Financial Results for the Fiscal Year Ending January 31, 2025

SanBio Company Limited

(TSE Growth: 4592)

March 18, 2025

SanBio
Pioneering Regenerative Medicine

Table of Contents

1. Financial Results for the Fiscal Year ending January 31, 2025

Consolidated Income Statement

- 3,516 million in operating expenses, primarily for the activities of the SB623 Chronic Traumatic Brain Injury Program.

Million Yen	FY2024.1 Results(A)	FY2025.1 Results(B)	(B)-(A)
Revenue	-	-	-
R&D expenses	2,849	2,357	▲491
Operating expenses	4,539	3,516	▲1,023
Operating income	▲4,539	▲3,516	1,023
Net income	▲2,644	▲2,882	▲238
Yen/US$ exchange rate	136.67	141.91	

Consolidated Balance Sheet

■ Maintain a certain level of cash and deposits necessary for the current year's activities.

Million yen	As of January 31, 2024(A)	As of January 31, 2025(B)	(B)-(A)
Cash & cash equivalents	4,454	2,921※	▲1,533
Current assets	4,937	3,335	▲1,601
Non-current assets	109	111	1
Total assets	5,047	3,447	▲1,599
Current liabilities	905	732	▲173
Non-current liabilities	1,349	952	▲396
Total liabilities	2,254	1,684	▲570
Net assets	2,792	1,762	▲1,029
Total liabilities and net assets	5,047	3,447	▲1,599

*Raised approximately 2 billion yen as a result of the issuance of new shares and unsecured convertible bonds with stock acquisition rights through a third-party allotment on March 3, 2025.

Consolidated Earnings Forecast

- **Projected total business expenses of 3,509 million yen, mainly for expenses related to obtaining approval for partial change of manufacturing and marketing approval items for AKUUGO® and expenses for establishing manufacturing, distribution, and sales systems for post-marketing activities in Japan.**

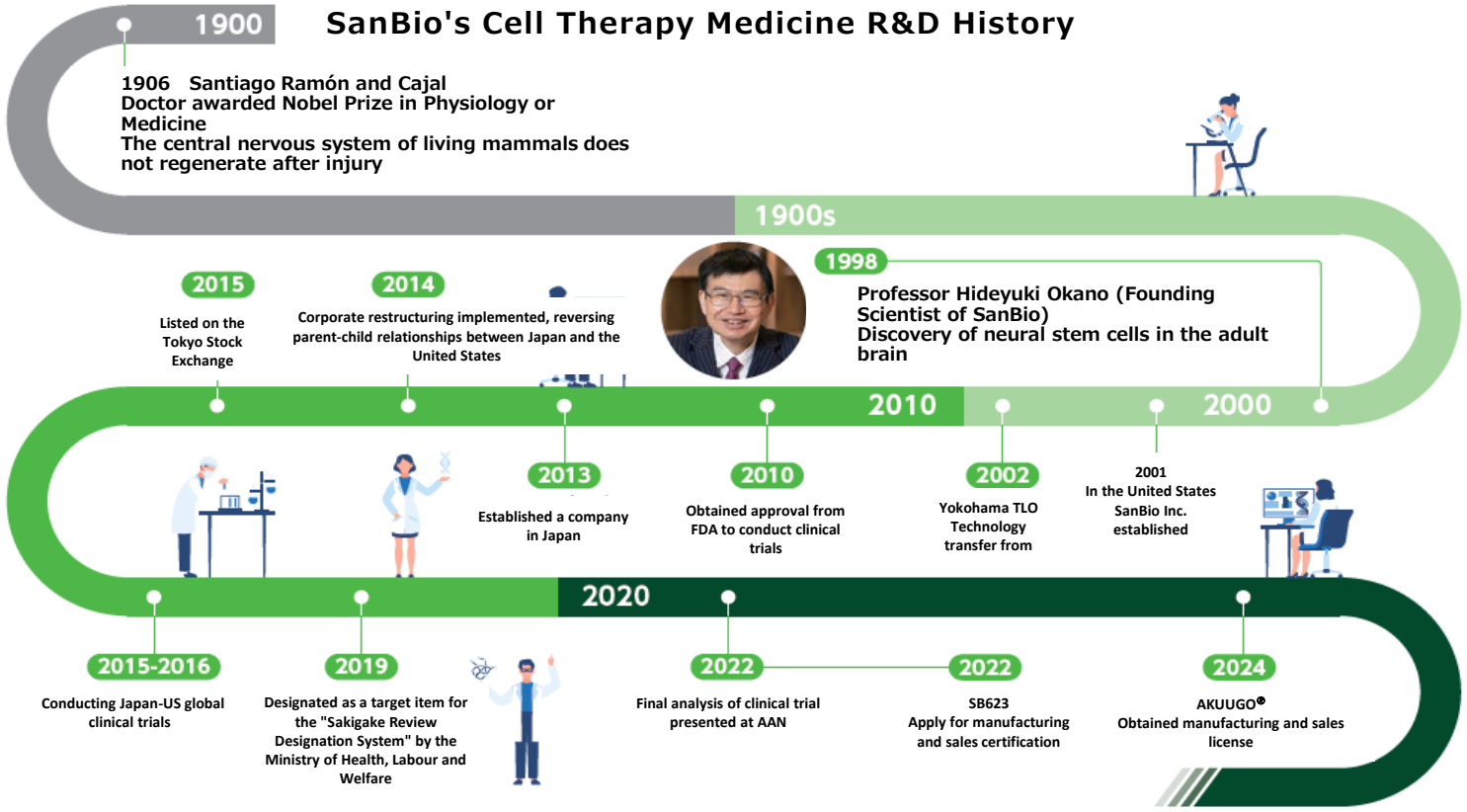
Million yen	FY2025.1 Results	FY2026.1 Forecast
Revenue	-	-
R&D expenses	2,357	2,405
Operating expenses	3,516	3,509
Operating income	▲3,516	▲3,509
Net income	▲2,882	▲3,554
Yen/US$ exchange rate	141.91	155.00

