



TSE Growth : 4891

Financial Results for FY02/2023

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Create impactful therapeutics by the power of
relentless exploration and challenge

1. Topics
2. Summary of Financial results for FY02/2023
3. TMS-007
4. TMS-008 / 009
5. Expansion of Pipelines
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Topics



1 TMS-007 (BIIB131) update

- Biogen has announced to initiate a Ph2b clinical trial in the first half of 2023. (Detailed clinical trial information is available at [ClinicalTrials.gov](https://clinicaltrials.gov).) ¹

2 Reduced net loss for the full year

- Operating loss and net loss have been reduced, compared to the forecast disclosed at the Initial Public Offering (IPO).
- Operating loss: 896m yen → 520m yen (376m yen, +42% vs forecast)
Net loss: 1,230m yen → 860m yen (369m yen, +30% vs forecast)

3 Co-founder Dr. Keiji Hasumi joined as full-time CSO

- Dr. Keiji Hasumi, Ph.D., the company's co-founder who was behind TMS-007 R&D, became CSO (Chief Scientific Officer), following his retirement from a full-time professor at Tokyo University of Agriculture and Technologies (TUAT) as of April 1, 2023.
- The company and TUAT establishes a collaborative research program and continue cooperation.

Summary of Financial results for FY02/2023



Recorded losses for Ordinary Income and Net Income for FY02/2023

	(million yen)		
	02/2022	02/2023	Increase/ decrease
Operating revenue	1,946	-	(1,946)
Operating expenses	810	520	(290)
Research and development expenses	304	297	(6)
Operating income	1,135	(520)	(1,655)
Non-operating income	38	0	(38)
Non-operating expenses	95	341	246
Ordinary income	1,079	(861)	(1,940)
Net income	1,076	(860)	(1,937)

No revenue was recorded in FY 02/2023, in contrast to FY02/2022 when there was revenue from Biogen's option exercise.

The expenses remained at low level due to;

- TMS-007 related expenses no longer incurred since FY02/2022.
- Other projects are still in the research phase.

Increase in IPO-related expenses.

R&D expenses are mainly for;

- Development of TMS-008
- Research activities for pipeline expansion
- Introduction of external assets

Expected expenses for FY02/2024

	(million yen)	
Research and Development expenses	500	- 800
Other selling, general and administrative expenses	350	- 450

Full Year Financial Results FY02/2023 - Cash flows



Cash and cash equivalents increased by 986m yen mainly due to issuance of new shares with IPO in November 2022. Runway until TMS-007 next milestone event is estimated to be secured.

	(million yen)	
	02/2022	02/2023
Cash flows from operating activities	1,261	(688)
Income before income taxes	1,079	(861)
Cash flows from investing activities	(16)	(13)
Cash flows from financing activities	246	1,688
Income from the issuance of shares	249	2,109
Net (decrease) increase in cash and cash equivalents	1,491	986
Cash and cash equivalents at beginning of period	1,106	2,598
Cash and cash equivalents at end of period	2,598	3,584

No income in FY02/2023. For FY02/2022, positive cashflow was due to option exercise revenue from Biogen.

Proceeds from the issuance of shares exceeded the outflow of 420m yen for IPO expenses.

Total assets increased due to financing from IPO in November 2022

(million yen)

	02/2022	02/2023	Increase/ decrease
Current assets	2,722	3,766	1,043
Cash and deposits	2,598	3,584	986
Non-current assets	16	23	6
Total assets	2,739	3,790	1,050
Current liabilities	285	76	(209)
Non-current liabilities	1	-	(1)
Total liabilities	286	76	(210)
Total net assets	2,453	3,714	1,261
Total liabilities and net assets	2,739	3,790	1,050

Cash and deposits increased due to IPO.

Mainly accrued royalties payable were recorded in FY02/2022.

Growing and Differentiated Drug Pipeline



TMS-007 Ph2a completed: Ph2b of TMS-007 (BIIB131) to be initiated by Biogen

TMS-008 Preclinical stage: Being developed by TMS under grant-back license from Biogen

Development Code	Target Disease	MoA	Research	Preclinical	Ph1	Ph2	Ph3	Development and Commercialization	Next Milestones
TMS-007 (BIIB131)	Acute Ischemic Stroke	sEH Inhibition Plasminogen				Ph2a completed in Japan ¹ Ph2b ¹		Biogen	Ph2b clinical trial to be initiated in 1H 2023 by Biogen ¹
TMS-008 ²	Acute Kidney Injury							TMS	IND Application expected to be filed and Ph1 expected to be started in FY02/2024
	Cancer Cachexia	sEH Inhibition					Anticipated Next Steps	TMS	
	Other indications								
TMS-009 ²	TBD	sEH Inhibition							
Pipeline candidates <Internal>					Search for novel sEH inhibitors and other compounds				
Pipeline candidates <External>					Evaluating multiple programs				

The above information contains forward-looking statements based on our judgement in light of the information currently available to us. Therefore, please be aware that the above information is subject to various risks and uncertainties, and actual development may differ significantly from these projections.

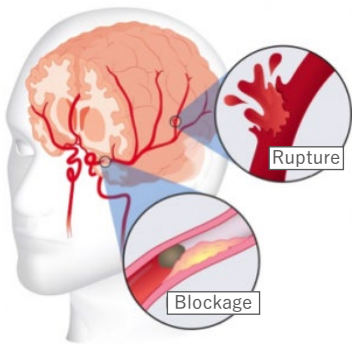
1. Biogen has registered and published detailed clinical trial information in ClinicalTrials.gov on March 10, 2023. <https://clinicaltrials.gov/ct2/show/NCT05764122>
2. Our development rights for TMS-008 and TMS-009, which are being developed under a free license from Biogen, are limited to certain indications, and TMS-009 is a backup compound for TMS-008.

TMS-007

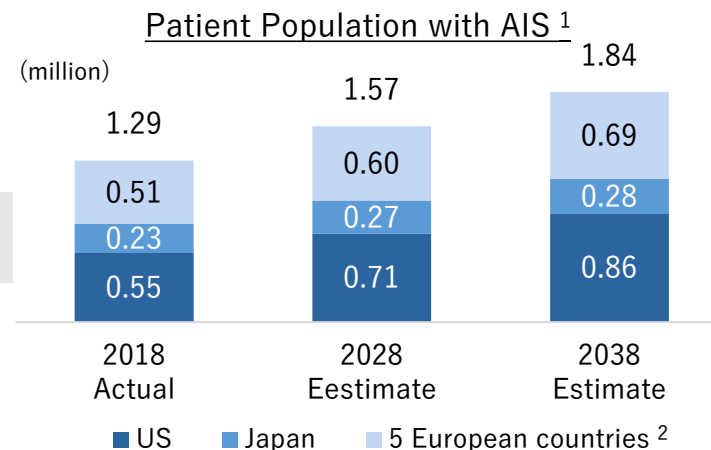
Potential Next Generation
Acute Ischemic Stroke
Treatment



Acute Ischemic Stroke (AIS) Overview



- AIS is caused by blockages of blood supply to the brain
- Potentially leads to permanent brain damage :
hemiplegia, memory loss, speech problems, reading and comprehension difficulties and other complications
- The number of patients with Ischemic Stroke: approx. 1.3 million/year (total of 7 major countries) and it is expected to increase



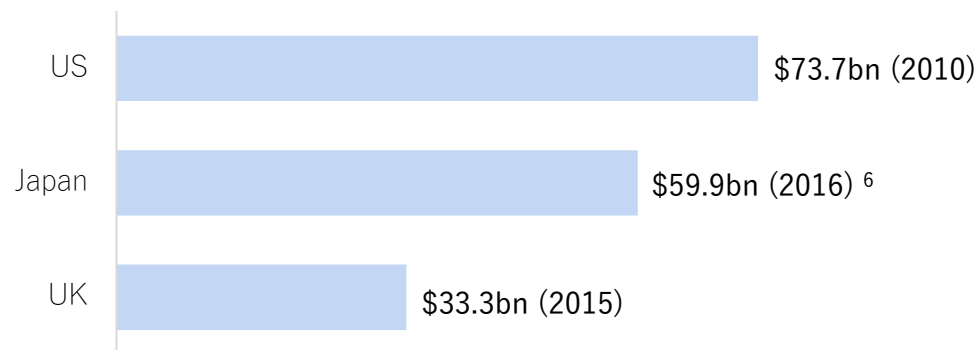
Important Unmet Medical Needs

Cause of death in the US (2019) ³

#	Disease	Ratio
1	Heart Disease	23.1%
:	:	:
4	CLRD	5.5%
5	Stroke	5.3%
6	Alzheimer	4.3%

Breakdown of Stroke ⁴

Stroke causes significant economic loss ⁵



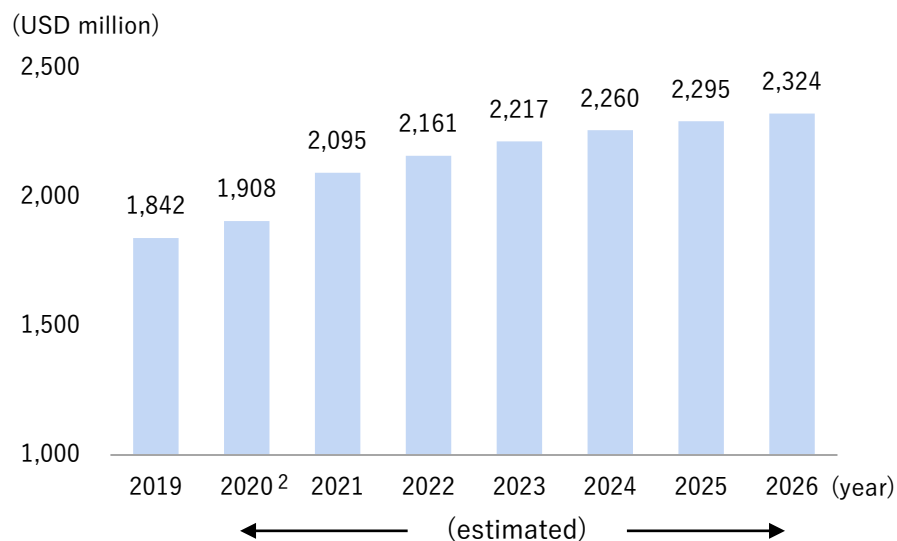
1. Datamonitor Healthcare, "Stroke Epidemiology", Ref Code:DMKC0201444, Published on 07 January 2019
 2. 5 European countries are composed of five major countries: Germany, France, Italy, Spain, and United Kingdom
 3. Centers for Disease Control and Prevention, "National Vital Statistics Reports volume 70"
 4. Tsao et al. (2022) Heart Disease and Stroke Statistics—2022 Update: A Report From the American Heart Association

5. National Stroke Association, Explaining stroke 101, 2011; Current, future and avoidable cost of stroke in the UK, 2017; Yamaga et al. (2016), "Cost of illness in cerebrovascular disease"
 Calculation based on exchange rates; USD/JPY=110, USD/GBP=1.3
 6. Estimated COI based on direct and indirect costs related to stroke for 1 year until November 2015

the only FDA-approved drug for AIS

Market size ¹ of the existing drug

- Sales of t-PA is estimated to be approx. **\$2.1bn** in 2021



Challenges of the existing drug

Incidence rate of fatal intracranial hemorrhage ^{3,5}



Mortality ^{4,5}



- t-PA (tissue Plasminogen Activator): the **only FDA-approved drug** for AIS (thrombolytic agent)
- t-PA generally needs to be administered within **4.5 hours** from symptom onset and is used for **<10% of patients** ⁶

