



**LUMOSA THERAPEUTICS CO., LTD.**  
**(TPEX:6535)**

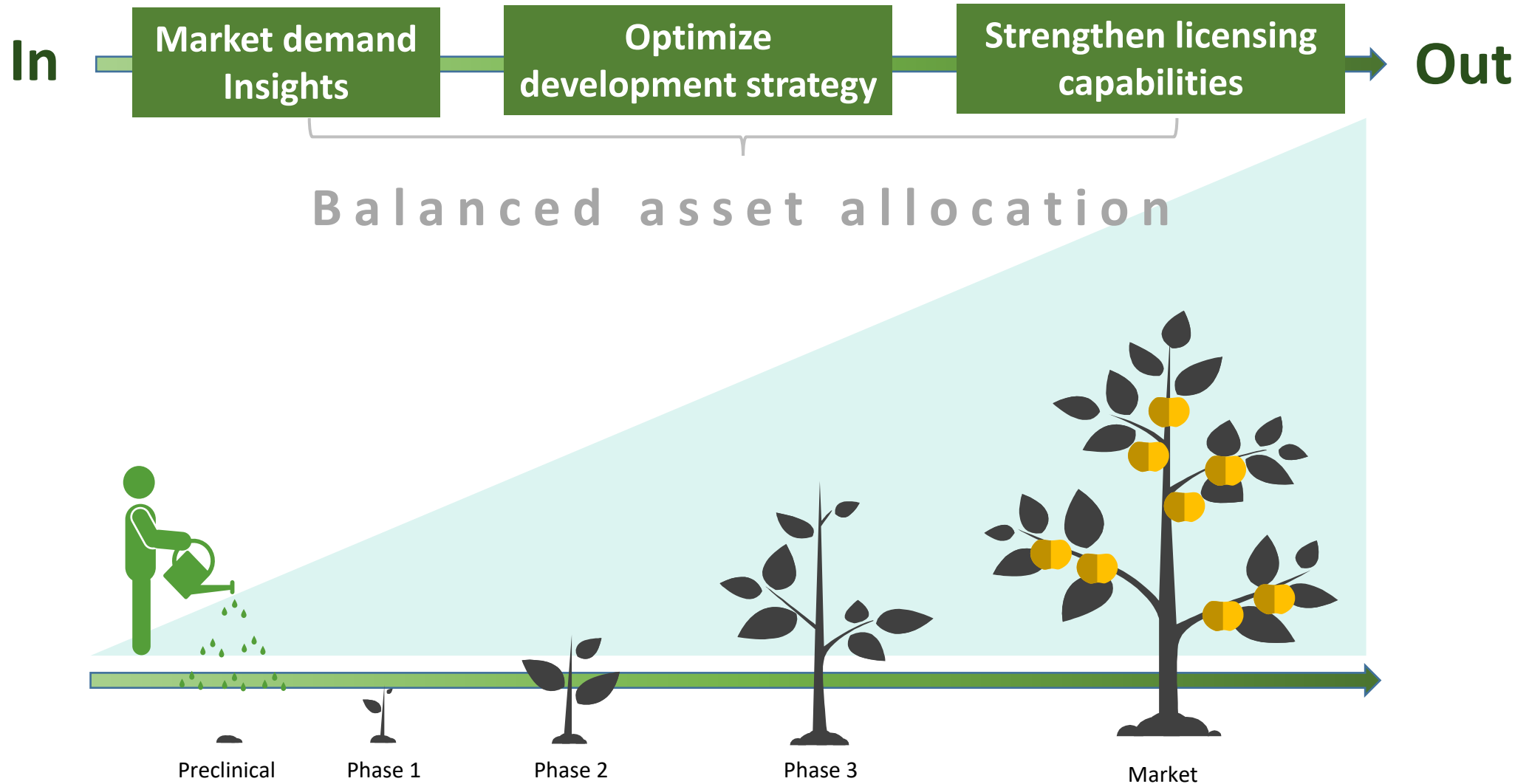
2021/08/04

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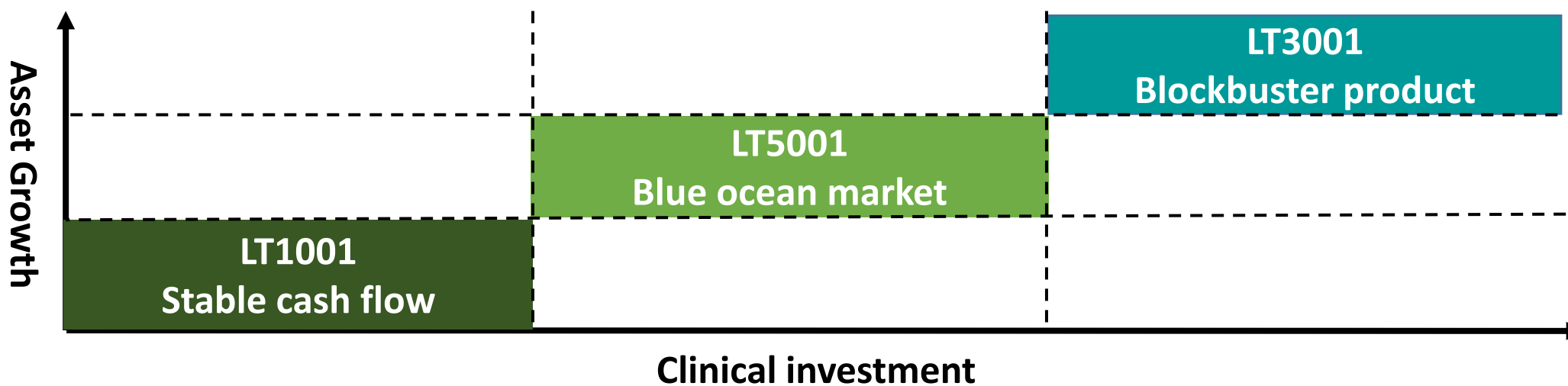
# A business-oriented innovative drug R&D company



# Balanced Asset Allocation



| Pipeline | Preclinical           | Phase 1 | Phase 2 | Phase 3 | Registration | Market |
|----------|-----------------------|---------|---------|---------|--------------|--------|
| LT1001   | Postoperative Pain    |         |         |         |              |        |
| LT3001   | Acute Ischemic Stroke |         |         |         |              |        |
| LT5001   | Uremic Pruritus       |         |         |         |              |        |
| LT2003   | Oncology              |         |         |         |              |        |



# What have we done this year?

|                      | LT1001<br>Stable cash flow  | LT5001<br>Blue ocean market                                  | LT3001<br>Blockbuster product   |
|----------------------|---|--|---|
| Development Progress | <u>Market approval by Singapore HSA</u><br>Advance to Southeast Asia    | <u>Completion of Phase 1b trial</u><br>To be unblinded in Q3 | <u>Completion of Phase 2a trial</u><br>(US & TW; single dose)<br>Good safety, efficacy trend    |
|                      | <u>NDA submission in Korea</u><br>Est. time to market 2020              |  | <u>Completion of Phase 1 trial</u><br>(CN; multi-dose)<br>Good safety, no ethnicity differences |
|                      | <u>Initiation of Phase 3 trial in China</u><br>Est. time to market 2024 |  | <u>Completion of Phase 1 trial</u><br>(US; multi-dose)<br>Good safety                           |
| Licensing Progress   | <u>Successful out-licensing to Ukraine and Korea</u>                    |  |   |

