Lumosa Therapeutics Co., Ltd.

(TPEX:6535)

2025/10

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LT3001

Innovative Small Molecule Drug for Treating Acute Ischemic Stroke

Development Progress

Phase 3 Regulatory Consultation with China’s CDE and the US FDA Planned for 2025

Phase 3 Patient Enrollment in China Planned for 2026

China Market Launch Targeted for 2030

LT3001 Development Goal - Superior Efficacy, Enhanced Safety – A Novel Stroke Treatment for Broader Patient Populations

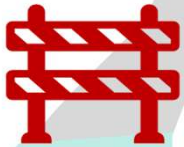
Unmet Medical Needs

Therapeutic dilemma for acute ischemic stroke treatments (IV tPA unmet need):

1. **2~6% Cerebral hemorrhage**
2. **Used in <10% AIS**

Global sales of tPA US$2 billion/yr

4.5 hr



LT3001 development goal:

To bring safer, better treatment for more AIS patients

>5x treatment window, without meeting specific imaging criteria

Peak sales US$6-8 billion

ACTIVASE rt-PA
– IV tPA package insert

1 INDICATIONS

ACTIVASE rt-PA (alteplase for injection) is indicated for: ①

- The management of **acute ischemic stroke** (AIS) in adults for improving neurological recovery and reducing the incidence of disability. Treatment should only be initiated within 3 hours after the onset of stroke symptoms, and after exclusion of intracranial hemorrhage by a cranial computerized tomography (CT) scan or other diagnostic imaging method sensitive for the presence of hemorrhage. Eligibility criteria of the National Institute of Neurological Disorders and Stroke (NINDS) protocol must be strictly adhered to (see 2 CONTRAINDICATIONS).

AHA 2019 Treatment Guidelines for Acute Ischemic Stroke (2019):

Table 8. Eligibility Recommendations for IV Alteplase in Patients With AIS

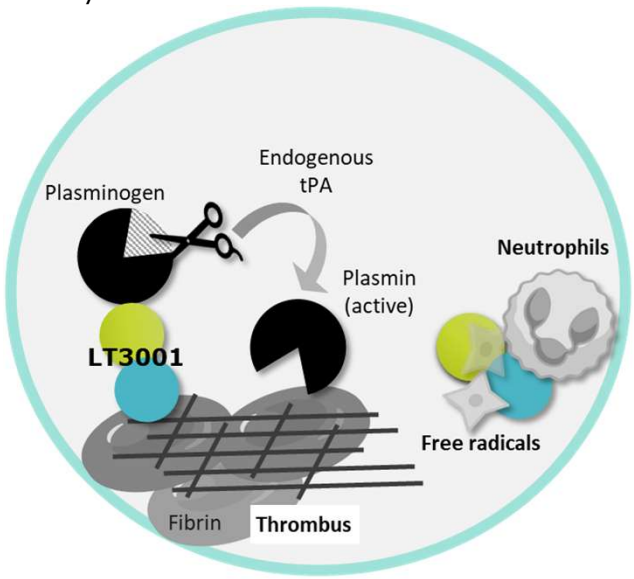
Indications (COR I)		
Within 3 h*	①	IV alteplase (0.9 mg/kg, maximum dose 90 mg over 60 min with initial 10% of dose given as bolus over 1 min) is recommended for selected patients who may be treated within 3 h of ischemic stroke symptom onset or patient last known well or at baseline state. Physicians should review the criteria outlined in this table to determine patient eligibility.† (*COR I; LOE A*)
3–4.5 h*	②	IV alteplase (0.9 mg/kg, maximum dose 90 mg over 60 min with initial 10% of dose given as bolus over 1 min) is also recommended for selected patients who can be treated within 3 and 4.5 h of ischemic stroke symptom onset or patient last known well. Physicians should review the criteria outlined in this table to determine patient eligibility.† (*COR I; LOE B-R*§)
Additional recommendations for treatment with IV alteplase for patients with AIS (COR IIa)		And (COR IIb)
Wake-up and unknown time of onset	③	IV alteplase (0.9 mg/kg, maximum dose 90 mg over 60 min with initial 10% of dose given as bolus over 1 min) administered within 4.5 h of stroke symptom recognition can be beneficial in patients with AIS who awake with stroke symptoms or have unclear time of onset >4.5 h from last known well or at baseline state and who have a DW-MRI lesion smaller than one-third of the MCA territory and no visible signal change on FLAIR. (*COR IIa; LOE B-R*‡)

Treatment window	Imaging criteria	Efficacy: complete or near-complete recovery mRS=0-1		Efficacy: Functional independence mRS=0-2		Safety: sICH
① **0-3 hrs** (NINDS, US, 1995)	Routine CT (exclude hemorrhagic stroke)	tPA (n=168): 39% vs placebo (n=165): 26% (p=0.019)	**+13%**	NA		**tPA: 6.4%** placebo: 0.6% (p<0.001)
② **3-4.5 hrs** (ECASS 3, EU, 2008)		tPA (n=418): 52% vs placebo (n=403): 45% (p=0.04)	**+7%**	tPA: 66.5% vs placebo 61.5%	**+5%**	**tPA: 2.4%** placebo: 0.2% (p=0.008)
③ **Wake-up Stroke** (WAKE-UP, EU, 2018)	MRI mismatch	tPA (n=254): 53% vs placebo (n=249): 42% (p=0.02)	**+11%**	tPA: 74% vs placebo 65%	**+9%**	**tPA: 2.4%** placebo: 0.4% (p=0.1)
4.5-9 hrs (Extend, Australian, 2019)	CTP mismatch	tPA (n=113): 35.4% vs placebo (n=112): 29.5% (p=0.04)	**+6%**	tPA:49.6% vs placebo:42.6%,	**+7%**	**tPA: 6.2%** placebo: 0.9% (p=0.053)
4.5-24 hrs LT3001	Routine CT (exclude hemorrhagic stroke)	**+ > 6%**		**+ > 7%**		**0%**

LT3001 Opportunities – Thrombolysis without Bleeding+Neuroprotection – May be administered for several days to improve brain functions continuously

Novel Thrombolytic Mechanism (MoA):

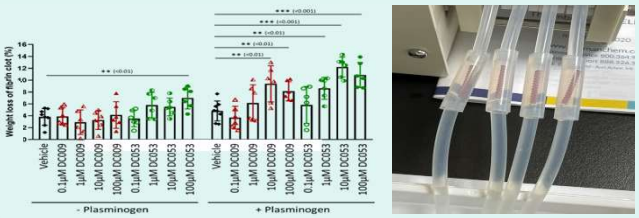
LT3001 binds directly to fibrin clots and plasminogen, concentrating plasminogen at the thrombus site to enhance targeted endogenous fibrinolysis.



