

Corporate Presentation

October 2024



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PHARMAZZ AT A GLANCE



Two first-in-class drug candidates with positive Phase 3 data Established and expanding partnership with major pharmaceutical companies

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, >45,000 patients treated since launch on September 14, 2023
- US IND for Phase 3 trial in acute cerebral ischemic stroke approved by the FDA, along with a Special Protocol Assessment agreement
- In the US, the treatment of ACIS is projected to generate \$3.6bn of net revenues with a 5-year CAGR of 132% by 2033

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. Launched March 22, 2024
- US IND for Phase 3 approved for hypovolemic shock
- US IND for Phase 2 approved for Acute Respiratory Distress Syndrome (ARDS)
- In the US, the treatment of Hypovolemic Shock is projected to generate \$1.0bn of net revenues with a 5-year CAGR of 161% by 2033

SALES & DISTRIBUTION



Sun Pharmaceuticals markets Sovateltide under its brand TyvalziTM in India



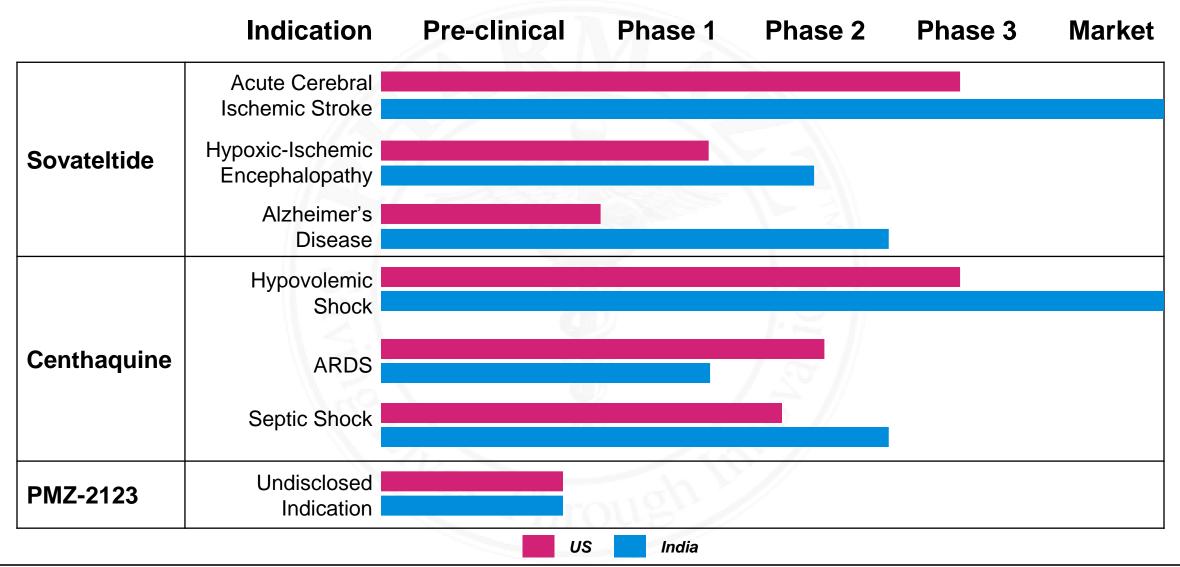
Centhaquine, branded as Lyfaquin® in India, marketed by Dr. Reddy's Laboratory





