



# Transforming Critical Care with First-in-Class Innovation

December 2025



# Investment Highlights

Two first-in-class treatments for critical care indications with products approved in India and ongoing US Phase 3

## Late-Stage Clinical Pipeline

### Sovateltide

*endothelin-B agonist  
for acute cerebral  
ischemic stroke  
(ACIS)*

- **US Phase 3 first patient dosed July 2025; full data readout anticipated 1Q'27**
- Approved and marketed in India as Tyvalzi <sup>TM\*</sup>
- Improved neurological outcomes at 90 days; first statistically significant clinical data in 25+ years
- Approved Phase 3 SPA with the U.S. FDA
- Phase 3 data analyzed per SPA showed 76% of Sovateltide vs 54% control ( $p=0.0031$ ) had mRS of 0-2 at Day 90
- **New India Phase 4 data (Sept. 2025)** – 92% of Sovateltide patients achieved mRS 0-2, vs 58% in control ( $P=0.0005$ )

### Centhaquine

*resuscitative agent  
without arterial  
constriction for  
hypovolemic shock*

- Approved and marketed in India as Lyfaquin®
- Phase 3 results (India) met all primary endpoints; showed a 75% reduction in 28-day mortality
- 2 Phase 3 U.S. INDs approved (hypovolemic shock and Acute Respiratory Distress Syndrome (ARDS))
- Phase 3 ready to start, pending additional funding

## Current Cash Supports Sovateltide Through Phase 3 Data; Centhaquine is Phase 3-Ready

- Previous \$40M strategic investment to advance life-saving therapies for critical care patients
- Sovateltide: ~\$3.6bn of revenues with a 5-year CAGR of 132% by 2033 (ACIS)
- Centhaquine: ~\$1.0bn of revenues with a 5-year CAGR of 161% by 2033 (*hypovolemic shock*)



\*Strategic partner, Sun Pharmaceuticals – with 100,000+ patients treated since the launch in September 2023 with no serious drug-related AE's reported

# Management Team

Experienced team with extensive drug development and clinical expertise



**Anil Gulati, MD, PhD**

*Chairman and Chief Executive Officer, Chief Medical Officer*

Inventor with 40 years of drug discovery, development, clinical and management experience. 300 peer-reviewed publications and >50 issued patents



**David Costello**

*Vice President, Corporate Affairs*

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



**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 enterprises



**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



**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



**Kabir Marwah**

*Chief Growth Officer*

Former NASA Engineer and founding engineer at a venture backed startup valued at over \$1b. Raised money from top tier funds such as In-Q-Tel, a16z, 8VC and Point72.

# US Product Pipeline

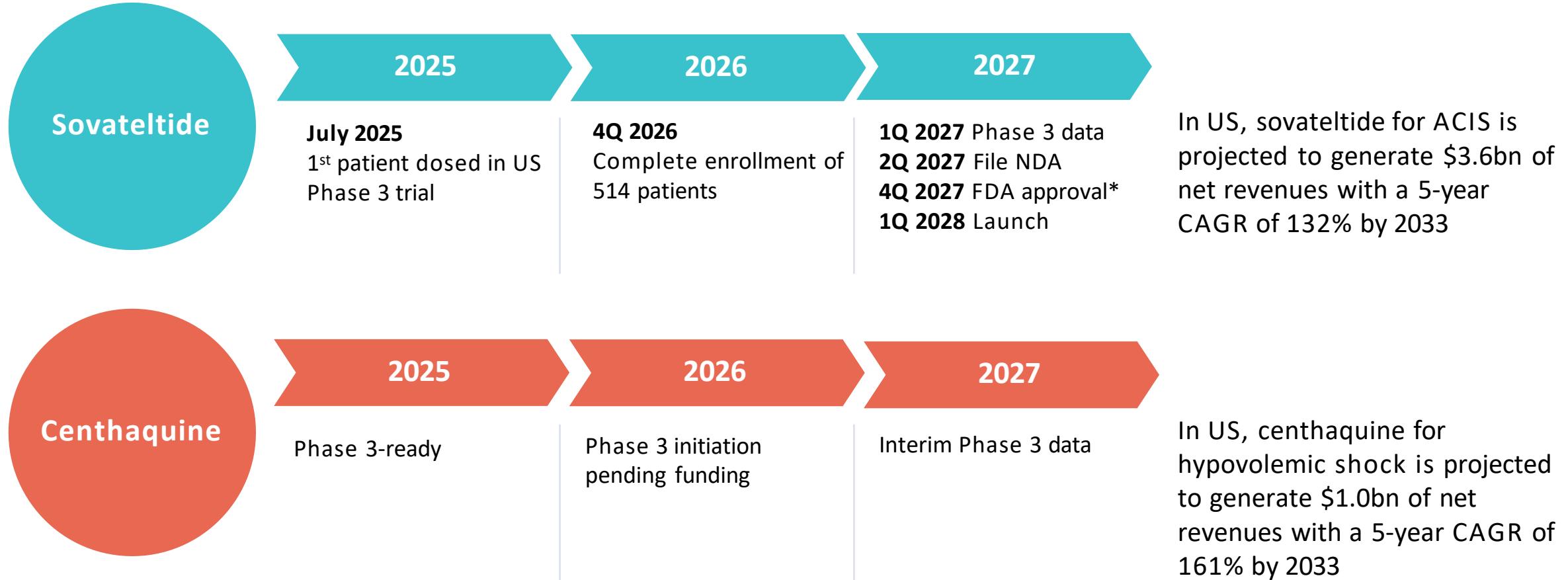
	Indication	Pre-clinical	Phase 1	Phase 2	Phase 3	Anticipated Milestones
Sovateltide	Acute Cerebral Ischemic Stroke					Phase 3 data (1Q'27)
	Hypoxic-Ischemic Encephalopathy					File NDA (2Q'27)
	Alzheimer's Disease					FDA Approval (4Q'27*) Launch (1Q'28*)
Centaquine	Hypovolemic Shock					Start Phase 3 (pending financing)
	ARDS					
	Septic Shock					

\* assuming priority review



# Upcoming Milestones

Phase 3 data from Indian trials successfully led to US FDA acceptance of Phase 3 protocols for both products