1. Informa; estimated as the sum of sales of Activase® and Actilyse® for each year

2. As Actilyse® sales in 2020 is not available, Actilyse® sales in 2019 is used for estimation for 2020

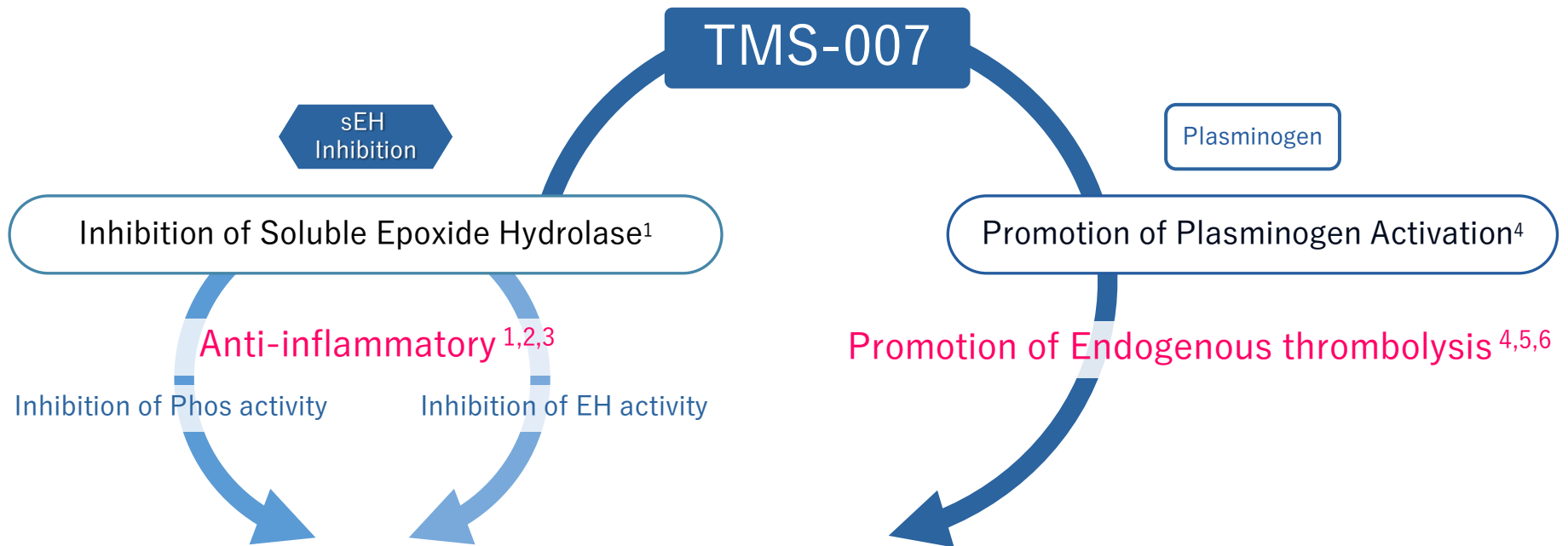
3. Incidence rate at 7 days

4. Mortality at 90 days

5. Emberson et al. (2014), "Effect of treatment delay, age, and stroke severity on the effects of intravenous thrombolysis with alteplase for acute ischaemic stroke: a meta-analysis of individual patient data from randomised trials"

6. Audebert et al. Nat. Rev. Neurol. 10.675-676, 2014 'Time is brain' after stroke, regardless of age and severity

Dual mechanism – “Anti-inflammatory” and “Thrombolytic” activities



Our SMTP-based small molecule analogues with unique therapeutic properties

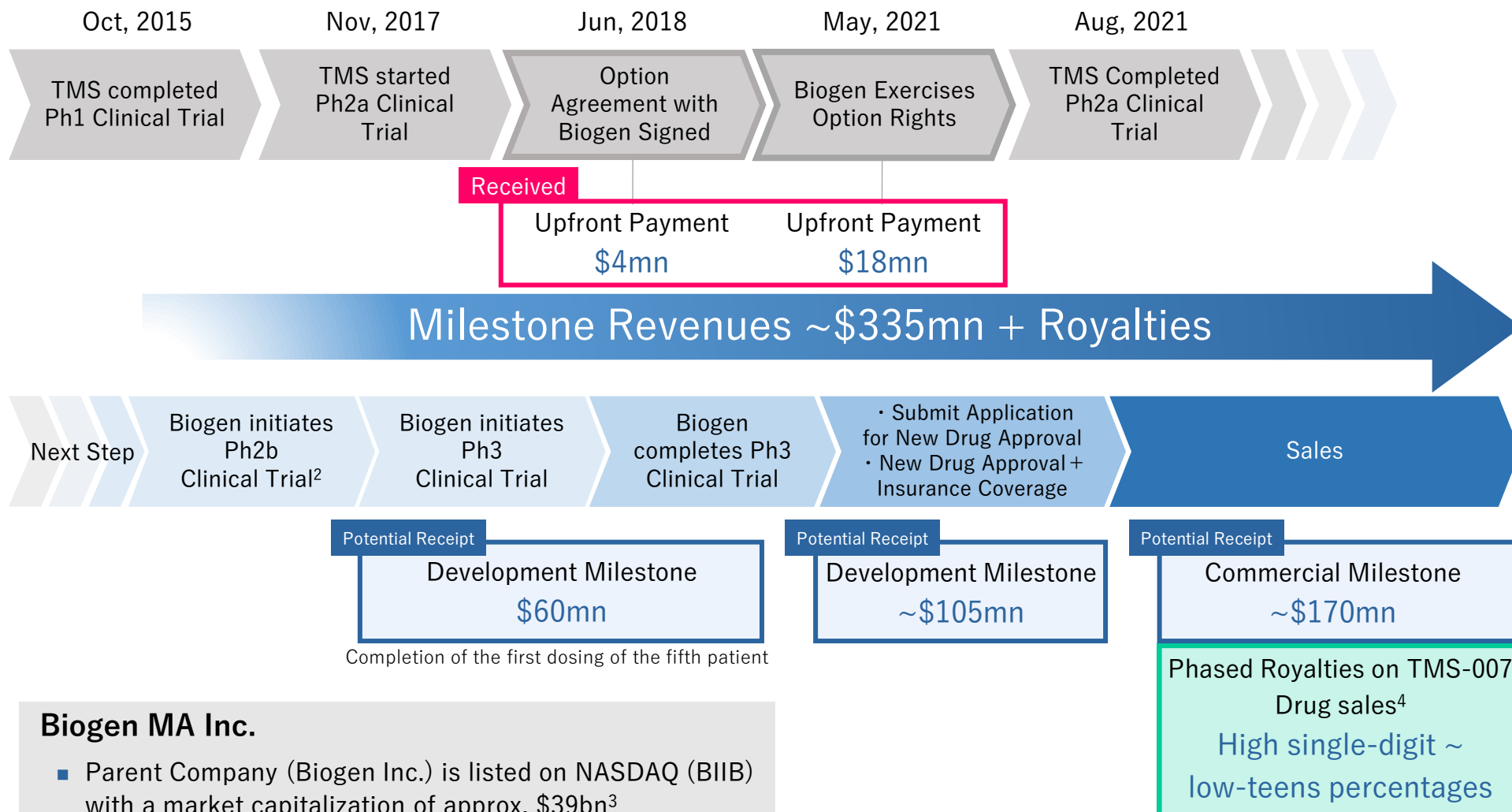
Anti-inflammatory and **thrombolytic** activities
Ideal profile for acute ischemic stroke treatment

1. Matsumoto et al. (2014) J Biol Chem
2. Shibata et al. (2011) N-S Arch Pharmacol
3. Ito et al. (2014) Brain Res
4. Hasumi et al. (2010) FEBS J
5. Hu et al. (2012) Thrombosis J
6. Miyazaki et al. (2011) Stroke

TMS-007 (BIIB131): Acquired by Biogen, the U.S. Biotech Company

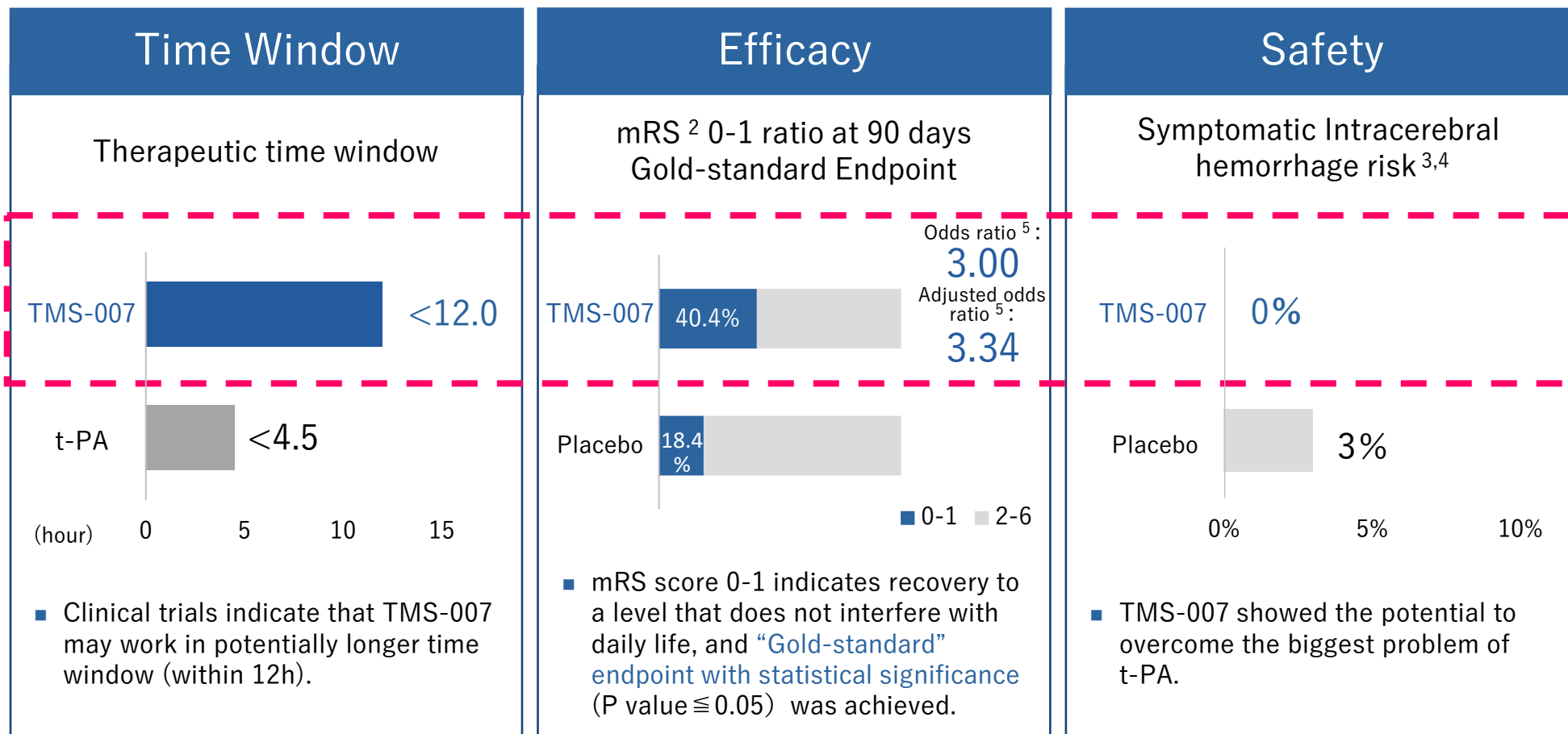


Biogen exercised its option to acquire all IP and assets related to TMS-007 and SMTP compound in May 2021¹



