Financial Results for the Second Quarter of the Fiscal Year Ending January 31, 2025

SanBio Company Limited

(TSE Growth: 4592)

September 18, 2024

SanBio
Pioneering Regenerative Medicine

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1. Financial Results for the FY ending Jan 31, 2025

Consolidated Income Statement

■ 1,571 million in operating expenses, mainly due to the cost of activities for the approval of the SB623 Chronic Traumatic Brain Injury Program.

Million Yen	Q2 FY2024.1 Results(A)	Q2 FY2025.1 Results (B)	(B)-(A)
Revenue	-	-	-
R&D expenses	2,112	1,024	▲1,087
Operating expenses	3,084	1,571	▲1,513
Operating income	▲3,084	▲1,571	1,513
Net income	▲1,787	▲1,309	478
Yen/US$ exchange rate	136.67	154.16	

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 July 31, 2025(B)	(B)-(A)
Cash & cash equivalents	4,454	3,081	▲1,373
Current assets	4,937	3,438	▲1,498
Non-current assets	109	119	10
Total assets	5,047	3,558	▲1,488
Current liabilities	905	649	▲256
Non-current liabilities	1,349	1,337	▲11
Total liabilities	2,254	1,986	▲267
Net assets	2,792	1,572	▲1,220
Total liabilities and net assets	5,047	3,558	▲1,488

2. World’s First Therapeutic Agent for Regenerating Brain

World’s First Therapeutic Agent for Regenerating Brain

Named by combining “Active Movement” in English and “UGOKU” in Japanese

AKUUGO®
vandefitemcel

Origin of the name
Coined from a combination of the English word Active Movement and the Japanese word UGOKU, meaning rebirth, embrace of the sun, change of life, good recovery and development.

Brand Colors　～ AKUUGO・BLUE ～
Blue as a primary color symbolizing trust, safety and security, Green as a complementary color that evokes healing and nature, Orange as an image of energy, movement, and warmth.

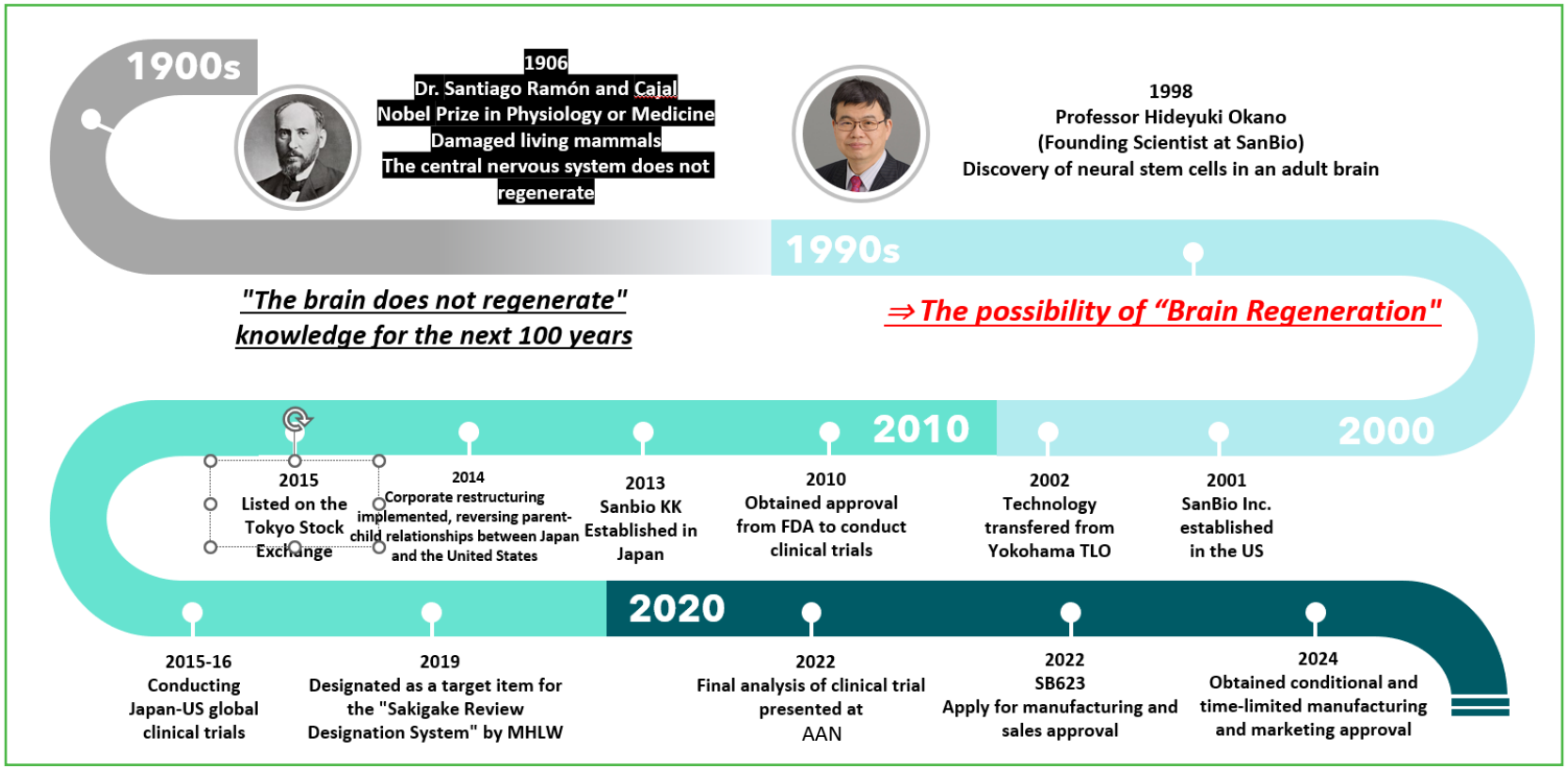
World’s First Therapeutic Agent for Regenerating Brain

