



# Lumosa Therapeutics Co., Ltd. (TPEX:6535)

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Presenter: June Kuo

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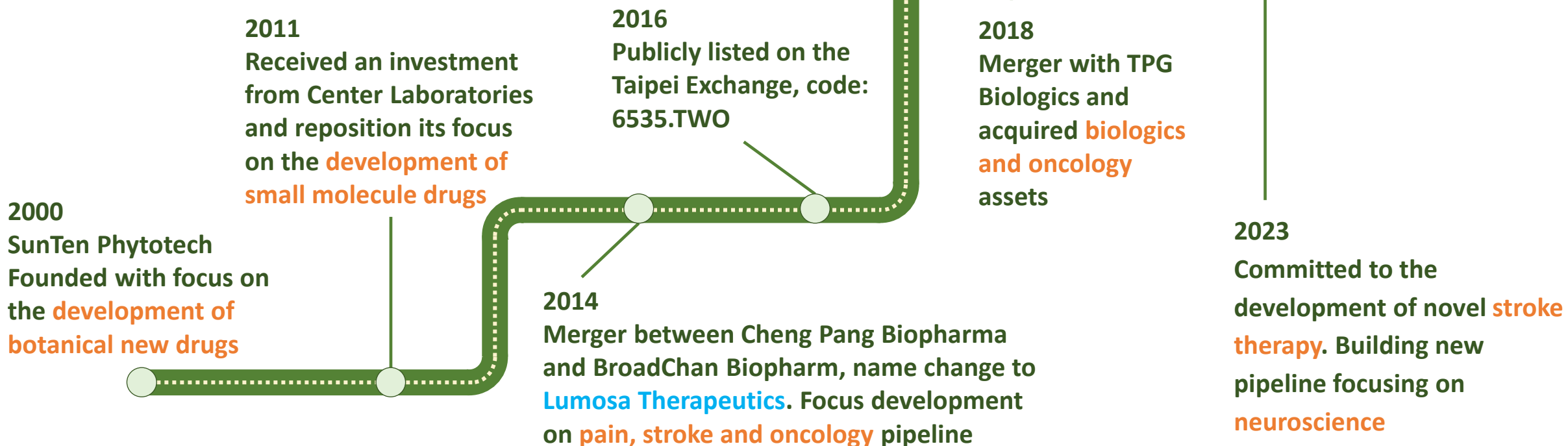
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# Overview of Lumosa

Founding Date	Nov, 2000
Paid-in capital	US\$ 52 million
Major shareholders	Center Laboratories Group (34%)
Chairman and CEO	Mr. Rong-chin Lin
Listing date (TWO.6535)	Sep, 2016
First merger (2014)	Expanded pipeline (acquired late-stage asset)
Second merger (2018)	Acquired biologics and oncology assets



Providing innovative medical solutions for the neuroscience field, aiming to become **a global leader in stroke**, nurturing **innovative treatment challenges**.



In **Market-oriented** **Innovative** **Licensing** Out

## LT6001 exosome asset

### Proof of concept

- Expands innovative technology in neuroscience
- Propels Lumosa as a leader in neuroscience



#### Cytoengine

Founded by Lumosa in 2022/01  
Paid-in-capital US\$ 4 million  
(2022/10/25 completed capital injection)

Lumosa licensed the **"stemcell exosome technology"** from NHRI and transferred to **Cytoengine**, which is jointly invested by Lumosa and Center Laboratories. Cytoengine will be responsible for the development of subsequent technologies

## LT3001, novel therapy for acute ischemic stroke

### Successful licensing:

- Brings sufficient resources to develop next-gen drugs
- Propels Lumosa to unicorn status



Out

## LT1001, ER analgesic injection

- Provide stable cash flow



Balanced Asset Allocation



# LT1001 (Naldebain®)

Week-long Extended-release Analgesic Injection

Approved in: Taiwan, Singapore, Thailand, Malaysia, Ukraine and Brunei





# LT1001 (Naldebain®): **World's First** Week-long Extended-release Analgesic Injection

## Patented compound + patented release formulation

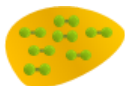
### ◆ Indications: Relief of moderate to severe postoperative pain