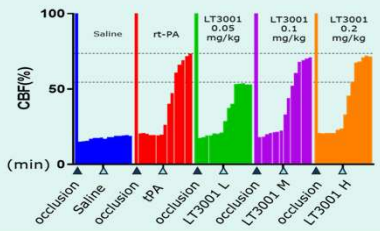
- Invented by Professor Shiqi Peng and Professor Ming Zhao of Capital Medical University, China
- Preclinical study conducted and published by Professor Eng Lo's laboratory at the Neuroprotection Lab at Harvard Medical School

(JMCB. 2016, Translational Stroke Res. 2022)

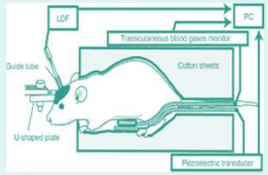
In-vitro studies showed that thrombus volume significantly reduced as LT3001 dose increase



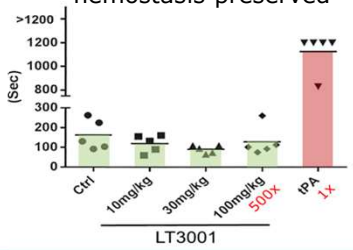
Animal studies showed that LT3001 effectively restores cerebral blood flow in thrombus-occluded vessels



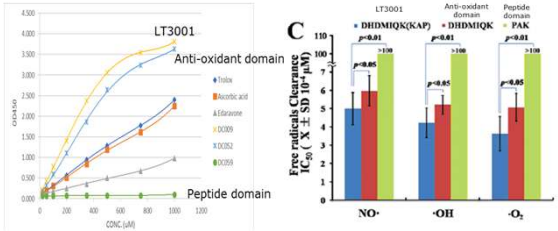
Cerebral blood flow



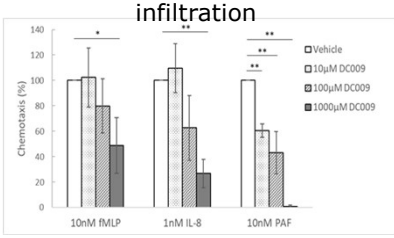
Animal study showed that normal hemostasis preserved



Inhibit oxidative response and clear various free radicals

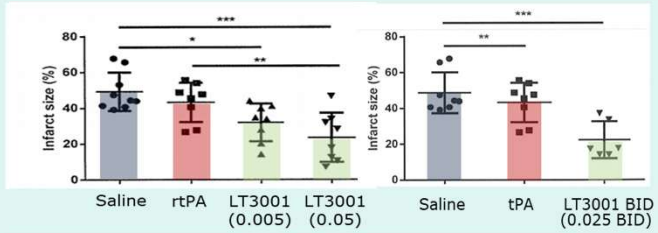


Suppress inflammatory cell infiltration

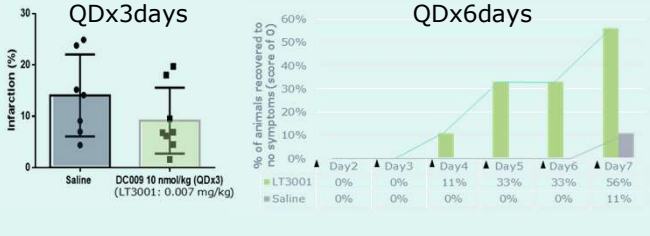


LT3001 demonstrated dose-dependent reduction in infarct volume and improved neurological outcomes: Superior efficacy when compared to tPA, particularly when treatment was initiated beyond the standard treatment window

Treated at **3 hour** after stroke onset



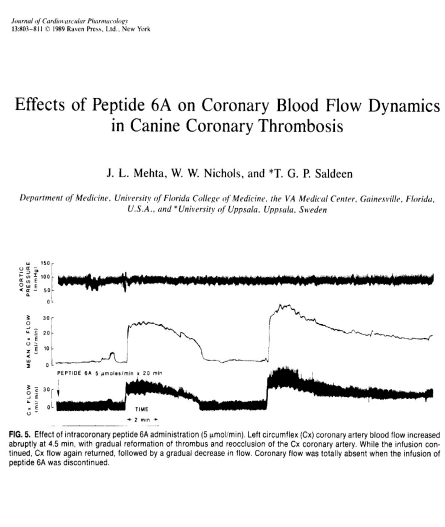
Treated at **24 hour** after stroke onset



LT3001 Research Milestones – Global Collaboration – Molecular Design to Phase 2a

Discovery of LT3001

The endogenous thrombolytic peptide underlying LT3001 was first discovered in the 1980s by Professor Saldeen's team in Sweden and validated for thrombolytic efficacy in canine coronary artery occlusion models.



Journal of Cardiovascular Pharmacology
13:803–811 © 1989 Raven Press, Ltd., New York

Effects of Peptide 6A on Coronary Blood Flow Dynamics in Canine Coronary Thrombosis

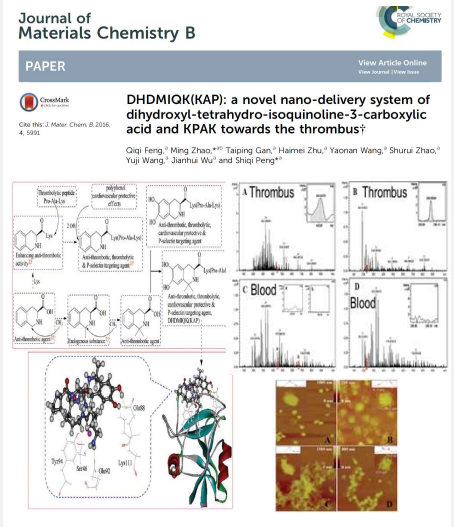
J. L. Mehta, W. W. Nichols, and *T. G. P. Saldeen

*Department of Medicine, University of Florida College of Medicine, the VA Medical Center, Gainesville, Florida, U.S.A., and *University of Uppsala, Uppsala, Sweden*

FIG. 5. Effect of intracoronary peptide 6A administration (5 μmol/min). Left circumflex (Cx) coronary artery blood flow increased abruptly at 4.5 min, with gradual reformation of thrombus and reocclusion of the Cx coronary artery. While the infusion continued, Cx flow again returned, followed by a gradual decrease in flow. Coronary flow was totally absent when the infusion of peptide 6A was discontinued.

Functional Optimization and Structural Innovation

Professors Peng and Zhao at Capital Medical University, China, engineered the peptide to incorporate free radical scavenging, anti-inflammatory, and thrombus-targeting capabilities, formally establishing LT3001 as a drug candidate. Results published in 2016.



Journal of Materials Chemistry B

PAPER

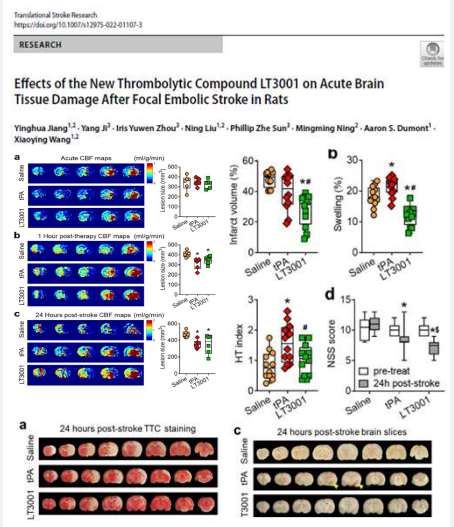
View Article Online

DHDMIQK(KAP): a novel nano-delivery system of dihydroxyl-tetrahydro-isoquinoline-3-carboxylic acid and KPAK towards the thrombus†

Qiqi Feng,[a] Ming Zhao,*[a] Taiping Gan,[a] Haimei Zhu,[a] Yaonan Wang,[a] Shurui Zhao,[a] Yuji Wang,[a] Jianhui Wu[a] and Shiqi Peng*[a]

Preclinical Validation

Preclinical studies conducted by Professor Eng Lo's team at Harvard Medical School demonstrated LT3001's superior efficacy compared to tPA, with sustained safety and activity beyond the standard treatment window. Results published in 2022.