SanBio
Pioneering Regenerative Medicine

2. The Birth of “Brain Regeneration” Therapeutics

Going “back to our original vision” ~The challenge of “brain regeneration” that overturns 100 years of conventional wisdom

- **SanBio was founded in 2001 in California, with the concept of “bringing regenerative medicine from Japan to the world**
- **Continuing the challenge of “brain regeneration,” which has overturned 100 years of conventional wisdom**



About “AKUUGO® suspension for intracranial implantation”

- **World’s First Therapeutic Agent for Regenerating Brain**
- **Obtained conditional and time-limited approval from the MHLW on July 31, 2024.**

ヒト体性幹細胞加工製品

薬価基準未収載

アクーゴ® 脳内移植用注

パンデフィテムセル

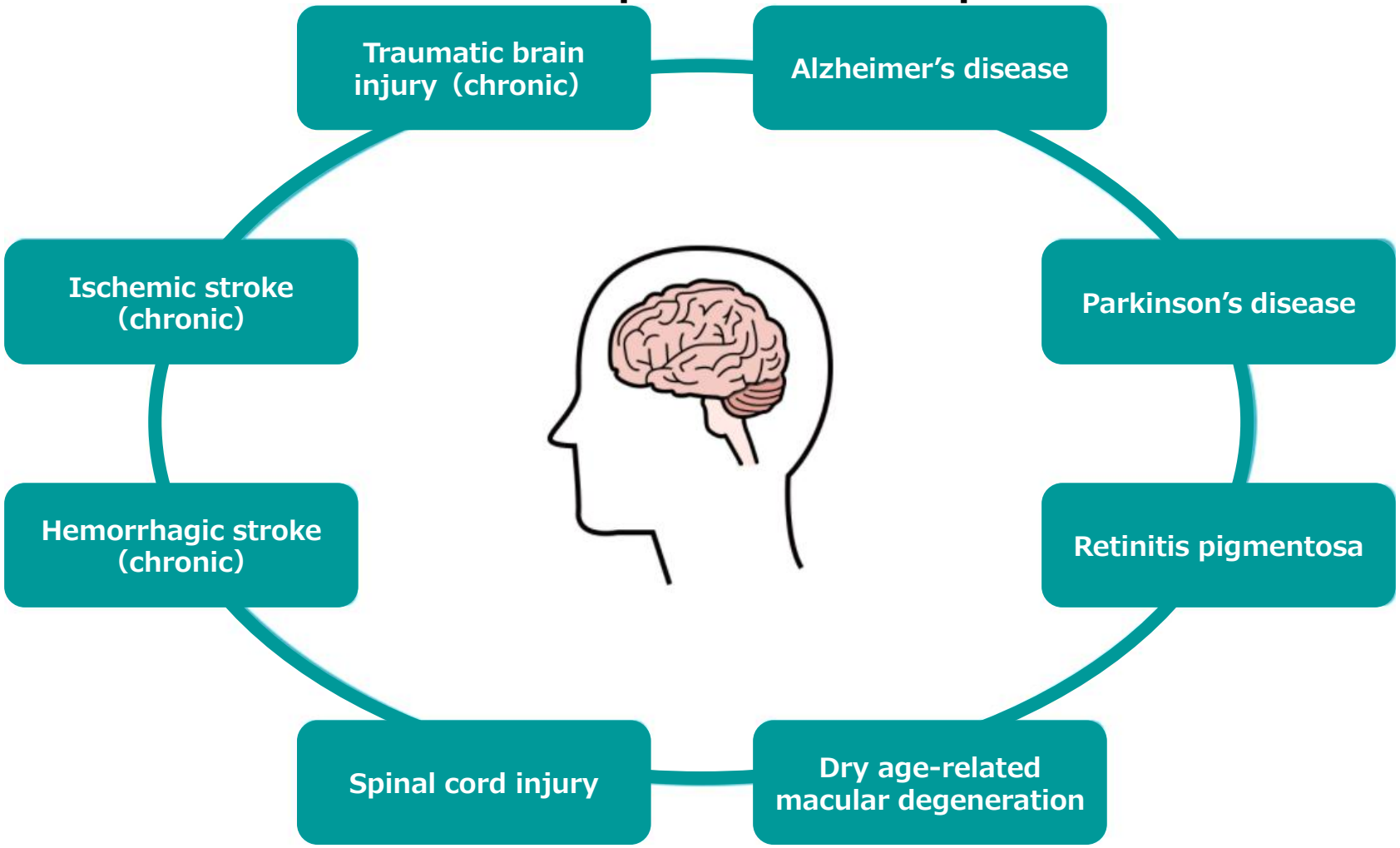
指定再生医療等製品

(hereafter referred to as “AKUUGO®”)