Product Pipeline

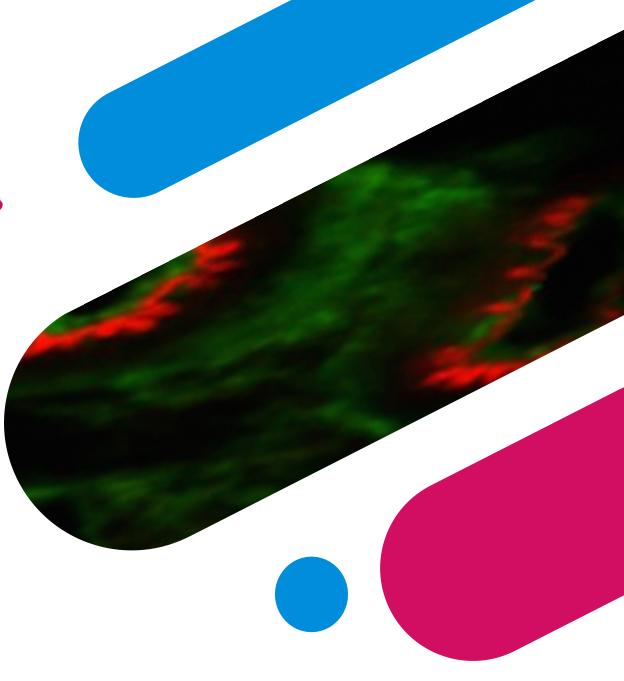




Sovateltide

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

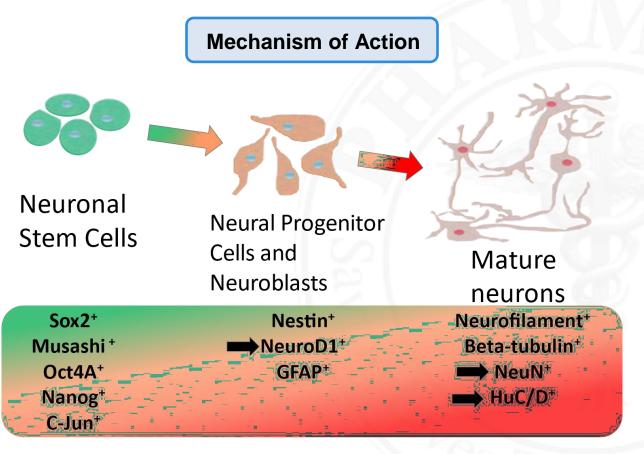




Sovateltide: Product Overview



A highly selective endothelin-B receptor agonist



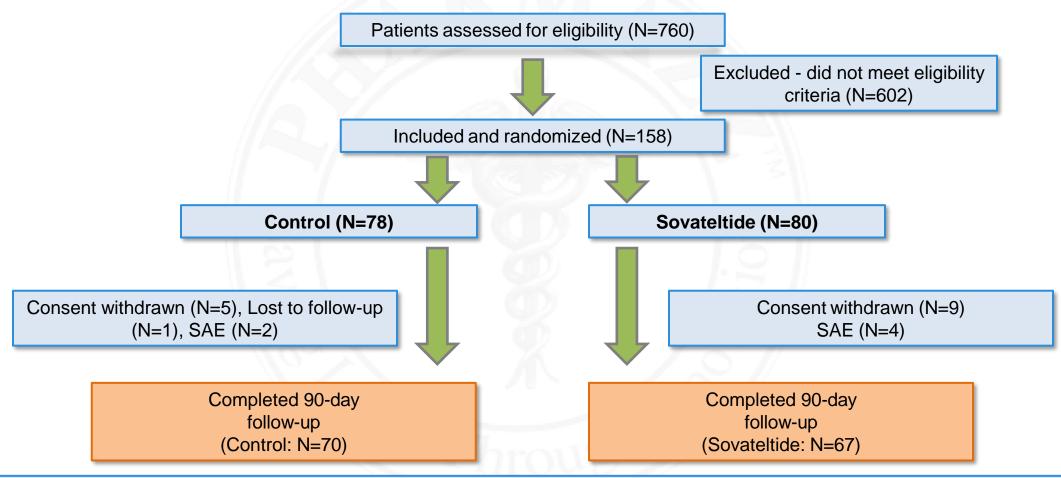
- Increases cerebral blood flow and has anti-apoptotic activity. Protects neural mitochondria and enhances their biogenesis
- Produces neurovascular remodeling through the formation of new neurons and blood vessels
- Significantly reduces infarct volume and improves neurological outcomes in an animal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

Sovateltide enhances the expression of markers for neural progenitor cells and neuronal cells, but not the stem cell markers (potential for multiple indications to repair damaged brain)

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)

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 ≥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 ≥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 ≥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

