



**Financial Results  
for the Fiscal Year  
Ending January 31, 2021**

March 18, 2021

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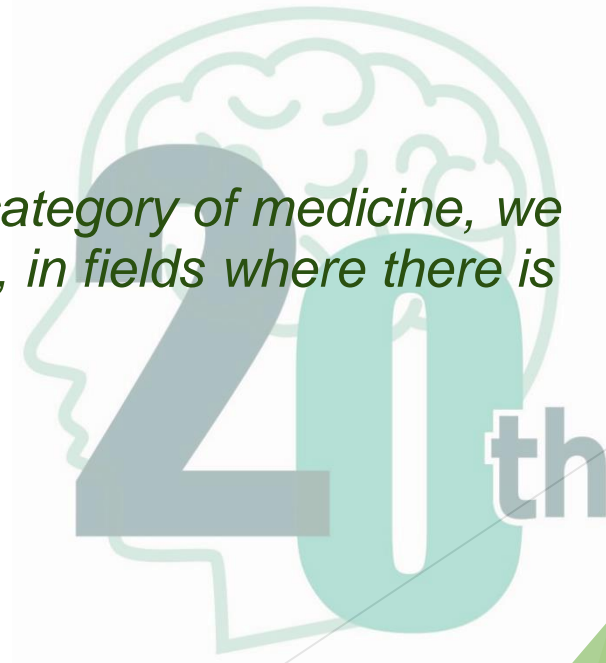
**SanBio Company Limited**  
(TSE Mothers: 4592)

# In the beginning...

*SanBio observed its 20<sup>th</sup> Anniversary on February 21<sup>st</sup>, 2021.*

*Obtaining SB623 product approval and executing this market launch is our current top priority. However, we expect soon to broaden our focus to include many additional indications and countries, and to make SB623 widely available globally.*

*Further, to fulfill our mission of pioneering a new category of medicine, we will pursue innovative new drugs including SB623, in fields where there is no effective treatment.*



**1**

## **Financial Results**

**2**

## **SB623 Clinical Data**

**3**

## **SB623 Japan Product Approval and Subsequent Developments**

**4**

## **Going Forward**

# 1. Financial Results

While operating expenses were in line with FY2020.1,  
net loss narrowed due to the sale of investment securities,

Unit: Million yen		FY2020.1 Results (A)	FY2021.1 Results (B)	(B)-(A)	FY2021.1 Forecast
Revenue		447	-	-447	-
	R&D cost	4,327	4,071	-256	3,757
Operating expenses		5,933	5,801	-131	5,453
Operating income		-5,486	-5,801	-316	-5,453
Net income		-5,157	-3,386	1,771	-5,544
Yen/US\$ exchange rate		109.08	106.34	-	110.00

## Cash and cash equivalents remained flat YoY due to the sale of investment securities

Unit: Million yen		As of January 31, 2020 (A)	As of January 31, 2021 (B)	(B)-(A)	Factors of Difference
	Cash & cash equivalents	13,646	12,480	-1,165	
	Supplies	469	444	-25	
Current assets		14,626	13,131	-1,494	
Non-current assets		979	211	-767	
Total assets		15,605	13,343	-2,261	
Current liabilities		1,175	2,469	+1,294	Increase in short-term loans payable and current portion of long-term loans payable
Non-current liabilities		3,500	2,525	-975	Decrease in long-term loans payable
Total liabilities		4,675	4,994	+319	
Net assets		10,930	8,349	-2,580	
Total liabilities and net assets		15,605	13,343	-2,261	

**Operating expenses expected to remain on par with FY2021.1 levels,  
with preparations underway for SB623 Japan product approval and launch**

Unit: Million yen		FY2021.1 Results	FY2022.1 Forecast
Revenue		-	-
	R&D cost	4,067	3,820
Operating expenses		5,801	5,786
Operating income		-5,801	-5,786
Net income		-3,386	-5,877
Yen/US\$ exchange rate		106.34	110.00

## **2. SB623 Clinical Data**



## Primary endpoint:

Statistically significant difference in change from baseline in the Fugl-Meyer Motor Scale (FMMS) score observed at 6 months for SB623-treated group versus control group.