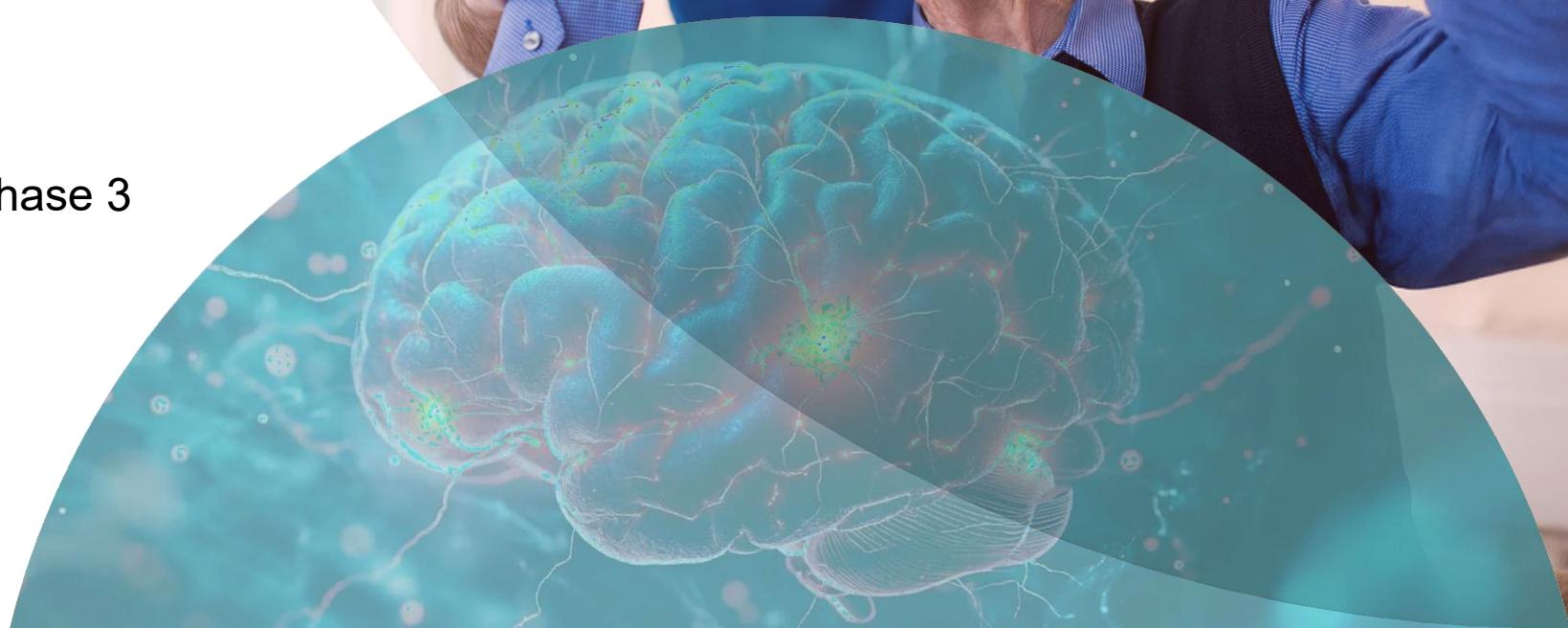
Current cash funds operations through sovateltide Phase 3 data in Q1 2027



\*assuming priority review

# SOVATELTIDE

A first-in-class drug candidate in Phase 3  
for acute cerebral ischemic stroke



# Unmet Need in Ischemic Stroke and Sovateltide Positioning

**Current treatment paradigms focus on re-establishing blood supply with clot busters or surgical intervention**

**795,000 patients per year in the US suffer from stroke**

- No FDA approved therapies in last 40 years since tPA in 1987
- 90% of US patients not eligible for TPA, due to arrival in ER outside treatment window or risk of bleeding
- Significant limitations: treatment window restricted to 3 hours post-stroke for tPA and 12 hours post-stroke for surgical intervention

**Sovateltide takes a novel approach with focus on neurogenesis and neuron preservation**

**24-hour treatment window post-stroke dramatically expands number of stroke patients eligible for sovateltide**

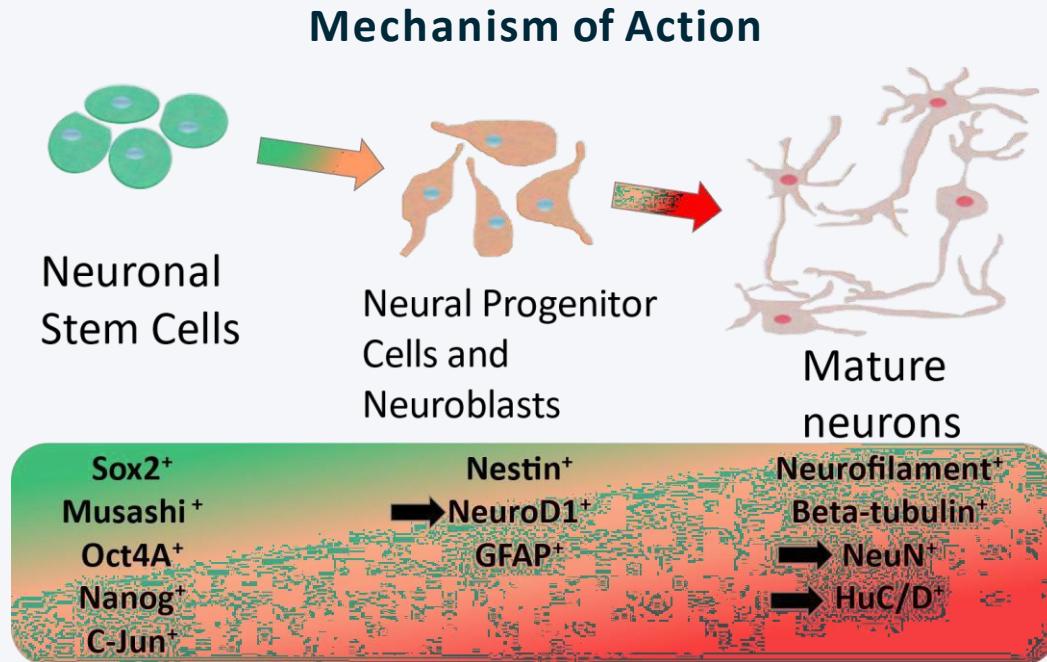
- Pharmazz focus is more on neurogenesis and neuron preservation
- Extensive safety database: >100,000 patients treated in India since 2023, with only 29 potential side effects reported in VigiBase database<sup>1</sup>
- Stroke patients at high-risk for bleeding complications not eligible for current interventions, are eligible under Sovateltide Phase 3 protocol
- Potential breakthrough therapy designation supported by clinical data from India and the US SPA



<sup>1</sup> VigiBase is the WHO global database for adverse event reporting (database accessed July 2025: <https://www.vigiaccess.org/>)

# Sovateltide is a Highly Selective Endothelin-B Receptor Agonist

Stimulates neural progenitor cells in the brain and promotes neurovascular remodeling