- **Approved for conditional and time-limited manufacture and marketing as a treatment for unmet medical needs in motor paralysis associated with chronic traumatic brain injury.**

3. Aiming to be a Global Leader in Regenerative Medicine

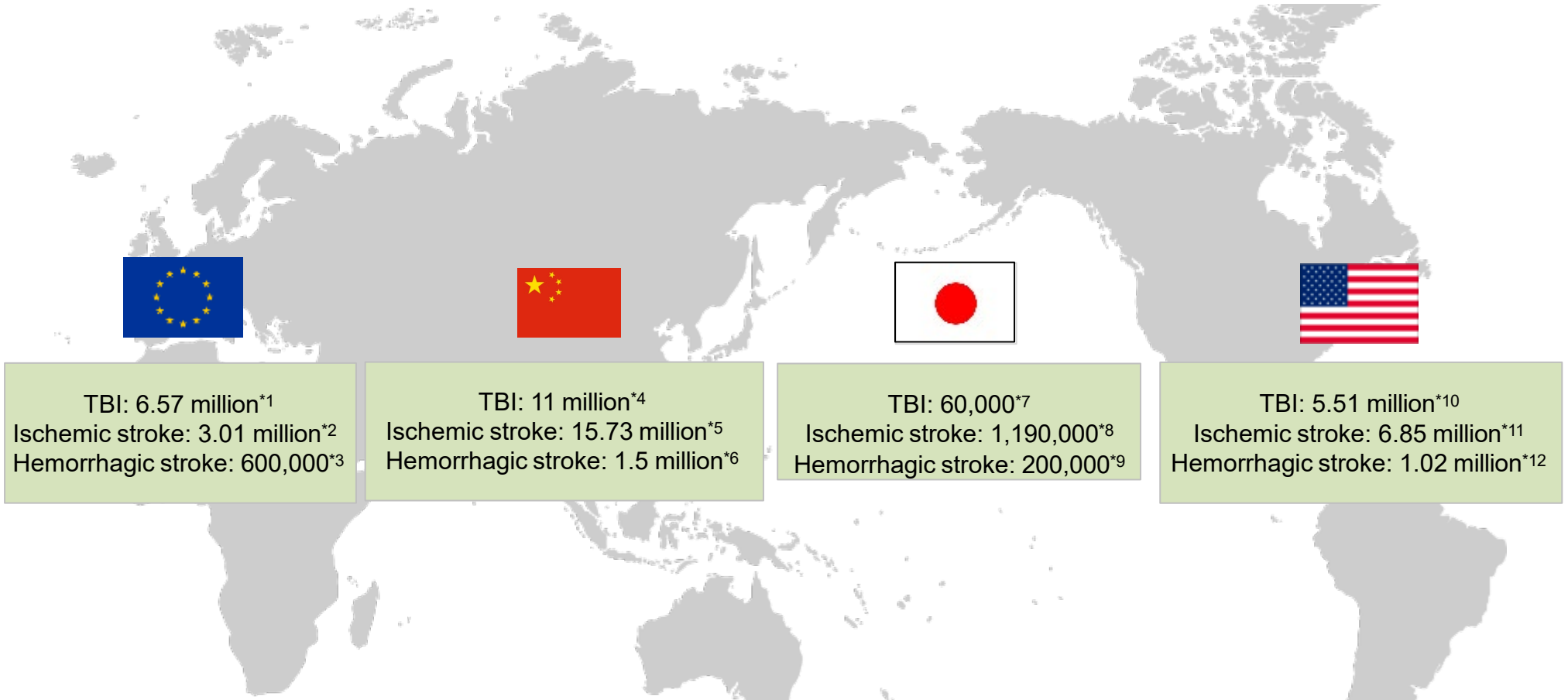
Returning to the starting point of the company's motives

