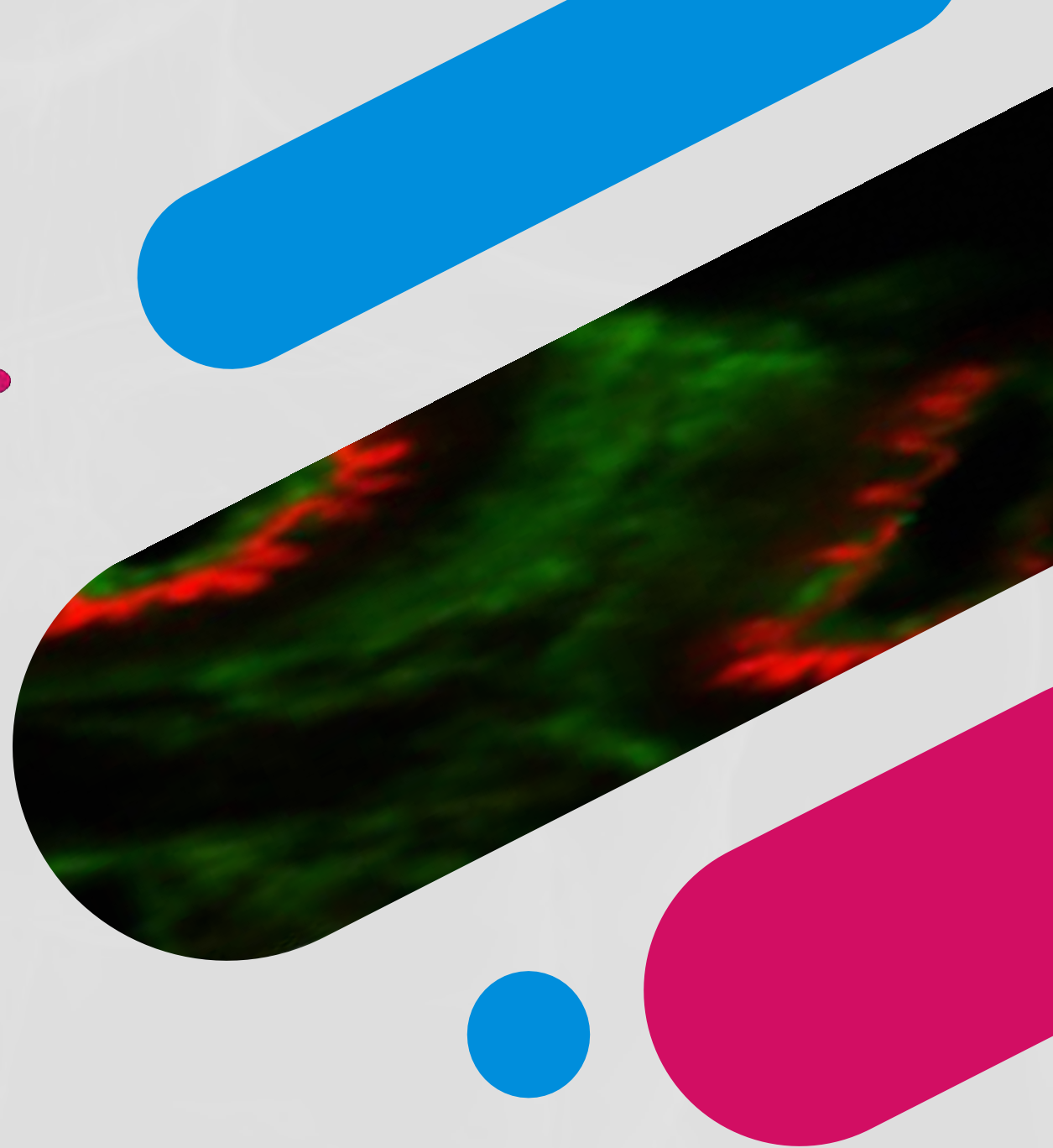




PHARMAZZ  
EXCELLENCE IN CRITICAL CARE MEDICINE

# Corporate Presentation

March 2024



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# PHARMAZZ AT A GLANCE



## Two first-in-class drug candidates with positive Phase 3 data in acute cerebral ischemic stroke and hypovolemic shock

### SOVATELTIDE



- **A neuroprotective, neuroregenerative, endothelin-B agonist for acute cerebral ischemic stroke**
- Phase 3 data showed statistically significant clinically meaningful improvement in key neurological outcomes
- Approved for marketing in India; partnership with Sun Pharmaceuticals, >15,000 patients treated since launch on September 14, 2023.
- US IND for Phase 3 trial in acute cerebral ischemic stroke approved by the FDA.
- A Special Protocol Assessment agreement was reached with the FDA for a Phase 3 trial of sovateltide to treat stroke
- Enrolling patients for phase II Hypoxic-Ischemic Encephalopathy

### CENTHAQUINE



- **A resuscitative agent without arterial constriction for hypovolemic shock**
- Promising results, improved stroke volume, cardiac output, and survival
- Approved for marketing in India; partnership with Dr. Reddy's Laboratory for sales and distribution in India
- US IND for Phase 3 approved for hypovolemic shock

### SALES & DISTRIBUTION



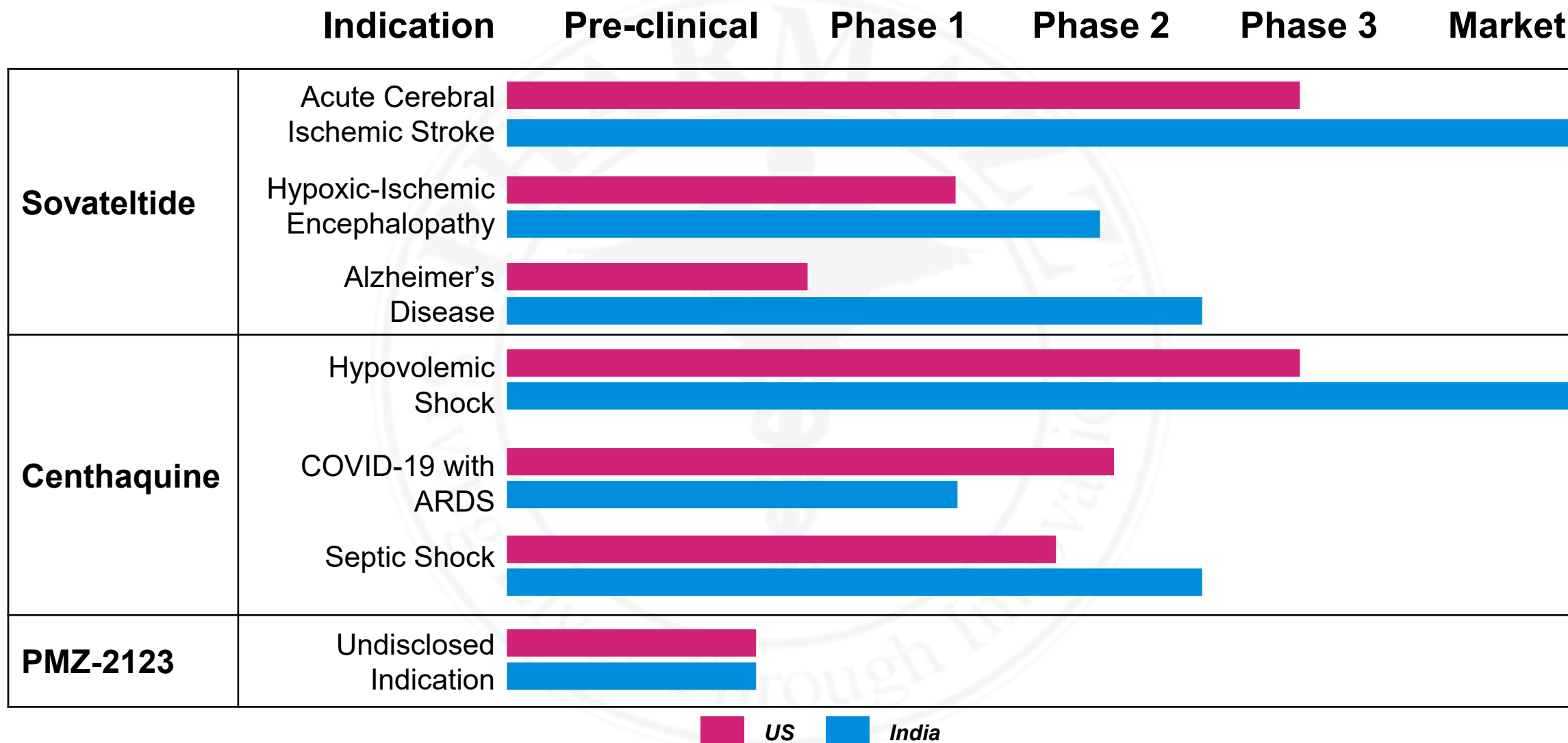
- Sun Pharmaceuticals markets Sovateltide under its brand Tyvalzi™ in India



- **Centhaquine, branded as Lyfaquin® in India, marketed by Dr. Reddy's Laboratory**