## Secondary endpoints & safety assessment

- ▶ Improvement from baseline in DRS (Disability Rating Scale), ARAT (Action Research Arm Test), GV (Gait Velocity), and GRPC (Global Rating of Perceived Change) scores observed at 6 months.
- ▶ No difference in adverse events between the SB623 group and the sham-surgery control group.
- ▶ SB623 treatment was well tolerated, and no patients withdrew due to adverse events.

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The most widely read and highly cited  
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January 04, 2021 ARTICLE

OPEN ACCESS

## Cell Therapy for Chronic TBI

### Interim Analysis of the Randomized Controlled STEMTRA Trial

© Masahito Kawabori, Alan H. Weintraub, Hideaki Imai, Laroslav Zinkevych, Peter McAllister, Gary K. Steinberg, Benjamin M. Frishberg, Takao Yasuhara, Jefferson W. Chen, Steven C. Cramer, Achal S. Achrol, Neil E. Schwartz, Jun Suenaga, Daniel C. Lu, Ihor Semeniv, Hajime Nakamura, Douglas Kondziolka, Dai Chida, Takehiko Kaneko, Yasuaki Karasawa, Susan Paadre, Bijan Nejadnik, Damien Bates, Anthony H. Stonehouse, © R. Mark Richardson, David O. Okonkwo

First published January 4, 2021, DOI: <https://doi.org/10.1212/WNL.00000000000011450>

## Objective

Evaluating the efficacy and safety of SB623 in patients with stable chronic motor deficits secondary to TBI

## Subject

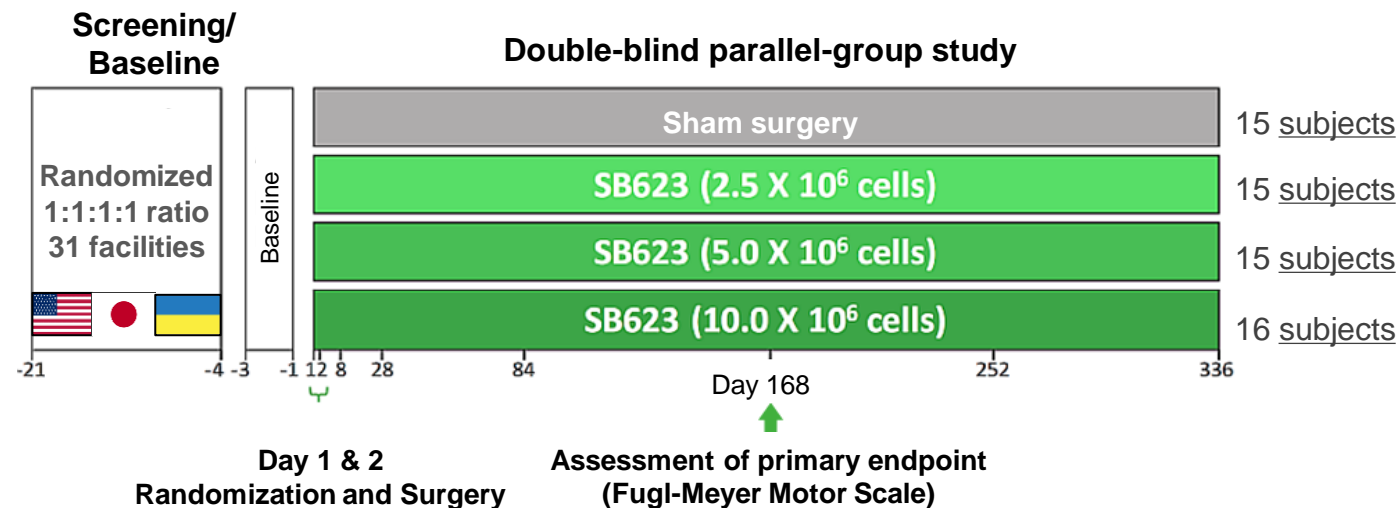
At least 12 months post-TBI, and having chronic motor deficit