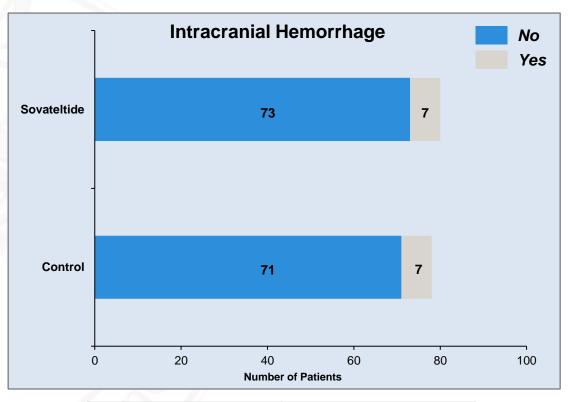
Note: IQR= Interquartile Range

Sovateltide: 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
Serious	2 events in 2 patients • Death (2)	5 events in 5 patients • Death (4) • Hyponatremia (1)
	22 events in 16 patients • Fever (5 events in 2 patients) • Hypertension (2 events in 2 patients) • Cold (2 events in 2 patients) • Headache (1) • Cough (1) • Pruritus (1) • Vomiting (1) • Hepatitis (1) • Hypocalcemia (1) • Hypokalemia (1) • Hypotension (1) • Lower respiratory tract infection (1) • Urinary tract infection (1) • Constipation (1) • Itching (1) • Body pain (1)	19 events in 7 patients Hypertension (3 events in 3 patients) Vomiting (2 events in 2 patients) Dizziness (2 events in 2 patients) Breathlessness (1) Cough (1) Headache (1) Hypotension (1) Tachypnoea (1) Rash (1) Urinary Incontinence (1) Sepsis (1) Septic shock (1) Fever (1) Increased Alkaline Phosphatase (1) Depression (1)
Mild	9 events in 6 patients • Abdominal pain (3 events in 3 patients) • Fever (1) • Headache (1) • Cough (1) • Sclera discoloration (1) • Burning sensation in feet (1) • Facial & pedal edema (1)	3 events in 3 patients • Dyspnea (1) • Chills (1) • Back pain (1)

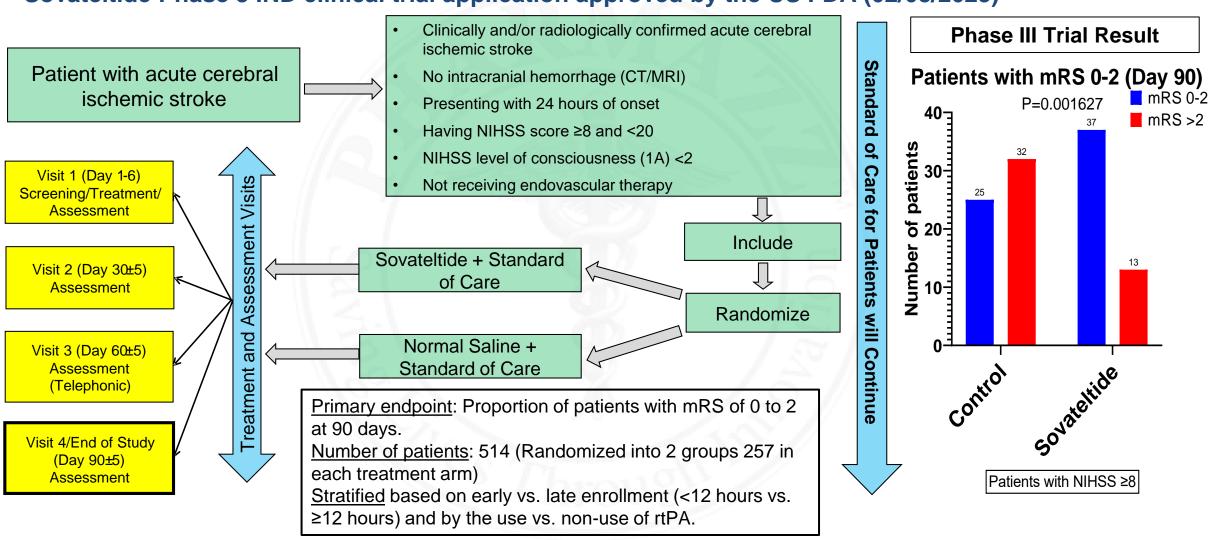


Chi-square, df	0.0025, 1
Control	8.97%
Sovateltide	8.75%
P-Value	0.9604

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 ≥8 to <20;	Age 18-78, Either sex; First time 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. The next Slide Table 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)