1. TMS and Biogen joint press release (May 12, 2021)
 2. Biogen, Third Quarter 2022 Financial Results and Business Update (October 25, 2022)
 3. Biogen Inc (BIIB) market capitalization as of February 28, 2023
 4. A percentage of worldwide annual sales of TMS-007 (under certain circumstances, payment may decrease due to changes in the cap)

TMS-007 has the potential to become the first line AIS treatment ¹



- The data comparisons above are not based on head-to-head clinical studies. Number of patients(N)=52 for TMS-007, N=3,391 and N=2,488 for t-PA
- mRS indicates modified Rankin Scale, and it refers to degree of independence in daily life
- Biogen, Investor Day Material (September 21, 2021), Q4 and Full Year 2021: Financial Results and Business Update

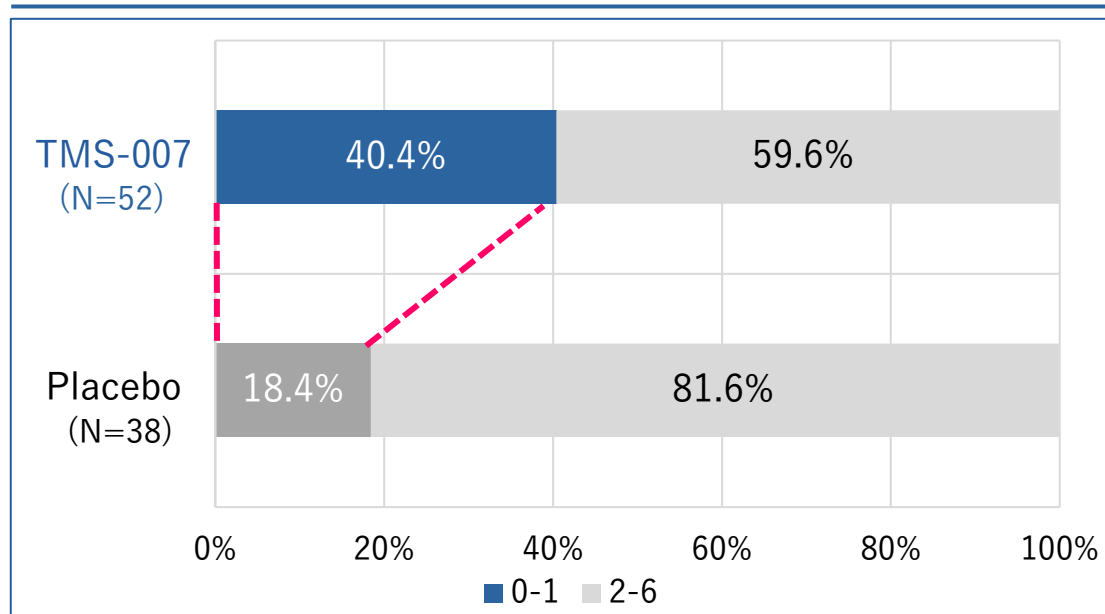
- Wardlaw et al. (2012), “Recombinant tissue plasminogen activator for acute ischaemic stroke: an updated systematic review and meta-analysis”, N=2,488
- Calculation of each odds ratio;
TMS-007: odds ratio 3.0=(40.4%/59.6%)/(18.4%/81.6%), adjusted odds ratio 3.34, (statistically adjusted to control for other predictor variables; Source: ISC2022 Poster)





TMS-007 achieved statistically significant improvement on mRS 0-1 ratio at 90 days, one of the most important indicators

	Placebo	TMS-007
Number of patients (N)	38	52
Number of patients scored mRS 0-1	7	21
mRS 0-1 ratio	18.4%	40.4%

- Odds ratio 3.00, Adjusted odds ratio 3.34
- P value \leq 0.05

mRS 0-1 ratio at 90 days¹

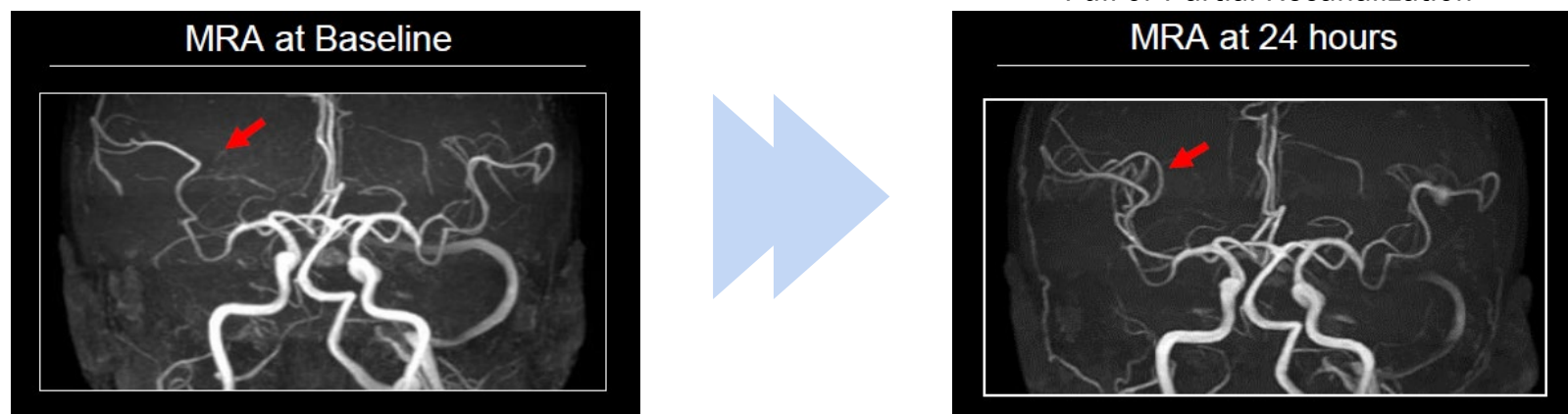


mRS (modified Rankin Scale)		
	0	No symptoms
	1	No significant disability, despite symptoms; able to perform all usual duties and activities
	2	Slight disability; unable to perform all previous activities but able to look after own affairs without assistance
	3	Moderate disability; requires some help, but able to walk without assistance
	4	Moderately severe disability; unable to walk without assistance and unable to attend to own bodily needs without assistance
	5	Severe disability; bedridden, incontinent and requires constant nursing care and attention
	6	Death

1. Biogen, Investor Day Material (September 21, 2021), Q4 and Full Year 2021: Financial Results and Business Update

TMS-007's promising efficacy is potentially backed by good recanalization outcome ¹

Effect of vessel recanalization confirmed for patients with full or partial vascular occlusion - MRA image



the percentage of subjects receiving TMS-007 achieving recanalization was greater than those treated with placebo

	Placebo Pooled	TMS-007 Pooled
Number of patients (N)	15 (100)	24 (100)
Number of patients with recanalization	4 (26.7)	14 (58.3)
Estimate of odds ratio (TMS-007 vs placebo)	-	4.23
95% CI for the odds ratio	-	0.99, 18.07

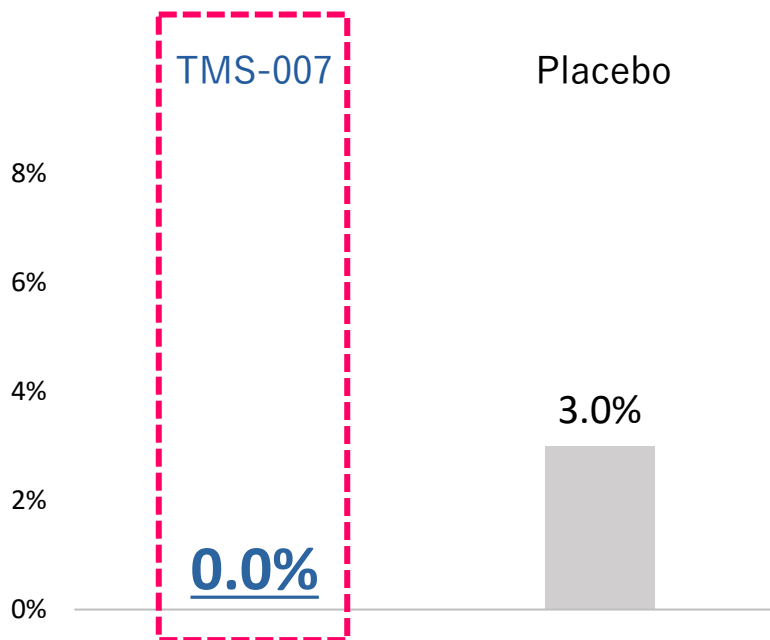
1. Biogen, Investor Day Material (September 21, 2021), Q4 and Full Year 2021: Financial Results and Business Update

In terms of safety, the biggest concern of t-PA, TMS-007 demonstrated reduced risk of the incidence of symptomatic Intracerebral Hemorrhage (sICH) ¹

Incidence rate of sICH¹

TMS-007 vs Placebo ²

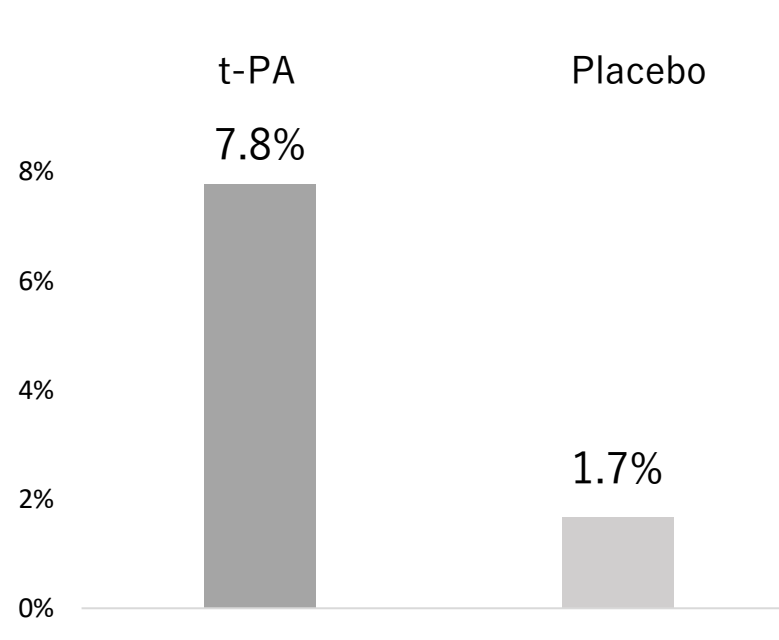
Ph2a



N	52	38
Prehospital time	9.5h (Average)	9.3h (Average)

t-PA vs Placebo ³

Meta-analysis



N	3,384	3,330
Prehospital time	Within 6h	

1. The data comparisons below are not based on head-to-head clinical studies. N=52 for TMS-007, N=3,384 for t-PA
 2. Biogen, Investor Day Material (September 21, 2021), Q4 and Full Year 2021: Financial Results and Business Update
 3. Wardlaw et al. (2012), "Recombinant tissue plasminogen activator for acute ischaemic stroke: an updated systematic review and meta-analysis"