# Product Pipeline

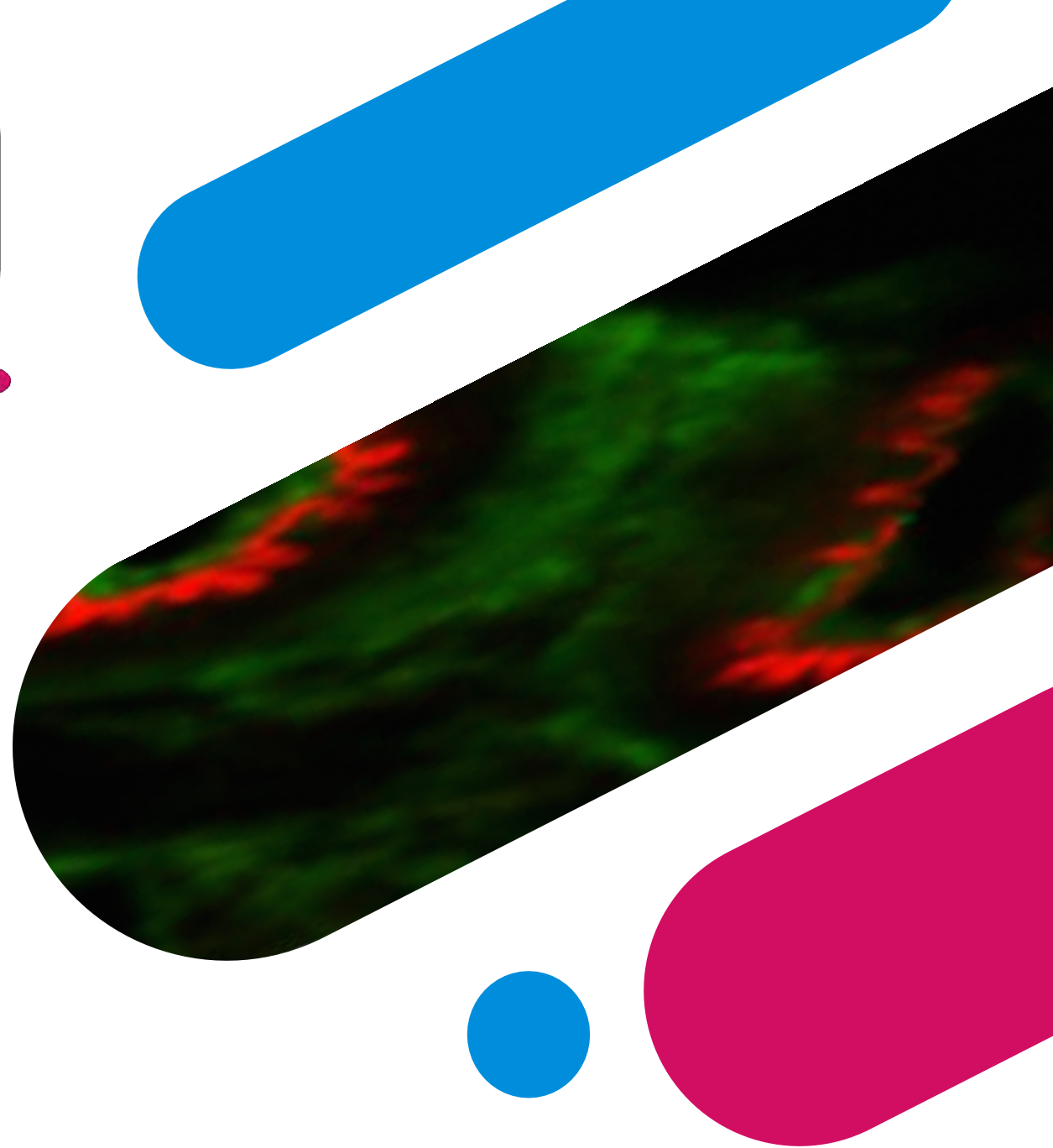


# Sovateptide

The first drug candidate  
to demonstrate  
statistically significant  
results in acute cerebral  
ischemic stroke since  
tPA



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# Sovateltide: Phase 3 Trial Results



## Sovateltide met Key Primary Endpoints

Primary Outcomes	Control (N=70)	Sovateltide (N=67)	Treatment Effect	P Value
Modified Rankin scale at 90 days (Median Score (IQR))	2.00 (1.00 to 3.00)	1.00 (0.00 to 2.00)	Mean diff. = -0.622 95% CI -1.078 to -0.167	0.0078
NIHSS scale at 90 days (Median Score (IQR))	3.00 (0.00 to 6.00)	1.00 (0.00 to 3.00)	Mean diff. = -1.586 95% CI -2.600 to -0.573	0.0024
Barthel Index at 90 days (Median Score (IQR))	85.00 (60.0 to 100.0)	95.00 (80.0 to 100.0)	Mean diff. = 10.190 95% CI 2.375 to 18.000	0.0110
Improvement of $\geq 2$ on Modified Rankin scale score at 90 days	52.86% (N=37)	76.12% (N=51)	Odds 2.843 95% CI 1.368 to 6.015	0.0045
Improvement of $\geq 6$ points on the NIHSS at 90 days	64.29% (N=45)	82.09% (N=55)	Odds 2.546 95% CI 1.176 to 5.798	0.0190
Improvement of $\geq 40$ points on the Barthel Index at 90 days	61.43% (N=43)	76.12% (N=51)	Odds 2.001 95% CI 0.938 to 4.276	0.0640