Brand name	AKUUGO® Suspension for Intracranial Implantation
Generic name	Vandefitemcel
Indications and effects	Improvement of chronic motor paralysis associated with traumatic brain injury
Dosage and administration	For adults, implant 5 x10^6 live human (allogeneic) bone marrow-derived mesenchymal stem cells (300μL of cell suspension) to perilesional brain tissues via stereotactic brain surgery using the dedicated delivery device set. Implant the cells into the perilesional area through three trajectories via a burr hole made in the skull. To each trajectory, inject 100μL of the cell suspension, depositing 20μL of the solution each across a total of five sites placed at 5–6mm intervals from the deepest site. The rate of implantation should be approximately 10μL/min. Follow the steps below for implantation. 1. Before starting the procedure, attach the guide & stop and stylet-equipped inserter from the dedicated delivery device set to the head fixation device for invasive neurosurgery. 2. Thaw the cell suspension for intracranial implantation, wash it with the dedicated preparation solution, and adjust the concentration of the cell suspension to 1.67 x 10^6 cells/100μL using the dedicated preparation solution. Cleanse the micro-syringe fixed with the cannula from the dedicated delivery device set with the dedicated preparation solution before filling it with the prepared cell suspension.
Date of marketing approval	July 31, 2024

Promising pipeline of AKUUGO®, “Brain Regeneration” Therapeutics

Focus on diseases of the central nervous system that cannot be addressed by existing medical and pharmaceutical products



From the presentation of Q2 of FY ending Jan 31, 2025

- Restarting US Initiatives
- Re-engaging in Ischemic Stroke Treatment
- Japan as a Mother Base

Global Leader in Regenerative Medicine

3. Japan as a Mother Base

The second manufacturing run was deemed compliant

- **The second manufacturing run cleared all specification requirements and was deemed compliant.**
- **With the compliance of this manufacturing run, the company will run one more manufacturing compliant with necessary specifications and plans to file a partial change application and subsequently obtain approval for the partial change to meet the shipment conditions.**

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2025年2月6日
サンバイオ株式会社

アクーゴ®脳内移植用注の出荷のための承認条件に関わる
第二回目の製造結果についてのお知らせ

サンバイオ株式会社(本社:東京都、代表取締役社長 森敬太、以下サンバイオ)は、2024年12月6日付けで、アクーゴ®脳内移植用注(一般名:バンディフィテムセル、以下アクーゴ®)の承認に伴う出荷に関する条件を達成するための第二回目の市販品製造について、収量が予定通り確保できたことをお知らせしました。この度、規格試験及び特性解析が終了し、今回の製造の結果が明らかとなりましたのでお知らせします。

第二回目の製造は、規格試験及び特性解析において全ての基準値を満たし適合となりました。引き続き、第三回目の製造を開始しております。

今回の製造が適合となったことから、あと1回の適合する製造を行った後、その結果を用いて一部変更申請を行い、出荷解除のための承認取得を目指します。

以上により、アクーゴ®の出荷が可能となる時期については、従来通り2026年1月期第2四半期(2025年5~7月)を想定します。

アクーゴ®脳内移植用注について

アクーゴ®脳内移植用注は、健康成人骨髄液由来の間葉系間質細胞を加工・培養して作製されたヒト(他家)骨髄由来加工間葉系幹細胞(国際一般名:バンデフィテムセル)です。脳内の損傷した神経組織に移植するとFGF-2(タンパク質の一種)が放出され、損傷した神経細胞が本来持つ再生能力を促し、神経細胞の増殖・分化を促進する効果が期待されています。

Conclusion of Contract Manufacturing Agreement with JCR Pharma for Trial Production of AKUUGO®

■ **Contract manufacturing agreement signed for trial production of AKUUGO® for commercial manufacturing.**