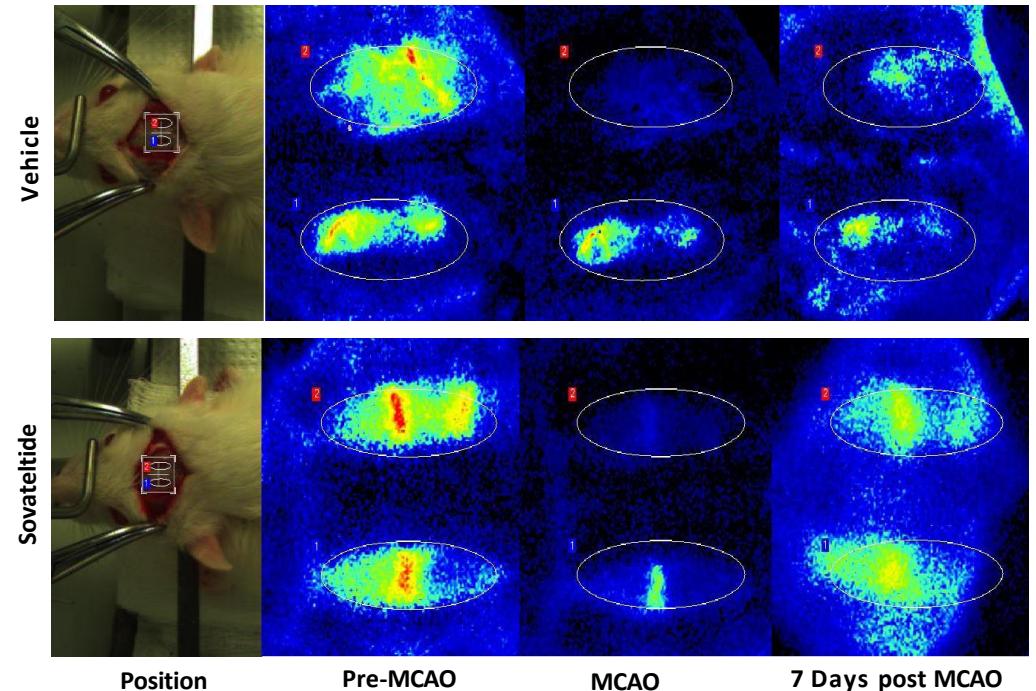
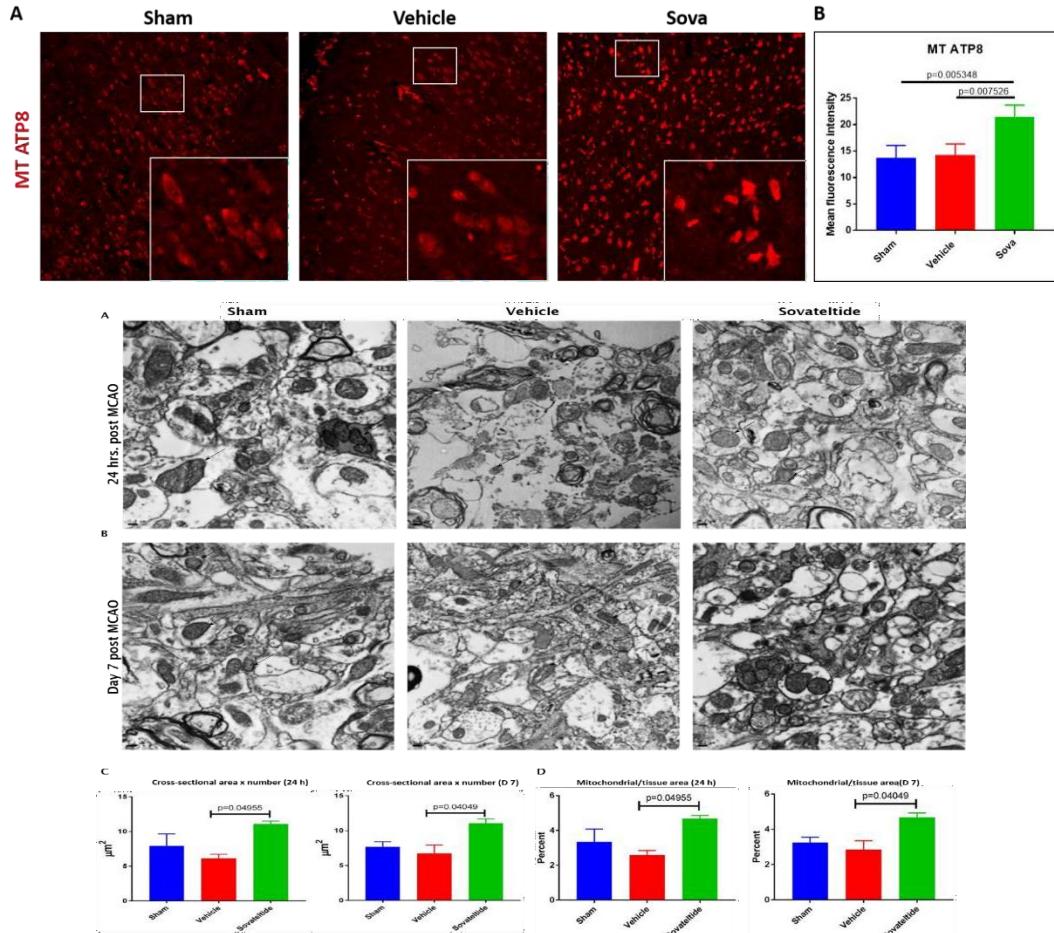
- Increases cerebral blood flow
- Anti-apoptotic activity with protection of neural mitochondria, enhancing biogenesis
- Produces neurovascular remodeling through formation of new neurons and blood vessels
- Reduces infarct volume and improves neurological outcomes in an animal model of ACIS\*

***Sovateltide enhances the expression of markers for neural progenitor cells and neuronal cells***

# Sovateltide – Preclinical Evidence

## A novel first-in-class drug to treat acute cerebral ischemic stroke (ACIS)

Sovateltide increases mitochondrial biogenesis (mitochondrial DNA; MT ATP8 DNA, content) in MCAO rat brains (Technique – *In situ* tissue PCR).



### Sovateltide in ischemic stroke model of rats:

- Increased cerebral blood perfusion in the brain of rats with ischemic stroke
- Increased mitochondrial biogenesis and improved mitochondrial morphology in rats with ischemic stroke
- Promoted differentiation of NPCs and plausible neural regeneration