- **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**



Number of target patients

■ 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)

Aiming to be a Global Leader in Regenerative Medicine

- **Restarting US Initiatives**
- **Re-engaging in Ischemic Stroke Treatment**
- **Japan as an innovation engine**

Global Leader in Regenerative Medicine

Restarting US Initiatives

■ Focusing on the US as the largest market, we will pursue our vision

AKUUGO®

- **Already in discussions with FDA in 2019 and 2022**
- **Plans to consult with FDA as soon as possible to conduct clinical trials**

Vision

Achieve global leadership in the regenerative medicine field:

International Publication of SB623（Neurology/Neuroscience）

Positive Results of Key Development Product SB623 for Chronic Effects of Traumatic Brain Injury, including Sustained Motor Function Improvement up to 48 weeks, published in Neurology

First author of a paper : Dr. David O. Okonkwo, Professor of neurological surgery

・ Results of analysis evaluating efficacy and safety up to 48 weeks (final) of the STEMTRA study*.

Significant difference in improvement from baseline in FMMS at 48 weeks in the SB623 medium-dose group (5.0 x 10^6 units group)

Improvement from baseline in motor function and activities of daily living in the Action Research Arm Test (ARAT), gait speed, and NeuroQOL upper and lower extremity function assessments at 48 weeks in the SB623 treatment group

[Quotation] Press release dated September 4, 2024

* A Phase 2 sham-operated, controlled, randomized, double-blind, Phase 2 multicenter study designed to evaluate the efficacy and safety of the lead development product SB623 in patients with chronic phase motor paralysis associated with traumatic brain injury, conducted from 2016 to 2019.

Publication of an Article on the Neuronal Activity and Network Formation Promotion of the Key Development Product SB623 on Neuroscience

- SB623 cells promote an increase of spike activity and number of network bursts.
- SB623 cells in coculture with neurons are superior to astrocytes in promoting neuronal activity.
- SB623 cells release higher levels of glutamate when compared to human astrocytes.
- Tonic glutamate released by SB623 cells promotes an increase of neuronal activity.