SanBio
Pioneering Regenerative Medicine

2025 年1月31日
サンバイオ株式会社

JCRファーマとのアクーゴ®脳内移植用注の商用製造に向けての
試製造に係る製造受委託契約締結について

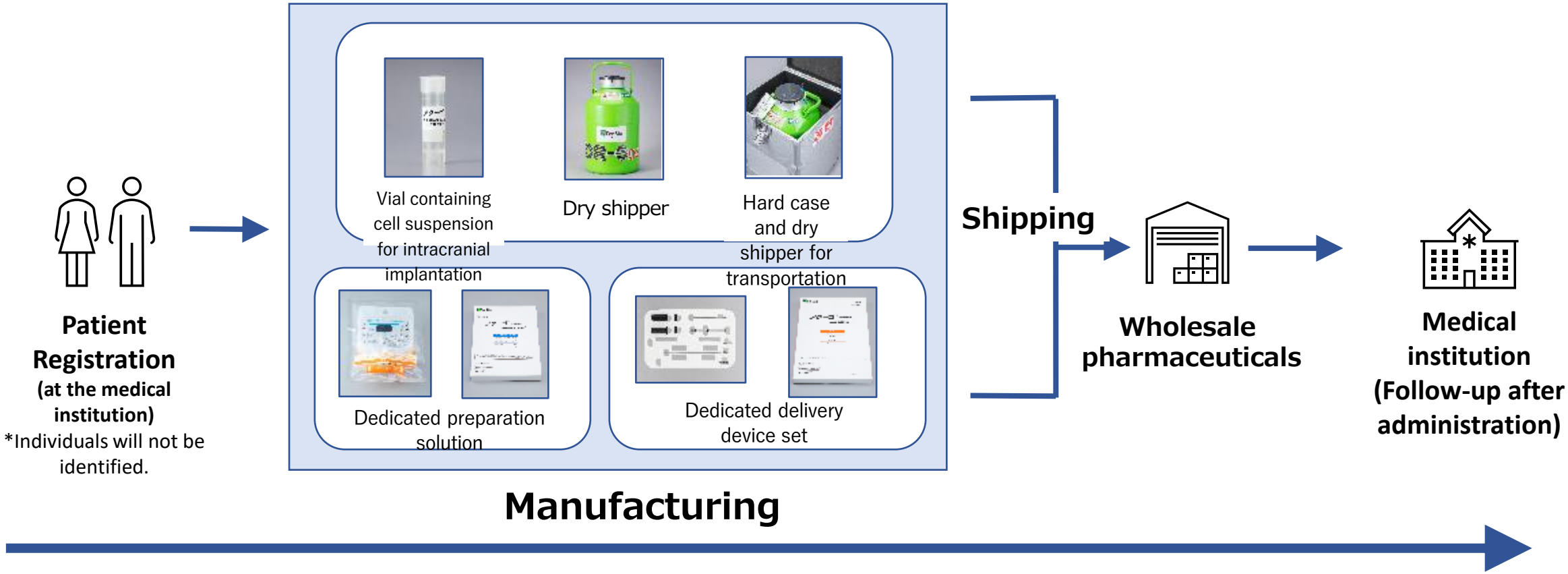
サンバイオ株式会社(本社:東京都、代表取締役社長 森敬太、以下サンバイオ)は、本日、JCRファーマ株式会社(本社:兵庫県芦屋市、代表取締役 芦田信、以下JCRファーマ)と、ヒト(他家)細胞治療薬「アクーゴ®脳内移植用注」(以下アクーゴ®)についての商用製造検討のための試製造に係る製造委受託契約を締結しましたのでお知らせします。

本契約は、アクーゴ®の商用製品の安定製造に加え、サンバイオの今後の脳梗塞等の適応拡大及び米国への市場拡大も見据えた製品供給の安定化・複線化を図るために、サンバイオとJCRファーマの両社で、将来的な製造委受託に向けた検討を行うことが目的です。

サンバイオの代表取締役社長 森敬太は、次のように述べています。「アクーゴ®は、外傷性脳損傷に伴う慢性期の運動麻痺に対する有効性が確認された他家細胞治療薬です。世界で初めて承認された唯一の脳を再生する治療薬であり、本適応以外にも、アンメットメディカル・ニーズの残るさまざまな中枢神経系疾患への活用を積極的に推進していきます。中長期的に拡大が見込まれるアクーゴ®の需要に対して、本契約締結により、供給能力を高めることが期待できます。」

なお、本件が今期の業績へ与える影響については、軽微であると認識しています。

Distribution System for AKUUGO®



R-SAT®

(Centralized management of information from patient registration to product delivery, dosing, and follow-up)

SanBio's Smart Regional Medical Cooperation Concept Image

■ Flow of AKUUGO® administration and postoperative rehabilitation

Patients
Facilities where patients go to the hospital

Recovery/Chronic Care Facilities

① Consultation facilities (set up for each region)

※Referral letter needed

② Surgical (transplant) facilities

③ Rehabilitation Facilities

Patient at home

No contact with medical institutions

Introduction to facilities/systems/consultation

- Therapist
- Medical Social Worker
- Higher brain dysfunction support coordinator
- Patient /Participant association

Disease awareness and support site for patients and their families

- Disease awareness videos are available on “TBI Navi®”（URL : https://tbi-navi.jp/）a disease awareness and support website for patients and their families

https://tbi-navi.jp/movie/index.html

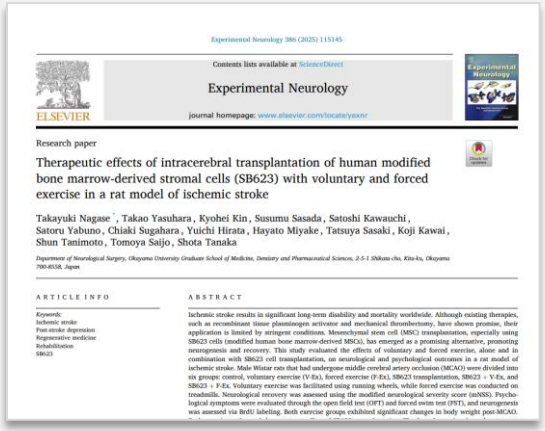
Progress of R&D on AKUUGO®

Publication of Results of Cell Implantation Location Analysis from Phase 2 Clinical Trial of Vandefitemcel (SB623) in TBI Patients (STEMTRA Trial) in Neurotrauma Reports

- The brain injuries responsible for motor paralysis were classified into two groups: the cortex group and the deep white matter (DWM) group.
- The study found that the correlation between the distance from the injury to the implantation site and treatment efficacy varied depending on the injury location. In the cortex group, shorter distances were associated with greater efficacy, while in the DWM group, shorter distances were linked to lower efficacy.