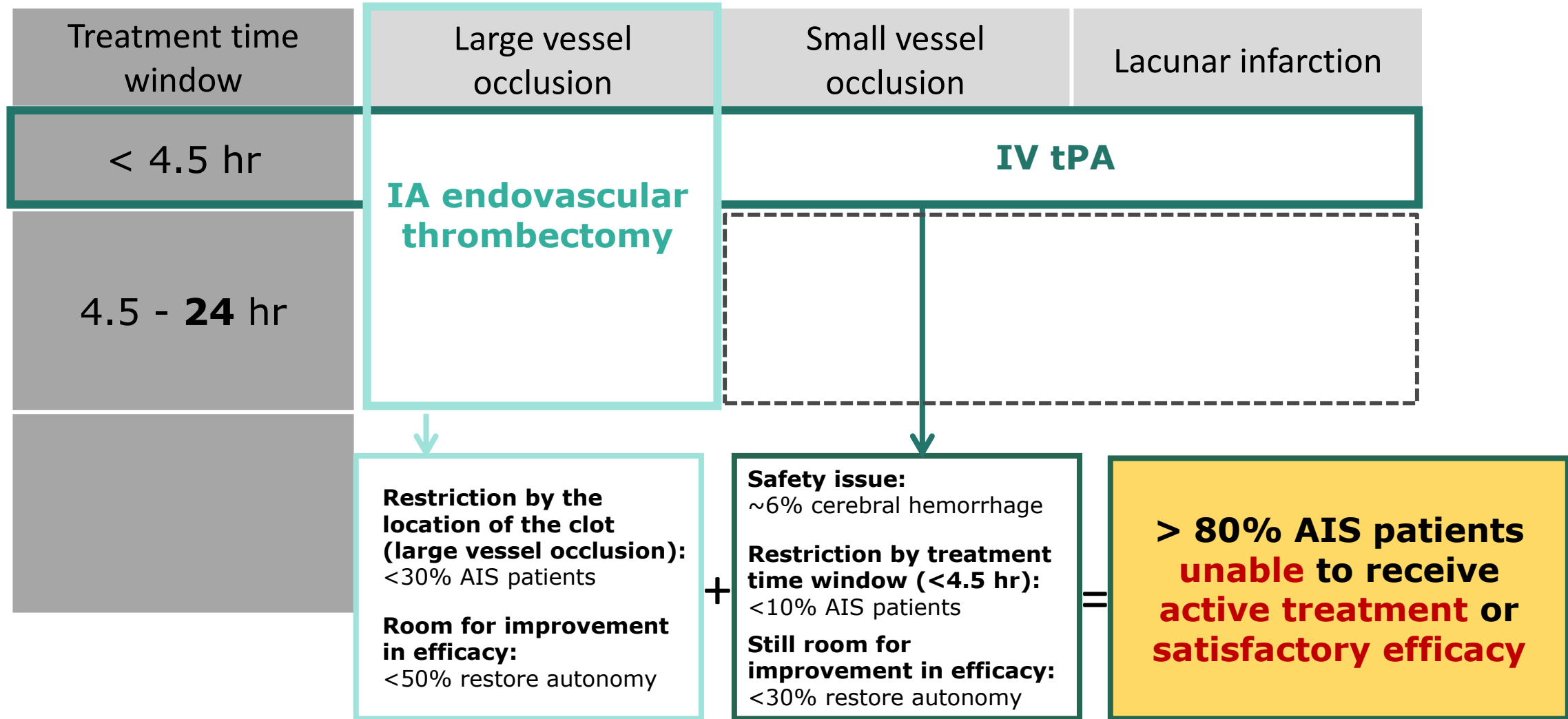


# LT3001

Novel dual-function molecule for Acute Ischemic Stroke

Phase 2 a completed → Primary safety endpoint met, efficacy trend

# Unmet Medical Need in AIS



# LT3001大幅增加可治療中風族群

| Treatment time window | Large vessel occlusion  | Small vessel occlusion   | Lacunar infarction |
|-----------------------|---|--|--------------------|
| < 4.5 hr              | IV tPA  |  |                    |
| 4.5 - 24 hr           | <b>LT3001 combination with thrombectomy</b><br>Improve mechanical thrombectomy efficacy | <b>LT3001 only</b><br>Patients illegible for IV tPA and/or mechanical thrombectomy |                    |

Vessel active peptide:  
restore blood flow



Free radical scavenger:  
reduce reperfusion injury



**> 80% AIS patients receiving active treatment or satisfactory efficacy**



# LT3001 : Novel Dual-Function Molecule



|                                |  |
|--------------------------------|--|
| <b>Targeted indication</b>     | Acute ischemic stroke  |
| <b>Administration route</b>    | Short infusion   |
| <b>Patent</b>                  | 2034 (composition)   |
| <b>Development status</b>      | <b>1) Phase 2a – completed</b><br>2) Phase 2b – to be initiated in Q4/2021   |
| <b>Target population</b>       | 1) Acute ischemic stroke patients with treatment time window < 24 hrs<br>2) Acute ischemic stroke patients receiving mechanical thrombectomy |
| <b>Est. peak sale (global)</b> | > USD 4.5 billion  |

## Study design

Phase 1 clinical trial completed (US; single dose):