Sovateltide: Phase III analysis of results using MICE

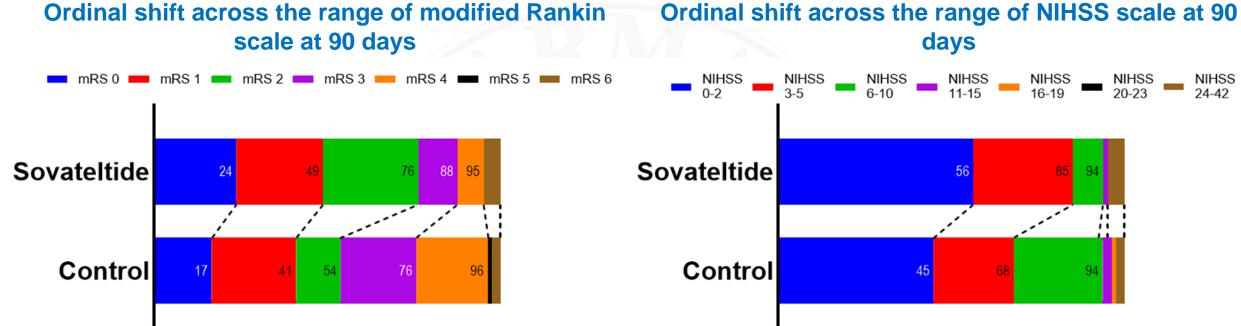


Data from 158 patients analyzed as per the agreed Special Protocol Assessment with the FDA

Number of patients with mRS of 0-2				
	Control (N=78)	Sovateltide (N=80)	P value	
Day 90 (Primary end point)	53.58% (N=42)	76.25% (N=61)	0.0031	
Day 30	41.03% (N=32)	63.75% (N=51)	0.0042	
Day 6	20.51% (N=16)	32.50% (N=26)	0.0882	
Numbe	r of patients with NII	HSS of 0-5		
	Control (N=78)	Sovateltide (N=80)	P value	
Day 90 (Secondary end point)	67.95% (N=53)	85.00% (N=68)	0.0114	
Day 30	58.97% (N=46)	78.75% (N=63)	0.0072	
Day 6	37.18% (N=29)	56.25% (N=45)	0.0163	
Numbe	er of patients with BI	of 90-100		
	Control (N=78)	Sovateltide (N=80)	P value	
Day 90 (Secondary end point)	43.59% (N=34)	57.50% (N=46)	0.0804	
Day 30	30.77% (N=24)	50.00% (N=40)	0.0138	
Day 6	8.97% (N=7)	20.00% (N=16)	0.0495	

Sovateltide: Phase III analysis of results using MICE





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Distribution of scores on the Modified Rankin Scale at 90 days in the Intentionto-Treat population The modified Rankin Scale (mRS) score is the most widely used primary outcome measure in trials for acute stroke interventions. A modified Rankin scale score of 0 indicates no disability, 1 no clinically significant disability, 2 slight disability, 3 moderate disability but able to walk unassisted, 4 moderately severe disability, 5 severe disability, and 6 death.

Percentage of patients with mRS (Day 90)

24-42 50 100 Percentage of patients with NIHSS (Day 90)

Distribution of scores on the NIHSS Scale at 90 days in the Intention-to-Treat population. The National Institutes of Health Stroke Scale (NIHSS) is used to assess the severity of a stroke and the neurological deficit in stroke patients. The NIHSS of 1-4 = minor stroke. 5–15 = moderate stroke. 15–20 = moderate/severe stroke. 21–42 = severe stroke.

Data analyzed as per the Statistical Analysis Plan in the SPA agreed with the FDA

Initiating US Phase 3 trial for sovateltide RESPECT-ET_B





A multicentric, randomized, double-blind, parallel, placebo-controlled phase III study will be conducted to assess the safety and efficacy of sovateltide in patients with acute cerebral ischemic stroke.