[Source] Sanbio press release dated February 12, 2025https://www.sanbio.com/wp/wp-content/uploads/2025/02/PR_20250212_Neurotrauma-Reports.pdf

Results of a joint study with Okayama University (effects of SB623 transplantation combined with exercise in a rat cerebral infarction model) published in Experimental Neurology



Experimental Neurology 386 (2025) 115145

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journal homepage: www.elsevier.com/locate/yexnr

Research paper

Therapeutic effects of intracerebral transplantation of human modified bone marrow-derived stromal cells (SB623) with voluntary and forced exercise in a rat model of ischemic stroke

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ARTICLE INFO

Keywords:
Ischemic stroke
Post-stroke depression
Regenerative medicine
Rehabilitation
SB623

ABSTRACT

Ischemic stroke results in significant long-term disability and mortality worldwide. Although existing therapies, such as recombinant tissue plasminogen activator and mechanical thrombectomy, have shown promise, their application is limited by stringent conditions. Mesenchymal stem cell (MSC) transplantation, especially using SB623 cells (modified human bone marrow-derived MSCs), has emerged as a promising alternative, promoting neurogenesis and recovery. This study evaluated the effects of voluntary and forced exercise, alone and in combination with SB623 cell transplantation, on neurological and psychological outcomes in a rat model of ischemic stroke. Male Wistar rats that had undergone middle cerebral artery occlusion (MCAO) were divided into six groups: control, voluntary exercise (V-Ex), forced exercise (F-Ex), SB623 transplantation, SB623 + V-Ex, and SB623 + F-Ex. Voluntary exercise was facilitated using running wheels, while forced exercise was conducted on treadmills. Neurological recovery was assessed using the modified neurological severity score (mNSS). Psychological symptoms were evaluated through the open field test (OFT) and forced swim test (FST), and neurogenesis was assessed via BrdU labeling. Both exercise groups exhibited significant changes in body weight post-MCAO.

[Source]

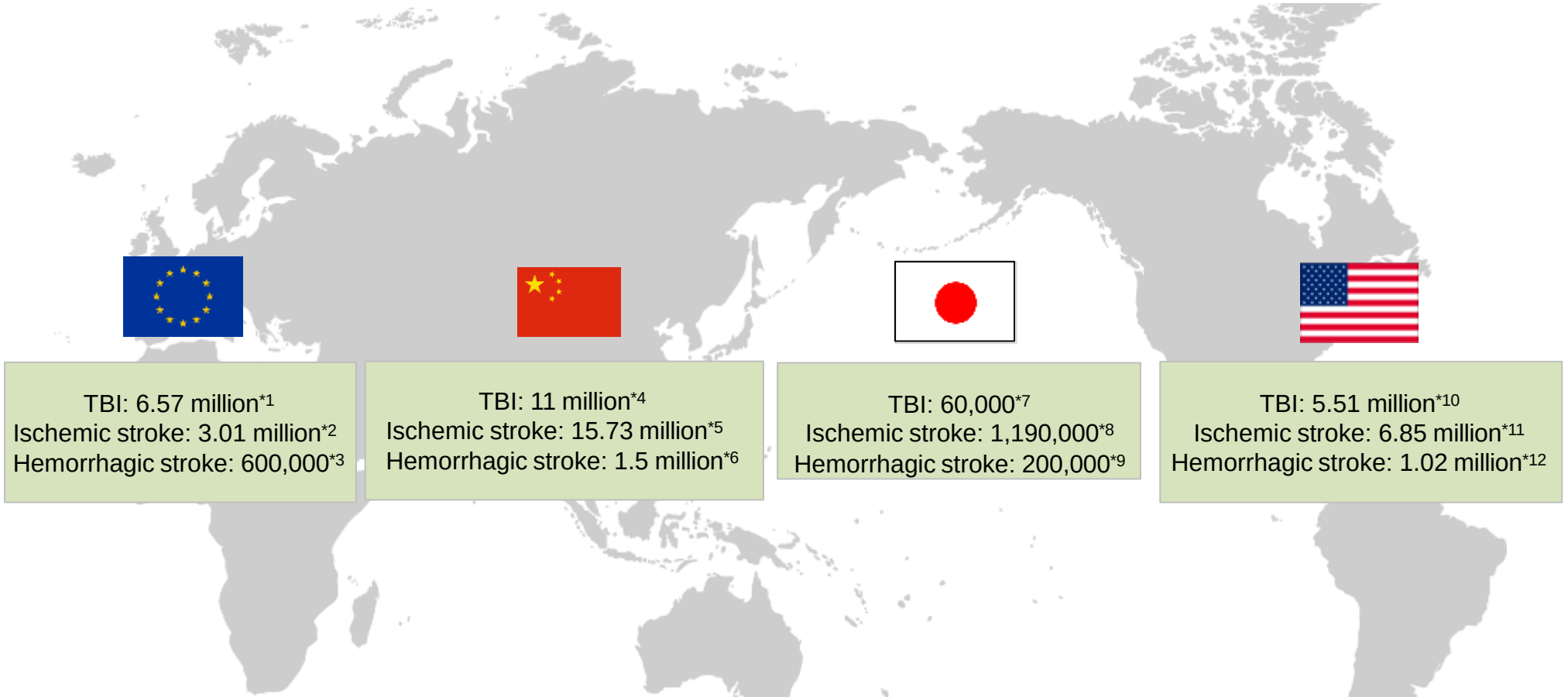
[Therapeutic effects of intracerebral transplantation of human modified bone marrow-derived stromal cells (SB623) with voluntary and forced exercise in a rat model of ischemic stroke]