**LT3001-101: A double-blind, randomized, placebo-controlled, single-dose via IV infusion study on healthy adult subjects**

|                          |  |
|--------------------------|--|
| <b>Sample size</b>       | 16 (LT3001 x6 + placebo x2/ dose cohort; total 2 dose cohorts)                                       |
| <b>Target population</b> | Healthy volunteers   |
| <b>Endpoint</b>          | <ul style="list-style-type: none"> <li>• Safety and tolerability</li> <li>• PK assessment</li> </ul> |

## Study result

- LT3001 was **safe and well tolerated** in the treatment group.
- **No SAEs reported in LT3001 treated groups.** All 2 AEs were classified as mild in severity and were resolved.
- LT3001 was only measurable within the first half-hour in the plasma samples after the start of infusion. **The mean t<sub>1/2</sub> was 0.1 hours. T<sub>max</sub> occurred between 6 and 18 minutes.**

## Phase 2a clinical trial completed (TW, US; single-dose) :

**LT3001-201 : A double-blind, randomized, placebo-controlled, single-dose via IV infusion**

**Sample size** 24 (LT3001 x16 + placebo x8)

**Target population** AIS patient who has onset stroke symptoms **within 24 hours** and is not to be treated with rtPA or endovascular thrombectomy

**Endpoints**

- **Primary endpoint:**  
Patient safety, the ratio on the occurrence of sICH within 36 hours after dosing
- **Secondary endpoints:**  
Efficacy (neurological outcome (NIHSS), functional outcome (mRS)); PK results

Study design

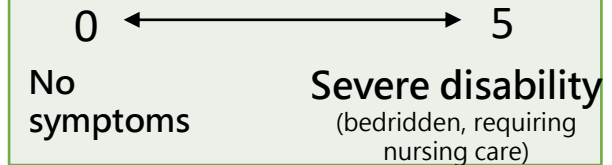
Study result

- **Primary endpoint achieved** – occurrence of sICH not increased
- **Efficacy trends in neurological outcome (NIHSS) and functional outcome (mRS)**, especially in AIS patients with baseline NIHSS $\geq$ 6
- Data support LT3001 having the potential of becoming a **standardized therapy for AIS patients with stroke onset within 24 hrs**

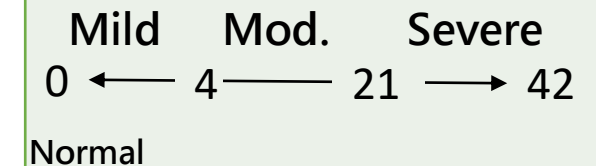
### Target population

| Treatment time window | Large vessel occlusion       | Small vessel occlusion | Lacunar infarction |
|-----------------------|------------------------------|------------------------|--------------------|
| < 4.5 hr              | IA endovascular thrombectomy | IV tPA                 |                    |
| 4.5 - 24 hr           |                              |                        |                    |