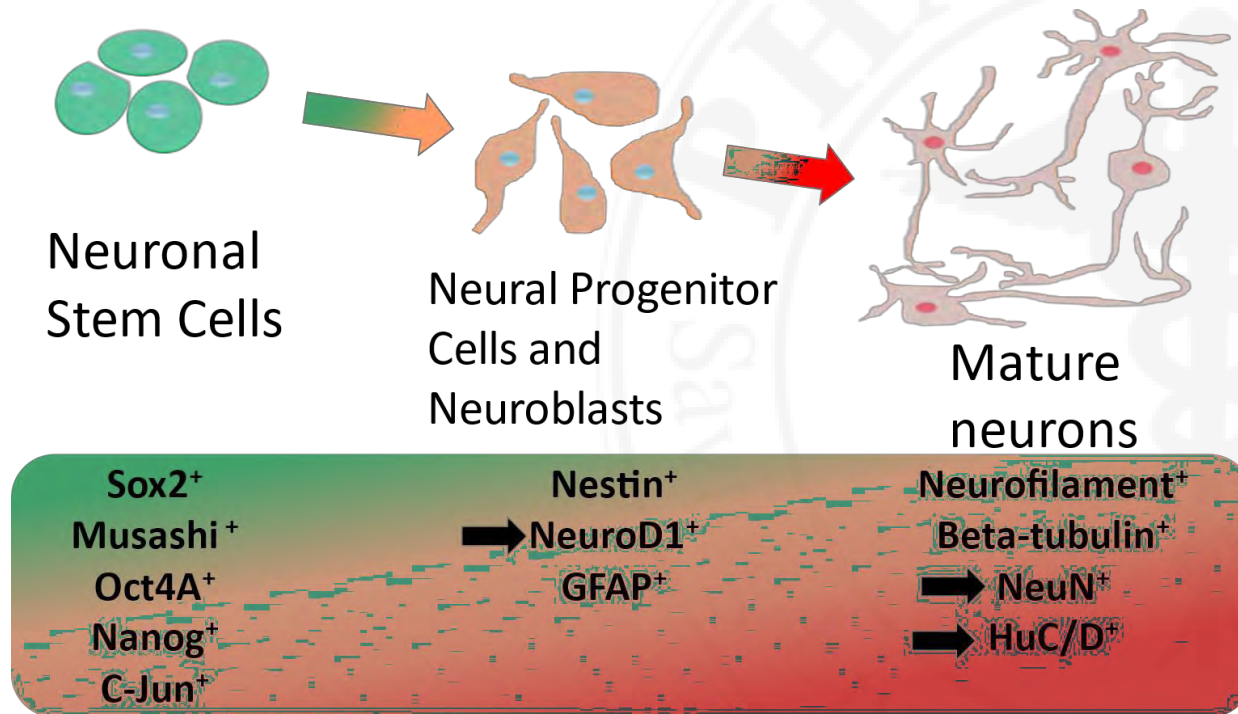
Note: IQR= Interquartile Range



# Sovateltide: Product Overview

A highly selective endothelin-B receptor agonist

## Mechanism of Action

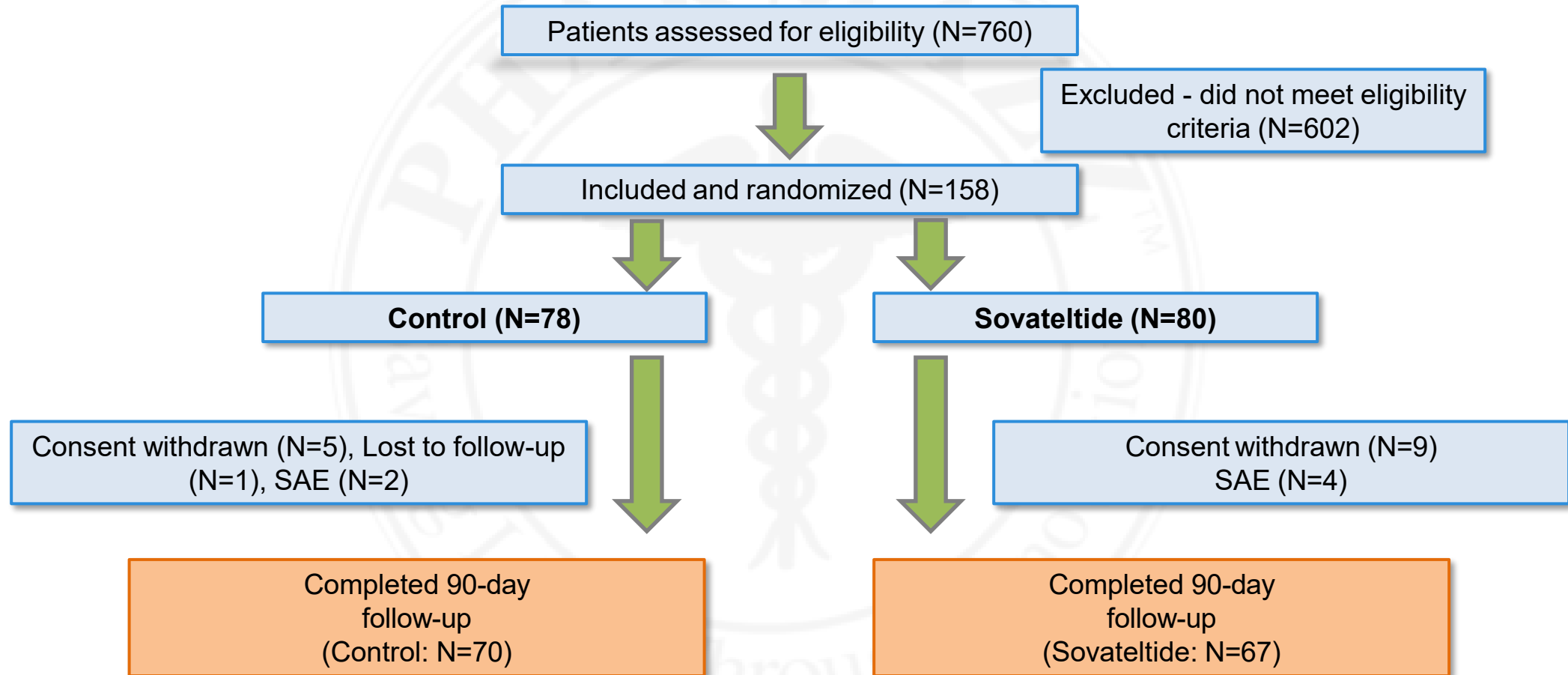


- Increases cerebral blood flow and has anti-apoptotic activity. Protects neural mitochondria and enhances their biogenesis
- Produces neurovascular remodeling through the formation of new neurons and blood vessels
- Significantly reduces infarct volume and improves neurological outcomes in an animal model of ACIS\*

***Sovateltide enhances the expression of markers for neural progenitor cells and neuronal cells, but not the stem cell markers***

# Sovateltide: Phase 3 Subject Recruitment

The Phase 3 trial was conducted in 18 centers, with 58.2% patients enrolled from 12 sites having more than 300 beds with at least 40 ICU beds



*Several centers have participated in global clinical trials (results published in well recognized journals)*



# Sovateltide: Phase 3 Trial Patient Demographics

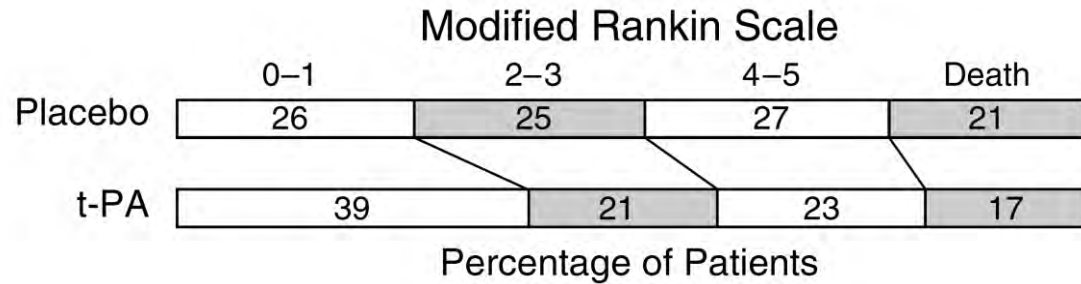
Below are the demographics of the patients enrolled in the Phase 3 trial of Sovateltide

Variable	Sovateltide (N=80)	Control (N=78)
Mean Age (years)	55.78	59.27
Mean Body Weight (Kg)	65.75	65.56
Male Sex (number, %)	53, 66.2%	48, 61.5%
Median NIHSS at Baseline (IQR)	9 (7 to 12)	10 (8 to 13)
Median ASPECTS (IQR)	8 (7 to 9)	8 (7 to 9)
Thrombolytic Therapy (number, %)	9, 11.2%	20, 25.6%
Large Artery Atherosclerosis (number, %)	37, 46.25%	29, 37.17%
Median Interval (hours) between of stroke onset and treatment (IQR)	18.58 (11.8 to 23.1)	19.71 (12.4 to 23.3)

Note: IQR= Interquartile Range

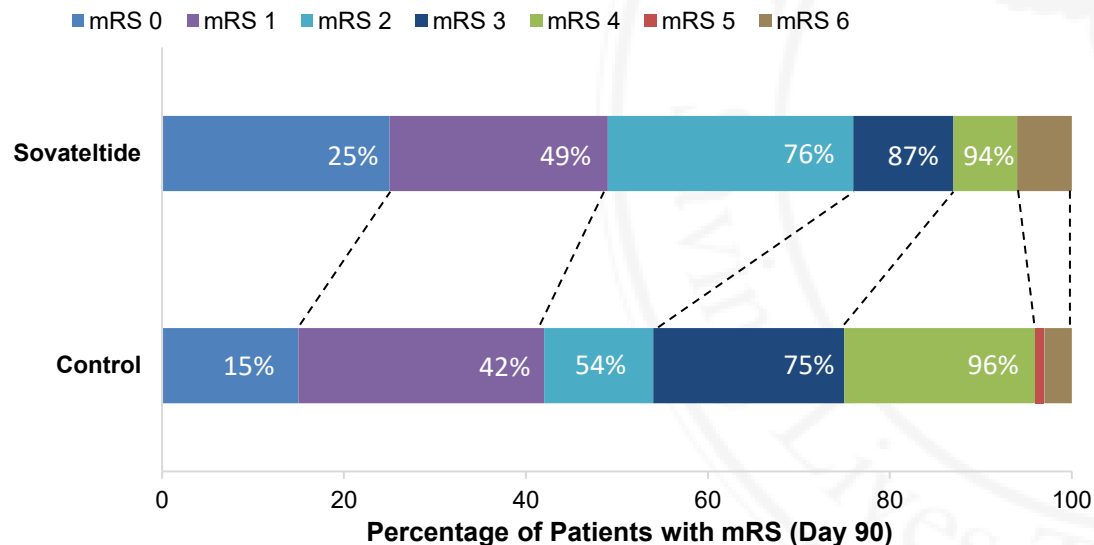
# Sovateltide: Additional Trial Results

## Ordinal shift in mRS across the range at day 90 compared to the rt-PA stroke study



An absolute increase in favorable outcome of 9% was observed with t-PA in patients with mRS of 0 to 3

Sovateltide: Meets the key primary endpoint of mRS 0 to 2 at 90 days (p=0.0016)



An absolute increase in favorable outcome of 12% was observed with Sovateltide in patients with mRS of 0 to 3

Number Needed to Treat (NNT) with Sovateltide is 5 compared to rt-PA of 10

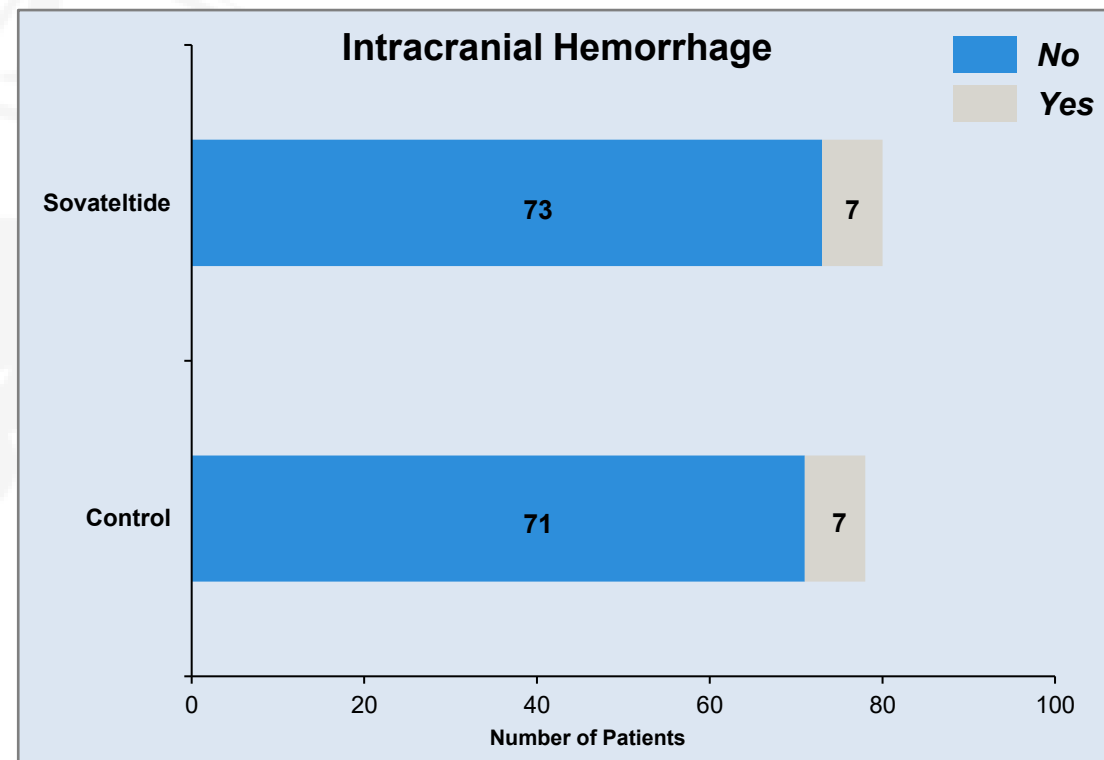
***Full recovery Sovateltide in at least 10% more patients compared to standard treatment***