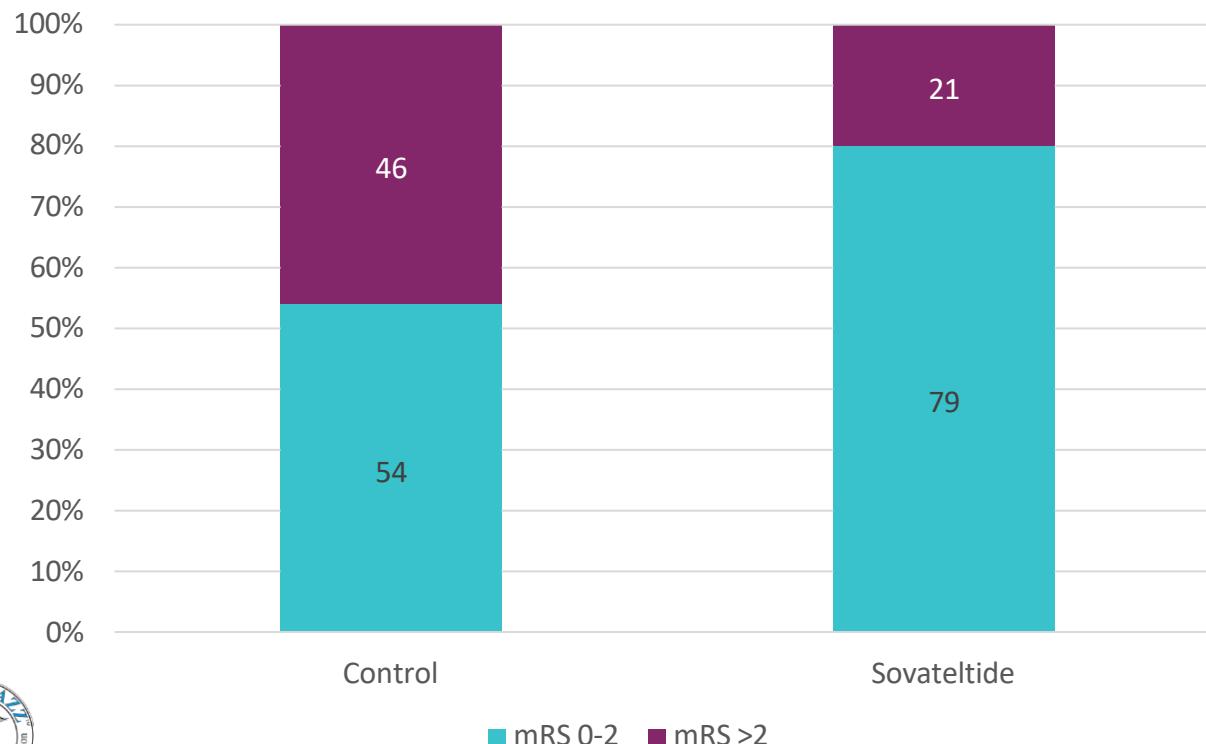
# Sovateltide Phase 3 Trial Met Primary Endpoint in Acute Ischemic Stroke

Approved in India in May 2023 and marketed by Sun Pharma as Tyvalzi

- 158 patients randomized to Sovateltide (n=80) or placebo (n=78)
- Sovateltide was administered ~18 hr of stroke onset in both treatment arms
- Primary endpoint: % patients with (mRS=0-2) improved neurological outcomes at 90 days

Percentage of Patients with mRS 0-2 (Day 90)

P=0.0009172



- Median NIHSS at randomization was similar between the control and sovateltide groups.
- The proportion of patients with (mRS 0-2 score) good neurological outcome at Day 90 post-randomization was 24% higher in the sovateltide group than placebo.
- The proportion of patients with good neurological outcome having an NIHSS score of 0–5 at Day 90 was 17% more in the sovateltide group than placebo.
- An improvement of  $\geq 2$  points on the mRS was observed in 72% patients treated with sovateltide compared to 51% in the placebo group.
- A greater number of cerebral ischemic stroke patients treated with sovateltide had better neurological outcome with lower mRS and NIHSS scores at 90 days post-treatment, compared to placebo.
- Adverse events were consistent with the placebo group.



# Sovateltide Phase 3 Safety Data

## Acceptable safety profile

	Saline (N=78) 33 adverse events in 24 patients	Sovateltide (N=80) 27 adverse events in 15 patients
<b>Serious</b>	<p><b>2 events in 2 patients</b></p> <ul style="list-style-type: none"> <li>Death (2)</li> </ul>	<p><b>5 events in 5 patients</b></p> <ul style="list-style-type: none"> <li>Death (4)</li> <li>Hyponatremia (1)</li> </ul>
<b>Moderate</b>	<p><b>22 events in 16 patients</b></p> <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>	<p><b>19 events in 7 patients</b></p> <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>	<p><b>9 events in 6 patients</b></p> <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>	<p><b>3 events in 3 patients</b></p> <ul style="list-style-type: none"> <li>Dyspnea (1)</li> <li>Chills (1)</li> <li>Back pain (1)</li> <li></li> </ul>

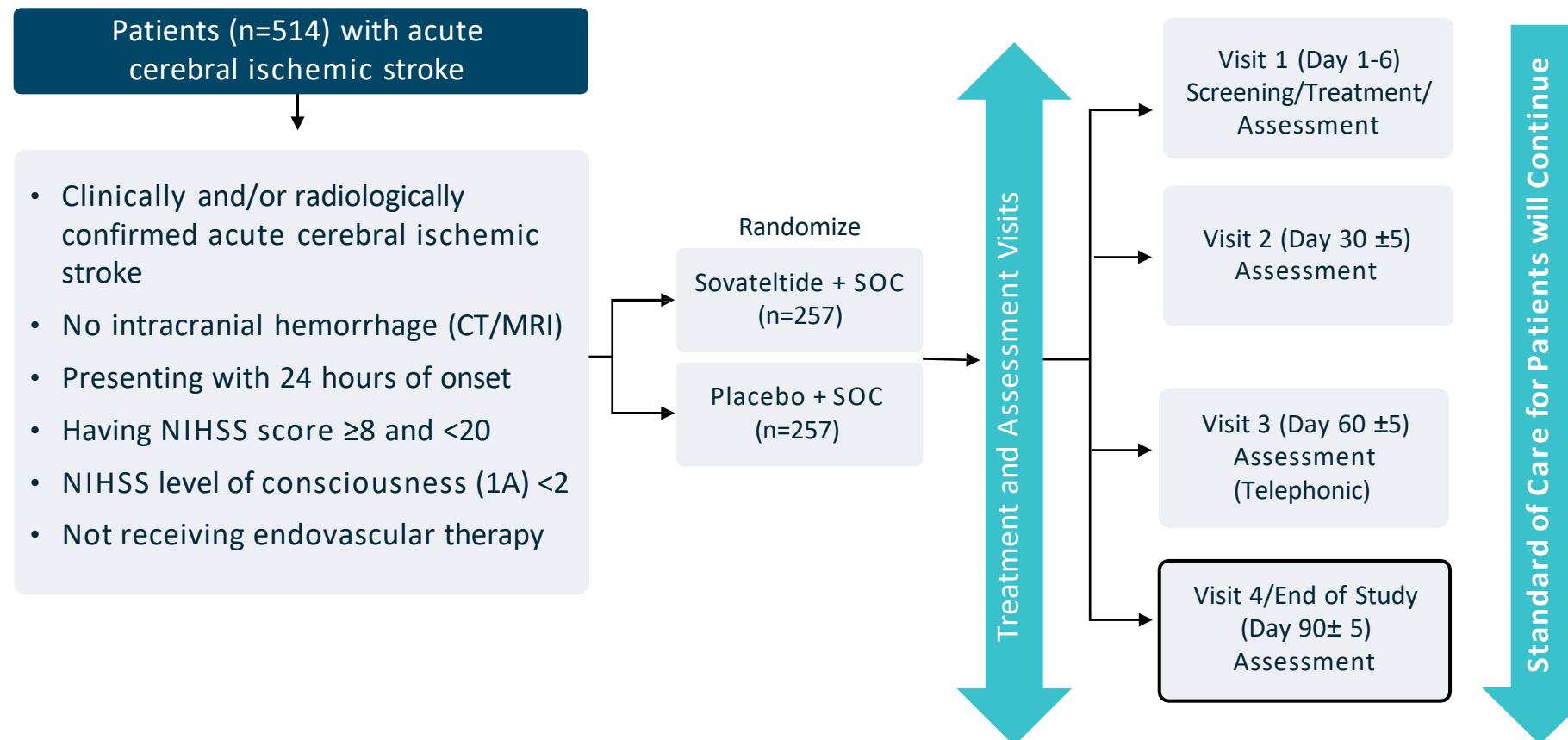
*Safety profile  
supported by post-  
marketing  
experience in India  
with over 100,000  
patients now treated  
since 2023\**