#### ◆ Patented compound

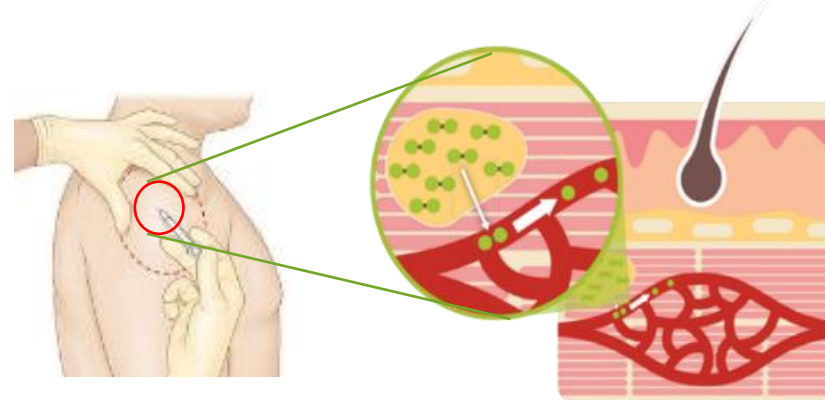


- ✓ Active ingredient: Dinalbuphine sebacate
- ✓ Prodrug of nalbuphine
- ✓ Analgesic effect comparable to that of morphine
- ✓ Excellent safety profile, low addiction potential, no respiratory depression

#### ◆ Patented release formulation



- ✓ Special formulation with intramuscular injection
- ✓ Extended-release analgesic with effective concentration for up to 7 days



**Unmet  
medical  
need**

### Effective

Analgesic effect comparable to that of morphine

### Safe

No opioid-related side effects (respiratory depression, addiction risk)

### Convenient

Single dose administration, reduced hospital stay, better pharmacoeconomics

The opioid crisis has led to a strong demand for **non-addictive** and **safer** postoperative analgesics

# LT1001 (Naldebain®): **World's First** Week-long Extended-release Analgesic Injection

Global strategic planning

## Approved

Taiwan (2017)  
Singapore (2020)  
Thailand (2021)  
Malaysia (2022)  
**Ukraine, Brunei (2023)**



Stable cashflow

## Registration

Korea  
Jordan



Robust growth momentum

## Clinical Trial

China  
(Planning)

India  
(Ongoing)

Animal drug  
(Pivotal trial ongoing)



Maximizing product value



## Approved in six countries:

Taiwan, Singapore, Malaysia, Thailand,  
**Ukraine, Brunei**

### • Continuous market expansion

Licensing or drug approval application using existing data; Korea, Jordan and India in progress.

### • Regulatory approval in China

Held discussions with Chinese regulatory agencies and licensed companies to reach a development consensus.

### • Animal drug

Pivotal study ongoing in 2023.

# LT3001

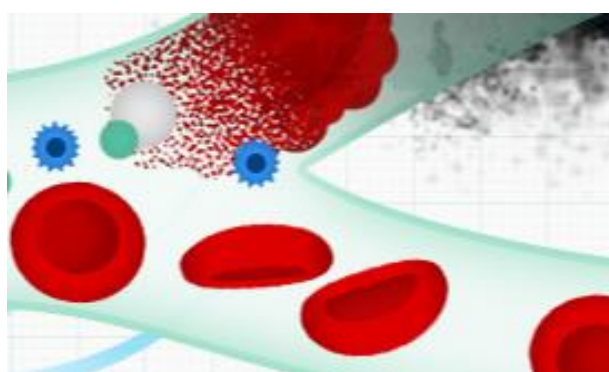
## Novel Dual-function Molecule for the Treatment of Acute Ischemic Stroke

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- The safety, pharmacokinetics, and drug-drug interactions confirmed by three Phase 1 trials
- Safety confirmed and efficacy trend observed in the Phase 2a trial
- Three Phase 2b trials ongoing, targeting enrollment completion and initiate out-licensing activities in 2024