Dr. Maeda presented the results of his research at “Frontiers of Basic Research for the Development of Diagnostic and Therapeutic Methods for Alzheimer's Disease” Keio University Joint Research: Biochemical Society of Japan 2024 Symposium (November 8, 2024)

4. Outlook

Background of Restarting the US Operations

■ The US and other markets are much larger than Japan



TBI: 6.57 million*1 Ischemic stroke: 3.01 million*2 Hemorrhagic stroke: 600,000*3	TBI: 11 million*4 Ischemic stroke: 15.73 million*5 Hemorrhagic stroke: 1.5 million*6	TBI: 60,000*7 Ischemic stroke: 1,190,000*8 Hemorrhagic stroke: 200,000*9	TBI: 5.51 million*10 Ischemic stroke: 6.85 million*11 Hemorrhagic stroke: 1.02 million*12

*1~*3,*10~*12: In-house analysis based on multiple sources
*4: Arch Neurol. 1986;43(6):570-572 (Wang et al.)
*5: Circulation. 2017;135:759-771 (Wang et al., 2017).
*6: GHDx Healthdata IQVIA analysis 2020

*7: Ministry of Health, Labour and Welfare 2020 (The total number of intracranial injury patients)
*8: Ministry of Health, Labour and Welfare 2020 (The total number of cerebral infarction patients)
*9: Ministry of Health, Labour and Welfare 2020 (The total number of cerebral hemorrhage patients)

Past achievements in the U.S.


(腕が上がらない)


(腕が上がる)


(生活を取り戻す)

(YouTube)

Year	Event
2011～2015	Ischemic stroke※ Phase 1/2a trial in the U.S. (18 cases at 5 sites)
2016～2018	Ischemic stroke※ Phase 2b trial in the U.S. (163 cases at 65 sites)
2016	Ischemic stroke※ Phase 1/2a Paper Receives “Innovation Award 2016”.
2016～2019	Phase 2b (STEMTRA study) of traumatic brain injury※ in Japan, US, and Ukraine (21 sites in US, 5 sites in Japan, 1 site in Ukraine, 63 cases)
2017	Received the largest grant ($20M) from the California Institute for Regenerative Medicine (CIRM)
2019	Granted RMAT (Regenerative Medicine Advanced Therapy) Designation from the U.S. FDA for SB623
2022	Final Analysis of the STEMTRA Study Presented in Plenary Session at the American Academy of Neurology (AAN) Annual Meeting

※ chronic

Facilities for the STEMTRA study: 21 facilities
Red - Facility Blue - Multiple facilities (numbers are number of facilities)

Major facilities :
UCLA, Stanford University, University of Pittsburgh, New York University,Northwestern University, etc.
（ClinicalTrial.gov）

Restarting the U.S. Operations

- **Already consulted with FDA in 2019 and 2022**
- **Resumed discussions with FDA to conduct clinical trials in traumatic brain injury※**
- **Preparations for clinical trials are ongoing for Ischemic stroke※**

※ chronic

AKUUGO®

Number of patients in the U.S.

Traumatic brain injury※ : 5.51 million*
Ischemic stroke※ : 6.85 million*
Hemorrhagic stroke※ :1.02 million*

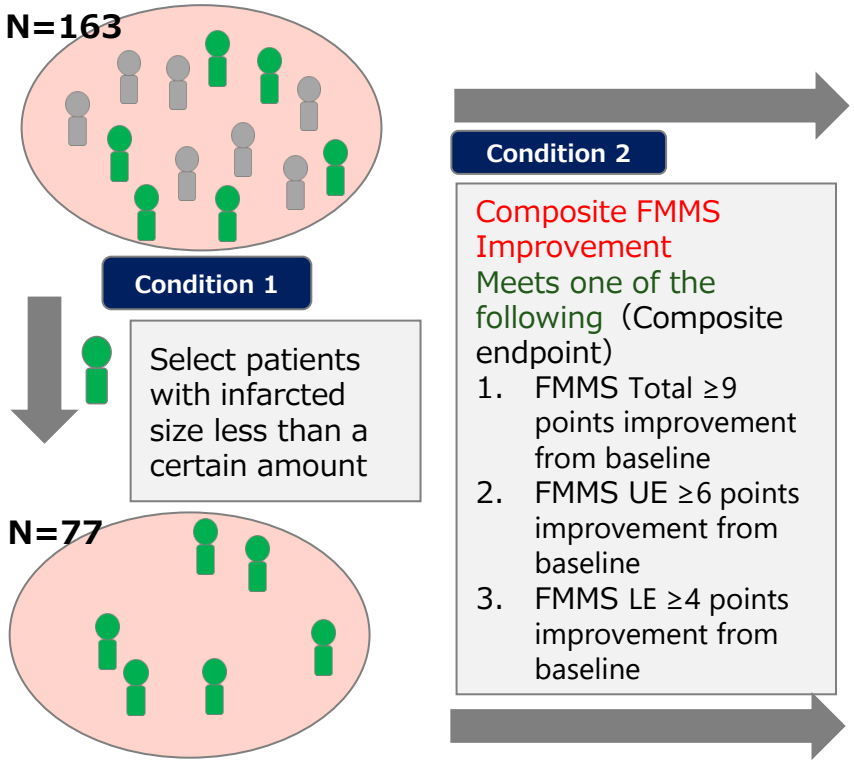
*In-house analysis based on multiple references