\*VigiBase is the WHO global database for  
adverse event reporting (database  
accessed July 2025:  
<https://www.vigiaccess.org/>)

# Sovateltide: SPA Agreement with FDA for Phase 3 Trial Design

Phase 3 trial is now actively enrolling patients and expected to be completed Q4 2026

A multicenter, randomized, double-blind, parallel, placebo-controlled study to assess the safety and efficacy of Sovateltide in patients with acute cerebral ischemic stroke



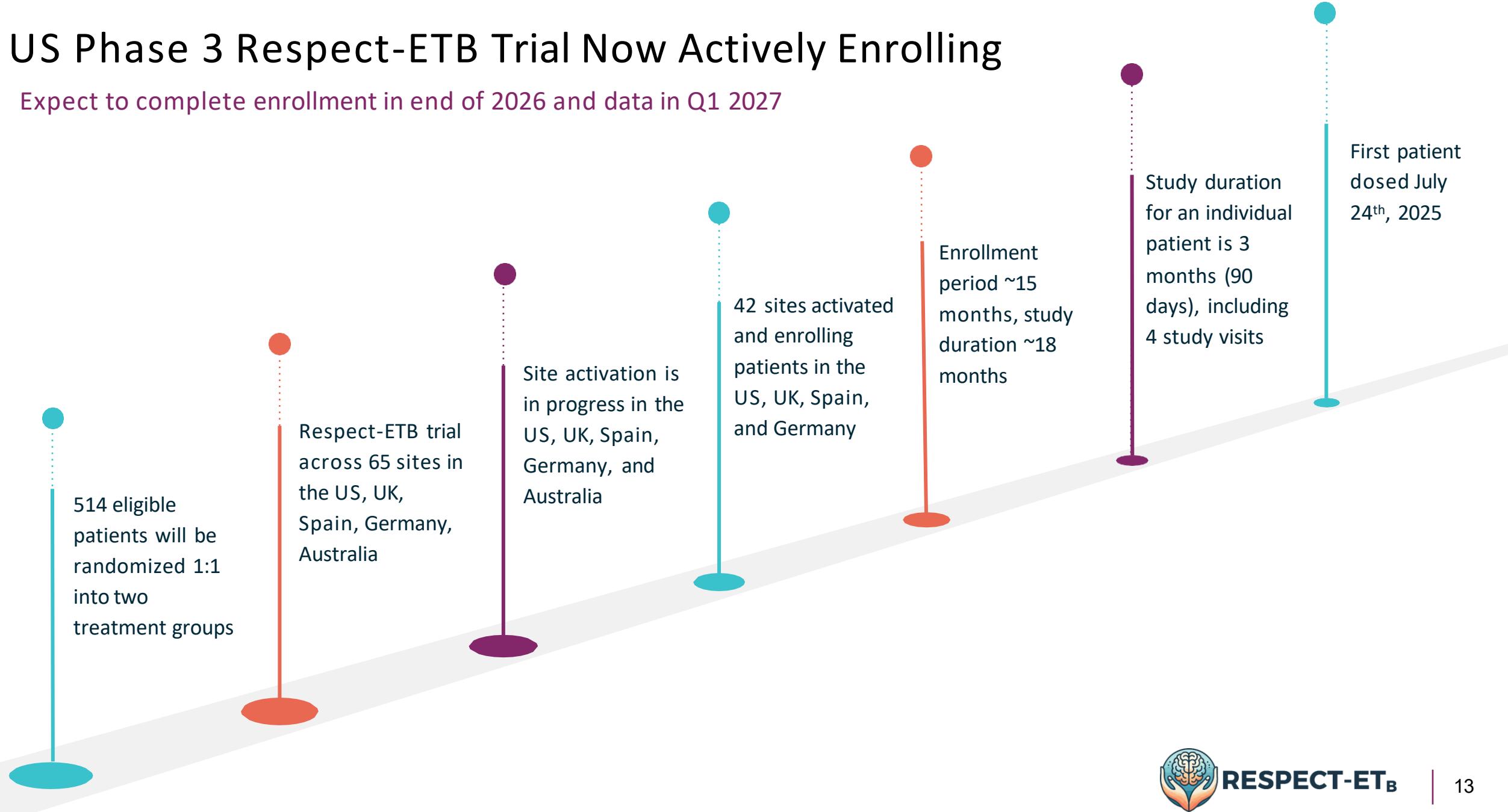
## Primary endpoint:

Proportion of patients with mRS of 0 to 2 at 90 days.

Stratified based on early vs. late enrollment ( $< 12$  hours vs.  $\geq 12$  hours) and by the use vs. non-use of rtPA.

# US Phase 3 Respect-ETB Trial Now Actively Enrolling

Expect to complete enrollment in end of 2026 and data in Q1 2027



**RESPECT-ET<sub>B</sub>**

# Sovateltide: Comparison of US and India Phase 3 Study Designs

Similar patient populations, the main difference is the NIHSS score  $\geq 8$  in the US and  $\geq 6$  in India at enrollment

Parameter	US Phase 3 Ongoing as per SPA	India Phase 3 Completed
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
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 3 Data from 158 Patients Analyzed per SPA

76% of sovateltide vs. 54% of control patients ( $p=0.0031$ ) had mRS of 0-2 at Day 90

Number of patients with mRS of 0-2			
	Control (N=78)	Sovateltide (N=80)	P value
<b>Day 90 (Primary end point)</b>	53.58% (N=42)	76.25% (N=61)	0.0031
<b>Day 30</b>	41.03% (N=32)	63.75% (N=51)	0.0042
<b>Day 6</b>	20.51% (N=16)	32.50% (N=26)	0.0882