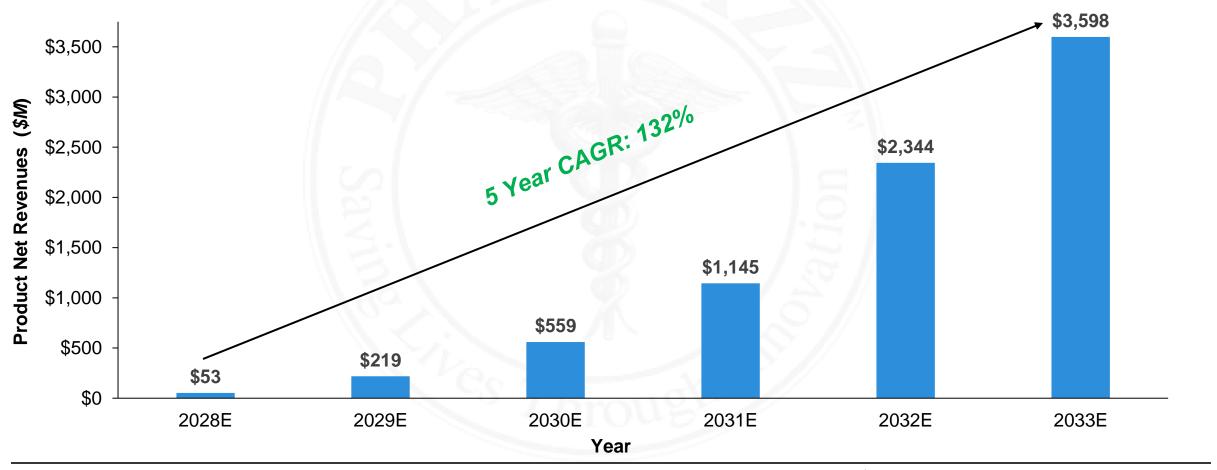
- Respect-ET_B trial across 65 sites in the United States, Canada, the United Kingdom, and Europe.
- Site activation is in progress in the United States, Spain, Germany, Belgium, and the United Kingdom.
- Thirty-two sites approved for visit and activation
- The study's enrolment period will be approximately 15 months, and its total duration will be approximately 18 months.
- The study duration for an individual patient will be 3 months (90 days), including 4 study visits.
- A total of 514 patients will be randomized 1:1 into two treatment groups after meeting the eligibility criteria:
 - Group 1 (Active Group): sovateltide + standard of care
 - Group 2 (Control Group): matching placebo for sovateltide + standard of care
- Details can be accessed at NCT05691244.

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 2033(1)

Sovateltide Revenue Forecast in the US (2028E - 2033E)



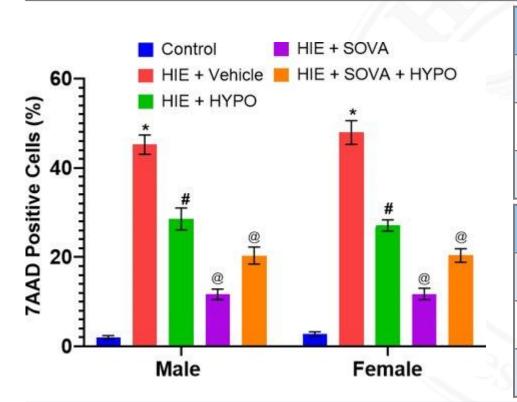
^{1.} Source: Pharmazz, Inc. Proprietary Research. Key Assumptions: Stroke patients per year = 795,000; patients eligible for Sovateltide treatment 464,000; price per patient \$22,500 with 2% annual increase; market penetration from 2.5% to 40% over 9 years. 16

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

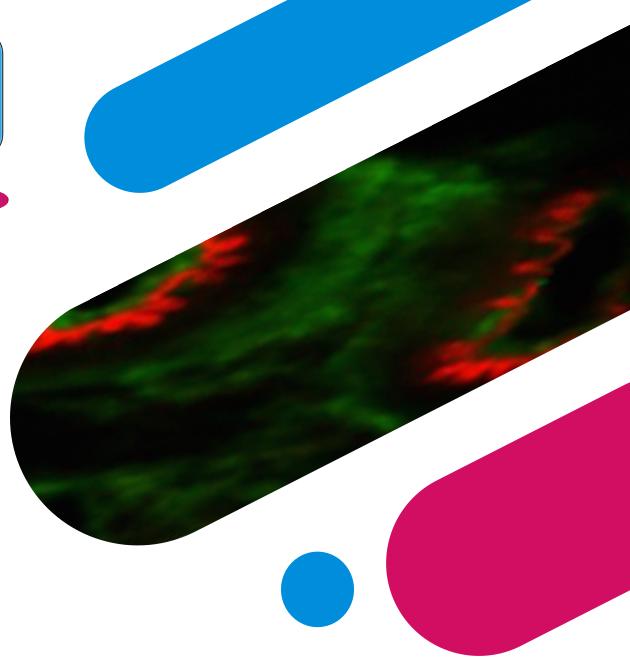
Tukey's multiple comparisons test	Mean Diff.	95.00% CI of Diff.	Summary	P-Value
Female: Control vs. HIE + Vehicle	-45.21	-53.42 to -37.01	*	<0.0001
Female: HIE + Vehicle vs. HIE + HYPO	20.83	12.62 to 29.03	#	<0.0001
Female: HIE + HYPO vs. HIE + SOVA	15.38	7.170 to 23.58	@	<0.0001