Summarized information, based on the publicly available information registered by Biogen ¹

Outline

- Multicenter, operationally seamless, double-blind, dose-ranging, placebo-controlled, randomized, parallel-group
- Estimated enrollment: 760 participants
- Estimated duration: Apr 2023 – July 2025

Key Inclusion Criteria

- “Patients with thrombus site confirmed by imaging” ² or “Patients with an estimation of penumbra ³ volume to be $\geq 10\text{ml}$ ” ⁴
- Presentation and treatment start are within 4.5 - 24 hours of LKW ⁵
- No statement regarding limitations with or without endovascular therapy
- Age 18 – 85 years

Part 1

4 groups: Low, Medium and High dose, and Placebo

Primary Outcome Measures

- Arterial revascularization ⁶
- Reduction of at least 90% of the area presumed to be penumbra for patients in whom the occlusion cannot be located⁷

Part 2

2 groups: a single dose specified in Part1 and Placebo

Primary Outcome Measures

- modified Ranking Scale (mRS) score at 90 days

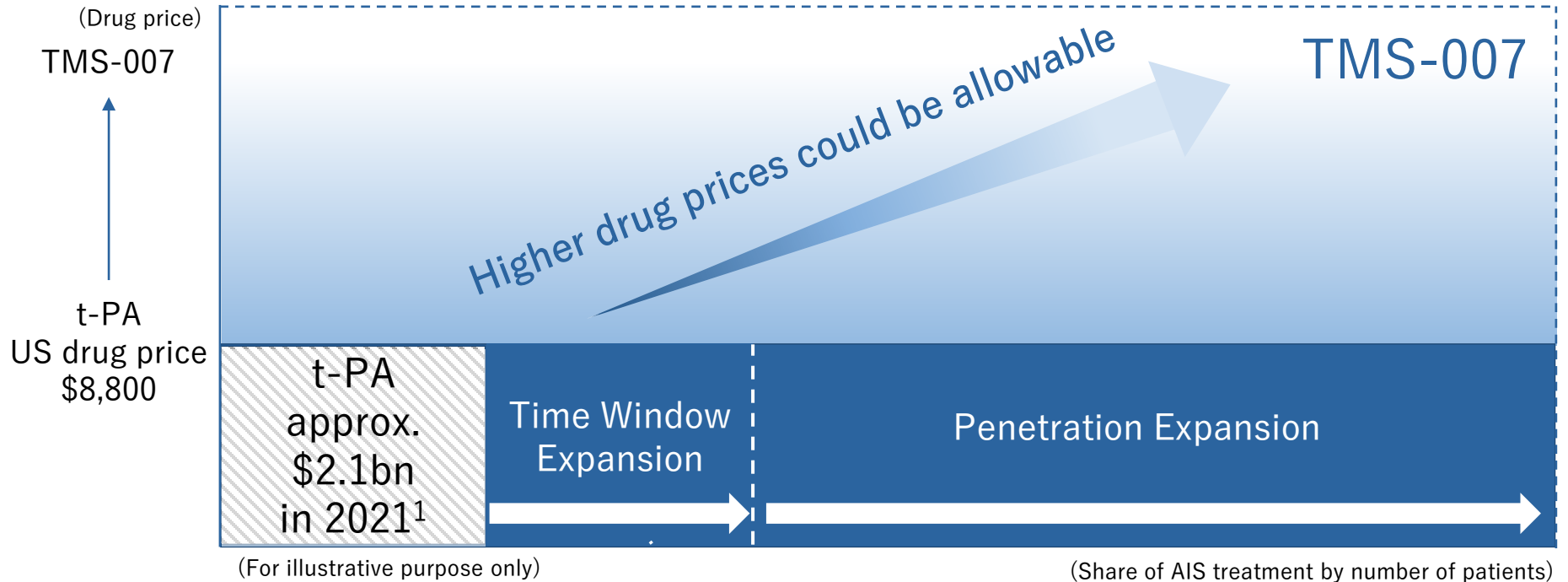
1. The above information are summarized by TMS Co., Ltd., based on the information registered and published in ClinicalTrials.gov (<https://clinicaltrials.gov/ct2/show/NCT05764122>) by Biogen. Therefore, the accuracy of the information cannot be assured.
2. Patients with CTA or MRA showing symptomatic intracranial occlusion, at one of the following locations: intracranial internal carotid, M1, M2 or distal branches of the middle cerebral artery (MCA), anterior cerebral artery (ACA), or posterior cerebral artery.
3. Penumbra is an area of brain, in the early (hyperacute) phase of cerebral infarction, where blood flow is reduced but cells have not yet become necrotic, and rapid vascular recanalization is expected to prevent the area from transition to infarction.
4. Patients with the volume of T_{max}>6s to be ≥ 10 mL on perfusion imaging.
5. LKW: Last Know Well, meaning the last time patient was confirmed to be normal before symptoms started.
6. Patients with an AOL score of 2 or 3 at 4 \pm 2 hours post-treatment (or at the time of the first angiogram for patients undergoing endovascular therapy).
7. For patients with no visible occlusion at baseline, >90% reduction of T_{max} > 6s at 4 \pm 2 hours after treatment completion.

Summarized information, based on the publicly available information registered by Biogen ¹

	Ph2a	Ph2b
Basic design	1 stage	2 stages (Part 1, Part 2)
Enrollment	90	760 (Estimated)
Primary efficacy endpoint	mRS 0-1 ratio	Part 1 • Arterial revascularization • Reduction of at least 90% of penumbra Part 2 • mRS score
Ages eligible for trial	Male: 20 - 88 years Female: 60 - 88 years	18 - 85 years
Time window	Within 12 hours after on set	Within 4.5 - 24 hours of LKW
Endovascular therapy (EVT)	Only for patients without EVT	May include patients undergoing EVT
Pre-treatment score of NIHSS	6 - 23 (Patients with moderate symptoms)	≥ 5 (Severe patients are also eligible)

1. The above information are summarized by TMS Co., Ltd., based on the information registered and published in ClinicalTrials.gov (<https://clinicaltrials.gov/ct2/show/NCT05764122>) by Biogen. Therefore, the accuracy of the information cannot be assured.

Potential Market Size for TMS-007 with possible outstanding Efficacy and Safety



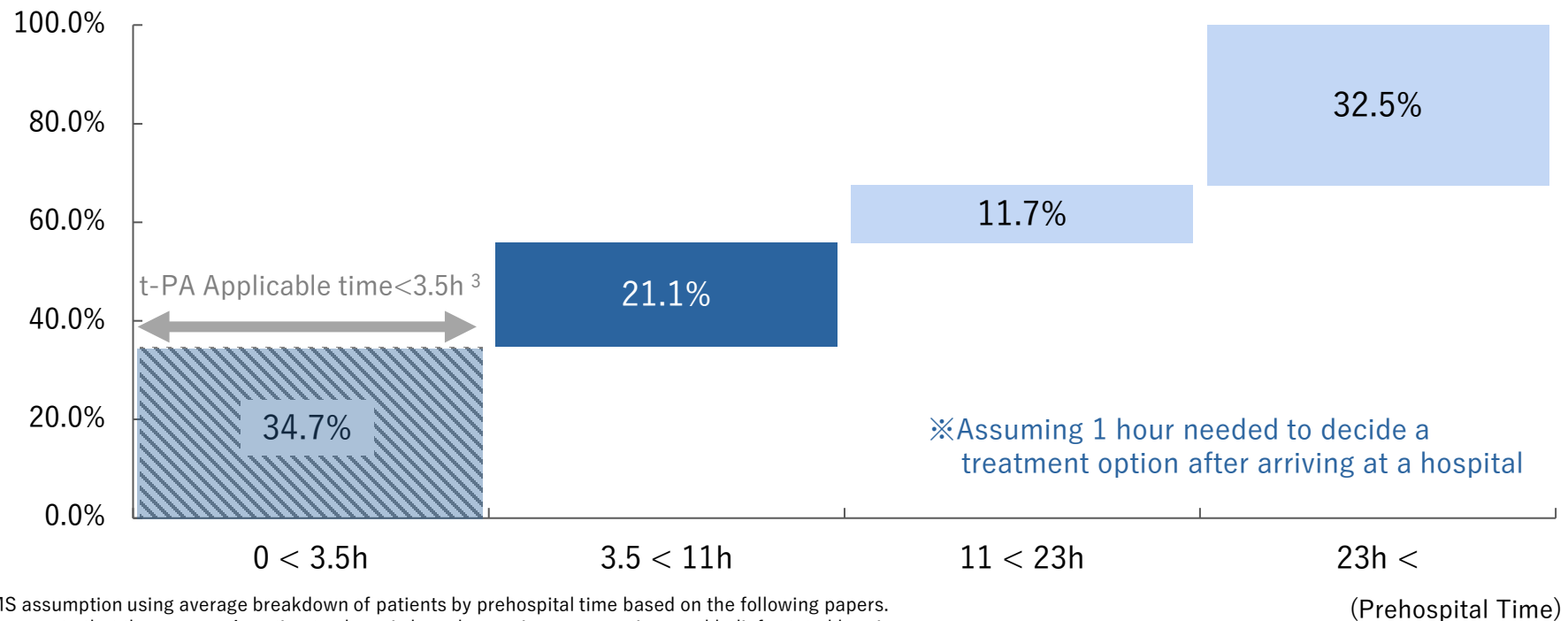
- TMS-007 has potential to realize the expansion of time window
⇒ Total addressable patients of TMS-007 may expand significantly
- If TMS-007 can achieve higher efficacy and safety than t-PA, higher drug price could be expected (sales of t-PA estimated to be approx. \$2.1bn in 2021¹)

1. For 2021, Informa; calculated as the sum of estimated sales of Activase® and Actilyse® in 2021. Actual market size may differ from the estimate due to the limitations peculiar to such statistical data and publications in terms of their accuracy

Relationship between Prehospital Time and treatment ¹

- Number of t-PA treated patients is only a part of entire patient population arriving at a hospital
- Time window expansion for TMS-007 could expand the target patient population ²

(Percentage of patients ¹)