## Patient eligibility criteria

- Patients aged 18-75
- At least 12 months post-TBI
- Focal cerebral injury identified on MRI
- GOS-E Score of 3–6 (i.e., moderate or severe disability)

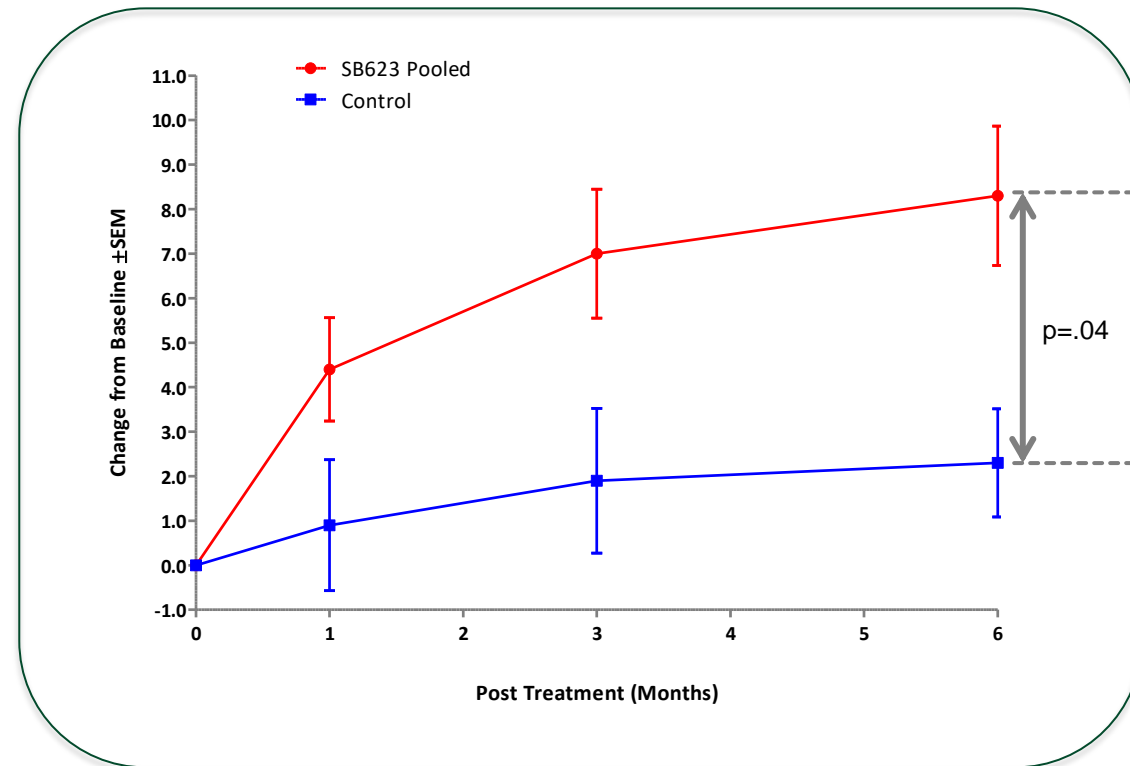
## Trial method

- The trial included three SB623-treated groups ( $2.5 \times 10^6$ ,  $5.0 \times 10^6$ , and  $10.0 \times 10^6$ ) and a sham-surgery control group, and subjects were randomized in a 1:1:1:1 ratio and observed for 12 months.
- 6-month, pre-specified interim analysis including primary efficacy endpoint of change from baseline in the Fugl-Meyer Motor Scale (FMMS) score for all patients who underwent surgery (N=61)



## Primary endpoint (change in FMMS\* score) achieved

- ▶ Change of FMMS score from baseline was significantly higher for SB623-treated compared to control patients at 6 months.
- ▶ Least square mean (SE): 8.3 (1.4) vs. 2.3 (2.5),  $p=0.04$
- ▶ Change of FMMS score from baseline at 1 and 3 months remained higher in the SB623-treated compared to control patients.



