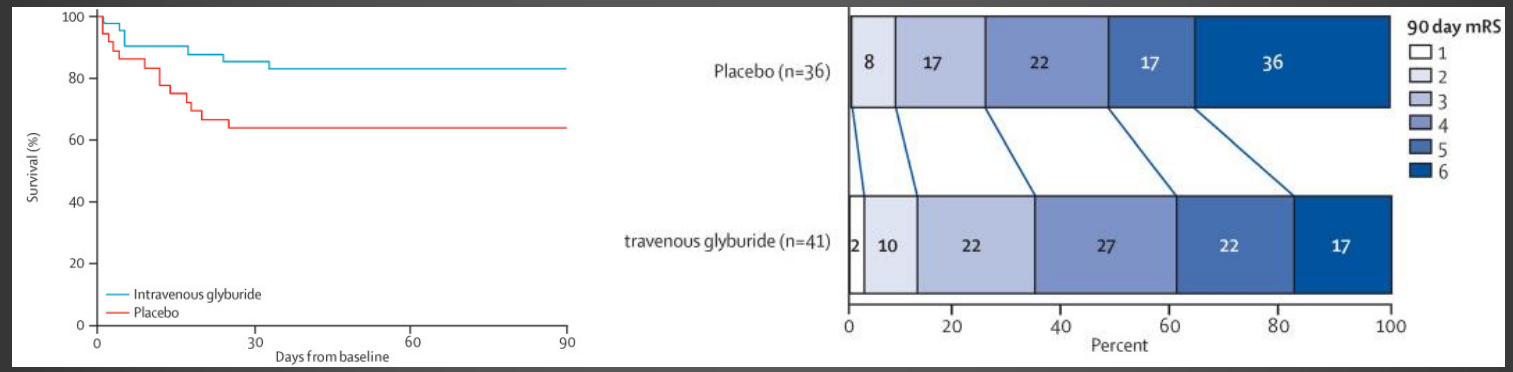
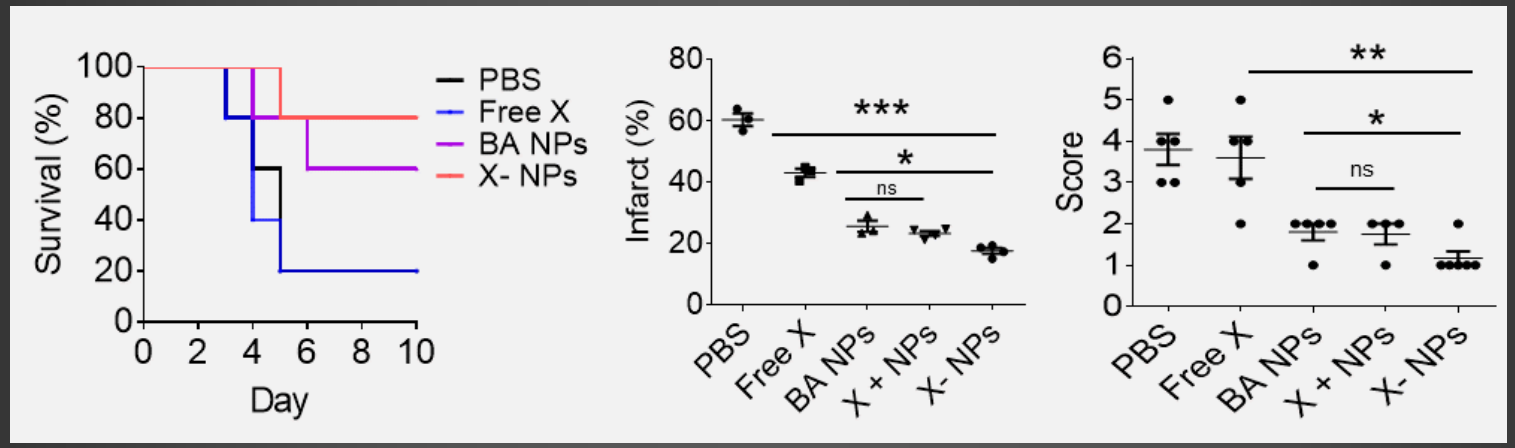
LEAD PRODUCT