[Quotation] Press release dated July 4, 2024

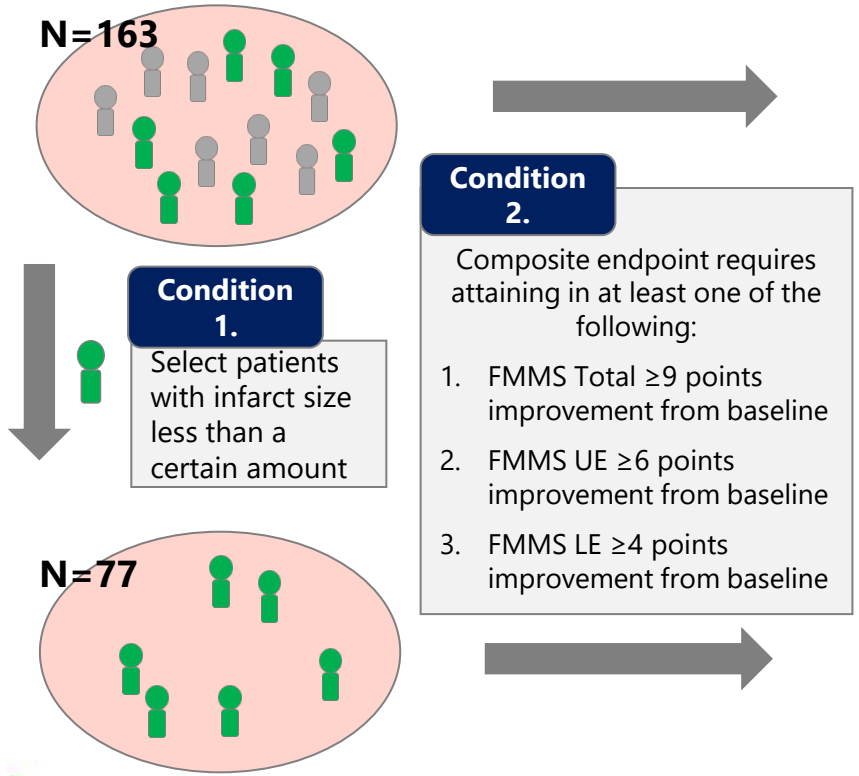
[Source]
https://www.sciencedirect.com/science/article/pii/S0306452224002720

SanBio Pioneering Regenerative Medicine

Re-engaging in Ischemic Stroke Treatment

- **Post-hoc analysis of STR-02 study provides perspective for next clinical trial**
- **Plans to Resume Discussions with Japanese and US Regulatory Agencies Regarding a Clinical Trial for an Additional Indication of Ischemic Stroke**

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 (%)
Treatment	107	42	44.87	39%
Control	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 %
Treatment	51	25	48.55	49%
Control	26	5	49.42	19%
p-value		0.02	0.8	0.02

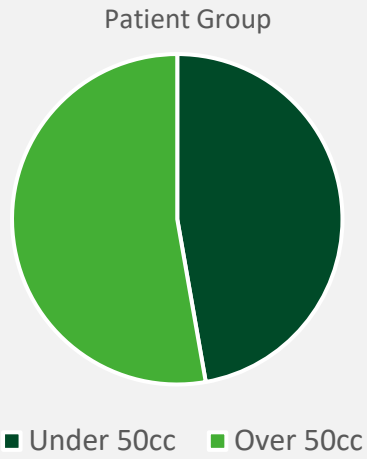
Notice of Allowance of New Patent for Cell Therapy Using SB623 for Chronic Ischemic Stroke in the US

- **Notice of Allowance of the patent filed for its key development product SB623 for the treatment of chronic ischemic based on Phase2b trial in the US**
- **The Notice of Allowance of the patent significantly will extend the term of the use patent for SB623 for the treatment of chronic ischemic stroke in the US, the largest market.**

Name of invention	CELL THERAPIES AND METHODS OF TREATMENT FOR SMALL-VOLUME STROKE
Country of filing	US
Patent application number	US 17/664,856
Notice of allowance date	July 15, 2024
Applicant	SanBio, Inc. Mountain View, CA (US)

About STR-02 Trial

Additional analysis of the study indicated that among patients with an infarction volume of 50cc or less (77 out of 163 patients), the percentage of patients that demonstrated composite improvement in the Fugl-Meyer Motor Scale score was significantly higher in the treatment group than in the sham surgery (control) group

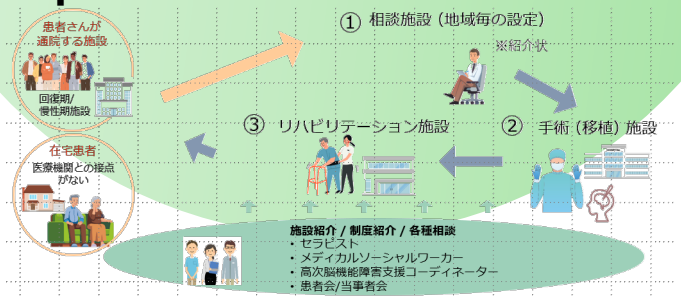


Japan as an innovation engine

■ Position Japan as a mother base for further growth in the future.