# Sovateltide: Adverse Events



Adverse events observed in the Phase 3 Study of Sovateltide are presented below

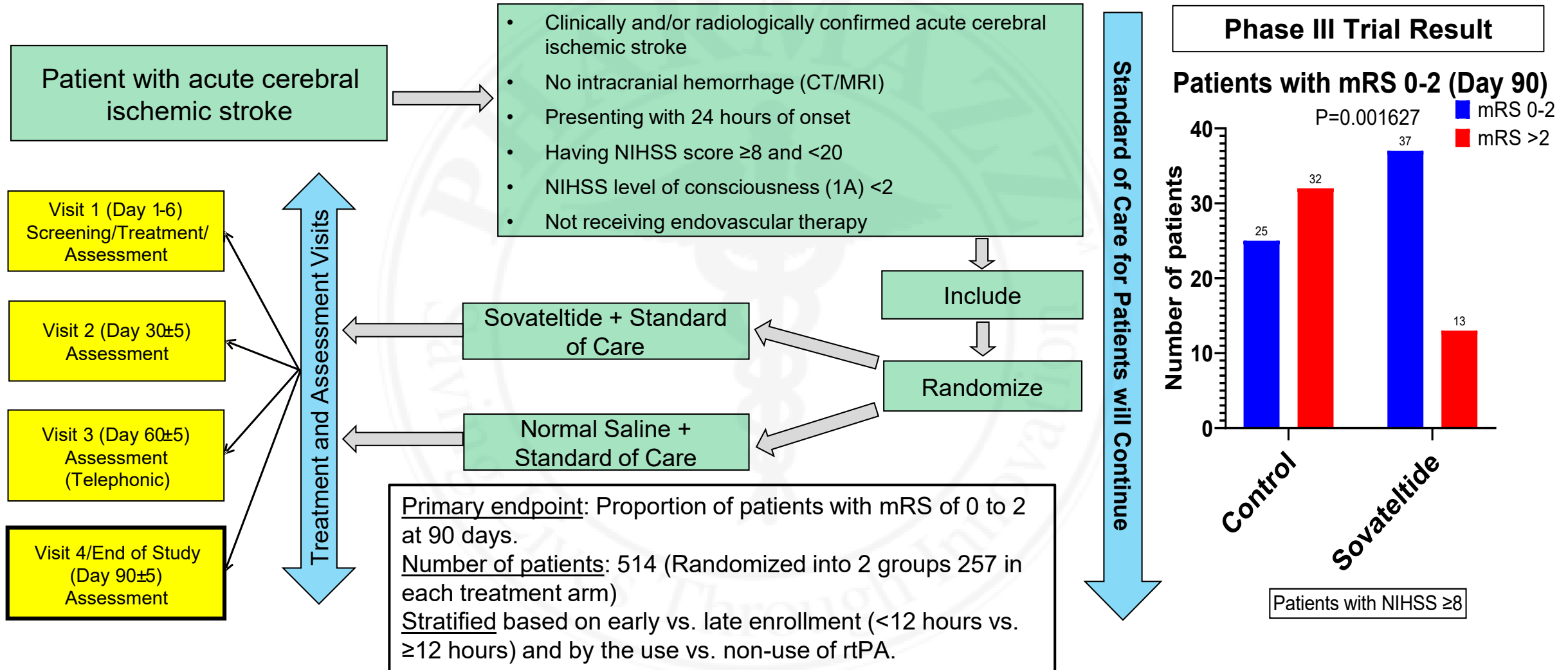
	Control (N=78) 33 adverse events in 24 patients	Sovateltide (N=80) 27 adverse events in 15 patients
<b>Serious</b>	<b>2 events in 2 patients</b> <ul style="list-style-type: none"> <li>• Death (2)</li> </ul>	<b>5 events in 5 patients</b> <ul style="list-style-type: none"> <li>• Death (4)</li> <li>• Hyponatremia (1)</li> </ul>
	<b>22 events in 16 patients</b> <ul style="list-style-type: none"> <li>• Fever (5 events in 2 patients)</li> <li>• Hypertension (2 events in 2 patients)</li> <li>• Cold (2 events in 2 patients)</li> <li>• Headache (1)</li> <li>• Cough (1)</li> <li>• Pruritus (1)</li> <li>• Vomiting (1)</li> <li>• Hepatitis (1)</li> <li>• Hypocalcemia (1)</li> <li>• Hypokalemia (1)</li> <li>• Hypotension (1)</li> <li>• Lower respiratory tract infection (1)</li> <li>• Urinary tract infection (1)</li> <li>• Constipation (1)</li> <li>• Itching (1)</li> <li>• Body pain (1)</li> </ul>	<b>19 events in 7 patients</b> <ul style="list-style-type: none"> <li>• Hypertension (3 events in 3 patients)</li> <li>• Vomiting (2 events in 2 patients)</li> <li>• Dizziness (2 events in 2 patients)</li> <li>• Breathlessness (1)</li> <li>• Cough (1)</li> <li>• Headache (1)</li> <li>• Hypotension (1)</li> <li>• Tachypnoea (1)</li> <li>• Rash (1)</li> <li>• Urinary Incontinence (1)</li> <li>• Sepsis (1)</li> <li>• Septic shock (1)</li> <li>• Fever (1)</li> <li>• Increased Alkaline Phosphatase (1)</li> <li>• Depression (1)</li> </ul>
<b>Mild</b>	<b>9 events in 6 patients</b> <ul style="list-style-type: none"> <li>• Abdominal pain (3 events in 3 patients)</li> <li>• Fever (1)</li> <li>• Headache (1)</li> <li>• Cough (1)</li> <li>• Sclera discoloration (1)</li> <li>• Burning sensation in feet (1)</li> <li>• Facial &amp; pedal edema (1)</li> </ul>	<b>3 events in 3 patients</b> <ul style="list-style-type: none"> <li>• Dyspnea (1)</li> <li>• Chills (1)</li> <li>• Back pain (1)</li> </ul>



Chi-square, df	0.0025, 1
Control	8.97%
Sovateltide	8.75%
P-Value	0.9604

# Sovateltide: SPA agreement with US FDA for Phase 3 Trial

Sovateltide Phase 3 IND clinical trial application approved by the US FDA (02/08/2023)



# Sovateltide: Key Differences In Study Protocol

## Differences and similarities between India and US studies

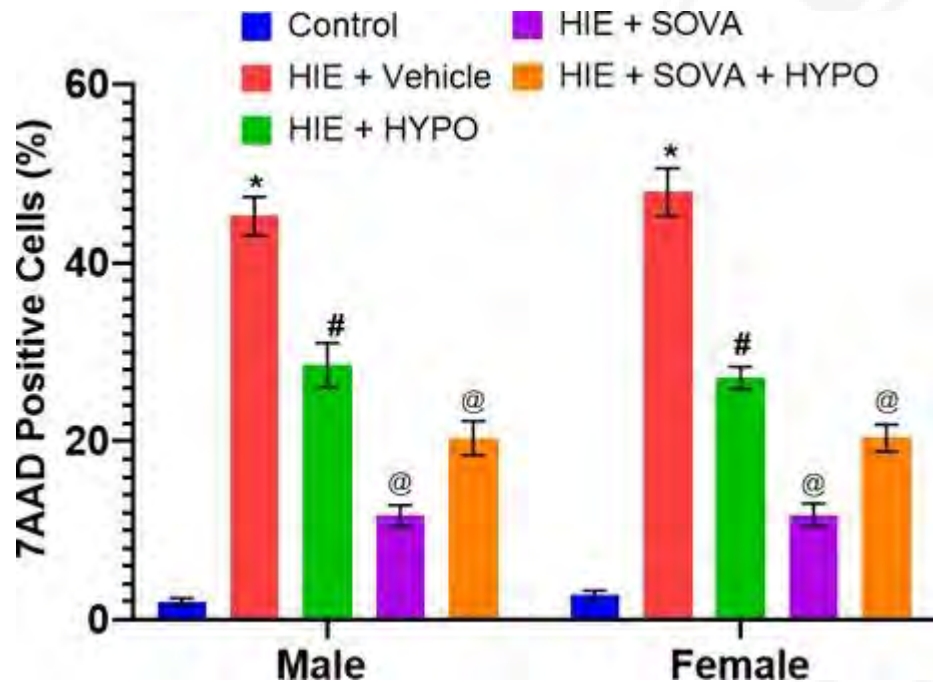
Parameter	US Study (Special Protocol Assessment)	India Study
Primary endpoint	The proportion of patients with mRS of 0-2 at 90 days	The proportion of patients with improved neurological outcomes (mRS, NIHSS, BI) at 90 days.
Inclusion criteria	Age 18-80, Either sex; Ischemic stroke; Within 24 hours of stroke onset; NIHSS $\geq 8$ to $< 20$ ;	Age 18-78, Either sex; Ischemic stroke; Within 24 hours of stroke onset; NIHSS $> 5$ ;
Exclusion criterion	Endovascular therapy, surgical intervention, intracranial hemorrhage, comatose, pregnancy	Endovascular therapy, surgical intervention, intracranial hemorrhage, comatose, pregnancy
Sample size; Randomization; Time from onset of stroke	514; 1:1 randomization; 50% within 12 hours (minimum 200 (40%) patients)	158; 1:1 randomization; within 12 hours 24% (38, 17 control and 21 sovateltide) patients
Interim analysis	No interim analysis	Trial complete, approved for marketing
Data analysis (Statistical Analysis Plan (SAP))	Multiple imputation for missing data, intention-to-treat (ITT) patients. SAP approved by FDA	No SAP. <b>Table below</b> is the data analyzed as per SAP with FDA, multiple imputation + ITT patients
Standard of care	SOC (thrombolytics, anti-coagulants, anti-hypertensive, anti-diabetic, mannitol, and other medication as needed)	SOC (thrombolytics, anti-coagulants, anti-hypertensive, anti-diabetic, mannitol, and other medication as needed)