# LT3001: The World's First Novel Dual-function Molecule



**Free radical scavenger**  
Reduce reperfusion injury  
Neuroprotection

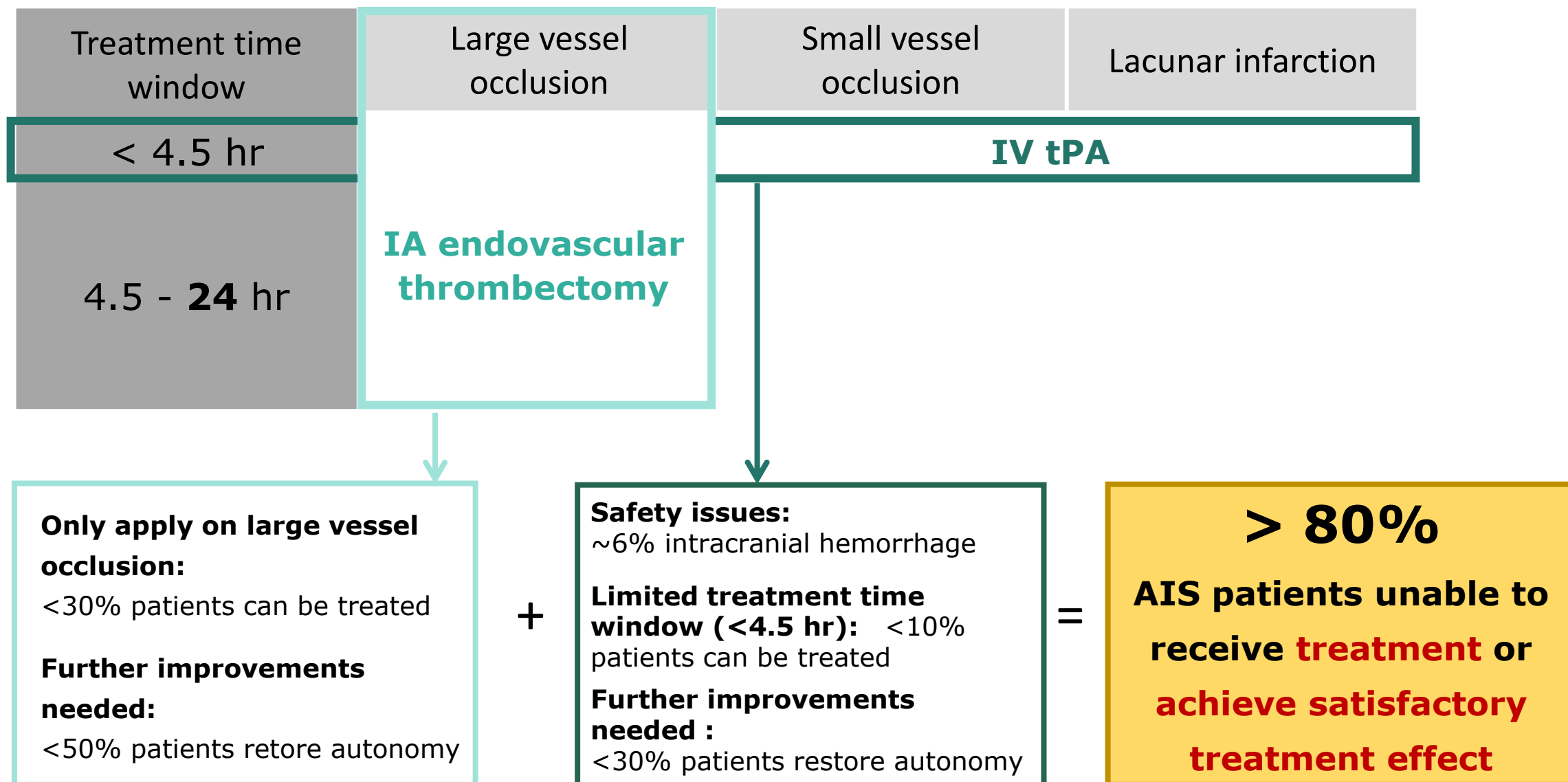


**Vessel active peptide**  
Thrombolysis  
Restore blood flow

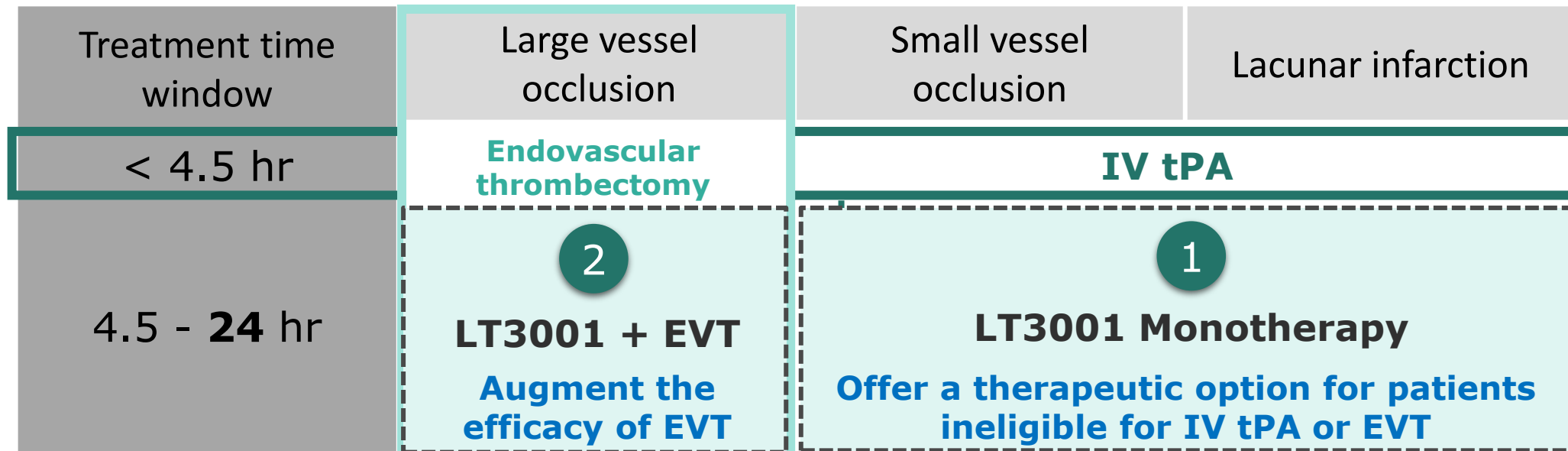


<b>Targeted indication</b>	Acute ischemic stroke (AIS)
<b>Administration route</b>	Short infusion
<b>Patent protection</b>	<b>2034</b> (Composition patent), <b>2040</b> (Formulation), <b>2042</b> (Method of use)
<b>Development status</b>	1) Phase 2a (single-dose) – completed 2) <b>Phase 2b – Three Phase 2b trials ongoing</b>
<b>Primary targeted population</b>	1) AIS patients < 24 hours after stroke symptoms 2) Concomitant use with endovascular thrombectomy in AIS patients
<b>Forecast (worldwide)</b>	US\$ 6.4 ~ 9.6 billion

# The Unmet Needs of Acute Ischemic Stroke and Product Positioning of LT3001



# The Unmet Needs of Acute Ischemic Stroke and Product Positioning of LT3001



**World's first novel therapy for AIS with an innovative MOA**

- ✓ Extends the treatment time window
- ✓ Thrombolysis and neuroprotection functions
- ✓ No hemorrhagic risk

**LT3001 Objective**

**Improve the outcomes of > 80% of the 16 million global AIS patients**

# LT3001 Clinical Status



**Publication of Phase 2a results**



**2021 WSC**



American Stroke Association  
International Stroke Conference

**2021 ISC**

**Three Phase 2b trials ongoing**

**Safety assessment and efficacy validation**

**Monotherapy**

**Phase 1 (US)**

**Phase 2a US/TW; N=24**

- Safety endpoint achieved
- Efficacy endpoint: Improve neurological function and outcome

**LT3001 received US FDA FTD**



Treatment time window	Large vessel occlusion	Small vessel occlusion	Lacunar infarction
< 4.5 hr	Endovascular thrombectomy	IV tPA	
4.5 - 24 hr	2 LT3001 + EVT Augment the efficacy of EVT	1 LT3001 Monotherapy Offer a therapeutic option for patients ineligible for IV tPA or EVT	