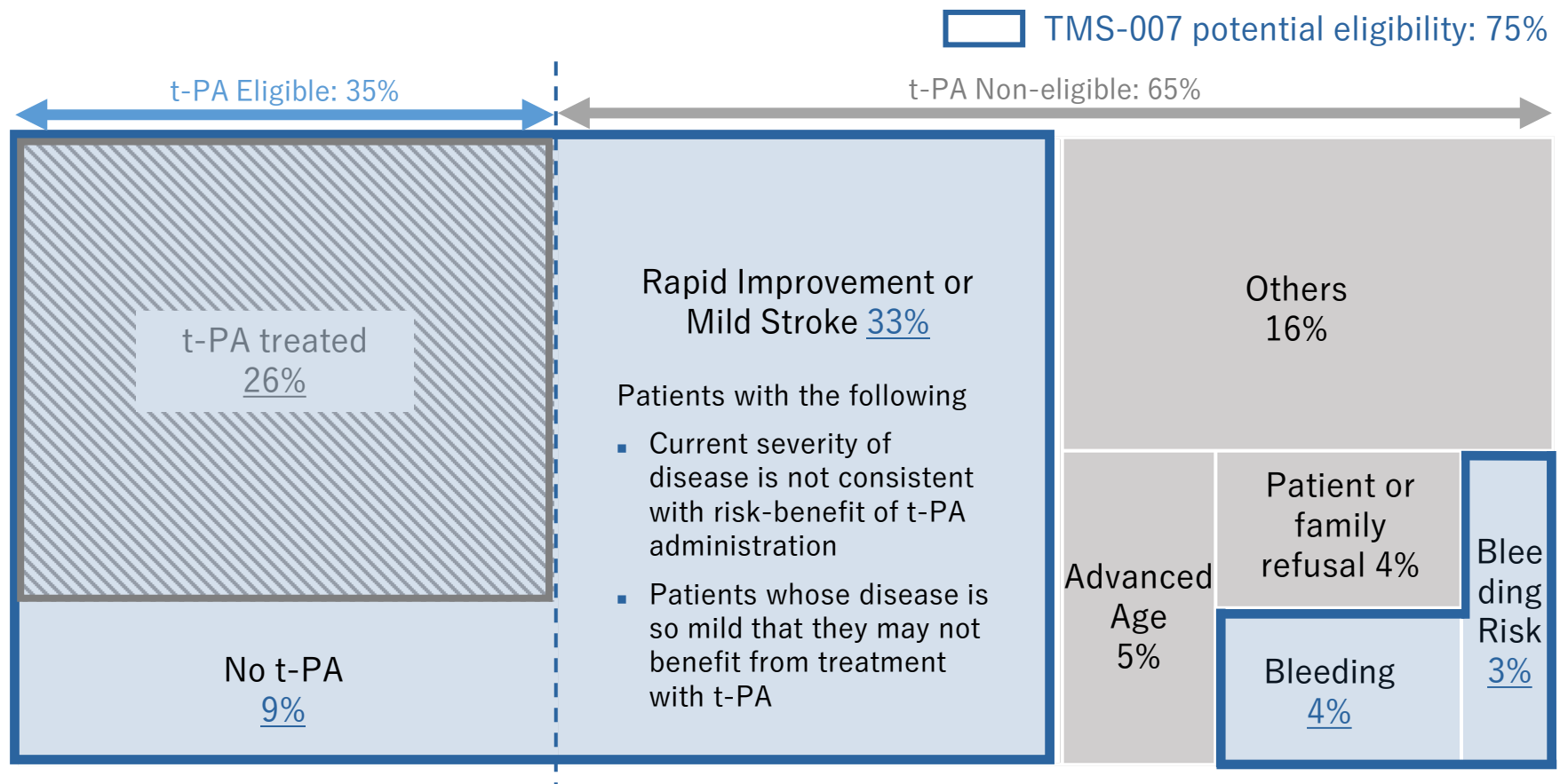


1. TMS assumption using average breakdown of patients by prehospital time based on the following papers. Please note that the company's estimate above is based on various assumptions and beliefs stated herein, including the available dose window, disregard certain significant conditions such as the eligibility of the patients and may not be supported by any clinical data;
 Tong et al. (2012), "Times From Symptom Onset to Hospital Arrival in the Get With The Guidelines-Stroke Program 2002 to 2009"
 Harraf (2002), "A multicenter observational study of presentation and early assessment of acute stroke"
 Kim (2011), "Stroke awareness decreases prehospital delay after acute ischemic stroke in Korea"
 Matsuo (2017), "Association Between Onset-to-Door Time and Clinical Outcomes After Ischemic Stroke"

2. Expansion of time window over 12 hours (maximum 24 hours) is based on the registered and published information by Biogen on ClinicalTrials.gov on March 10, 2023.
 3. Assuming 1 hour needed to decide a treatment option after arriving at a hospital

How t-PA is treated for patients arriving within 2 hours from symptom onset ¹

- Due to its high safety profile, TMS-007 has a potential to [expand its penetration](#)
- It is estimated that TMS-007 may be used for [up to 75%](#) of patients, within the dosing window



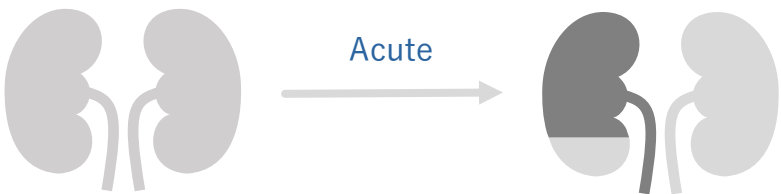
1. Messe (2016), "Why are acute ischemic stroke patients not receiving IV t-PA"

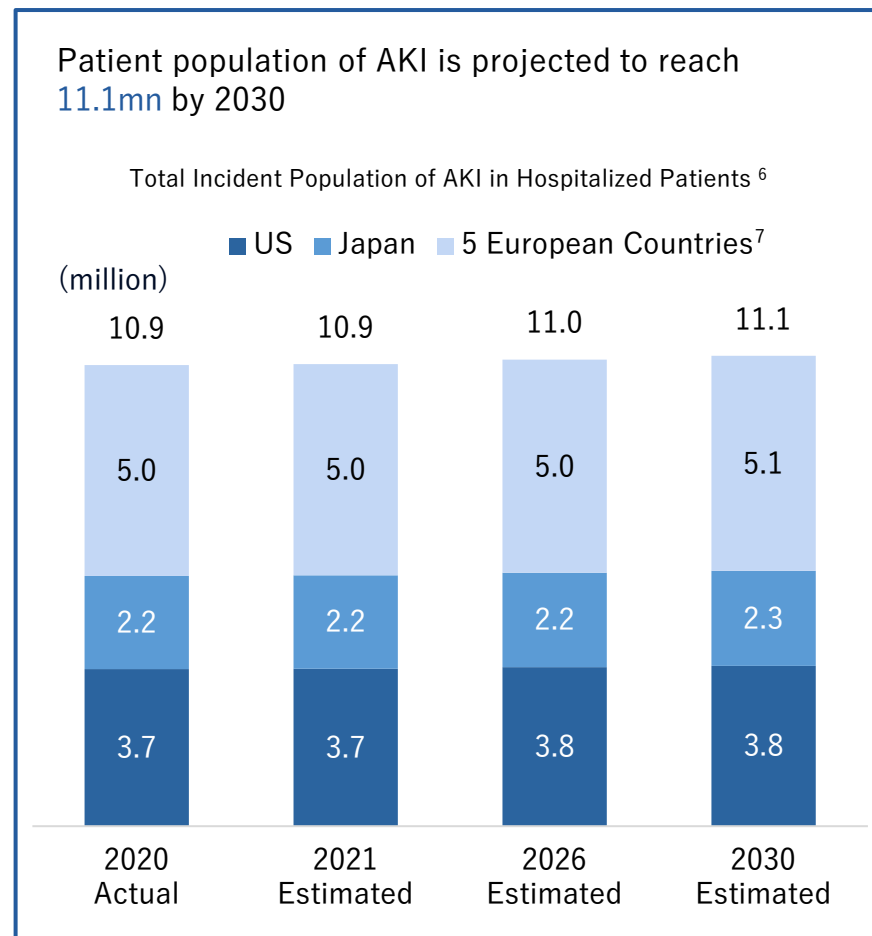
TMS-008/009

Acute Kidney Injury
and other indications



TMS-008 development is directed to take advantage of its strong anti-inflammatory properties

Indication	<p>No protein leakage Appropriate toxin excretion</p>  <p>Decreased renal function adversely affects heart and other organs</p>
Overview	<ul style="list-style-type: none"> Acute Kidney Injury (AKI) is a rapid decline in renal function over a period of hours to days 20-25% mortality rate in hospitalized AKI patients AKI causes chronic kidney disease (CKD) and end-stage renal disease (ESRD)
Number of patients	<ul style="list-style-type: none"> 5 European countries: ~5,080,000 United States: ~3,800,000 Japan: ~2,300,000 <p>(Patients assumptions for year 2030 as of 2020)</p>
Treatment method	<ul style="list-style-type: none"> No approved therapeutic drug ⁵



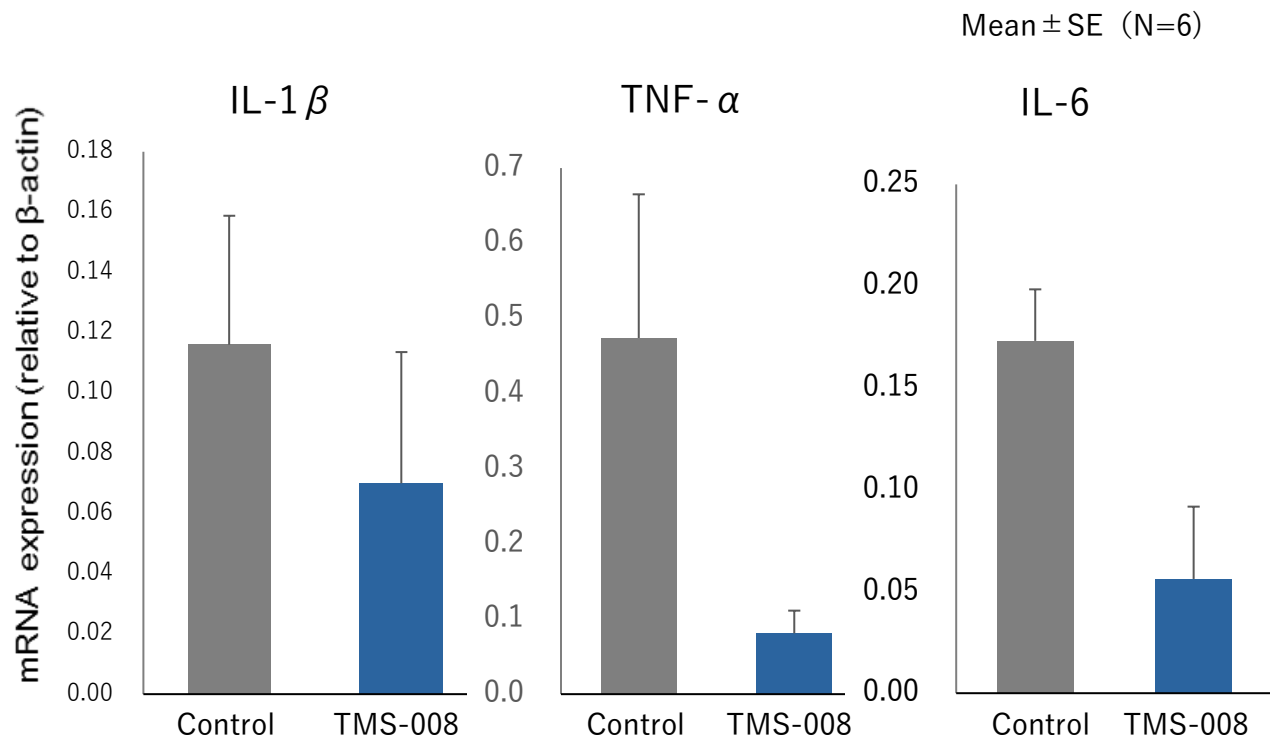
- Nature Reviews Nephrology volume 16, pages747–764 (2020)
- Adv Chronic Kidney Dis. 2017;24(4):194-204
- Nephron. 2017 ; 137(4):297-301
- Delveinsight, “Acute Kidney Injury - Market Insights, Epidemiology, and Market Forecast—2030”