Compound X-loaded BA NPs significantly outperform free compound for stroke treatment



Characterization of compound X- loaded BA NPs in stroke mice



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COMPOUND X- LOADED BA NPS VERSUS FREE COMPOUND X

	Compound X	Compound X- BA NPs
Efficacy*	**	*****
Biological function	Anti-edema	Anti-edema + Antioxidant
Brain penetration	*	*****
Convenience for clinical use	**Not**	**Yes**
Human patients	Continuous infusion for 7 d	Single injection daily for 2 d
Animal studies	Continuous infusion for 3 d	TBD
Accessibility to patients	*	*****
Storage and transport	Poor. Special storage needed	Great. Stable lyophilized powder

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PLATFORM TECHNOLOGY

Robust IP protection with freedom to operate

Compound X as the payload is an off-patent generic drug without IP protection

OCR has filed 1 patent to protect the platform

PCT/US 2018/038686

Nanomaterials with enhanced drug delivery efficiency

Patent application for Compound X-load BA-NPs is being filed

Platform has been validated for delivery of therapeutic agents

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MARKET & COMPETITION ANALYSIS

Ischemic Stroke US Market Fast Facts

- Affects 790,000+ in the US
- Causes 1 out of every 20 deaths, costs ~$34B annually in the US
- Projected US market size of $9B by 2023
- Growing at a CAGR of 5.6%
- **No FDA approved pharmacotherapies for neuroprotection**

Available Therapies

Tissue Plasminogen Activator (tPA)
only FDA approved treatment

Genentech
A Member of the Roche Group

Activase (alteplase)

Competition

- **NA1**, the only other CNS drug aimed at neuroprotection (PSD-95 inhibitor) beyond phase I
  - Narrow population
  - Also does not penetrate the blood-brain-barrier
  - Unless you use our platform!.

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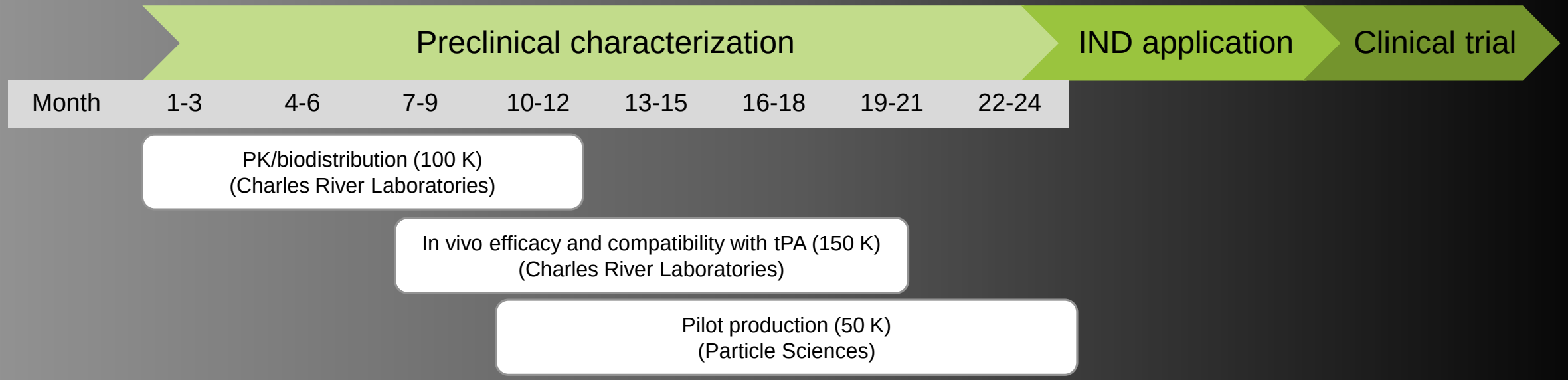
USE OF BLAVATNIK FUNDS (300K)



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