American Stroke Association  
International Stroke Conference

**2024 ISC**

**Multiple-dose, single-use (3-day dosing)**

**Multiple-dose combination with EVT**



**Phase 1 (CN)**

**Phase 1 (DDI, US)**

**Safety**

**Efficacy validation**

**LT3001-202 Phase 2b CN (27 sites, 161 subjects); N=300**

**LT3001-205 Phase 2b US (15), TW (6), EU (22); N=200**

**LT3001-203 Phase 2 US (4), TW(3); N=66**

**1**

**2**

**2024**

- ✓ Complete Phase 2 clinical trial in China and obtain unblinded data;
- ✓ Complete multinational, multicenter trial in TW/US/EU

# LT3001-205 Phase 2 Trial: European Site Initiation Visit (October 2023)

A total of 22 sites in 7 European countries participated LT3001-205 trial :





# Medical Advisors



**Dr Marc Fisher**

President of World Stroke Organization  
Professor of Neurology at Harvard  
Medical School



**Dr Gregory Albers**

Director, Stanford Stroke Center,  
Stanford Medical Center, US



**Dr Pooja Khatri**

Director of Acute Stroke Program for  
the University of Cincinnati, US



台灣腦中風學會  
Taiwan Stroke Society

**Dr Han Hua Hu**

Founding Chairman of Taiwan Stroke Society  
Neurology and Cerebrovascular Center, Taipei VGH  
Treatment and Research Center for Cerebrovascular Diseases, TMU



**Dr Tom Devlin**

Director of CHI Memorial Stroke and  
Neuroscience Center, US



**Dr Yongjun Wang**

Deputy Superintendent, Beijing Tiantan Hospital  
Director of Neurology Center  
Executive Vice President, China Stroke Association

# LT6001

## Innovative Induced Exosomes

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**Drug Delivery Platform + Novel Therapy**

# Innovative Exosome Development Strategy: New Therapies & Platforms



**Neurological therapy pioneer**  
**Strategic out-licensing**



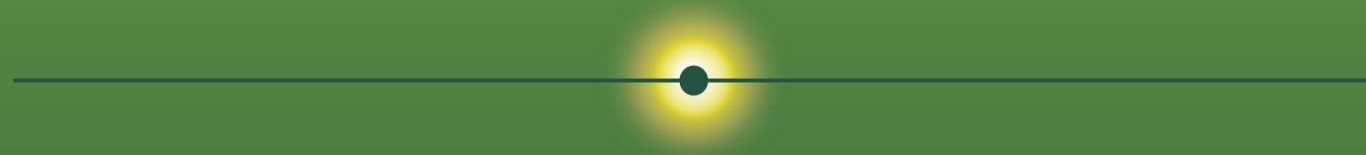
**Leveraging delivery platforms**  
**Fostering tech transfer or co-development**



**Engineering targeted exosomes**  
**Fostering tech transfer or co-development**

Item	Description	2023	2024	2025	2026
Platform	Delivery platform & targeting research				
LT6001	Targeted delivery platform R&D				
LTxxxx	Neuroregenerative therapy				
LTxxxx	Neuroimmunological therapy				

# Lumosa's Future and Outlook





# Becoming the Global Leader in Neuroscience



## Successful LT3001 out-licensing

AIS R&D expertise  
Global network of experts



## LT6001 reaching clinical stage

Exosome production technology validation  
AIS animal model validation

### Innovative approach to ischemic stroke management

Treatment time window	Large vessel occlusion	Small vessel occlusion	Lacunar infarction
< 4.5 hr	EVT	IV tPA	
4.5 ~ 24hr	LT3001 + EVT	LT3001 Monotherapy	
> 24hr	LT6001 concomitant use		

## Exosome platform

Continual process and manufacturing optimization to meet industry standards

Delivery and targeting platform development



Neurological therapy pioneer  
Strategic out-licensing



Leveraging delivery platforms  
Fostering tech transfer or co-development



Engineering targeted exosomes  
Fostering tech transfer or co-development

Resources from LT3001



Novel exosome platform

**= Innovative neurological therapies**

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Thank You