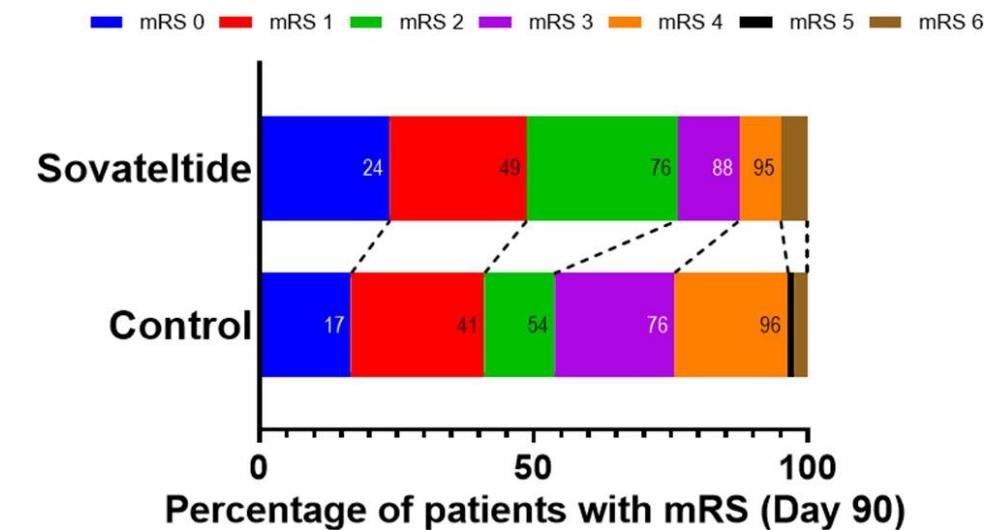
Number of patients with NIHSS of 0-5			
	Control (N=78)	Sovateltide (N=80)	P value
<b>Day 90 (Secondary end point)</b>	67.95% (N=53)	85.00% (N=68)	0.0114
<b>Day 30</b>	58.97% (N=46)	78.75% (N=63)	0.0072
<b>Day 6</b>	37.18% (N=29)	56.25% (N=45)	0.0163

Number of patients with BI of 90-100			
	Control (N=78)	Sovateltide (N=80)	P value
<b>Day 90 (Secondary end point)</b>	43.59% (N=34)	57.50% (N=46)	0.0804
<b>Day 30</b>	30.77% (N=24)	50.00% (N=40)	0.0138
<b>Day 6</b>	8.97% (N=7)	20.00% (N=16)	0.0495



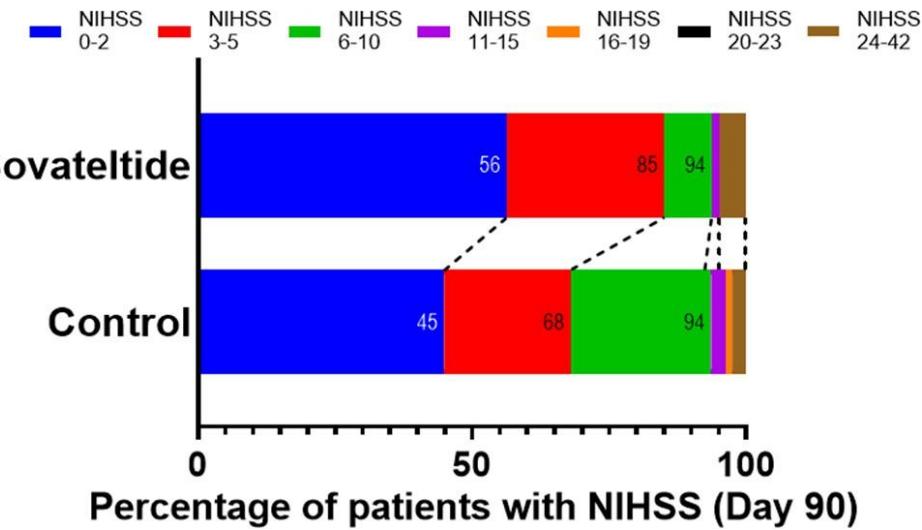
# Sovateltide: Phase 3 Data from 158 Patients Analyzed per SPA

Ordinal shift across the range of modified Rankin scale at 90 days



**Distribution of scores on the Modified Rankin Scale at 90 days in the Intention-to-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.

Ordinal shift across the range of NIHSS scale at 90 days



**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.

**An absolute increase in the favorable outcome of more than 17% was observed with sovateltide in patients with cerebral ischemic stroke**

# India Phase 4 trial – Ongoing as Post-Approval Commitment

Prespecified interim efficacy analysis conducted in September 2025 after 80 patients reached 90-day endpoint

- **Phase 4 trial is a regulatory requirement in India**
- **Identical protocol, inclusion/exclusion and endpoints as previous Phase 3**
  - N=160, double blind, placebo-controlled (details: [NCT05955326](https://www.clinicaltrials.gov/ct2/show/NCT05955326))
- **Primary endpoint:**
  - Percentage of patients with mRS 0-2 at Day 90
- **Provides confirmation of Phase 3 that formed basis of approval**
  - Minimal overlap of centers and researchers with the original Phase 3
- **Study initiated in January 2024**
  - Prespecified interim analysis conducted with 50% patients
  - Final analysis with 160 patients anticipated in Q4 2025

# India Phase 4 Trial – Interim Efficacy Results Meet Primary Endpoint

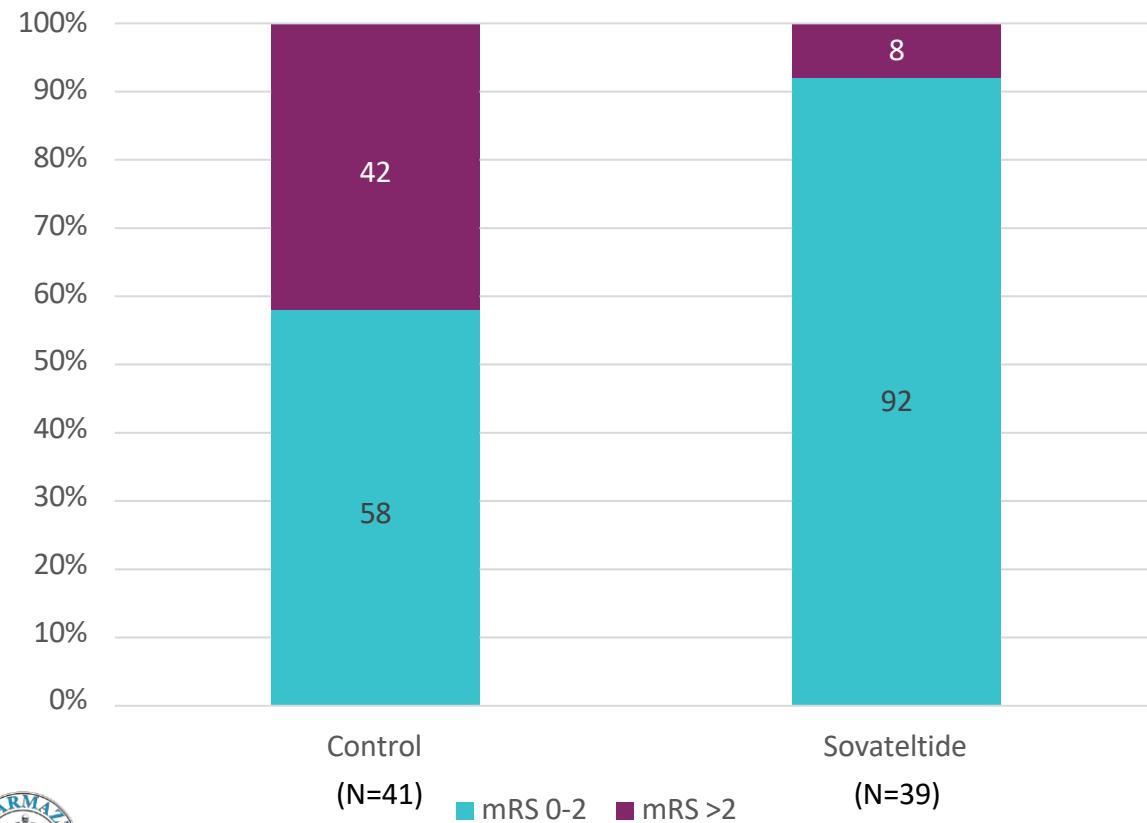
New data (Sept. 2025) show 92% response rate for Sovateltide vs. 58% placebo – 34% delta (p=0.0004889)