- Perioperative renal protection, Current Opinion in Critical Care December 2021 - Volume 27 - Issue 6 pages 676-685
- Delveinsight, “Acute Kidney Injury - Market Insights, Epidemiology, and Market Forecast—2030”
- 5 European countries includes Germany, France, Italy, Spain, and the UK

High anti-inflammatory and antioxidant activity

Inflammation-related parameter using AIS model mouse ¹

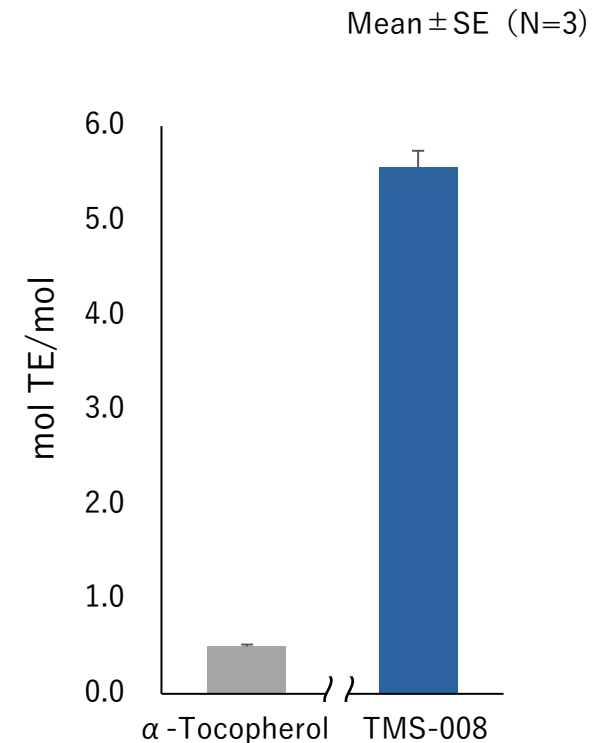
- One hour after the start of ischemia, 10 mg/kg was administered continuously intravenously for 30 minutes. Brain slices at 24 hours were evaluated by RT-PCR method.



** P<0.01、 * P<0.05 (vs. control)

Antioxidant activity test ^{1,2}

- H-ORAC : hydrophilic oxygen radical absorbance capacity method



1. Source European Journal of Pharmacology Volume 818, 5 January 2018, "Evaluation of the effects of a new series of SMTPs in the acetic acid-induced embolic cerebral infarct mouse model" Publication number : WO 2011/004620

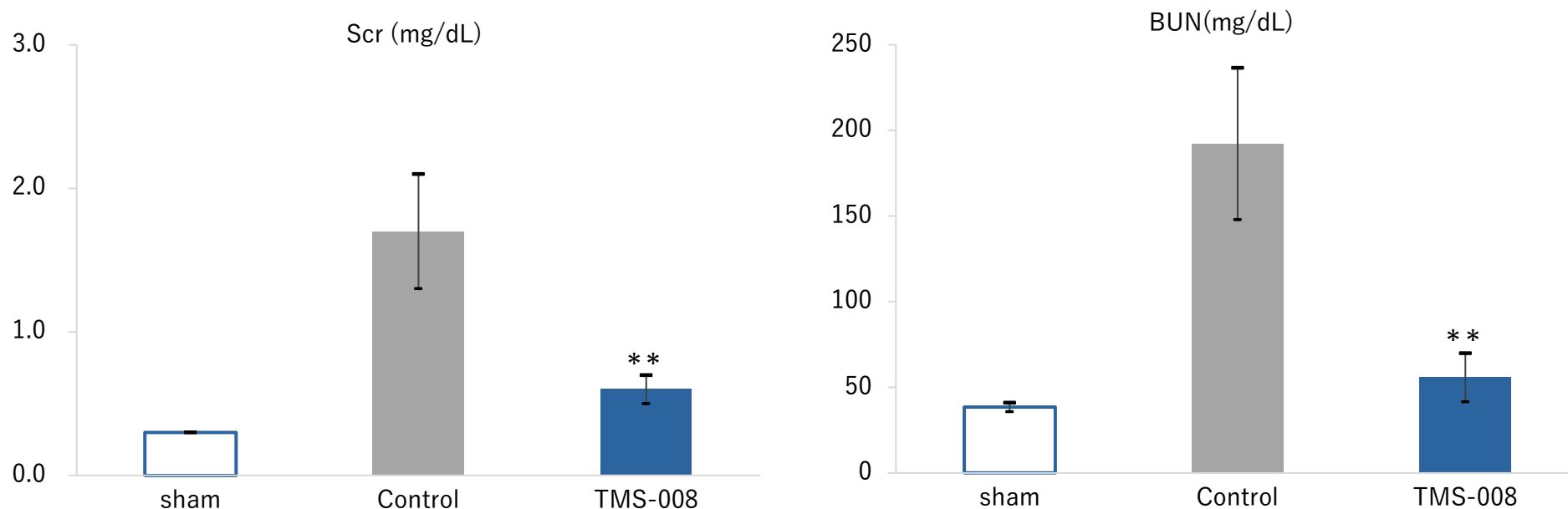
2. Results are shown in Trolox equivalents (TE). α -Tocopherol ORAC Values are for reference (Huang et al., J. Agric. Food Chem., 50, 1815-1821 (2002)).

Preclinical studies in collaboration with Japanese university using AKI mouse models confirmed its potential as a new treatment for AKI

Preclinical studies confirmed efficacy in two animal models, indicating the feasibility of TMS-008 for practical use

- Improvement on Scr (serum creatine) and BUN (blood urea nitrogen), which are parameters of renal function, has been observed

AKI model mouse experiment at Showa University ¹



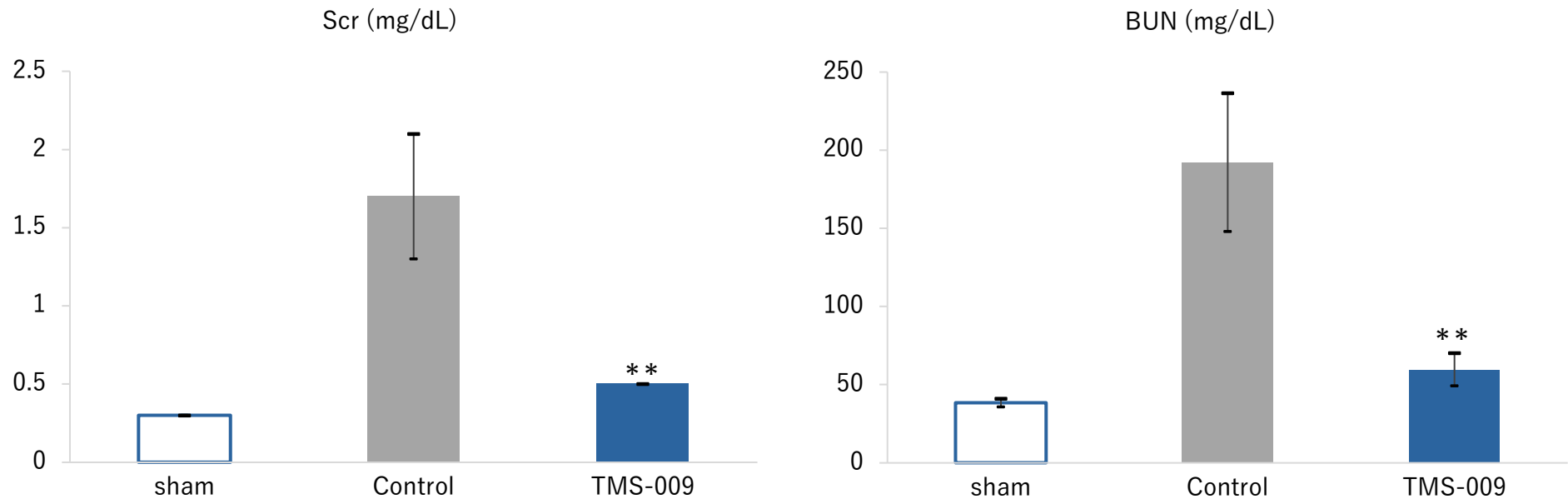
1. Mean \pm SE (n = 6), *p value < 0.05 and **p value < 0.01 as compared with control groups by using ANOVA with Bonferroni correction

TMS-009 showed compelling potential as an anti-inflammatory agent with strong sEH¹ inhibition observed

TMS-009 is protective of renal function in a mouse model of AKI

- Demonstrated equivalent pharmacological activity as TMS-008 in vitro² and in vivo³ studies
- Designated as a backup clinical candidate by taking advantage of dissimilar chemical structure and safety profile to TMS-008

AKI model mouse experiment at Showa Univ



1. sEH refers to soluble epoxide hydrolase

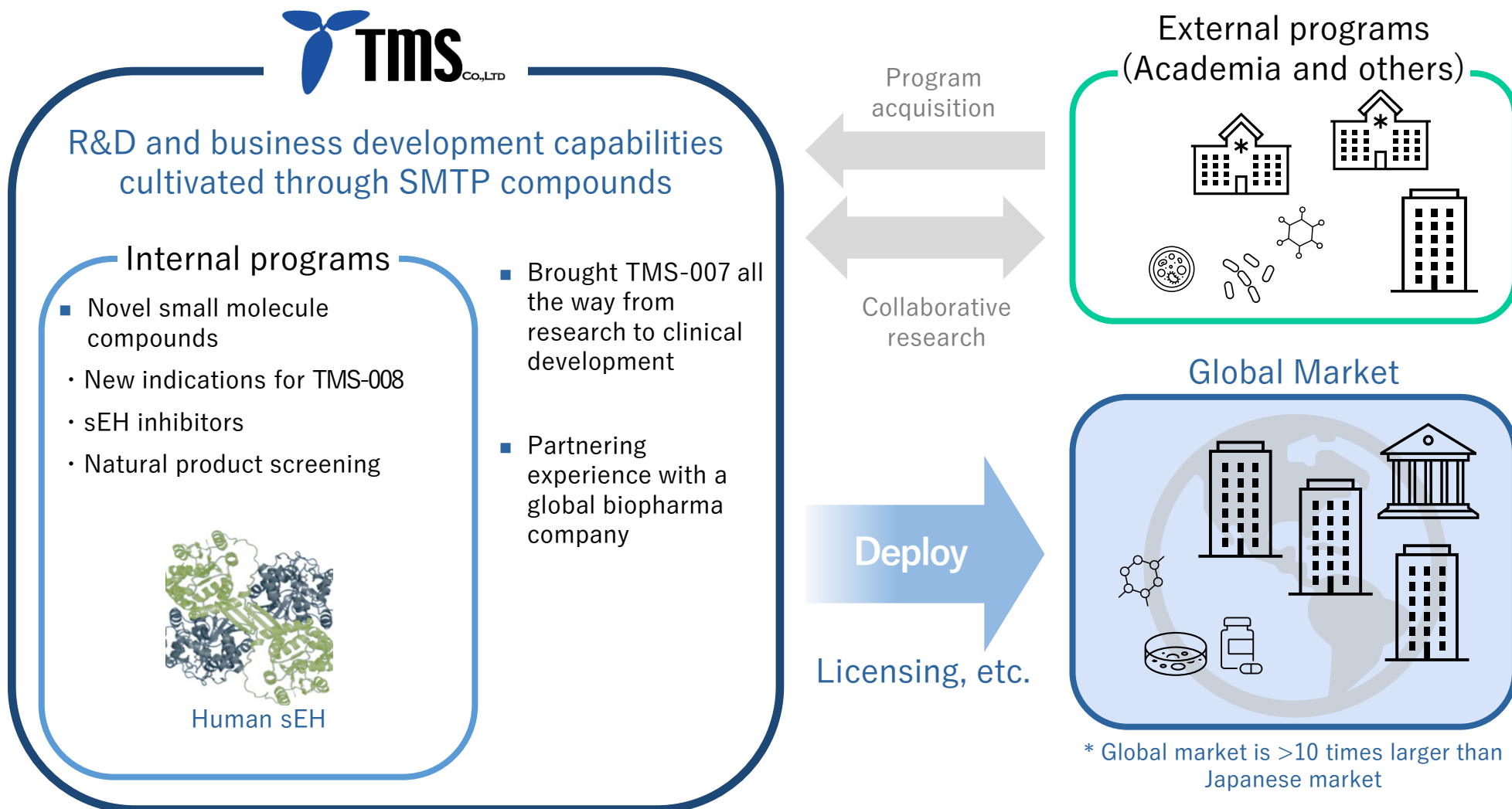
2. in vitro refers to a medical experiment which uses human or animal tissue to detect drug responses within the confines of a test tube or laboratory dish