Translational Stroke Research
https://doi.org/10.1007/s12975-022-01107-3

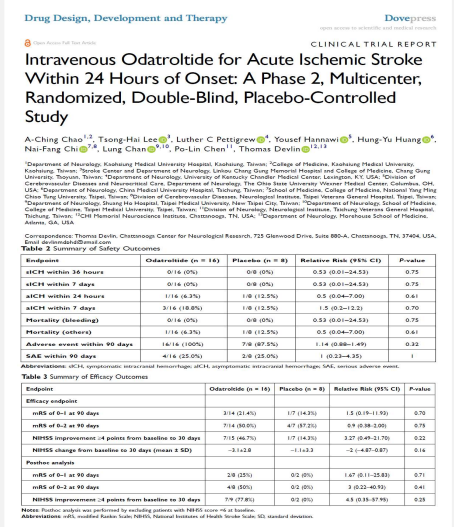
RESEARCH

Effects of the New Thrombolytic Compound LT3001 on Acute Brain Tissue Damage After Focal Embolic Stroke in Rats

Yinghua Jiang[1,2] · Yang Ji[3] · Iris Yuwen Zhou[2] · Ning Liu[1,2] · Phillip Zhe Sun[2] · Mingming Ning[2] · Aaron S. Dumont[1] · Xiaoying Wang[1,2]

Early Clinical Results

The LT3001-201 trial (Phase 2A, n=24) demonstrated good tolerability with single-dose administration in acute ischemic stroke patients treated within 24 hours of last known normal, with trends toward neurological improvement. Results published in 2024.



Drug Design, Development and Therapy

Dovepress

CLINICAL TRIAL REPORT

Intravenous Odatroltide for Acute Ischemic Stroke Within 24 Hours of Onset: A Phase 2, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study

A-Ching Chao[1,2], Tsong-Hai Lee[3], Luther C Pettigrew[4], Yousef Hannawi[5], Hung-Yu Huang[6], Nai-Fang Chi[7,8], Lung Chan[9,10], Po-Lin Chen[11], Thomas Devlin[12,13]

Table 2 Summary of Safety Outcomes

Endpoint	Odatroltide (n = 16)	Placebo (n = 8)	Relative Risk (95% CI)	P-value
sICH within 36 hours	0/16 (0%)	0/8 (0%)	0.53 (0.01–24.53)	0.75
sICH within 7 days	0/16 (0%)	0/8 (0%)	0.53 (0.01–24.53)	0.75
aICH within 24 hours	1/16 (6.3%)	1/8 (12.5%)	0.5 (0.04–7.00)	0.61
aICH within 7 days	2/16 (18.8%)	1/8 (12.5%)	1.5 (0.2–12.2)	0.70
Mortality (bleeding)	0/16 (0%)	0/8 (0%)	0.53 (0.01–24.53)	0.75
Mortality (others)	1/16 (6.3%)	1/8 (12.5%)	0.5 (0.04–7.00)	0.61
Adverse event within 90 days	16/16 (100%)	7/8 (87.5%)	1.14 (0.88–1.49)	0.32
SAE within 90 days	4/16 (25.0%)	2/8 (25.0%)	1 (0.23–4.35)	1

Abbreviations: sICH, symptomatic intracranial hemorrhage; aICH, asymptomatic intracranial hemorrhage; SAE, serious adverse event.

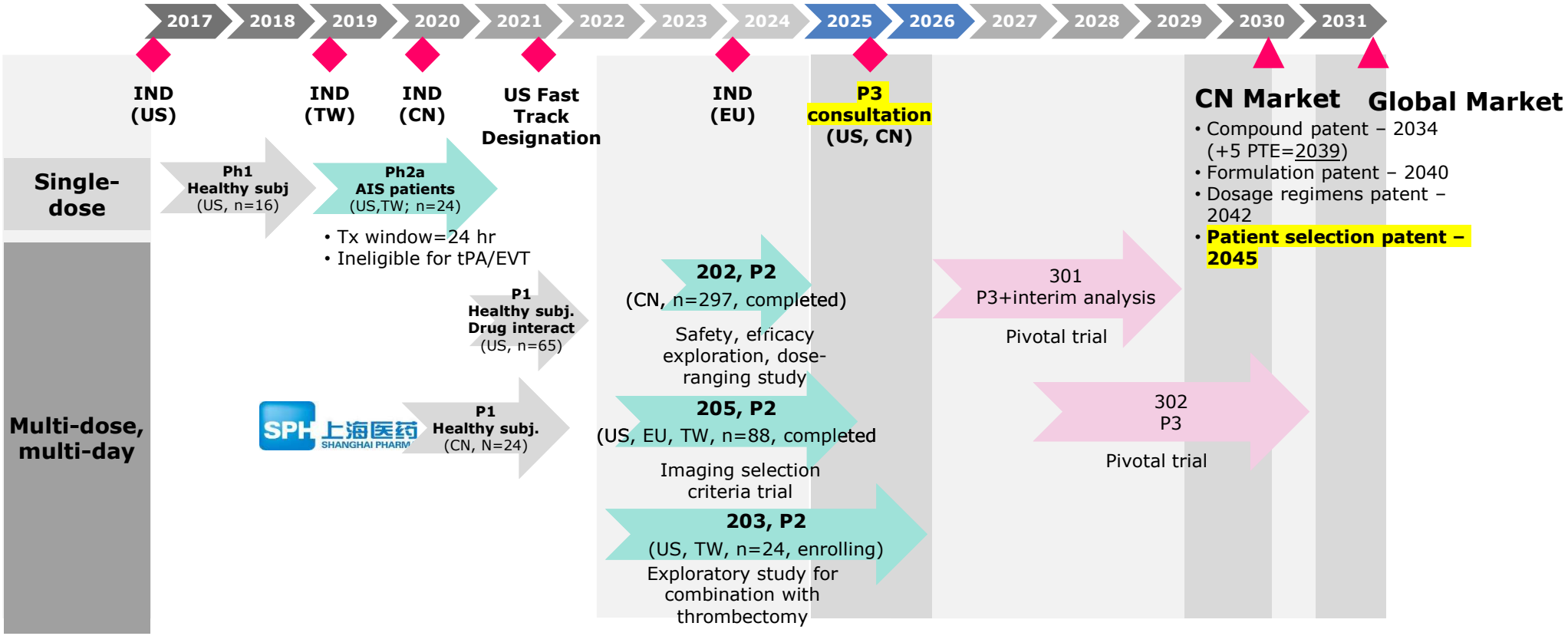
Table 3 Summary of Efficacy Outcomes

Endpoint	Odatroltide (n = 16)	Placebo (n = 8)	Relative Risk (95% CI)	P-value
Efficacy endpoint				
mRS of 0–1 at 90 days	3/14 (21.4%)	1/7 (14.3%)	1.5 (0.19–11.93)	0.70
mRS of 0–2 at 90 days	7/14 (50.0%)	4/7 (57.2%)	0.9 (0.38–2.00)	0.78
NIHSS improvement ≥4 points from baseline to 30 days	7/15 (46.7%)	1/7 (14.3%)	3.27 (0.49–21.70)	0.22
NIHSS change from baseline to 30 days (mean ± SD)	−3.1±2.8	−1.1±3.3	−2 (−4.87–0.87)	0.16
Posthoc analysis				
mRS of 0–1 at 90 days	2/8 (25%)	0/2 (0%)	1.67 (0.11–25.83)	0.71
mRS of 0–2 at 90 days	4/8 (50%)	0/2 (0%)	3 (0.22–40.93)	0.41
NIHSS improvement ≥4 points from baseline to 30 days	7/9 (77.8%)	0/2 (0%)	4.5 (0.33–97.95)	0.28

Notes: Posthoc analysis was performed by excluding patients with NIHSS score =6 at baseline.
Abbreviations: mRS, modified Rankin Scale; NIHSS, National Institutes of Health Stroke Scale; SD, standard deviation.