Rechallenge to Ischemic Stroke※

- **Post-hoc Analysis of STR-02 Trial Provides Prospects for Next Clinical Trial**
- **Plans to resume discussions with Japanese and U.S. regulatory authorities regarding clinical trials for an additional indication in ischemic stroke※**

※ chronic

In patients with infarct size less than a certain amount, a 30% difference in composite FMMS improvement was observed, 49% in the SB623 group and 19% in the sham surgery group



Overall Population: Of the 163 enrolled patients, 158 were evaluable at 6 months

	Count	Composite Responders	Avg. Baseline FMMS	Composite Response (%)
therapeutic group	107	42	44.87	39%
sham surgery group	51	16	47.35	31%
p-value		0.42	0.33	0.42

Population with infarct size less than a certain amount (77patients: 48.7%)

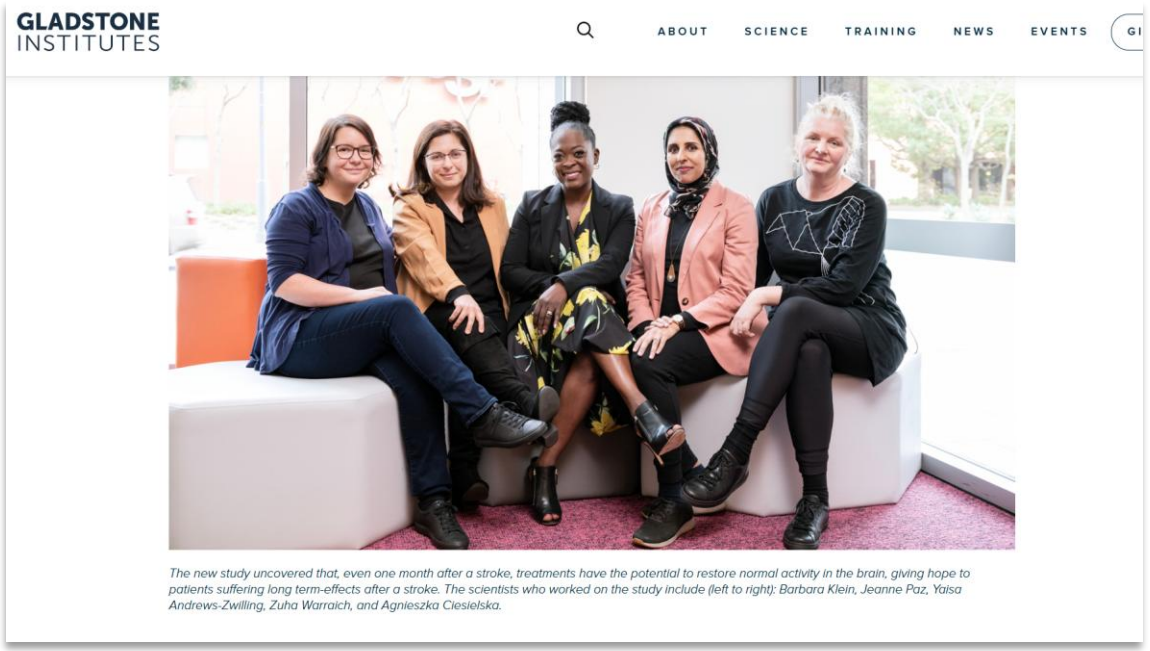
	Count	Composite Responders	Avg. Baseline FMMS	Composite Response %
therapeutic group	51	25	48.55	49%
sham surgery group	26	5	49.42	19%
p-value		0.02	0.8	0.02

About the results of the joint research with GLADSTONE INSTITUTES

Paper published in Molecular Therapy showing that human bone marrow-derived processed mesenchymal stem cell vandefytem cell (SB623) improves cortical excitability in rats with focal cerebral ischemia

- Mechanism of action: Transplantation of hMSC-SB623 cells (bande phytem cell) was found to reduce cortical hyperexcitation caused by cerebral ischemia and restore normal brain function
- Therapeutic potential: hMSC-SB623 cells (bandeftemcell) promote neural regeneration, synaptic plasticity, and immunomodulation, suggesting the potential to treat a variety of neurological diseases caused by network hyperexcitation

[Source] Sanbio Press release dated January 7, 2025
https://ssl4.eir-parts.net/doc/4592/tdnet/2546077/00.pdf



“There are currently no treatments that can be given weeks or months after a stroke to prevent long-term symptoms, so this is incredibly exciting,”

[Reference]
https://gladstone.org/news/stem-cell-therapy-jumpstarts-brain-recovery-after-stroke

Area/Indication expansion outlook

- **Resumed discussions with FDA to conduct clinical trials in the US for traumatic brain injury※1**
- **Preparing to conduct clinical trials in Japan and the U.S. for cerebral ischemic stroke ※1**

			
Traumatic brain injury (TBI) ※1	**Conditional and time-limited approved**	**Resumed discussions with FDA regarding initiation of clinical trials**	Discussion on the timing of the start of clinical trials※2
Ischemic stroke※1	Plans to discuss with PMDA to start clinical trials	Preparing to start clinical trials	Discussion on the timing of the start of clinical trials※2
Hemorrhagic stroke※1	Plans to discuss with PMDA to start clinical trials	Discussion on the timing of the start of clinical trials※2	Discussion on the timing of the start of clinical trials※2