3. in vivo refers to a medical experiment that detects drug responses in living organisms or cells, such as a laboratory animal or human

Expansion of Pipelines

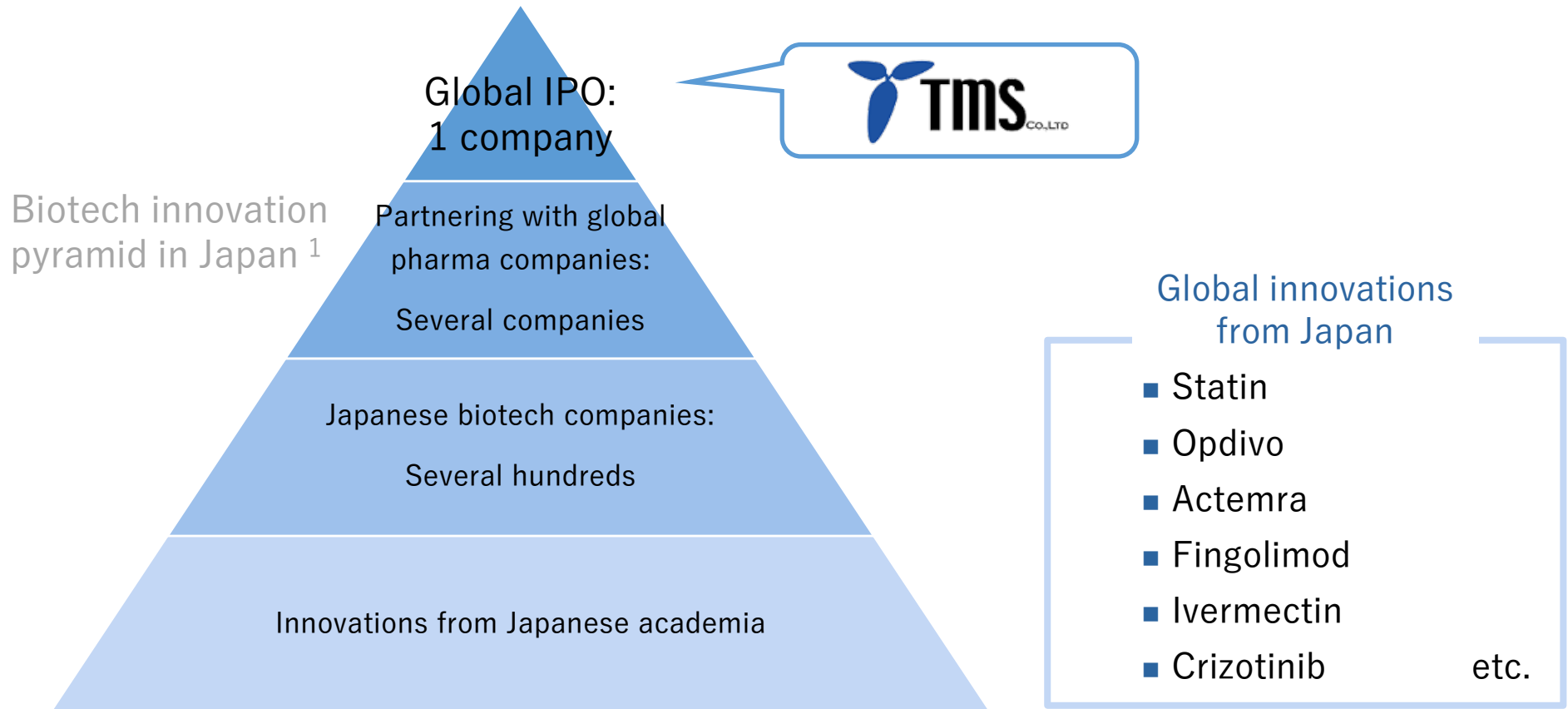


Pursue internal and external paths for pipeline expansion, leveraging knowledge and experience through SMTP compounds development



Bridge science from Japanese academia to the global market

- Business opportunities through bridging innovative science from local to global market
- Evaluating hundreds of seeds



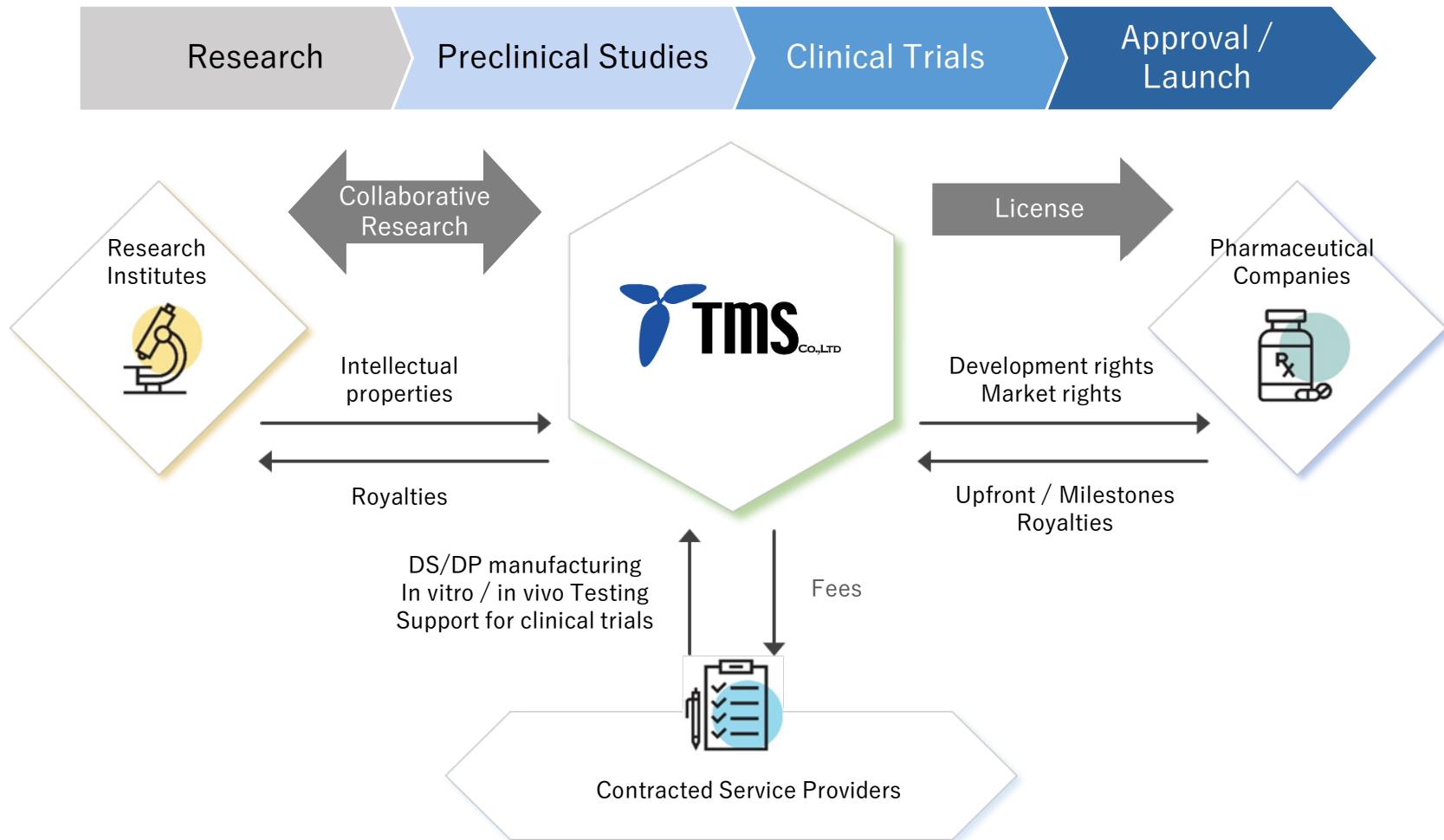
1. As of February 28, 2023, according to our research.

Appendix



Name	TMS Co., Ltd. (Stock Code: 4891)
Established	February 17, 2005
Closing month	February
Representative Directors	Takuro Wakabayashi Chief Executive Officer
Address	Headquarters: 1-9-11F, Fuchu-cho, Fuchu-shi, Tokyo JAPAN
Business Field	Research and development of drug products
Management	Board Member: 6 Audit & Supervisory Board Member: 4
Number of employee	14 (as of February 28, 2023)

History	
Feb. 2005	TMS Co., Ltd. founded
2005 - 2011	Demonstrated thrombolytic and anti-inflammatory activities of SMTP ameliorate ischemic stroke in pharmacological studies of SMTP
Nov. 2011	Started IND-enabling study of TMS-007
Oct. 2014	Started Phase I clinical trial of TMS-007
Oct. 2015	Completed Phase I clinical trial of TMS-007
Feb. 2018	Started phase IIa clinical trial of TMS-007 for ischemic stroke patients
Jun. 2018	Option agreement with Biogen on TMS-007
May. 2021	Biogen exercised an option to acquire TMS-007
Aug. 2021	Completed phase IIa clinical trial of TMS-007
Nov. 2022	Listing on the Tokyo Stock Exchange Growth Market (Stock code: 4891)



- The basic model is that TMS Co., Ltd. conduct drug development from the discovery and research stage to the early clinical stage in collaboration with research institutions and contracted service providers, and partner with pharmaceutical companies from late development stage to commercialization.
- Depending on the disease area, TMS Co., Ltd. may execute late-stage clinical development, obtaining regulatory approval, and even marketing.