Data of 158 patients analyzed with imputation as per SAP with FDA	Control	Sovateltide	P value
<b>Primary end point:</b> Number of patients with mRS of 0-2 at 90 days	53.58% (N=42 out of 78)	78.75% (N=63 out of 80)	0.0009
<b>Secondary end point:</b> Number of patients with NIHSS of 0-5 at 90 days	67.95% (N=53 out of 78)	85.00% (N=68 out of 80)	0.0114

# Sovateltide: Hypoxic-Ischemic Encephalopathy

## Currently therapeutic hypothermia is the only approved treatment

The incidence of HIE ranges from 2-4/1000 live births in developed countries and as high as 26/1000 live births in developing countries. Up to 25% of neonates diagnosed with HIE result in death and around 35% have long-term neurodevelopmental sequelae



Tukey's multiple comparisons test	Mean Diff.	95.00% CI of Diff.	Summary	P-Value
Male: Control vs. HIE + Vehicle	-43.17	-51.37 to -34.96	*	<0.0001
Male: HIE + Vehicle vs. HIE + HYPO	16.63	8.425 to 24.84	#	<0.0001
Male: HIE + HYPO vs. HIE + SOVA	16.91	8.705 to 25.12	@	<0.0001
Tukey's multiple comparisons test	Mean Diff.	95.00% CI of Diff.	Summary	P-Value
Female: Control vs. HIE + Vehicle	-45.21	-53.42 to -37.01	*	<0.0001
Female: HIE + Vehicle vs. HIE + HYPO	20.83	12.62 to 29.03	#	<0.0001
Female: HIE + HYPO vs. HIE + SOVA	15.38	7.170 to 23.58	@	<0.0001

***Sovateltide has neuroprotective effects and significantly reduced number of apoptotic cells***

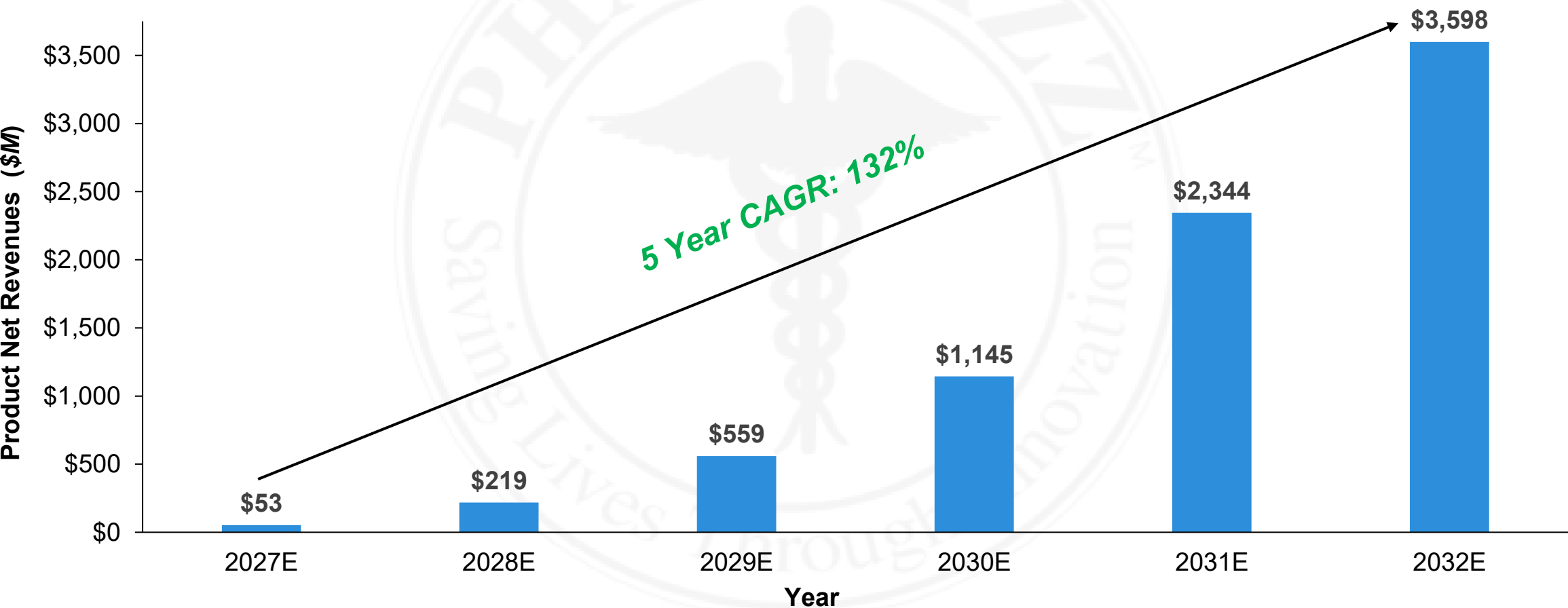


# Acute Cerebral Ischemic Stroke - US Market Opportunity



The market opportunity of Sovateltide for acute cerebral ischemic stroke in the US is estimated to achieve net revenues of \$3.6B by 2032<sup>(1)</sup>

Sovateltide Revenue Forecast in the US (2027E – 2032E)



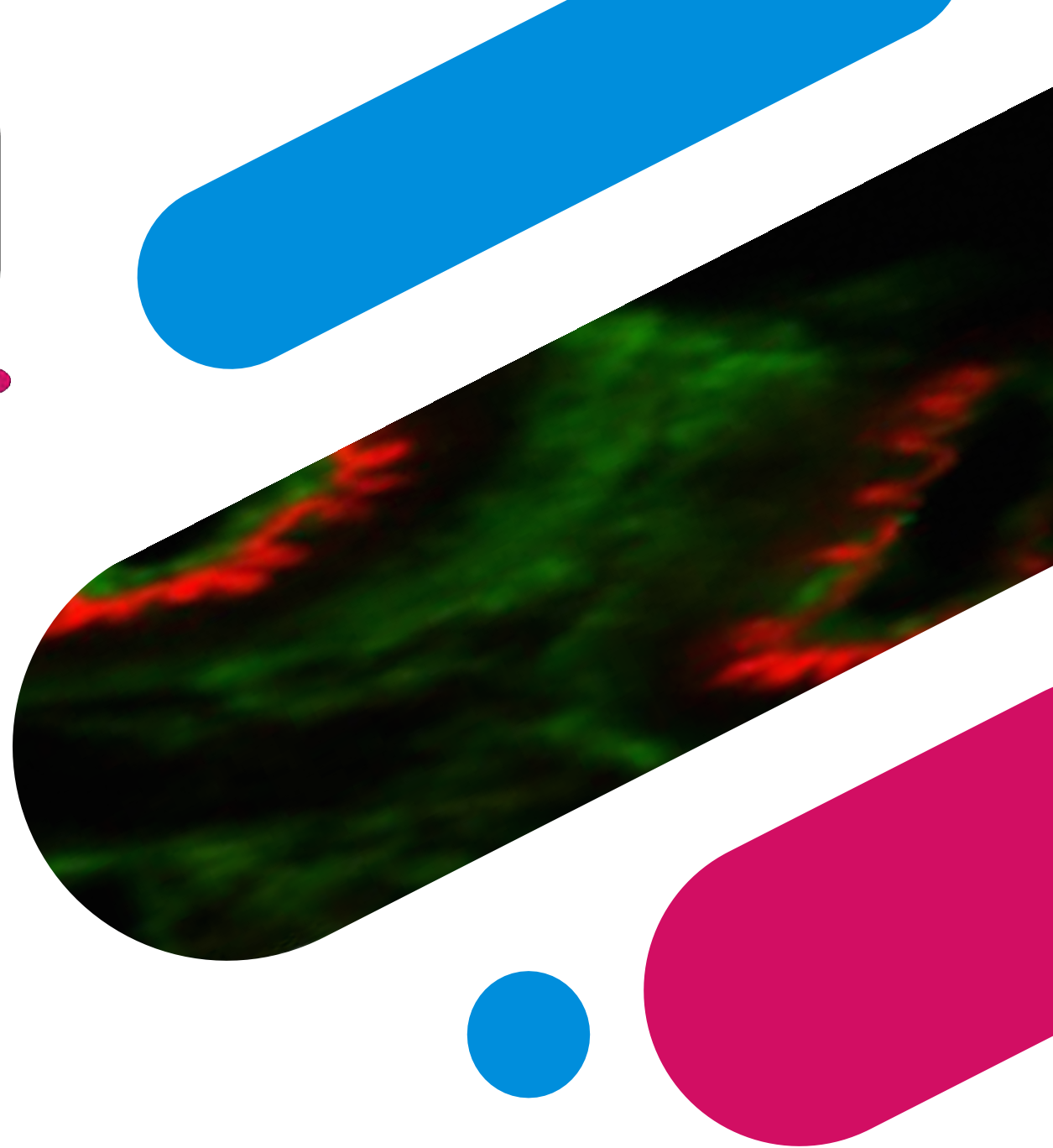
1. Source: Pharmazz, Inc. Proprietary Research. Key Assumptions: Stroke patients per year = 795,000; patients eligible for Sovateltide treatment 464,000; price per patient \$22,500 with 2% annual increase; market penetration from 2.5% to 40% over 9 years.