\*FMMS: Fugl-Meyer Motor Scale

## The STEMTRA paper was featured in a Neurology® Editorial by neurology world authorities Dr. Masha Savelieff and Dr. Eva Feldman, as well as in several other media

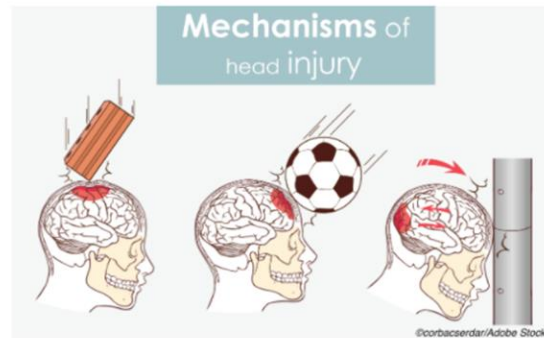
### PHYSICIAN'S WEEKLY

Home Specialties Doctor's Voice Meeting Coverage Continuing Education Podcast #PWChat Covid-19

## Cell Therapy for Chronic TBI Shows Promise

Jan 12, 2021

Treatment well tolerated and tied to improvement in motor status



Implanting allogeneic modified bone marrow-derived mesenchymal stromal/stem cells in patients with traumatic brain injury (TBI) met efficacy and safety endpoints in an interim analysis from the phase II randomized controlled [STEMTRA](#) trial.

[Stromal/stem cell implant improves motor function in patients with history of TBI \(healio.com\)](#)

[Stem cell implants show promise in chronic traumatic brain injury | Nature Reviews Neurology](#)

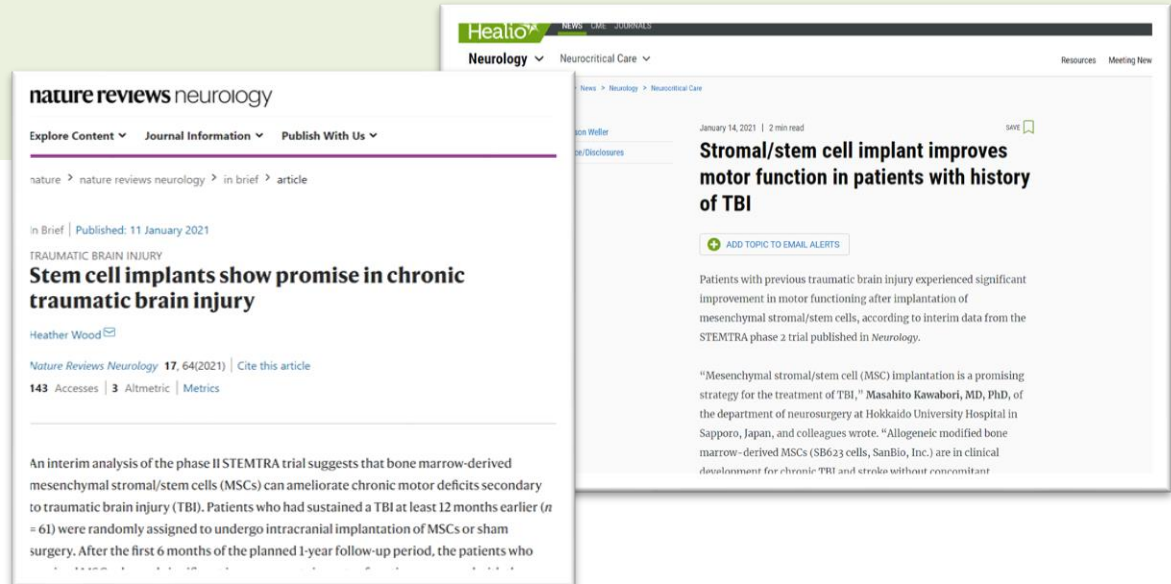
[Stromal/stem cell implant improves motor function in patients with a history of TBI - Brain Health Education and Research Institute](#)