Sovateltide (reduced brain cell death) Phase II is ongoing in India, with 14 out of 40 patients enrolled

Centhaquine

A resuscitative agent that is free of arterial constriction





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

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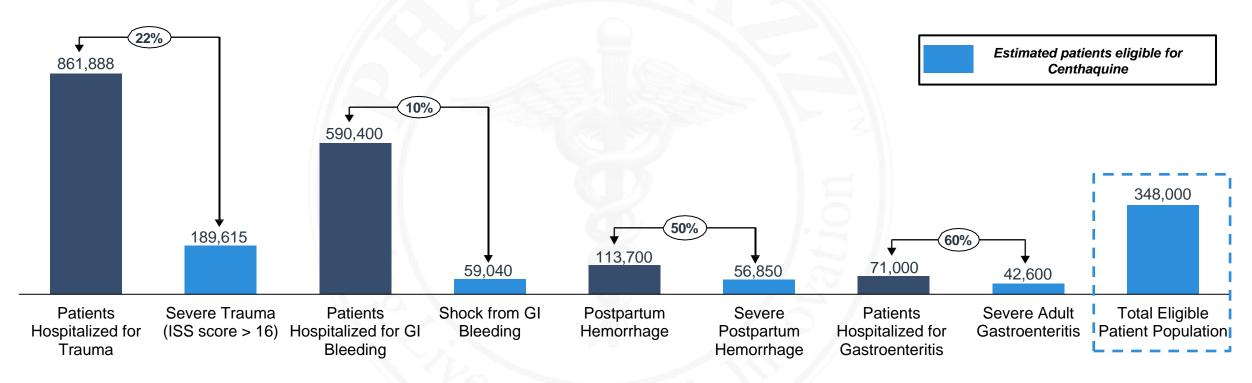
Decreased Cardiac Output	Caused by severe blood or fluid loss	Blood Pressure		
Hypoperfusion of Organs	Due to poor cardiac output and perfusion of vital organs	Oxygen Levels		
Multiple Organ Failure	This is the critical driver of mortality	Organ Failure		
DEATH				

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⁽¹⁾

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 AABB; 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

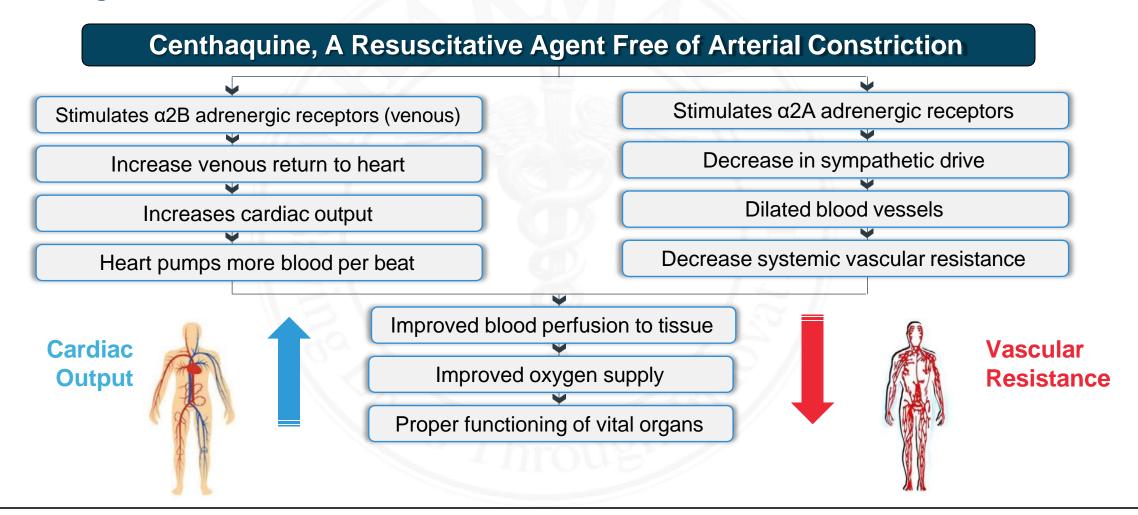
- Arterial constriction, reduced tissue blood perfusion
- Cardiac Arrhythmias
- Fluid Extravasation
- Vasopressor Infusion requires careful titration