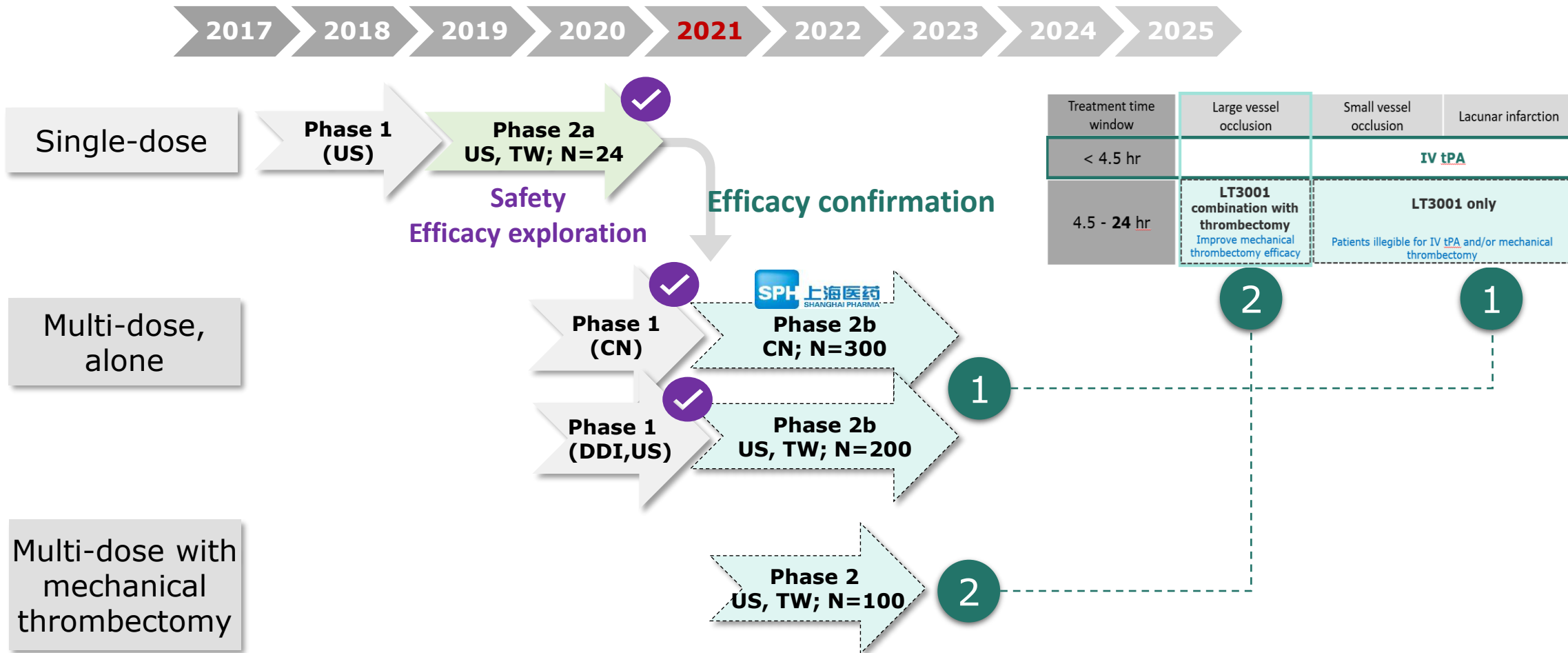
### Functional outcome mRS



### Neurological outcome NIHSS (language, movement, facial, consciousness)



# LT3001 Clinical Development Plan



## Consultants



**Dr Marc Fisher**

President-elect, World Stroke Organization  
Professor, Harvard Medical School



**Dr Gregory Albers**

Director, Stanford Stroke Center



**Dr Pooja Khatri**

Director, Acute Stroke Program for  
the University of Cincinnati

## Principle investigators



台灣腦中風學會  
Taiwan Stroke Society

**Dr Han-Hwa Hu**

Founding Chairman, Taiwan Stroke Society  
Department Head, Department of Neurology and Department  
of Cerebrovascular Disease, Taipei Veterans General Hospital  
Director, Neuroscience Research Center, Taipei Medical  
University



**Dr Tom Devlin**

Director, Stroke and Neuroscience Center,  
CHI Memorial Hospital



**Dr Yongjun Wang**

Deputy superintendent, Beijing Tiantan Hospital  
Executive Vice President, China National Clinical  
Research Center for Neurological Diseases

# LT5001

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Topical Ointment for Uremic Pruritus

**Phase 1b Enrollment Completed**

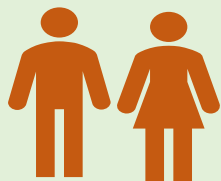
# LT5001 : World's first Topical Ointment for Uremic Pruritus

Unmet medical needs



End-stage CKD or Under dialysis

>7m



Uremic pruritus

~3m

“Nothing seems to work very well. An important area of an unmet need”

Nephrologist, and Professor at University of Alberta Department of Medicine, Division of Nephrology

“About 80% of the patients we have are complaining about uremic pruritus. It is a huge issue and we need something that is effective but also safe”

Pharmacist & Clinician Scientist, University Health Network, Hemodialysis Unit/Nephrology

Only one medication available in Japan and Korea (Remitch); 5 companies currently at clinical stage of development

| Product  | Target   | Company                 | Stage        | Route   |
|----------|--|-------------------------|--------------|---------|
| Korsuva  | K-receptor agonist                             | Cara Therapeutics       | Phase 3      | Oral    |
|          |  |                         | NDA          | IV      |
| HSK21542 |  | Haisco Pharmaceutical   | Phase 2 (CN) | IV      |
| SK-1405  | Not disclosed                                  | Sanwa Kagaku Kenkyusho  | Phase 2 (JP) | Oral    |
| LT5001   | K-receptor agonist/ $\mu$ -receptor antagonist | Lumosa Therapeutics     | Phase 1b/2   | Topical |
| EP-547   | MRGPRX4 antagonist                             | Escient Pharmaceuticals | Phase 1      | Oral    |