Accumulation of know-how in regenerative medicine

- Accumulation of high-quality efficacy and safety data to promote research and development
- Building a seamless infrastructure from manufacturing to distribution and administration of cell therapy products to patients
- Promote appropriate use of regenerative medical products



4. Toward the popularization of AKUUGO® in Japan

Product Overview of AKUUGO®

■ Obtained conditional and time-limited marketing approval from the MHLW on July 31.

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

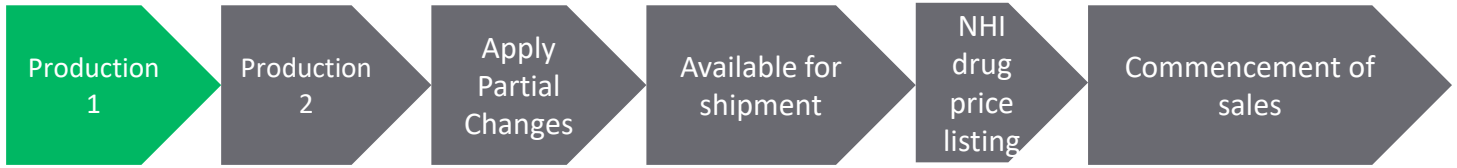
ヒト体性幹細胞加工製品 薬価基準未収載
アクーゴ® 脳内移植用注
バンデフィテムセル 指定再生医療等製品

For AKUUGO® shipment

- **Run two or so rounds of commercial production to accumulate inventories in preparation for launch, confirming the product's equivalence and homogeneity during this process.**
- **The earliest possible timing for fulfillment of conditions and shipment is assumed to be the first quarter of the following fiscal year (February-April 2025), when the inventory is ready.**

Evaluation	[Condition of approval]
Seven years	1. Considering the limited manufacturing record for the Product, the Company shall promptly collect information on the Product's quality based on a pre-determined plan, and evaluate and report on the equivalence/homogeneity, in terms of quality, of the investigational product (clinical trials product) and the Product intended for commercial distribution. Based on the evaluation results, the Company shall apply for a partial change of approved matters. It shall not ship the Product until the partial change application has been approved. 2. The Company must ensure that the Product is used in medical facilities fully equipped to handle emergencies, by physicians who possess sufficient knowledge and experience in the diagnosis and treatment of traumatic brain injury and stereotactic brain surgery techniques. The physicians must also have sufficient knowledge of the clinical trial results and adverse events of the Product. 3. Until the Company re-applies for marketing approval for the Product prior to the expiration of the conditional and time-limited approval, the Company must conduct post-marketing evaluation of all cases where the Product is used. 4. Until the Company re-applies for marketing approval for the Product prior to the expiration of the conditional and time-limited approval, the Company must collect information on the biological characteristics reflecting the mechanisms of action of the Product and take necessary measures, such as improving its quality control strategy.