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	 71 patients: experimental arm: Centhaquine + standard of care 34 patients: comparator arm: standard of care
Dosage	Centhaquine administered at 0.01mg/kg, i.v. in 100 mL of normal saline
Efficacy Assessment	SBP, DBP, Blood Lactate, base-deficit Secondary endpoint: 28-day Mortality

Phase 3 Primary and Secondary Endpoints

Endpoints	Results (%	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

Centhaquine: Trial Results (Continued)

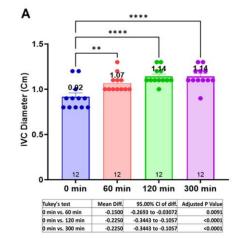


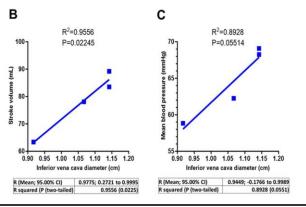
The Indian Phase 3 study showed a ~75% reduction in mortality. Meta-analysis of Phase 2 and 3 data reach statistical significance Additionally, a prospective, multi-centric, open-labeled study of 400 patients to assess the safety and efficacy of centhaquine is ongoing, more than 260 patients enrolled

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 increase in stroke volume correlates with increase in inferior vena cava diameter in shock patients





Centhaquine: Phase 3 Trial Protocol



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

Study Design		
Design Parameters	Multi-Center, Randomized, Double- Blinded, Placebo-controlled	
Dosage	0.01 mg/kg of Centhaquine + Standard of Care	
No. of Participants	430 patients, randomly assigned equally to both arms	
Time Frame	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 ≤ 90 mm Hg, blood lactate > 2 mmol/L and receiving SOC	SBP ≤ 90 mm Hg, blood lactate > 2 mmol/L and receiving SOC
Exclusion criterion	Exclude if hypovolemic shock etiology is unavailable	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 ≤ 0.435) and efficacy (p ≤ 0.003)	Does not specify details
Standard of care	Crystalloids, Colloids, Blood Products, Vasopressors	Crystalloids, Colloids, Blood Products, Vasopressors

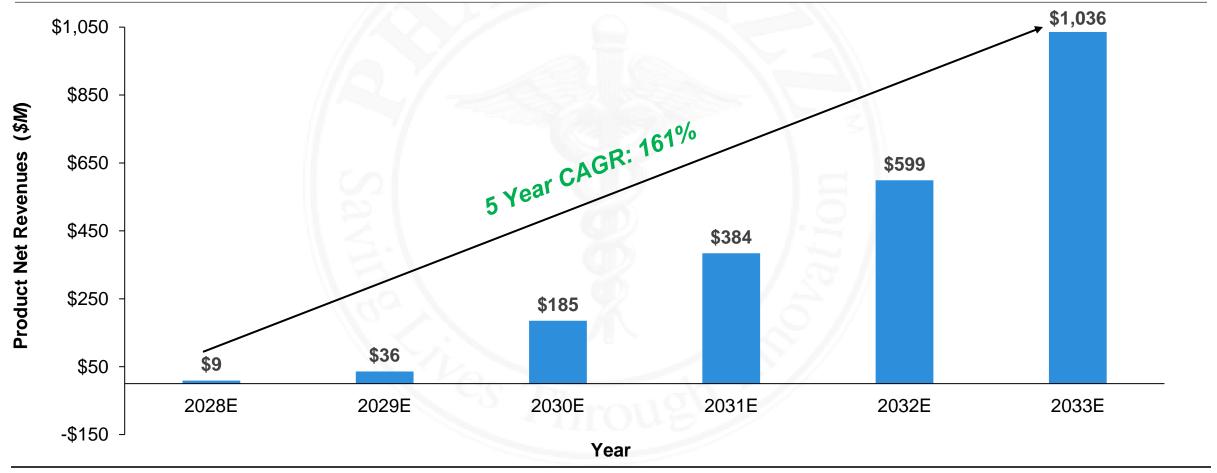
- Majority of patients enrolled were hemorrhagic shock: 65 (45 in Centhaquine, 20 in control); Number of patients with fluid loss: 37 (23 in Centhaquine, 14 in control)
- Coagulopathy, acidosis, and hypothermia make a deadly cycle of a lethal triad in patients with acute hemorrhage. Centhaquine resuscitation within the Golden Hour is likely to be more effective in attenuating the lethal triad than missing the Golden Hour.
- Literature¹ 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 <u>achieve net</u> revenues of ~\$1.0B by 2033⁽¹⁾