Recruitment for Phase 1b study completed, unblinding by Q3

LT5001: The only topical formulation at clinical stage

**Effective**

Clinically proven target

**Safe**

Topical application, no systemic side effects

**Convenient**

Apply locally to the affected site

Blue ocean market

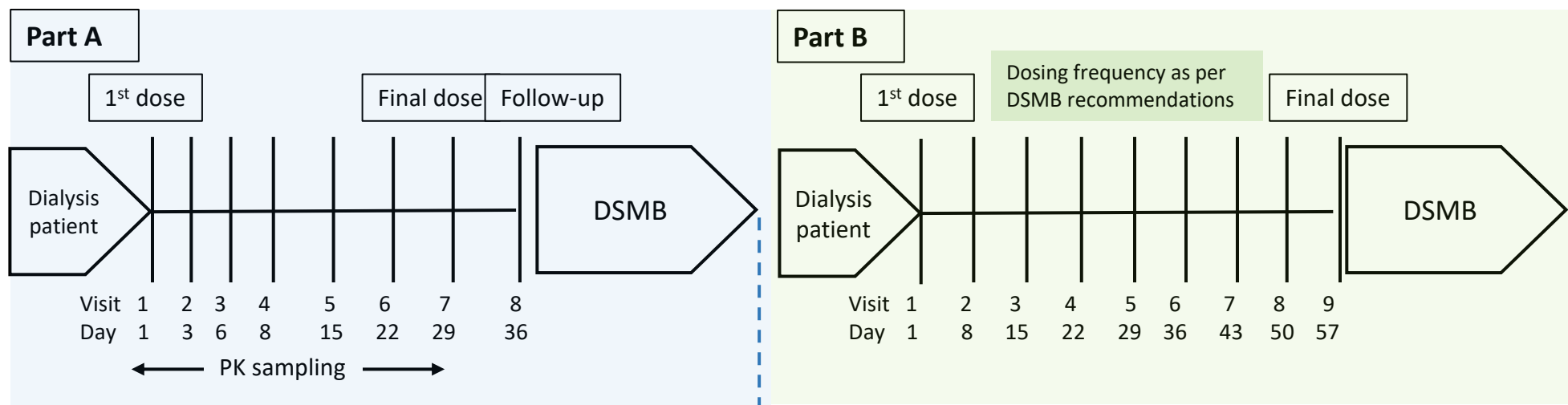
Development progress

# LT5001 : Clinical Progress

Study design

Development Progress

| LT5001-101                 | Part A (Phase 1b)   | Part B (Phase 2)              |
|----------------------------|---|-------------------------------|
| <b>Sample size</b>         | 18 (LT5001:placebo : 2:1)   | 60- 90 (LT5001:placebo : 1:1) |
| <b>Treatment period</b>    | 4 weeks   | 8 weeks                       |
| <b>Treatment frequency</b> | BID   |                               |
| <b>Endpoint</b>            | 1. Safety<br>2. Efficacy (WINRS, 5-D itch scale, Dermatology Quality of Life Index) |                               |



Enrollment for Phase 1b completed

Unblinding by Q3



# LT1001 (Naldebain<sup>®</sup>)

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Week-long Postoperative Analgesic Injection

**Approved in Taiwan and Singapore**

# LT1001 : **World's first** week-long extended-release postoperative analgesic injection

Unmet  
medical  
need

The abuse of opioids has created a crisis for mankind. There is a strong demand for postoperative analgesics that are less addictive with better safety profiles

## Effective

Comparable analgesic effect to morphine

## Safe

No opioid-related side effects (respiratory depression, abuse)

## Convenient

Single-dose, reduce days of being hospitalized

Stable  
cash flow

## Approved

Taiwan  
(2017)

Singapore  
(2020)