# Centhaquine

A resuscitative agent  
that is free of arterial  
constriction

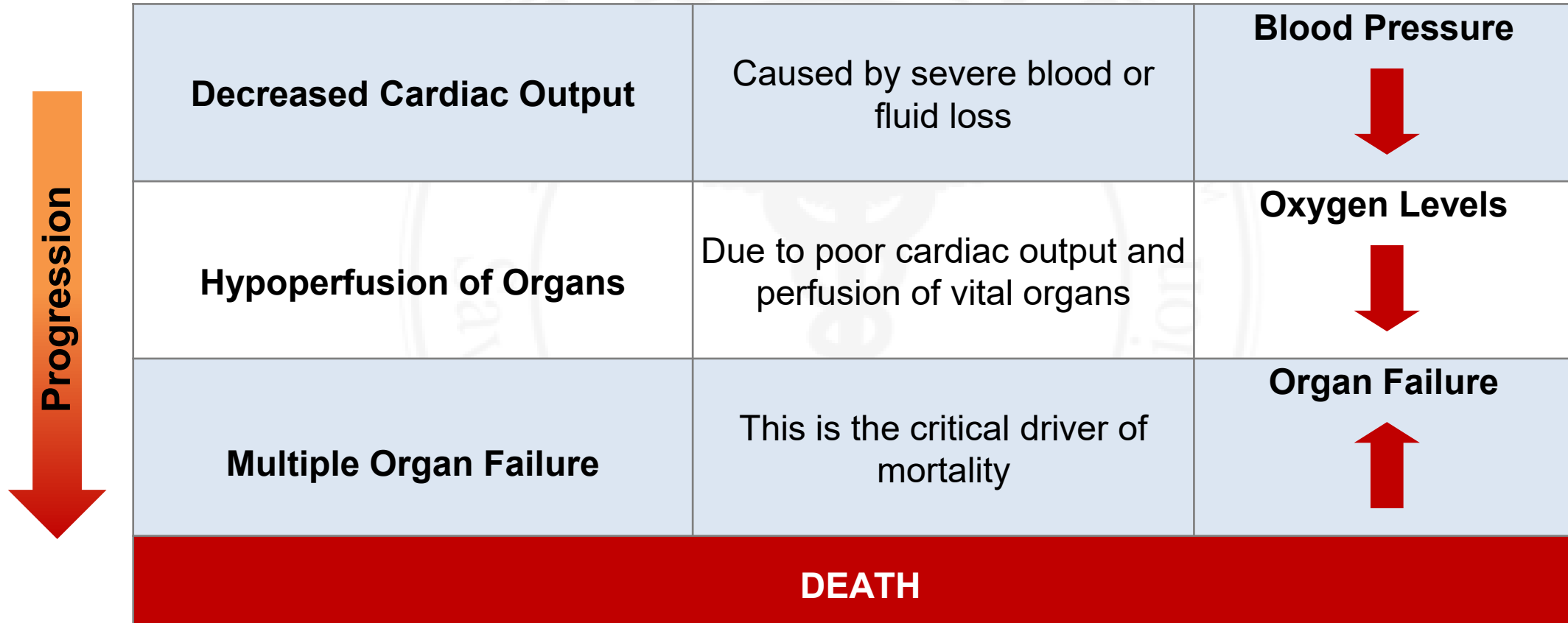


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# Centhaquine: Hypovolemic / Hemorrhagic Shock

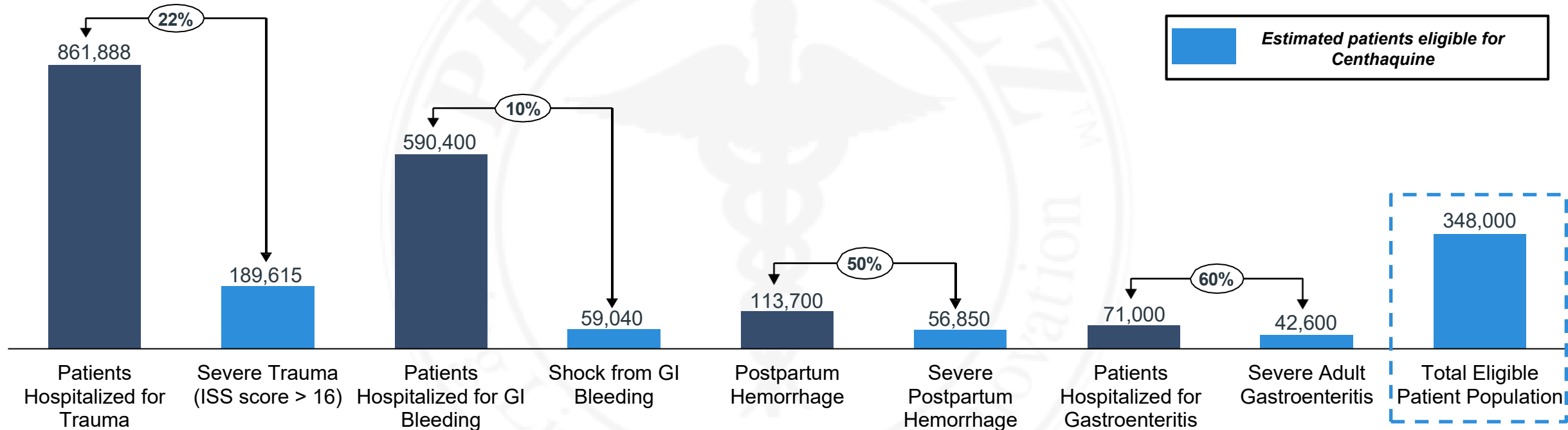
Hypovolemic / Hemorrhagic Shock is a life-threatening condition with high mortality rates. The annual incidence is 0.3 to 0.7 per 1,000 in the US with a 15% to 20% mortality rate



# Centhaquine: Market Sizing

Every year ~1.7 Million Americans suffer hypovolemic shock, of which 348,000 suffer severe symptoms and are therefore eligible for Centhaquine<sup>(1)</sup>

## Current Annual Incidence of Hypovolemic Shock in the US



**Severe trauma, GI bleeding, postpartum hemorrhages, and gastroenteritis are the primary triggers for severe hypovolemic shock among adults in the US (excluding hypovolemia from other shock etiologies)**

1. Source: IQVIA Inc. Reference: Eastridge et al. 2019 Journal of AAB; Marshall et al. 2017 Am J Obstet Gynecol; Zhou et al. 2008 AHRQ; Standl et al. 2018 Dtsch Arztebl Int; National Trauma Databank 2016 Annual Report (ACS)

# Centhaquine: Current Treatment Protocol

The current treatment protocol for hypovolemic shock includes a mix of fluid replacement and vasopressors

## Current Treatment: Hypovolemic / Hemorrhagic Shock

Fluid Replenishment: Colloid / Crystalloid Solutions +/- Blood Products



If fluids insufficient: Vasopressors

## Challenges with Current Treatment Protocol

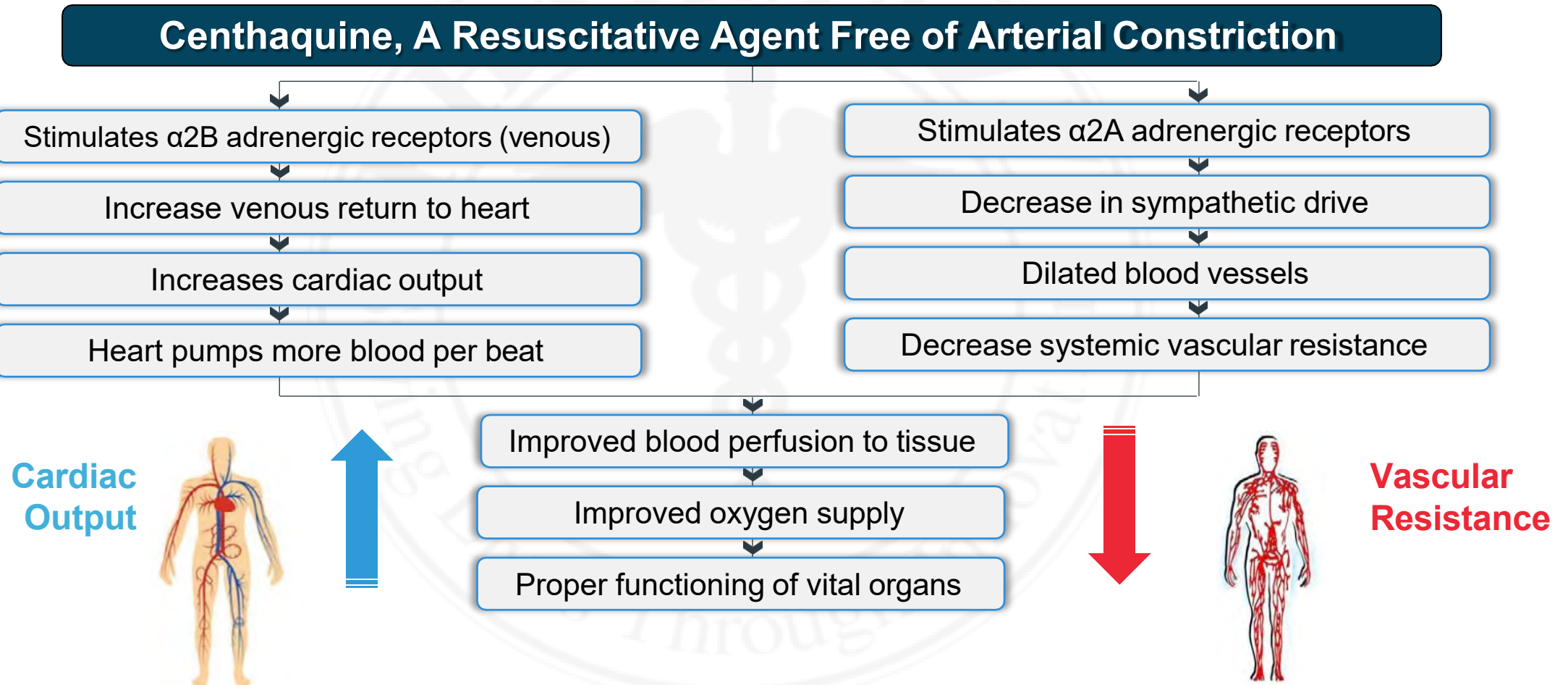
- Arterial constriction, reduced tissue blood perfusion
- Cardiac Arrhythmias
- Fluid Extravasation
- Vasopressor Infusion requires careful titration