LT3001 Clinical Development – Completion of Several Multinational Phase 1 and 2 Trials – Demonstrating Safety and Efficacy

- Treatment Window=Within 24 hours after stroke onset



A Phase 2, Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Safety and Efficacy of Multiple Doses of LT3001 in Patients with Acute Ischemic Stroke (AIS)

Leading Site : Beijing Tiantan Hospital, Capital Medical University

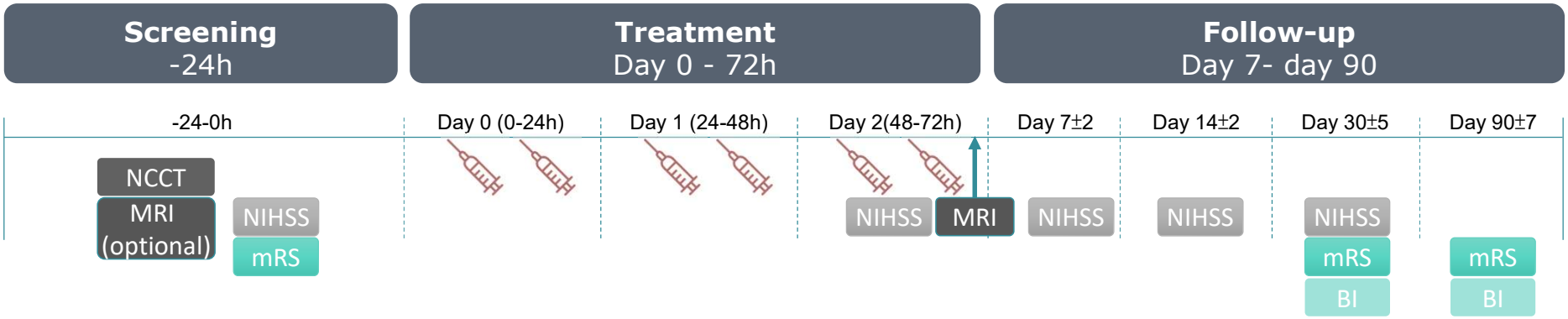
Leading PI : Professor Yongjun Wang

Sponsor : Shanghai Pharmaceuticals Holding Co., Ltd.

Study Period : 2023/4/6 ~ 2024/9/27

LT3001-202: Study Design

A multicenter, randomized, double-blind, placebo-controlled phase 2 clinical trial in China



Primary I/E Criteria:

- AIS
- Age 18-80
- Baseline NIHSS=4-25
- LKN<24h
- Exclude patients receiving or planned for EVT or IV thrombolytics.

R

N=300
1:1:1

- LT3001 Full-dose 0.05 mg/kg
- LT3001 Half-dose 0.025 mg/kg
- Placebo

30min-IV infusion

- **Primary Endpoint – Safety**
  - Incidence of AEs and ADRs within 90 days post-first dose.
  - Number and incidence of symptomatic or asymptomatic intracranial hemorrhages within 3 days post-first dose.
- **Secondary Endpoint – Efficacy**
  - mRS, NIHSS, BI

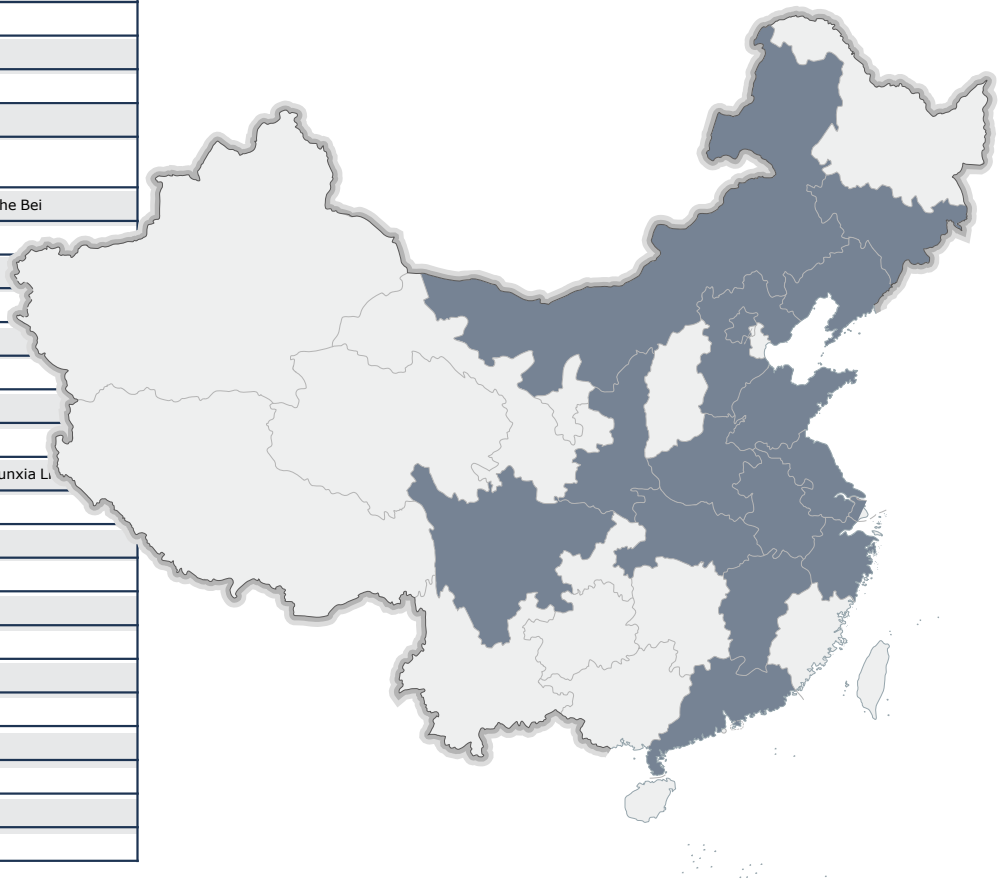
- The sample size of this study had been determined by referring to the sample size of Phase 2 of other drugs for AIS treatment, combined with the new drug clinical development experience of clinical research experts
- Central randomized with stratification factor of ① baseline MRI (Y/N), ②baseline NIHSS of 4~6, 7~10, 11~25

From April 2023 to July 2024, 301 subjects were enrolled across 28 medical centers; 297 were randomized and received study drug.