["Cell Therapy for Chronic TBI Shows Promise | Physician's Weekly](#) (excerpt below)

*In an accompanying editorial, Masha Savelieff, PhD, and Eva Feldman, MD, PhD, both of the University of Michigan in Ann Arbor, wrote that "STEMTRA used a targeted delivery of stem cells to the injury site, an approach further supported by the recent failed phase III clinical trial of non-targeted intrathecal injections in amyotrophic lateral sclerosis."*

*Potential advantages of allogeneic bone marrow-derived mesenchymal stromal/stem cell implants include no requirement for concomitant immunosuppression, readily available cells free of ethical concerns, and a low risk of malignant transformation, they pointed out.*

*"Therefore, in light of the lack of current TBI therapies, and if these positive findings hold at the study conclusion," the results of this STEMTRA phase II trial would advocate a phase III trial," they said.*



"This is the first ever report that demonstrates the efficacy of intracranial administration of mesenchymal stromal cells in a double-blind, controlled study for motor dysfunction caused by traumatic brain injury, which previously had no effective treatment." (Dr. Kawabori's comment)



## Presentation of STEMTRA Phase 2 Trial Results at the 44th Annual Meeting of the Japan Society of Neurotraumatology

Tokyo, Japan and Mountain View, Calif. - Mar. 1, 2021 - The SanBio Group (SanBio Co., Ltd. and its subsidiary SanBio, Inc.) (TSE:4592), hereby announce that Masahito Kawabori, Specially Appointed Associate Professor of the Department of Neurosurgery and Neuronal Cell Therapy, Hokkaido University Hospital presented the results of the global Phase 2 clinical trial of SB623 targeting chronic effects associated with traumatic brain injury (STEMTRA study) during Symposium 3, Brain Protection and Regenerative Medicine, of the 44th Annual Meeting of the Japan Society of Neurotraumatology commenced on the day of this release (February 26–27, 2021) in Takamatsu, Kagawa Prefecture.

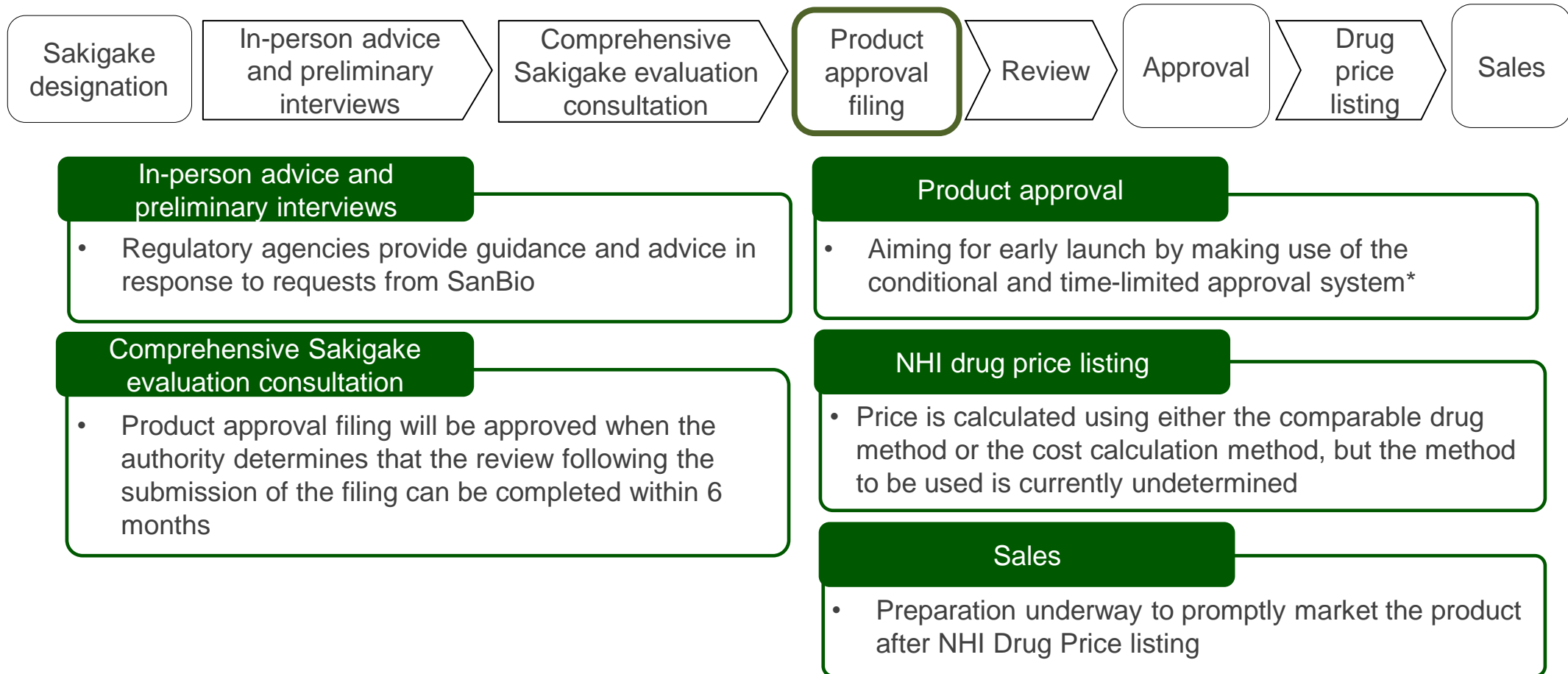
### Feb. 26-27 44th Annual Meeting of the Japan Society of Neurotraumatology in Kagawa