***The administration of Centhaquine does not require the insertion of a Central Venous Line (peripheral IV administration instead)***

# Centhaquine: Mechanism of Action

Centhaquine's MOA is distinct among resuscitative agents as it increases cardiac output while decreasing vascular resistance





# Centhaquine: Phase 3 Trial Results

Centhaquine’s Phase 3 trial in India met all four primary efficacy endpoints. The trial’s secondary endpoint, 28-day mortality, also trended toward benefit

## Study Design Summary

Key Parameters	Overview
Treatment Arms	<ul style="list-style-type: none"> <li>71 patients: experimental arm: Centhaquine + standard of care</li> <li>34 patients: comparator arm: standard of care</li> </ul>
Dosage	<ul style="list-style-type: none"> <li>Centhaquine administered at 0.01mg/kg, i.v. in 100 mL of normal saline</li> </ul>
Efficacy Assessment	<ul style="list-style-type: none"> <li>SBP, DBP, Blood Lactate, base-deficit</li> <li>Secondary endpoint: 28-day Mortality</li> </ul>

## Phase 3 Primary and Secondary Endpoints

Endpoints	Results (% of patients)		P Value
	Control	Centhaquine	
SBP ≥ 110 mmHg at 24 hrs.	60.6	79.7*	P=0.0444
DBP ≥ 70 mmHg at 24 hrs.	51.5	76.6*	P=0.0122
Blood Lactate of ≤ 1.5	46.9	69.4*	P=0.0336
Base-Deficit <- 2.0 (mmol/L)	43.8	69.8*	P=0.0137
28-day Mortality	11.8	2.94	P=0.0742

Clinical Trials Identifier: CTRI/2019/01/017196 and NCT04045327

Reference: Gulati et al., (2021) Drugs. 2021 Jun;81(9):1079-1100; doi: 10.1007/s40265-021-01547-5; Gulati et al., (2021) Advances in Therapy 38 (6), 3223-3265. doi: 10.1007/s12325-021-01760-4.; Gulati et al., (2020) Drugs Fut 2020, 45(3): 153; doi: 10.1358/dof.2020.45.3.3098155.; Lyfaquin® clinical data

# Centhaquine: Phase 3 Trial Results (Continued)

The Indian Phase 3 study showed a ~75% reduction in mortality. Meta-analysis of Phase 2 and 3 data reach statistical significance

Additionally, a prospective, multi-centric, open-labeled study of 400 patients to assess the safety and efficacy of centhaquine is ongoing, more than 200 patients enrolled

Meta-analysis of Phase 2 and 3 data (similar inclusion criteria)	
Phase 2 + 3 Control (N=56)	10.71% (6)
Phase 2 + 3 Centhaquine (N=91)	2.20% (2)
Odds Ratio 5.340 (95% CI 1.27-26.50)	P=0.03

***We believe the larger trial size of 430 patients planned for the US Phase 3 trial is likely to produce statistically significant results in 28-day mortality***

# Centhaquine: Phase 3 Trial Protocol

**Centhaquine's Phase 3 IND approved, and protocol agreed to by the FDA**

Study Design	
<b>Design Parameters</b>	Multi-Center, Randomized, Double-Blinded, Placebo-controlled
<b>Dosage</b>	0.01 mg/kg of Centhaquine + Standard of Care
<b>No. of Participants</b>	430 patients, randomly assigned equally to both arms
<b>Time Frame</b>	Enrollment period 12 months and total duration 24 months

## Primary Endpoint

- All cause mortality at day 28

## Secondary Endpoints

- Mortality 60 days
- Ventilator free days
- Days in hospital
- Days in ICU
- Days on organ support

## Exploratory Endpoints

- Systolic and diastolic blood pressure
- Blood lactate
- Amount of fluid or blood infused
- Change in Multiple Organ Dysfunction Syndrome score

# Centhaquine: Key Differences In Study Protocol

## Differences between India and US studies focus patient population to those most likely to benefit

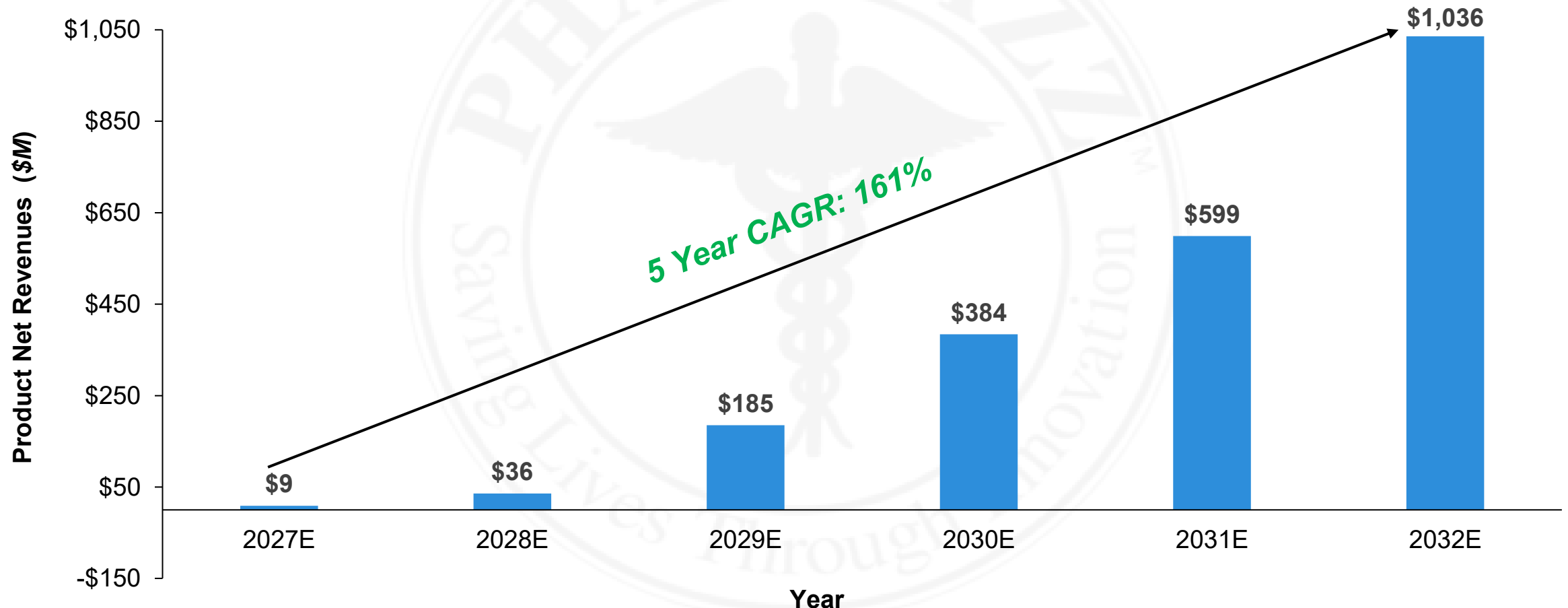
Parameter	US Study	India Study
Primary endpoint	All-cause mortality at 28 days	SBP, DBP, blood lactate & base deficit
Inclusion criteria	SBP $\leq$ 90 mm Hg, blood lactate $>$ 2 mmol/L and receiving SOC	SBP $\leq$ 90 mm Hg, blood lactate $>$ 2 mmol/L and receiving SOC
Exclusion criterion	<b>Exclude if hypovolemic shock etiology is unavailable</b>	Etiology of hypovolemic shock not specified
Sample size	430 (assuming 7% reduction in mortality and achieving statistical significance at 95% CI)	105
Randomization	1:1 Randomization	2:1 Randomization
Interim analysis	For futility ( $p \leq 0.435$ ) and efficacy ( $p \leq 0.003$ )	Does not specify details
Standard of care	Crystalloids, Colloids, Blood Products, Vasopressors	Crystalloids, Colloids, Blood Products, Vasopressors

- Majority of patients enrolled were hemorrhagic shock: 65 (45 in Centhaquine, 20 in control); Number of patients with fluid loss: 37 (23 in Centhaquine, 14 in control)
- Coagulopathy, acidosis, and hypothermia make a deadly cycle of a lethal triad in patients with acute hemorrhage. Centhaquine resuscitation within the Golden Hour is likely to be more effective in attenuating the lethal triad than missing the Golden Hour.
- Literature<sup>1</sup> suggests higher mortality in the control group in the US vs. India due to inclusion of patients with severe hemorrhage. Expect greater reduction in mortality.