Primary endpoint: % Patients with mRS 0-2

(Day 90)

P=0.0004889



- Interim analysis conducted when 80 patients reached the 90-day endpoint
- 92% of Sovateltide patients achieved mRS 0-2 at 90 days vs 58% in the control arm
- 34% difference between the two arms compares favorably to the 25% difference seen in the previous Phase 3
- US Phase 3 is 90% powered to show at least a 10-percentage point delta between the active and control arms
- Final analysis with 160 patients anticipated in Q4 2025

# Sovateltide Summary and Key Events

## Key points

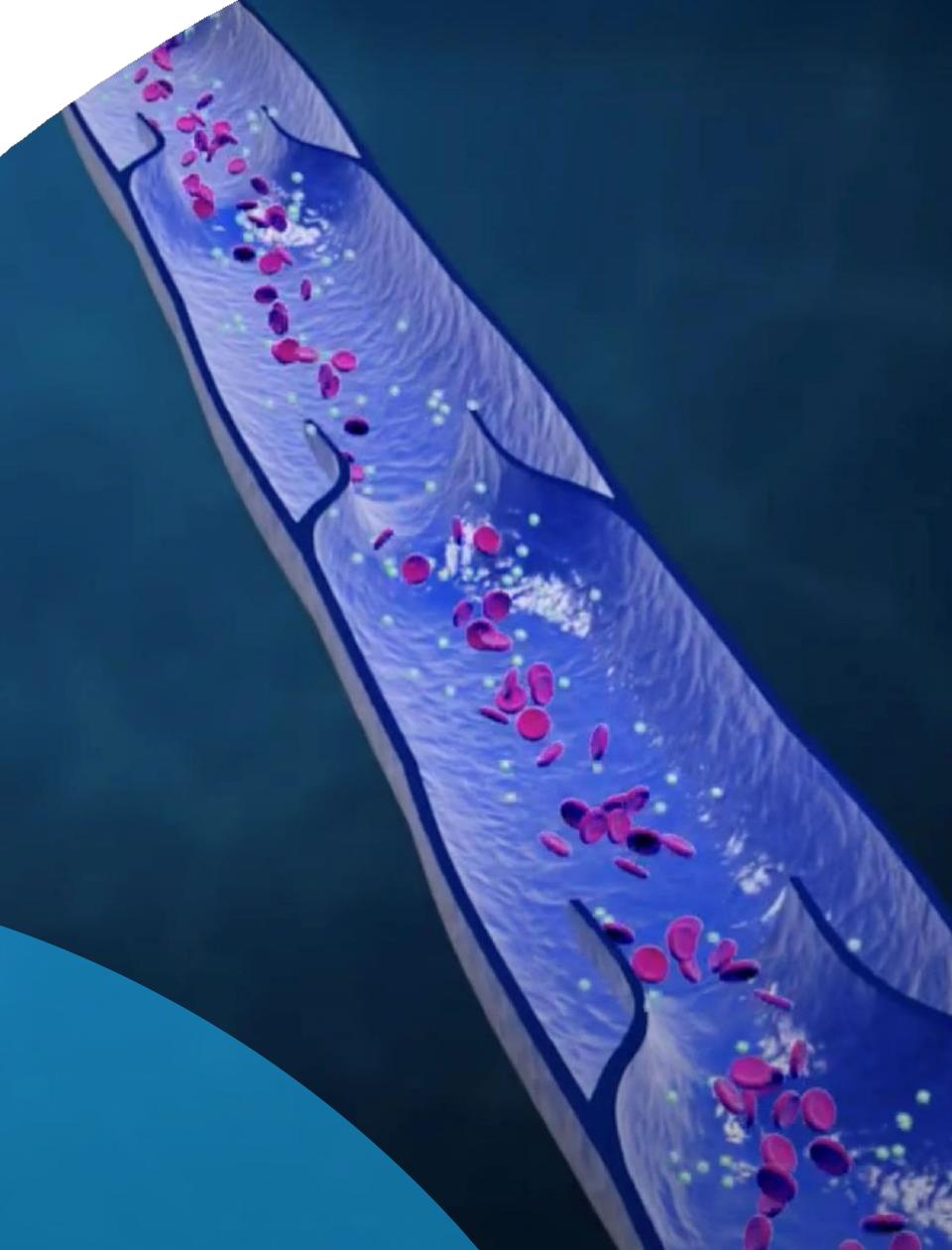
- ✓ Successful Phase 3 served as basis of 2023 approval in India and marketed as Tyvalzi
- ✓ US Phase 3 now actively enrolling under an SPA agreement with the FDA
- ✓ Indian P3 analyzed with SPA primary endpoint: 76% sovateltide vs. 54% placebo (p=0.0031)
- ✓ Current cash of \$25M fully funds Phase 3 to completion – data expected in Q1 2027

## Key events

- ✓ July 2025 – First patient enrolled and treated in US Phase 3
- ✓ September 2025 – Interim analysis of ongoing Indian Phase 4 trial met primary endpoint
- End-2026 – US Phase 3 enrollment expected to be completed
- Q1 2027 – US Phase 3 topline data expected

# CENTHAQUINE

A first-in-class Phase 3-ready drug candidate for hypovolemic shock



# Unmet Needs for Hypovolemic/Hemorrhagic Shock

**Hypovolemic / Hemorrhagic Shock is a life-threatening condition with high mortality rates**

**Annual incidence is 0.3 to 0.7 per 1,000 in the US with a 15% to 20% mortality rate**

- Decreased cardiac output, leading to lower blood pressure
- Hypoperfusion of organs, leading to lower oxygen levels
- Multiple organ failure
- Death