- Presentation Date: Feb. 26, 2021 (Fri) / Session: Symposium 3: Brain Protection and Regenerative Medicine
- Keynote speech: Clinical trial results of intracranial administration of mesenchymal stem cells (SB623) to patients suffering from chronic effects associated with traumatic brain injury (STEMTRA study) by Dr. Masahito Kawabori, Department of Neurosurgery and Neuronal Cell Therapy, Hokkaido University Hospital



### **3. SB623 Japan Product Approval and Subsequent Developments**

Discussions are underway with authorities within the framework of the Sakigake designation system



The Pharmaceutical and Medical Devices Law, which came into effect on November 25, 2014, introduced an early approval system (approval with conditions and time limits). For regenerative medicine products that are not homogeneous, if safety can be confirmed and efficacy is presumed, the system allows approval for manufacturing and sales with conditions and time limits (from Article 23-26 of the Pharmaceutical and Medical Devices Law).

## Japan launch preparation status

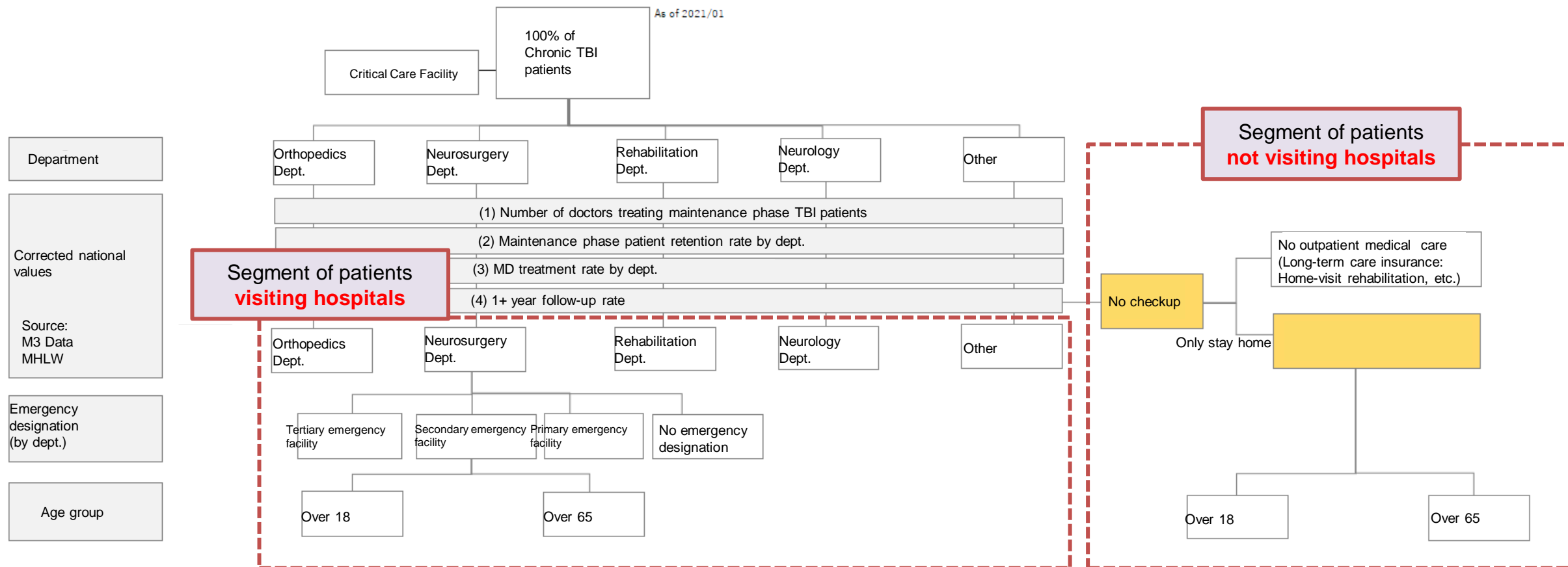
We will finalize the HC for the launch activities and details once the requirements for product approval (post-marketing surveys, promotion of appropriate usage guideline, etc.) are determined. We are currently working with our partners and municipalities to prepare to help TBI patients as quickly as possible.

	Current status
Pricing	Prepare documents to negotiate for appropriate drug prices
Review medical fees	Address the Japan Neurosurgical Society and Insurance Committee
Build sales structure	Clarify the actual treatment circumstances, and develop strategies for each treatment phase based on the views of doctors and patients
	Develop strategies for regional activities centered on pre-surgery and post-surgery patient follow-up