# Hypovolemic Shock - US Market Opportunity

The market opportunity of Centhaquine for hypovolemic shock in the US is estimated to achieve net revenues of ~\$1.0B by 2032<sup>(1)</sup>

Centhaquine Revenue Forecast in the US (2027E – 2032E)

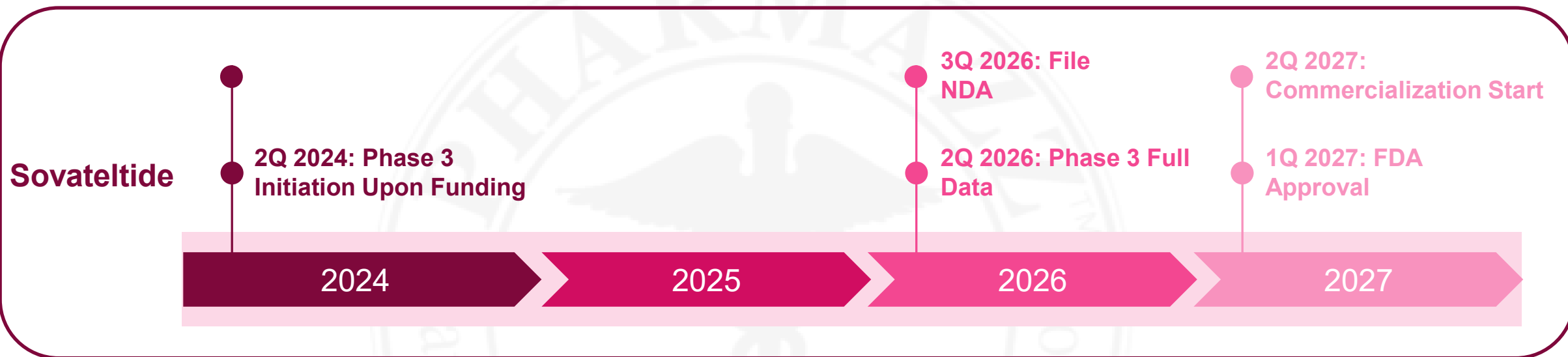


1. Source: IQVIA Inc. Key Assumptions: Severe Hypovolemic Shock patients per year = 350,000; price per patient \$8,800 with 2% annual increase; market penetration from 1.0% to 40% over 9 years. Reference Company Websites, Clinicaltrials.gov.

# Upcoming Milestones



**\$30M projected to fund through Sovateltide commercialization**



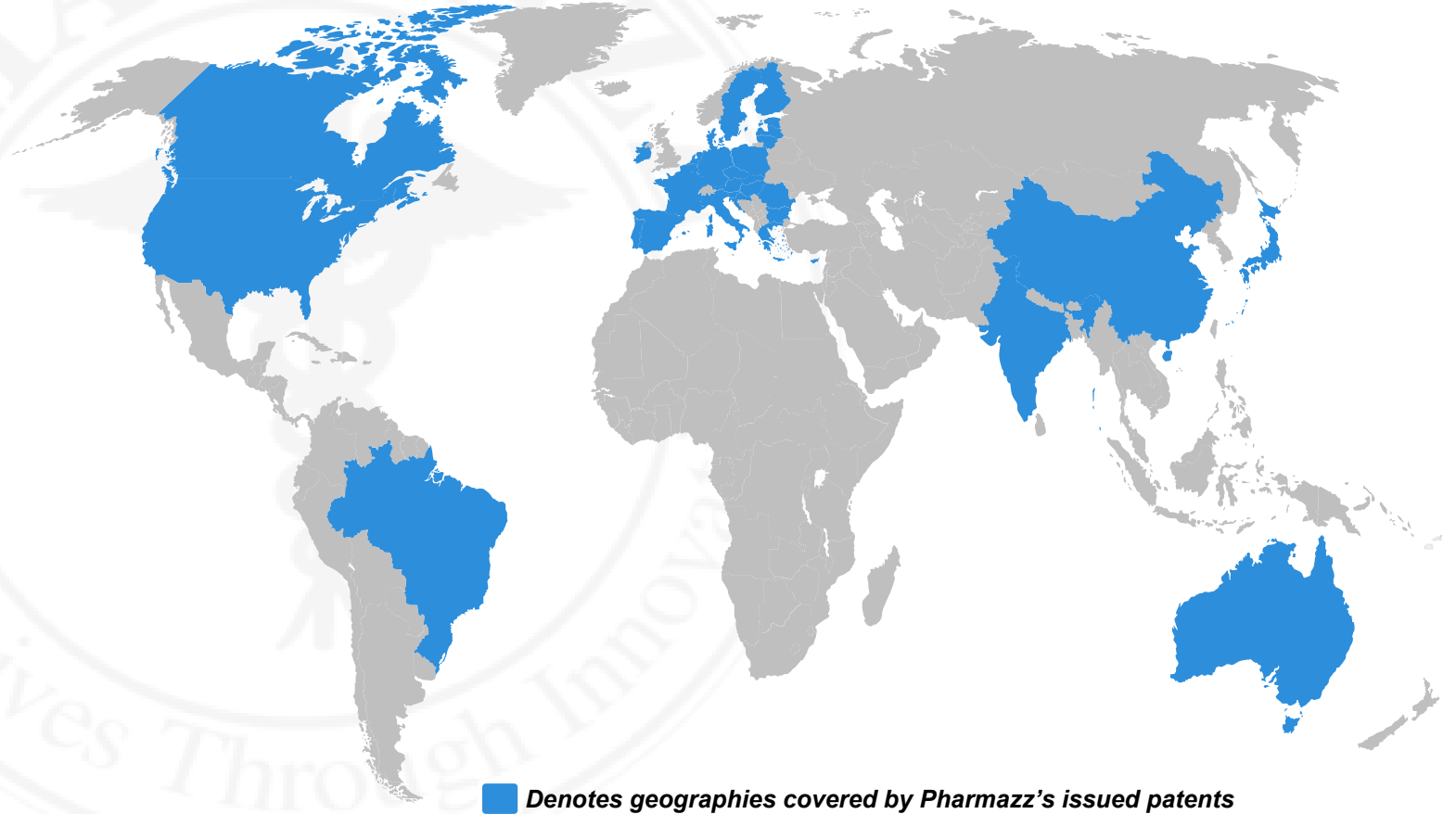


# Patents and Licenses



Over 50 Issued Patents Covering Relevant Geographies With Expiry Between 2028 and 2038





- **Exclusive worldwide rights of intellectual property** from Midwestern University with, single-digit royalties due once commercialized
- **Several patent applications** related to Sovateltide and Centhaquine composition and methods Inc. under examination.
- **New patent application** in filing process currently



# Ongoing Patent Applications



## Patent Applications Assigned to Pharmazz with Compositions and Methods Protected Through 2043

Title	Pharmaceutical formulation for the treatment of cerebral stroke	Lyophilized sovateptide-based injectable formulation and method for preparation thereof
Applicant	 	 
Application Number	18/343,087	18/478,528
Priority Date	June 28 <sup>th</sup> 2023	June 28 <sup>th</sup> 2023

# The Team



## Experienced team with extensive drug development and clinical expertise



**Anil Gulati, MD, PhD**  
*Chairman and Chief  
Executive Officer*

- >40 years of drug discovery, development, clinical and management experience.
- >300 peer reviewed publications, and 54 issued patents



**Daniel Stauder**  
*Chief Investment  
Officer*

- >35 years of experience in healthcare capital markets and investment banking
- Assisted raising >\$20 billion in over 500 transactions



**Manish Lavhale, PhD**  
*Managing Director,  
India*

- >20 years of pharmaceutical industry experience
- Expertise in regulatory strategy, with lead role in development of Centhaquine and Sovateltide



**David Costello**  
*Controller and Vice  
President*

- >25 years of financial and accounting experience
- Assisted closing of >\$500 million in structured finance and equity transactions



**Sunil Gulati, PhD**  
*Chief Operating Officer*

- >35 years of running medium sized companies with governance and compliance expertise
- In house development of clinical trials team and successful completion of numerous trials



**Shruthi Rammohan, MD**  
*Manager, Medical  
Affairs*

- >15 years of clinical and pharmaceutical industry experience
- Expertise in medical affairs with role in development of Centhaquine and Sovateltide



# PHARMAZZ Investment Summary



Late-stage biopharmaceutical company with **two US FDA approved Phase 3 INDs for clinical programs** addressing the underserved critical care market



Lead pipeline programs designed to address multibillion dollar end markets and **line of sight on market debut by early 2027**



Lead asset (Sovateltide) designed to transform the treatment of acute cerebral ischemic stroke, supported by **the first statistically significant clinical data in 25+ years**



**Worldwide rights in hand** with potential to partner both Sovateltide and Centhaquine in selected geographies



Secondary asset (Centhaquine) designed to **reduce mortality as a resuscitative agent and improving cardiac output and blood pressure** without arterial constriction in hypovolemic shock patients



**Validating and functional partnerships** for sales and distribution in India



Sovateltide



Centhaquine



PHARMAZZ  
EXCELLENCE IN CRITICAL CARE MEDICINE

Thank You