Future Flow



PMCT Overview of AKUUGO®

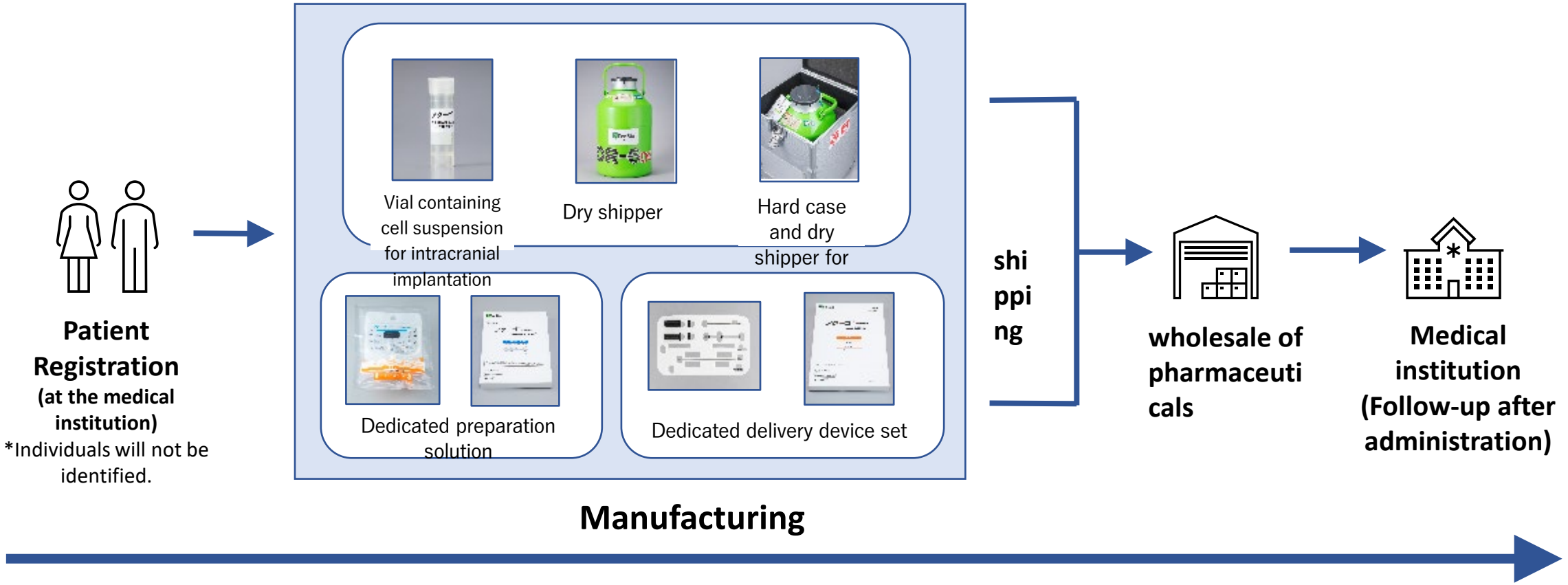
■ Obtain a full approval by conducting PMCT

PMCT Overview

Objective	**To evaluate the efficacy of this product in patients with motor paralysis associated with chronic TBI**
Trial Design	Design Multicenter, randomized, open-label, no-treatment, parallel-group controlled trialPatients will be assigned 2:1 to two groups: one group to receive AKUUGO® transplantation and rehabilitation (this product group) or one group to receive rehabilitation only (control group).
Subjects	Adults with chronic motor paralysis associated with traumatic brain injury
Number of facilities	Surgical facilities: 5-7 Rehabilitation facilities: 10-21 facilities
Target number of cases	42 cases (28 in the product group and 14 in the control group)

Clinical trial page set up on website on August 8, and call center begins inquiries.

Distribution System for AKUUGO®



(Centralized management of information from patient registration to product delivery, administration, and post-administration 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

Patient at home

No contact with medical institutions

① Consultation facilities (set up for each region)

*Referral letter needed

② Surgical (transplant) facilities

③ Rehabilitation Facilities

Introduction to facilities/systems/consultation

- Therapist
- Medical Social Worker
- Higher brain dysfunction support coordinator
- Patient/participant associations

Disease awareness and support site for patients and their families

- TBI Navi®” (URL: https://tbi-navi.jp/), an information website for traumatic brain injury patients, opened on September 12.

Plans to start activities to inform healthcare professionals involved in medical coordination about AKUUGO®

Brain Regeneration and Rehabilitation

～ The world's first regenerative medicine product "AKUUGO®" for the improvement of chronic motor paralysis by TBI ～

❑ Academic Society Cosponsored Seminars

- The 8th Autumn Annual Meeting of the Japanese Association of Rehabilitation Medicine
- The 45th Annual Conference of the Japanese Association of Rehabilitation Medicine
- The 25th Annual Meeting of the Japanese Association for Molecular Neurosurgery
- The 84th Annual Meeting of the Japanese Neurosurgical Society

❑ Lectures hosted by the company

- Lecture on "Akuugo®" Launch Commemorative Meeting
- Web-based lectures by region

SanBio's Vision

Becoming a Global Leader in Regenerative Medicine

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

Disclaimer

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Pioneering Regenerative Medicine