SMTP



Stachybotrys
Microspora
Triprenyl
Phenol

A small molecule compound produced by Stachybotrys microspore, a type of fungus



Keiji Hasumi

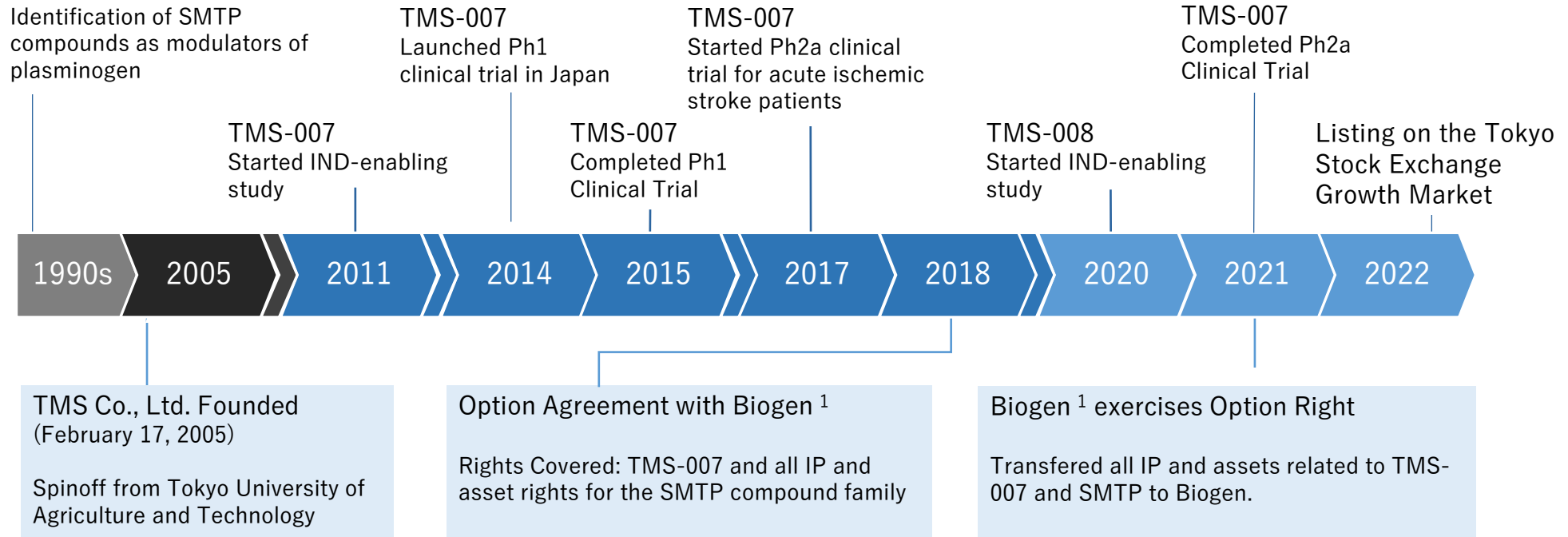
Ph.D.
Founder
Chief Scientific Officer

Worked alongside Dr. Akira Endo for 17 years
Succeeded Dr. Endo's lab in 1997

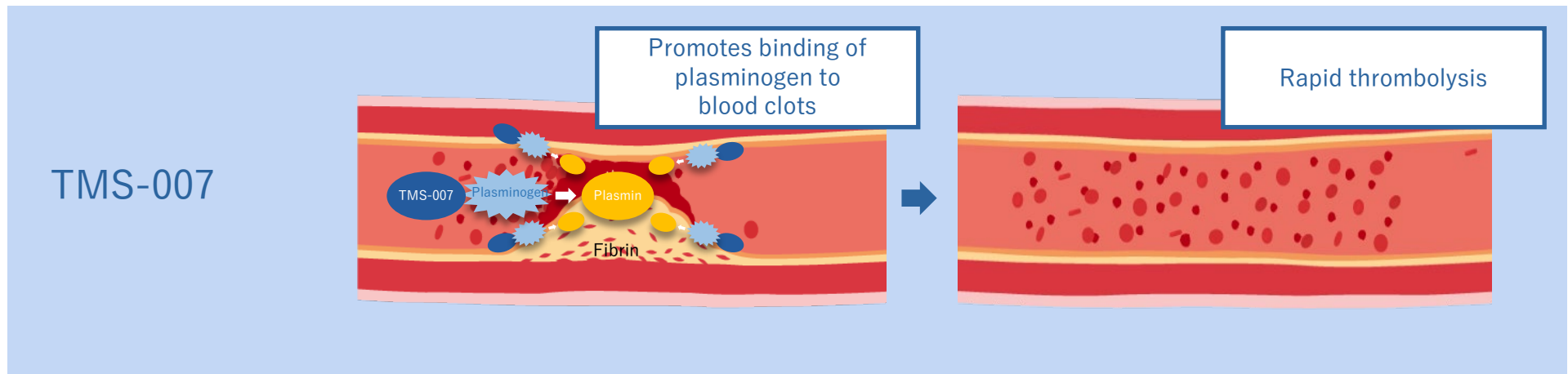
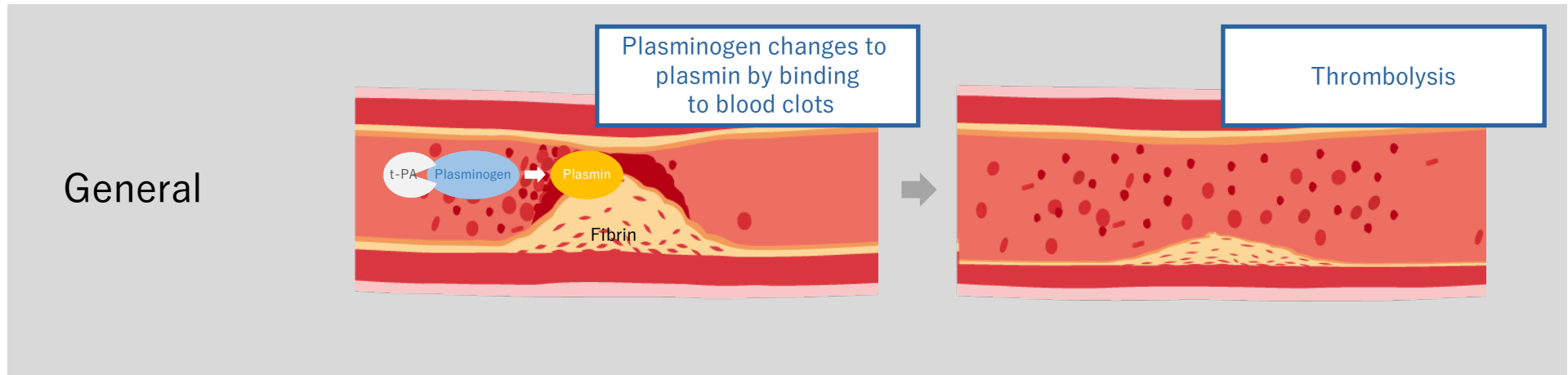
Dr. Akira Endo

Distinguished Professor Emeritus of Tokyo University of Agriculture and Technology

Invention of the hyperlipidemia drug statin (HMG-CoA reductase inhibitor), one of the best-selling category of drugs in history.

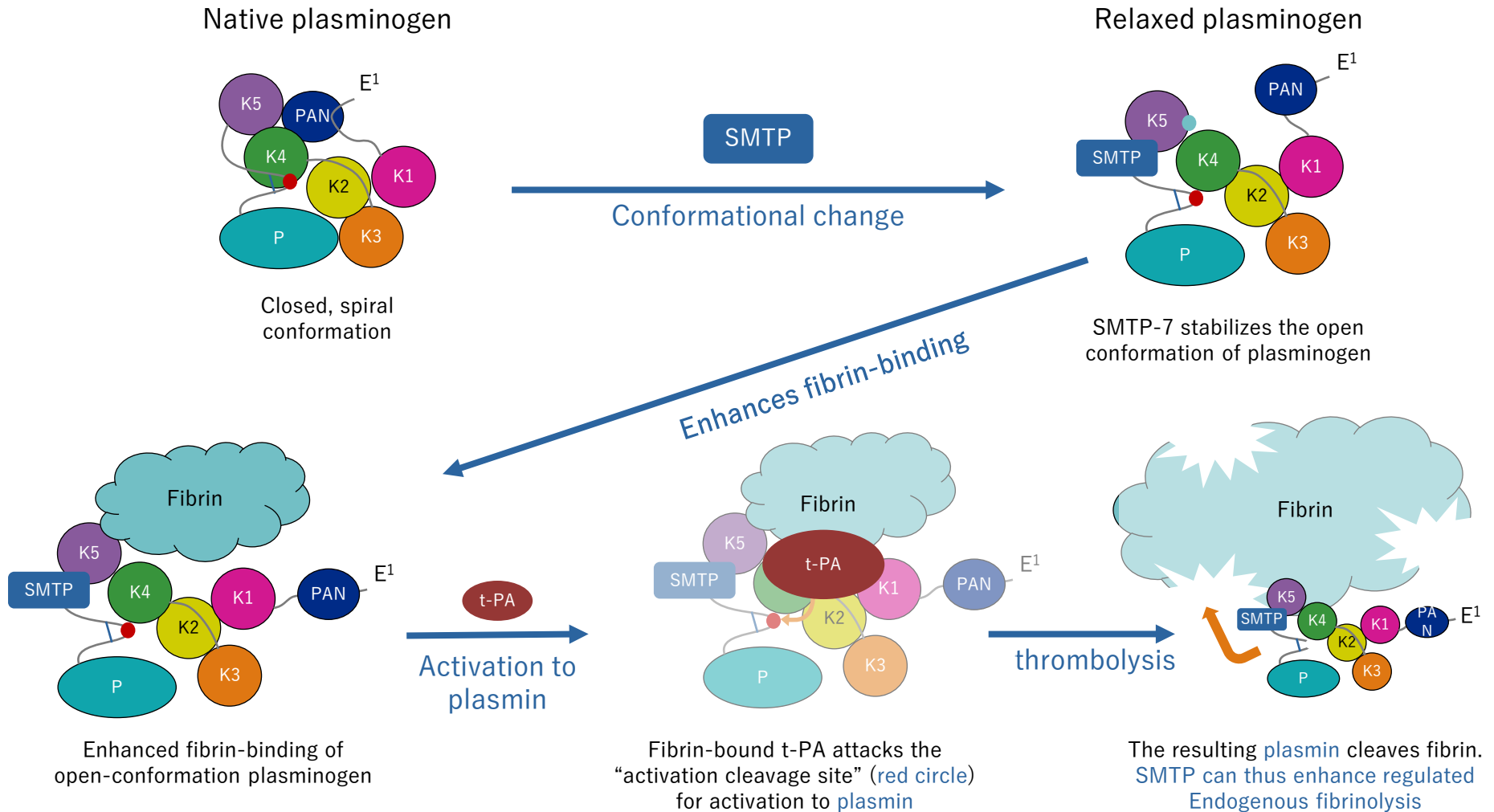


1. The contract party is Biogen MA Inc.



1. For illustrative purposes only

TMS-007 promotes binding of fibrin to blood clots¹



1. Hasumi & Suzuki (2021), "Impact of SMTP Targeting Plasminogen and Soluble Epoxide Hydrolase on Thrombolysis, Inflammation, and Ischemic Stroke" Diagrams shown above have been modified by the Company from the original versions. For illustrative purposes only



www.tms-japan.co.jp