List of Study Sites and Investigators

Site Name	Investigator
Beijing Tiantan Hospital, Capital Medical University (Leading site)	Yongjun Wang
The First Hospital of Jilin University	Yi Yang
The First Affiliated Hospital of Jinan University (Guangzhou Overseas Chinese Hospital)	Anding Xu
Beijing Tsinghua Changgung Hospital	Jian Wu
Beijing Luhe Hospital, Capital Medical University	Yanling Wang
Daqing Oilfield General Hospital	Jianghua Liu
Beipiao Central Hospital	Yutong Ma
The First Affiliated Hospital of Baotou Medical College, Inner Mongolia University of Science and Technology	Bo Liu
Baogang Hospital of Inner Mongolia	Dong Wang/Hongzhe Bei
People's Hospital of Hengshui (Harrison International Peace Hospital)	Yan Wei
Luoyang Third People's Hospital	Bing Sun
Xi'an Gaoxin Hospital	Yi Jia
Liaocheng People's Hospital	Cunju Guo/Lin Ma
Huai'an Second People's Hospital	Liandong Zhao
The Affiliated Hospital of Xuzhou Medical University	Deqin Geng
The Second Affiliated Hospital of Soochow University	Chunfeng Liu
Shanghai Pudong Hospital	Shuangxing Hou/Yunxia Li
Zhongnan Hospital of Wuhan University	Yumin Liu
Zhejiang Hospital	Yaguo Li
Taizhou First People's Hospital	Zhimin Wang
Taizhou Municipal Hospital	Hao Xu
Pingxiang People's Hospital	Fei Yi
Xianyang Hospital of Yan'an University	Lei Lei
Linfen Central Hospital	Hongguo Dai
Linfen People's Hospital	Junfang Hao
Central People's Hospital of Zhanjiang	Hui Mai
Nanshi Hospital of Nanyang	Bin Liu
The Third Hospital of Mianyang	Diwen Zhang

A total of 28 study sites participated in this study and had subjects enrolled.



LT3001-202: Baseline Demographic

- LT3001-202 enrolled 297 AIS patients (median age 63, ~70% male) with median baseline NIHSS 8. The majority were treated >12 h from onset (Q1–Q3 ~11–20 h, up to 24 h). ~55% were moderate strokes and ~55–60% LAA etiology, balanced across groups.

		0.05 mg/kg	0.025 mg/kg	Placebo
N		99	96	102
Distribution	Yrs, median (Q1, Q3) Yrs, mean (SD)	65 (59,73) 63.6 (10.6)	64 (56,70) 62.5 (10.0)	63 (56,72) 62.8 (10.2)
Age	Male%	70.7%	68.8%	71.6%
Gender	Kg, median (Q1, Q3) Kg, mean (SD)	68 (60,75) 68.47 (10.30)	70 (60,79) 68.87 (11.64)	70 (60,75) 68.51 (11.63)
Weight	h, median (Q1, Q3) h, mean (SD)	12.44 (11.07, 16.42) 13.83 (4.29)	11.81 (10.59, 19.80) 14.41 (5.39)	12.15 (10.77, 20.02) 14.74 (5.31)
Time from symptom onset to first dose	median (Q1, Q3) (Min, Max) mean (SD)	8 (6, 10) (4, 15) 8.4 (2.5)	8 (7, 10) (4, 16) 8.5 (2.5)	8 (6, 10) (4, 17) 8.4 (2.8)
Baseline NIHSS score	N (%)	25 (25.3%)	20 (20.8%)	27 (26.5%)
4 ~ 6	N (%)	56 (56.6%)	55 (57.3%)	55 (53.9%)
7 ~ 10	N (%)	18 (18.2%)	21 (21.9%)	20 (19.6%)
11 ~ 25				
Stroke classification	N (%)	52 (53.1%)	56 (58.3%)	61 (59.8%)
Large artery atherosclerosis (LAA)	N (%)	1 (1%)	2 (2.1%)	2 (2%)
Cardiac source of embolism	N (%)	44 (44.9%)	38 (39.6%)	38 (37.3%)
Small artery occlusion (SAO)	N (%)	0	0	0
Others	N (%)	1 (1%)	0	1 (1%)

LT3001-202 Safety Result: No Increased Risk of sICH

- **Primary Endpoint** :
  - LT3001 was well tolerated across all dose groups.
  - The incidence of adverse events (AEs) and adverse drug reactions (ADRs) within 90 days after first dosing was similar among the high-dose LT3001, low-dose LT3001, and placebo groups, with most events being mild.
  - No symptomatic intracranial hemorrhage occurred in any group within 3 days after first dosing.
  - Three cases of asymptomatic intracranial hemorrhage were reported — all in the placebo group.

Proportion of Subjects with Asymptomatic Intracranial Hemorrhage (ICH) Within 3 Days After First Dose

		0.05 mg/kg	0.025 mg/kg	Placebo
N		99	96	102
Asymptomatic ICH	N (%)	0	0	3 (2.9%)
HI Type 1	N (%)	0	0	1 (1%)
HI Type 2	N (%)	0	0	2 (2%)
PH Type 1	N (%)	0	0	0
PH Type 2	N (%)	0	0	0

LT3001-202 Efficacy: mRS=0-1, mRS=0-2, NIHSS outcome

1. Favorable indicators were observed in mRS0-1, mRS0-2, and NIHSS results.
2. An 7.3% enhancement in mRS0-2 was detected in all study population.
3. Early improvement in NIHSS scores, signaling reperfusion, has been consistently observed.

		LT3001 0.05 mg/kg	LT3001 0.025 mg/kg	Placebo	0.05 - Placebo	0.025 - Placebo
All	n	99	96	102		
	mRS 0-1, d90	67.7%	69.8%	66.7%	**1.1%**	**5.3%**
	mRS 0-2, d90	85.9%	80.2%	78.4%	**7.3%[1]**	**3.4%**
	NIHSS Improvement*	71.7%	71.9%	65.7%	**5.3%**	**5.6%**

[1]RR = 1.1 (95% CI: 1.0, 1.2) marginal statistical difference.
*NIHSS reduced ≥4 points and/or achieved ≤1 on d14 in patients had completed d14 assessment.

LT3001-202 Efficacy: Stroke Severity Subgroups

1. Moderate strokes (NIHSS 7–10) were well represented (≥50 participants per group) and showed consistent efficacy, with a +9% improvement in 90-day mRS across both dose levels.
2. The 0.05 mg/kg dose demonstrated greater therapeutic potential than 0.025 mg/kg in patients with moderate-to-severe strokes (NIHSS 11–25).

		LT3001 0.05 mg/kg	LT3001 0.025 mg/kg	Placebo	0.05 - Placebo	0.025 - Placebo
Mild Stroke Baseline NIHSS 4~6	n	25	20	27		
	mRS 0-1, d90	88.0%	90.0%	88.9%	**-0.9%**	**1.1%**
	mRS 0-2, d90	96.0%	90.0%	96.3%	**-0.3%**	**-6.3%**
Moderate Stroke Baseline NIHSS 7~10	n	56	55	55		
	mRS 0-1, d90	69.6%	76.4%	67.3%	**2.4%**	**9.1%**
	mRS 0-2, d90	87.5%	87.3%	78.2%	**9.3%[1]**	**9.1%[2]**
Moderate-severe Stroke Baseline NIHSS 11~25	n	18	21	20		
	mRS 0-1, d90	38.9%	38.1%	35.0%	**3.9%**	**3.1%**
	mRS 0-2, d90	66.7%	42.9%	55.0%	**11.7%**	**-12.1%**

[1]RR = 1.1 (95% CI: 1.0, 1.4) [2]RR = 1.2 (95% CI: 1.0, 1.4)

LT3001-202 Efficacy: TOAST Subgroups

- LT3001 shows potential for a better treatment effect in AIS patients with large artery atherosclerosis (LAA) compared to small artery occlusion (SAO) based on their TOAST classification upon hospital presentation.