※1 chronic
※2 Consider options such as in-house development or partnering

Anticipated events for this financial year

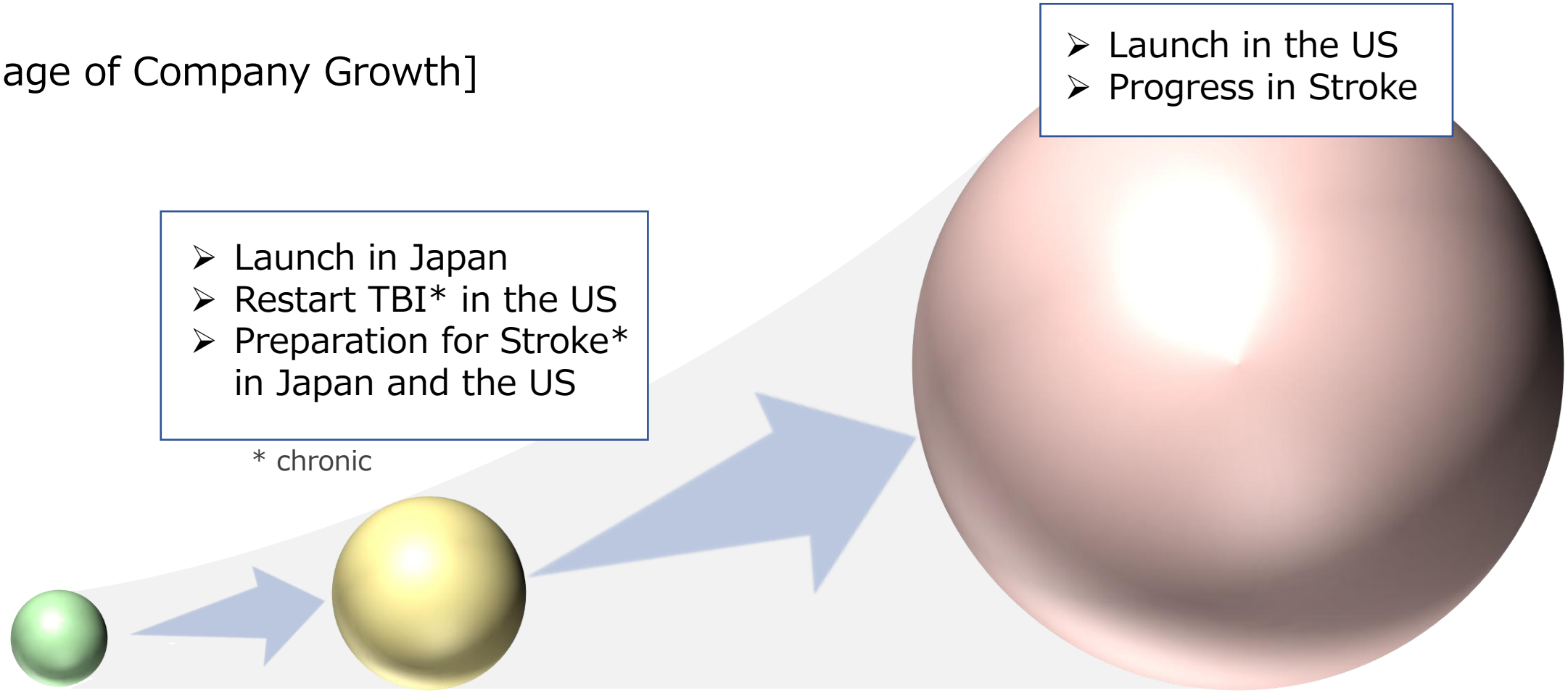
	FY2026.01 the first half-year	FY2026.01 the second half-year
Japan	• Approval of AKUUGO®※1 (Release of shipment)	• Listing of AKUUGO® on the NHI drug price list and launching of sales. • Start negotiation with PMDA regarding a clinical trial for Ischemic stroke ※2
US	• Resumed discussions with FDA regarding P3 clinical trial of TBI ※2	• Agreement with FDA on P3 clinical trial for TBI ※2

※1 Partial change of manufacturing and marketing approval items
※2 chronic

5. Becoming a Global Leader in Regenerative Medicine

Going “back to our original vision” to become a global leader in regenerative medicine: Dramatic growth through restarting stroke and re-entry into the U.S. market“

[Image of Company Growth]



SanBio's Vision

Becoming a global leader in regenerative medicine

SanBio Develops Regenerative Medicines, Creating Benefits for Patients and Value for Stakeholders.

APPENDIX:　Promising pipeline for SB623

Q&A
(For institutional investors and analysts)

Financial Results Briefing for the Fiscal Year Ending January 31, 2025

SanBio Company Limited

(TSE Growth: 4592)

Question and Answer session for the press
is available at
will begin at 4:30 p.m.

Please wait a moment.

SanBio
Pioneering Regenerative Medicine

Q&A
(For the press)

Disclaimer

This presentation material, including any comments made during or following the presentation, is provided solely for the purpose of reference to those investors who make their own evaluation of the company at their own risk. This material contains estimates, such as plans, strategies and judgments, that are forward-looking statements which are made based on management's assumptions and beliefs in light of the information currently available to it and may contain risks and uncertainty. Therefore you should not place undue reliance on them in making investment decisions.

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