Stabilize cash flow

## Registration (est. 2021-22 approval)

Thailand  
Malaysia  
Korea  
Ukraine



Growth momentum

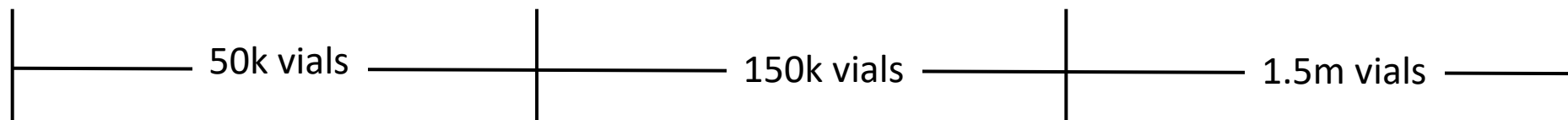
## Clinical Trial (est. 2023 approval)

China  
(Phase 3, >40% enrollment completed)  
Veterinary Medicine  
(Pivotal study)



Max. product value

Peak sale



## Global strategy

### First goal: Market approval in China

Accelerate the enrollment of the Phase 3 study. Estimated completion by the end of 2021, MA by 2023

### Second goal: Expansion to developing countries

MA submission using current data; successful licensing in Korea and Ukraine and MA package is to be submitted. Licensing in South America, Middle East expected by the end of the year

### Third goal: Adjust EU and US strategy

Sought advice from US and Swiss authority and a costly Phase 3 clinical trial is needed. Lumosa to seek partners who are willing to invest in the development to balance Lumosa resources

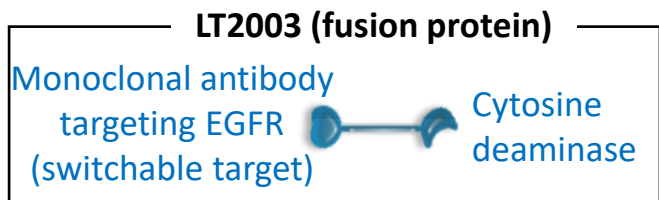


# LT2003

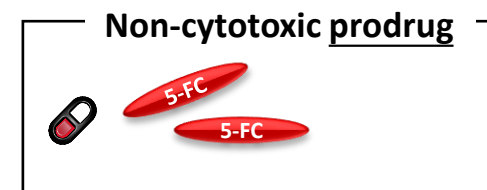


*A First-in-class Target Therapy for the  
Treatment of Advanced Tumor*

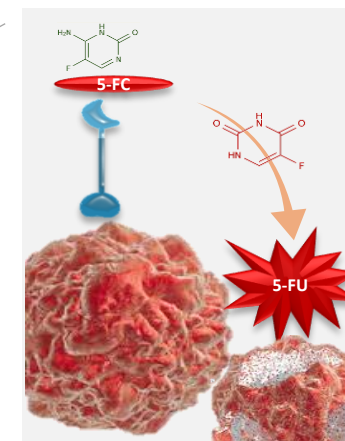
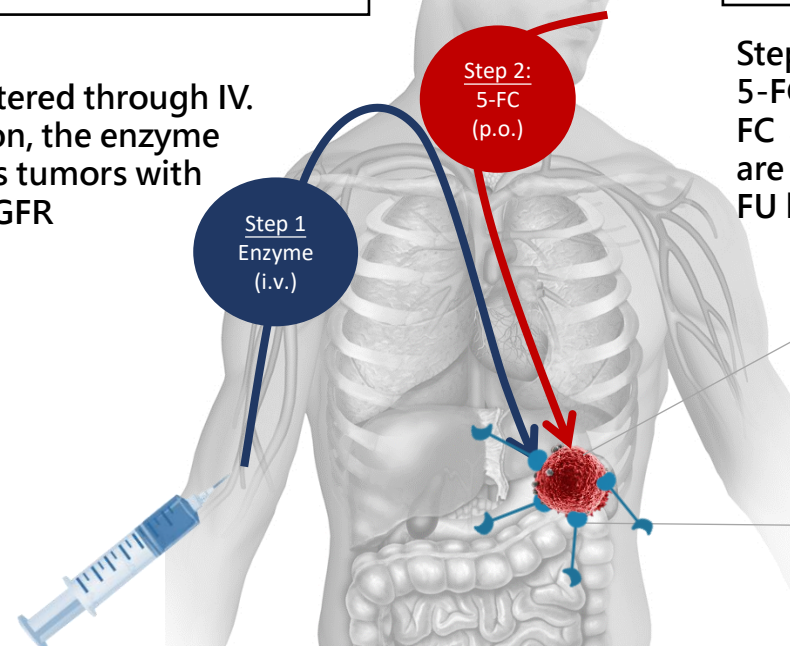
## Product feature