**Current SOC treatment protocol is fluid replenishment with colloid / crystalloid solutions +/- blood products. If fluids are insufficient, treatment requires vasopressors**

**Challenges with current SOC treatment include:**

- Arterial constriction, reduced tissue blood perfusion
- Cardiac arrhythmias
- Fluid extravasation
- Vasopressor infusion requires careful titration

***A resuscitative agent that increases cardiac output while decreasing vascular resistance is a significant, medical unmet need***

# Centraquine: Mechanism of Action

Centraquine increases cardiac output while decreasing vascular resistance

## Centraquine, A Resuscitative Agent Free of Arterial Constriction

Stimulates  $\alpha$ 2B adrenergic receptors (venous)

Increase venous return to heart

Increases cardiac output

Heart pumps more blood per beat

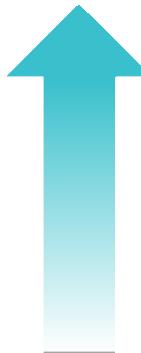
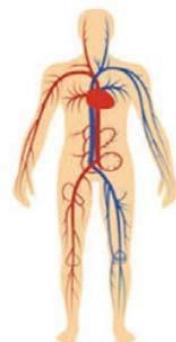
Stimulates  $\alpha$ 2A adrenergic receptors

Decrease in sympathetic drive

Dilated blood vessels

Decrease systemic vascular resistance

Cardiac Output

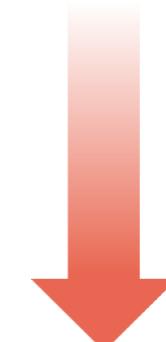


Improved blood perfusion to tissue

Improved oxygen supply

Proper functioning of vital organs

Vascular Resistance



# Centhaquine: Phase 3 Trial Results (India)

## 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 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

All four primary efficacy endpoints of blood lactate, base-deficit, systolic and diastolic blood pressure were met

28-day mortality, trended toward the benefit (*secondary endpoint*)

**~75% reduction in mortality. A Phase 2 and 3 data meta-analysis reached statistical (p=0.03) significance.**



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

# Centhaquine: US Phase 3 Trial Protocol

Start of Phase 3 pending additional sources of funding

## 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 Summary and Key Events

## Key points

- Novel, first-in-class, frontline resuscitative agent that has significantly reduced AEs and mortality in patients with hypovolemic shock
- Effective in small volume (100 ml over 60 min) without need for titration and not likely to produce fluid extravasation
- Produces arterial dilation to enhance blood supply to the tissues
- Arrhythmias and fluid extravasation have not been observed with centhaquine
- Does not act on  $\beta$ -adrenergic receptors and has no isomers, providing significant advantage because of minimal risk to produce cardiac complications

## Key events

- Phase 3-ready 2025
- Phase 3 initiation pending funding in 2026
- Interim Phase 3 data 2027



# Patents, Licenses and Exclusivity

Over 50 issued patents covering relevant geographies with expirations ranging out to 2044

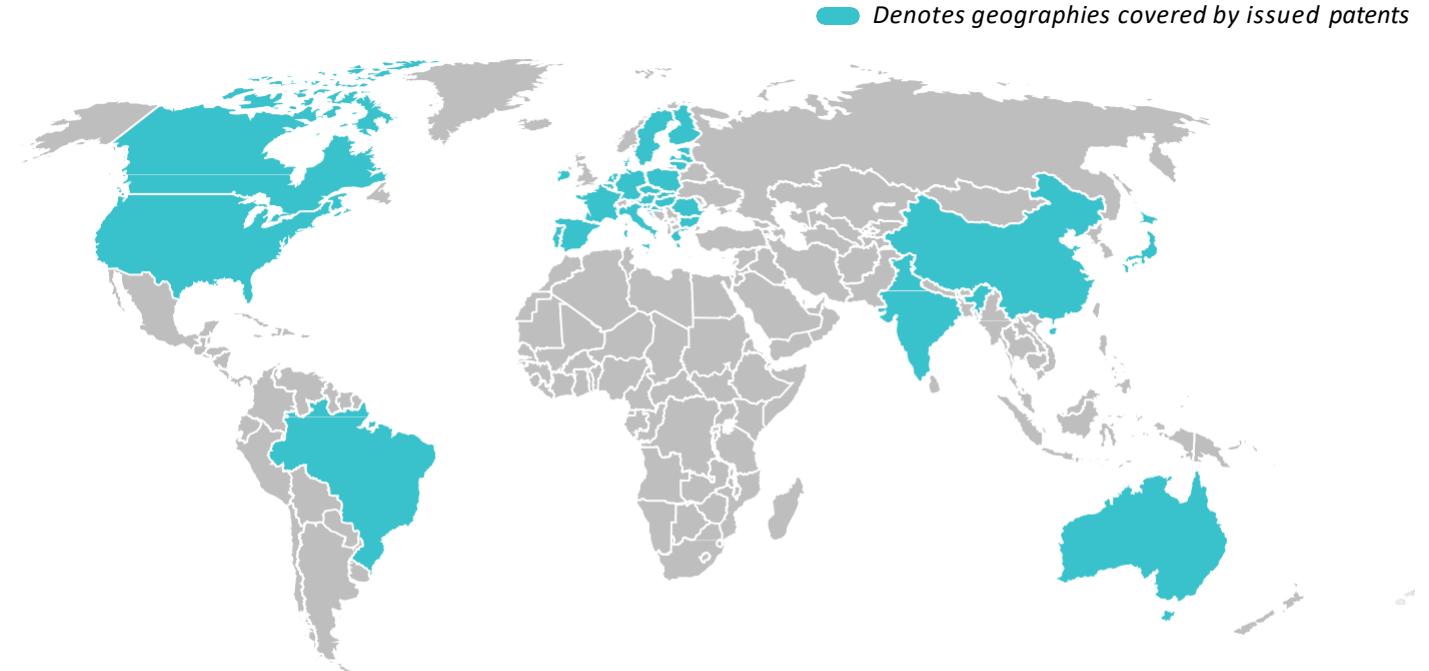
Exclusive worldwide rights of intellectual property from Midwestern University; only single-digit royalties due once commercialized

Multiple issued method-of-use patents, eligible for term restoration; issued manufacturing patents

Several patent applications related to composition and methods under examination at PTO

Upon approval, 5 years of NCE exclusivity in US

Defensible IP protection in the US until early 2040s



## Multiple Patents Issued and Under Review

Method of Use

Issued

Pharmaceutical Composition

Under PTO review

Process & Manufacturing

Issued

# Summary and Upcoming Milestones



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 2028**



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 key 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 partnership** for sales and distribution in India



Sovateltide

# Transforming Critical Care with First-in-Class Innovation

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