		LT3001 0.05 mg/kg	LT3001 0.025 mg/kg	Placebo	0.05 mg/kg - Placebo	0.025 mg/kg - Placebo	Combined - Placebo
Large artery atherosclerosis (LAA)	n	52	56	61			
	mRS 0-1, d90	61.5%	66.1%	57.4%	**4.1%**	**8.7%**	**+6.5%**
	mRS 0-2, d90	75.0%	76.8%	65.6%	**9.4%**	**11.2%**	**+10.4%**
Small artery occlusion (SAO)	N	44	38	38			
	mRS 0-1, d90	70.5%	71.1%	76.3%	-5.9%	-5.3%	-5.6%
	mRS 0-2, d90	86.4%	78.9%	92.1%	-5.7%	-13.2%	-9.2%

*post-hoc analysis was performed by non-imputation dataset.

LT3001-202 Efficacy: Disabling Stroke Subgroups

- LT3001 shows potential for a better treatment effect in AIS patients with disabling stroke, such as arm motor drift, and leg motor drift, based on their baseline NIHSS deficits upon hospital presentation.

		LT3001 0.05 mg/kg	LT3001 0.025 mg/kg	Placebo	0.05 mg/kg - Placebo	0.025 mg/kg - Placebo	Combined - Placebo
Arm motor drift Baseline NIHSS #5>2	n	30	30	31			
	mRS 0-1, d90	36.7%	53.3%	29%	**7.7%**	**24.3%**	**+16.0%**
	mRS 0-2, d90	63.3%	63.3%	41.9%	**21.4%**	**21.4%**	**+21.4%**
Leg motor drift Baseline NIHSS #6>2	n	38	35	37			
	mRS 0-1, d90	47.4%	57.1%	43.2%	**4.2%**	**13.9%**	**+8.8%**
	mRS 0-2, d90	71.1%	68.6%	56.8%	**14.3%**	**11.8%**	**+13.1%**
Arm or leg motor drift Baseline NIHSS #5>2 or #6>2	n	43	36	40			
	mRS 0-1, d90	46.5%	55.6%	42.5%	**4.0%**	**13.1%**	**+8.1%**
	mRS 0-2, d90	69.8%	66.7%	55%	**14.9%**	**11.7%**	**+13.4%**
Aphasia Baseline NIHSS #9≥1	n	51	41	45			
	mRS 0-1, d90	62.7%	68.3%	55.6%	**7.1%**	**12.7%**	**+9.7%**
	mRS 0-2, d90	78.4%	75.6%	62.2%	**16.2%**	**13.4%**	**+15.0%**

*post-hoc analysis was performed by non-imputation dataset.

Key Takeaways from the LT3001-202 Study

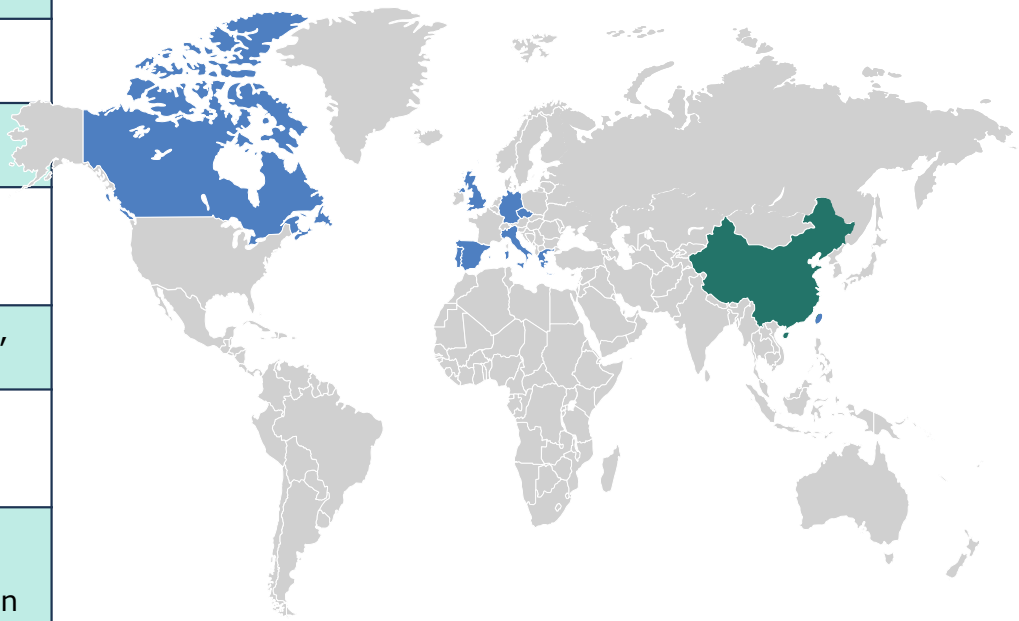
1. **Primary safety outcomes:** LT3001's six-dose, three-day regimen showed **no increased bleeding risk** in ~200 patients, meeting the primary endpoint.
2. **Secondary efficacy outcomes:**
    1) **Moderate strokes (NIHSS 7–10)** showed **+9% 90-day mRS** improvement across both doses. The high dose showed greater potential in moderate-to-severe strokes (NIHSS 11–25).
    2) In **disabling subgroups—motor drift, aphasia, and LAA**—LT3001 demonstrated additional gains of **+8–15% at day 90 mRS**, highlighting its potential to improve recovery in patients with greater neurological deficits**.**
3. **Extends treatment to 24 hours without advanced imaging**; however, findings are based on small sample sizes phase 2 study and **require confirmation in larger trials.**

LT3001 Phase 2b Program

	LT3001-202 (completed)	LT3001-205 (early termination)
Number of centers activated	34 Centers **CN**	21 Centers **US, TW, EU** (ES, DE, IT, CZ, PT, GR, UK)
Target disease	Acute ischemic stroke	Acute ischemic stroke
Treatment window	Within 24 hrs of stroke symptoms	Within 24 hrs of stroke symptoms
Enrollment / target number	297 / 300	**88 /** 200 (44%, early termination)
Trial protocol	Double-blind, randomized, placebo-controlled	Double-blind, randomized, placebo-controlled
Dosing regimen	Twice daily for three consecutive days (total 6 doses)	Twice daily for three consecutive days (total 6 doses)
Study objectives	1. Multiple-dose safety (sICH) 2. Clinical symptom treatment effect analysis 3. Dose comparison (0.05, 0.025 mg/kg)	1. Multiple-dose safety (sICH) 2. Imaging-based selection (mismatch) for identifying treatment responders

LT3001-205
- Patients number: **88**
- Sites activated: 21 centers in **the US, EU, UK and Taiwan**

LT3001-202
- Patients number: **297**
- Sites activated: 34 centers in **China**



LT3001-202 and LT3001-205: Baseline Characteristics

- LT3001-205 enrolled a smaller global cohort (n=88, US/EU/Taiwan) vs. 202 in China (n=297), with later treatment (~15–17h vs. ~12h), more moderate-to-severe strokes, and inclusion of mismatch imaging.