**Step 1:**  
LT2003 is administered through IV. Through circulation, the enzyme specifically targets tumors with over-expressive EGFR



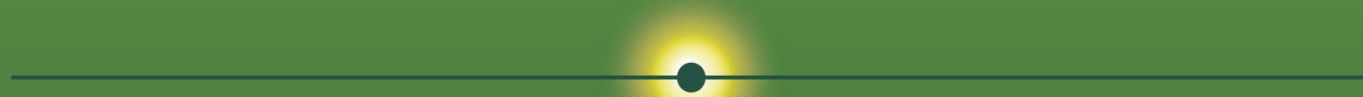
**Step 2:**  
5-FC is administered orally. 5-FC arriving at the tumor site are converted to cytotoxic 5-FU by *cytosine deaminase*







## Development Progress

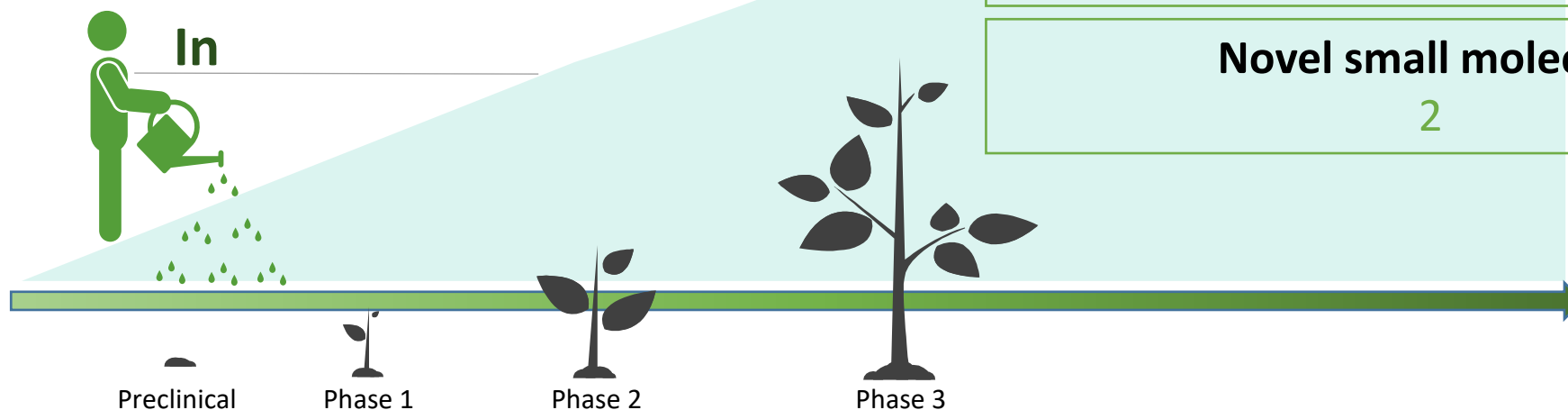
- Animal efficacy studies completed
- **Primate toxicology study completed** → NOAEL 10x that of human effective dose
- Targeted indication: **Rare, refractory cancers with highly expressive EGFR** (such as: peritoneal pseudomyxoma, cholangiocarcinoma, pancreatic cancer )

# Future Pipeline Strategy



|                            |   |                   |  |
|----------------------------|---|-------------------|--|
| Commercial Value           |  | Clinical Needs    |  |
| Technological Breakthrough |  | Matching Strategy |  |

|   |
|---|
| <b>New projects under assessment</b>  |
| <b>Allogeneic cell therapy</b><br><b>Nucleic acid and peptide delivery system</b><br>3 Cell therapies<br>2 Delivery systems |
| <b>Antibody–drug conjugate (ADC)</b><br>2   |
| <b>Innovative antibody drugs</b><br>1   |
| <b>Novel small molecule</b><br>2  |



Thank You