Centhaquine Revenue Forecast in the US (2028E – 2033E)

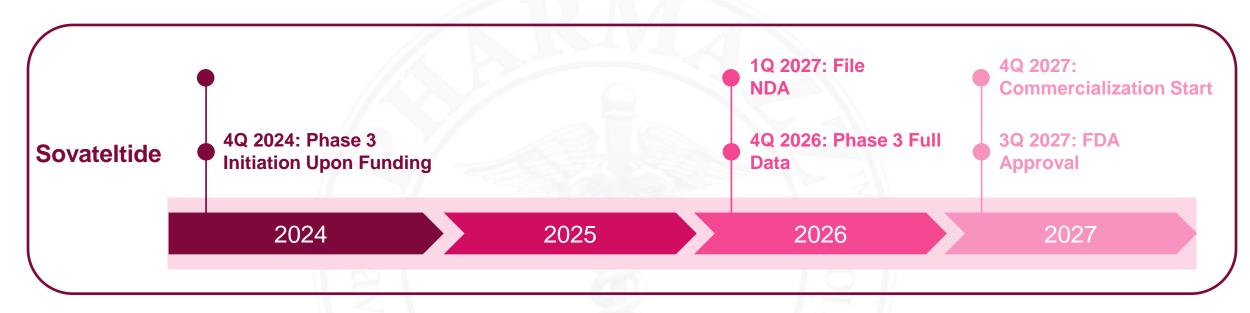


^{1.} Source: IQVIA Inc. Key Assumptions: Severe Hypovolemic Shock patients per year = 350,000; price per patient \$8,800 with 2% annual increase; market penetration from 1.0% to 40% over 9 years. Reference Company Websites, Clinicaltrials.gov.

Upcoming Milestones



\$35M projected to fund through Sovateltide commercialization



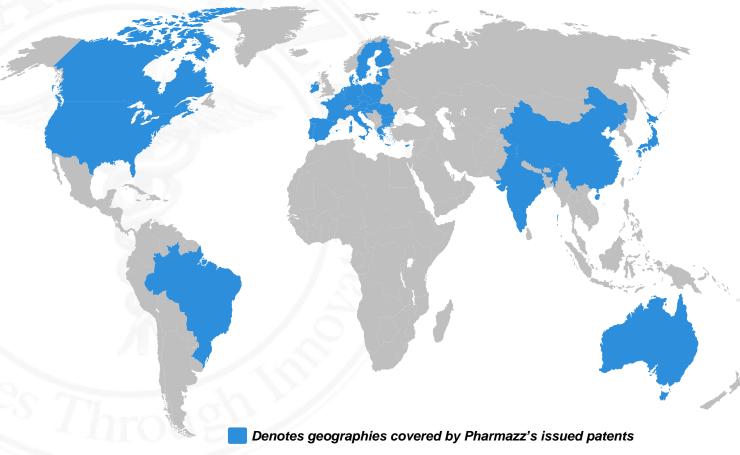


Patents and Licenses



- 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 2043-44		
Title	Lyophilized centhaquine citrate injection formulation and a method for the same	Lyophilized sovateltide-based injectable formulation and a process for preparation
Applicant	EXCELLENCE IN CRITICAL CARE MEDICINE	EXCELLENCE IN CRITICAL CARE MEDICINE
Application Number	IN202411028038	WO2024057296 A2
Priority Date	April 4 th 2024	June 28 th 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



Neil Marwah, MD

President

 >30 years of experience in large healthcare provider organizations, government relations, managed care, private equity, and senior management at Global 500 enterprise



Manish Lavhale, PhD

Managing Director,
India

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



Dharmesh Shah, MD, DM

Assistant Medical

Director

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





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



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



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



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



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



Validating and functional partnerships for sales and distribution in India



Dr.Reddy's

e Centhaquine



Thank You