		LT3001-202			LT3001-205	
		0.05 mg/kg	**0.025 mg/kg**	**Placebo**	**0.05 mg/kg**	**Placebo**
N		99	96	102	43	45
Region Distribution		China 100%			US 19%, EU 33%, Taiwan 48%	
Age	Yrs, median (Q1, Q3)	65 (59,73)	64 (56,70)	64 (57,71)	68 (57,77)	67 (59,74)
Gender	Male%	70.7%	68.8%	71.6%	67%	71%
Weight	Kg, median (Q1, Q3)	68 (60,75)	70 (60,79)	70 (60,75)	72	72
Time from symptom onset to first dose	h, median (Q1, Q3)	12.44 (11.07, 16.42)	11.81 (10.59, 19.80)	12.15 (10.77, 20.02)	15.4 (11.8, 20.0)	16.8 (10.7, 20.7)
Baseline NIHSS score	median (Min, Max)	8 (4, 15)	8 (4, 16)	8 (4, 17)	7 (4, 23)	8 (4, 20)
4 ~ 6	N (%)	25 (25.3%)	20 (20.8%)	27 (26.5%)	17 (40%)	15 (33%)
7 ~ 10	N (%)	56 (56.6%)	55 (57.3%)	55 (53.9%)	14 (33%)	16 (36%)
11 ~ 25	N (%)	18 (18.2%)	21 (21.9%)	20 (19.6%)	12 (27%)	14 (31%)
Stroke classification						
Large artery atherosclerosis (LAA)	N (%)	52 (53.1%)	56 (58.3%)	61 (59.8%)		
Cardiac source of embolism	N (%)	1 (1%)	2 (2.1%)	2 (2%)		
Small artery occlusion (SAO)	N (%)	44 (44.9%)	38 (39.6%)	38 (37.3%)		
Others	N (%)	0	0	0		
Unknown	N (%)	1 (1%)	0	1 (1%)		
Mismatch						
Yes					18 (42%)	16 (36%)

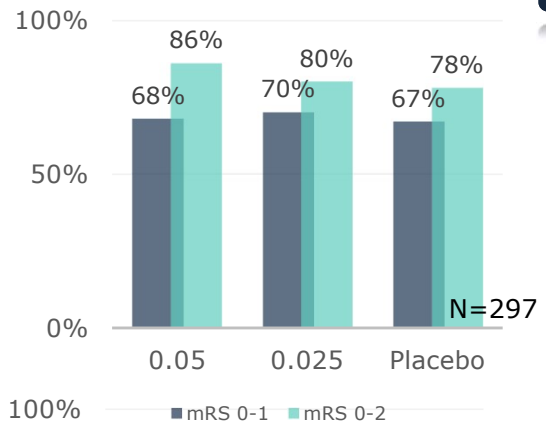
LT3001-202 and LT3001-205: Consistent Functional Improvement Benefit Observed

- **Safety broadly confirmed; No LT3001-related symptomatic intracranial hemorrhage (sICH) observed in either Phase 2 trial.**
- **Consistent efficacy across key populations:** moderate-to-severe stroke, disabling stroke, large artery atherosclerosis, and mismatch-positive patients.
- **Supports MOA:** Promotes clot removal while protecting threatened but salvageable brain tissue.
- **Demonstrates clinical value:** Particularly suited for patients with urgent demand, representing a differentiated solution for unmet medical needs.

202 trial

China Phase 2

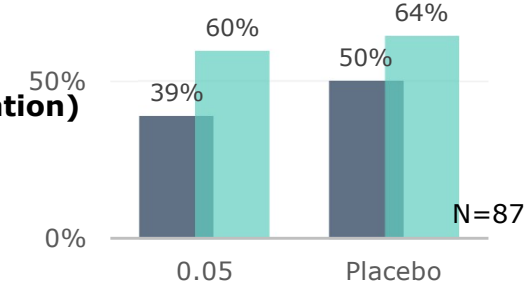
N=297



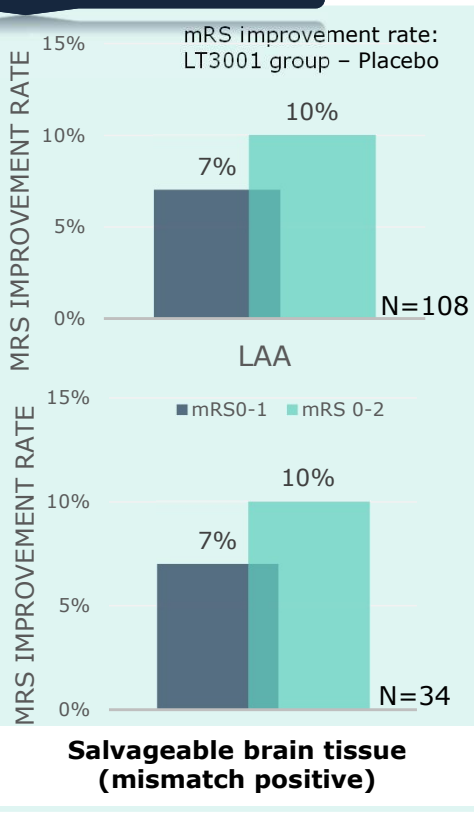
205 trial

Global Phase 2

N=87 (early termination)

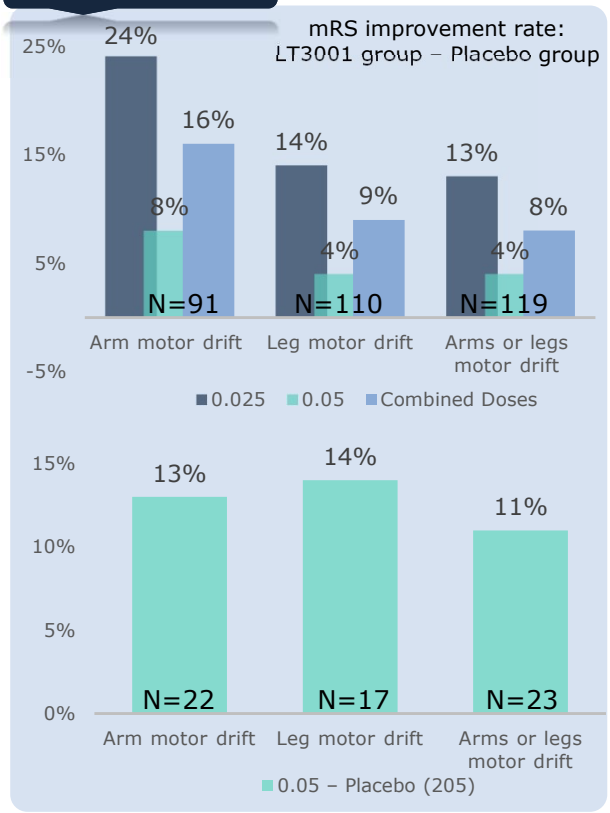


Imaging-confirmed stroke



Salvageable brain tissue (mismatch positive)

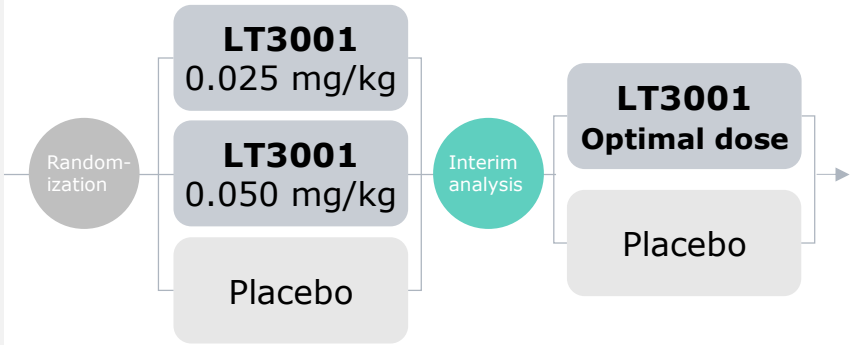
Disabling stroke



LT3001-301 Phase 3 Trial Design

Target patient population:

- Acute ischemic stroke
- **24 Hrs** within symptomatic onset
- Ineligible for tPA thrombolysis or mechanical thrombectomy
- Moderate-to-severe
- Disabling symptoms



Twice daily for three consecutive days (total 6 doses)

Total subj<1200

Primary endpoint:

Day 90 mRS 0-2 improvement rate

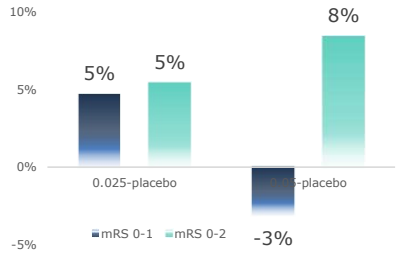
Secondary endpoints:

- **mRS shift**
- **mRS 0-1**
- NIHSS response
- BI 75-100
- EQ-5D

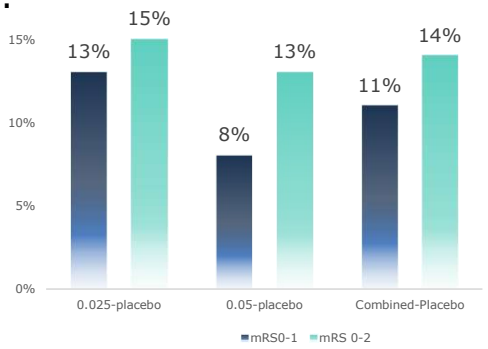
Safety endpoints:

- sICH
- SAE

Phase 3 sample size calculation assumptions:
Efficacy Δ=8%, requires N<1200



Focus on high0responder patients identified in Phase 2 subgroup analysis to maximize efficacy demonstration



LT3001 Development Goal - Superior Efficacy, Enhanced Safety – A Novel Stroke Treatment for Broader Patient Populations

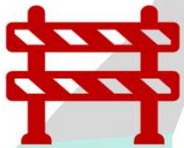
Unmet Medical Needs

Therapeutic dilemma for acute ischemic stroke treatments (IV tPA unmet need):

1. **2~6% Cerebral hemorrhage**
2. **Used in <10% AIS**

Global sales of tPA US$2 billion/yr

4.5 Hr



LT3001 development goal:

To bring safer, better treatment for more AIS patients

>5x treatment window, without meeting specific imaging criteria

Peak sales US$6-8 billion

ACTIVASE rt-PA
– IV tPA package insert

1 INDICATIONS

ACTIVASE rt-PA (alteplase for injection) is indicated for: ①

- The management of **acute ischemic stroke** (AIS) in adults for improving neurological recovery and reducing the incidence of disability. Treatment should only be initiated within 3 hours after the onset of stroke symptoms, and after exclusion of intracranial hemorrhage by a cranial computerized tomography (CT) scan or other diagnostic imaging method sensitive for the presence of hemorrhage. Eligibility criteria of the National Institute of Neurological Disorders and Stroke (NINDS) protocol must be strictly adhered to (see 2 CONTRAINDICATIONS).

AHA 2019 Treatment Guidelines for Acute Ischemic Stroke (2019):

Table 8. Eligibility Recommendations for IV Alteplase in Patients With AIS

Indications (COR I)		
Within 3 h*	①	IV alteplase (0.9 mg/kg, maximum dose 90 mg over 60 min with initial 10% of dose given as bolus over 1 min) is recommended for selected patients who may be treated within 3 h of ischemic stroke symptom onset or patient last known well or at baseline state. Physicians should review the criteria outlined in this table to determine patient eligibility.† (*COR I; LOE A*)
3–4.5 h*	②	IV alteplase (0.9 mg/kg, maximum dose 90 mg over 60 min with initial 10% of dose given as bolus over 1 min) is also recommended for selected patients who can be treated within 3 and 4.5 h of ischemic stroke symptom onset or patient last known well. Physicians should review the criteria outlined in this table to determine patient eligibility.† (*COR I; LOE B-R*§)
Additional recommendations for treatment with IV alteplase for patients with AIS (COR IIa)		And (COR IIb)
Wake-up and unknown time of onset	③	IV alteplase (0.9 mg/kg, maximum dose 90 mg over 60 min with initial 10% of dose given as bolus over 1 min) administered within 4.5 h of stroke symptom recognition can be beneficial in patients with AIS who awake with stroke symptoms or have unclear time of onset >4.5 h from last known well or at baseline state and who have a DW-MRI lesion smaller than one-third of the MCA territory and no visible signal change on FLAIR. (*COR IIa; LOE B-R*‡)

Treatment window	Imaging criteria	Efficacy: complete or near-complete recovery mRS=0-1		Efficacy: Functional independence mRS=0-2		Safety: sICH
① **0-3 hrs** (NINDS, US, 1995)	Routine CT (exclude hemorrhagic stroke)	tPA (n=168): 39% vs placebo (n=165): 26% (p=0.019)	**+13%**	NA		**tPA: 6.4%,** placebo: 0.6% (p<0.001)
② **3-4.5 hrs** (ECASS 3, EU, 2008)		tPA (n=418): 52% vs placebo (n=403): 45% (p=0.04)	**+7%**	tPA: 66.5% vs placebo 61.5%	**+5%**	**tPA: 2.4%,** placebo: 0.2% (p=0.008)
③ **Wake-up Stroke** (WAKE-UP, EU, 2018)	MRI mismatch	tPA (n=254): 53% vs placebo (n=249): 42% (p=0.02)	**+11%**	tPA: 74% vs placebo 65%	**+9%**	**tPA: 2.4%,** placebo: 0.4% (p=0.1)
4.5-9 hrs (Extend, Australian, 2019)	CTP mismatch	tPA (n=113): 35.4% vs placebo (n=112): 29.5% (p=0.04)	**+6%**	tPA:49.6% vs placebo:42.6%,	**+7%**	**tPA: 6.2%** placebo: 0.9% (p=0.053)
4.5-24 jrs LT3001	Routine CT (exclude hemorrhagic stroke)	**+ 11%**		**+ 14%**		**0%**

LT3001: Phase 2 Achievements and Phase 3 Outlook

1. **Established safety:** No LT3001-related symptomatic intracranial hemorrhage (sICH) observed in either Phase 2 trial, confirming the drug's safety profile.
2. **Clear efficacy trends:** Most pronounced benefit observed in disabling stroke patients, with consistent support from large artery atherosclerosis and mismatch-positive subgroup analyses, demonstrating protection of salvageable brain tissue and functional recovery – particularly benefiting high-speed patient populations.
3. **Global Phase 3 design:** Focuses on disabling stroke populations with interim analysis mechanisms to confirm dosing and adjust sample size, ensuring maximum clinical benefit
4. **Enhanced success probability:** Robust safety foundation and clear efficacy signals, combined with a precision Phase 3 strategy, **substantially increase likelihood of clinical and developmental success.**

Global Market

Europe: Over 900,000 annual incident ischemic strokes

US: Over 700,000 annual incident ischemic strokes

>30% Are target moderate-to-severe disabling patients
Limited treatment options
High healthcare burden

Leading cause of disability
The primary driver of long-term severe disability

Market Potential

- **Substantial market opportunity –** Over 7 million AIS patients globally each year, with >30% representing the target moderate-to-severe disabling population
- **Strong market demand –** EU and US market research indicates high physician prescribing intent; payers estimate treatment costs at $25,000 per case in the US and $16,000 in EU.
- **Comprehensive patent protection -** Compound patent extends to 2039; formulation and method-of-use patents provide protection through 2045.

Thank you