Build logistics system	Prepare to implement R-SAT system with Suzuken
	Carry out activities to build logistics scheme in various communities
Create promotional materials	Prepare promotional materials and video content based on product marketing strategy
	Prepare content for product website
Build system for appropriate use	Collect scientific insights needed for appropriate use
	Establish qualification assessment system that leverages ICT
	Prepare e-learning content needed for appropriate use after launch



# Current Status of Chronic TBI Medical Treatment (Japan)

1. There are no effective treatments for chronic TBI patients, and many stop going to the hospital (about 40% of patients do not get checkups at hospitals\*1).
2. Not all doctors in all departments treat patients with chronic brain injuries.
3. The doctor seeing the patient and the doctor performing the cell transplant are different.



\*1 SanBio Quantitative Head Trauma Survey (conducted in October 2020)

**Established first Asian subsidiary SANBIO ASIA PTE. LTD. in Singapore on February 1, 2021**

## Purpose of incorporation in Singapore

- ✓ To establish a global structure for SanBio by allocating appropriate personnel for manufacturing, distribution, and Asian expansion
- ✓ After Japan approval of SB623, the corporation will serve as a hub to expand business channels in the Asian region




## Company profile

- ◆ Entity Name: SANBIO ASIA PTE. LTD.
- ◆ UEN: 202104096W
- ◆ Transaction Name: Incorporation of Local Company
- ◆ Transaction No.: C210074644



**Began market research with aims to expand into Taiwan, S. Korea, and China**

**We will introduce products at an appropriate time  
while checking the relevant laws for regenerative medicine in each country**

	 <b>China</b>	 <b>Korea</b>	 <b>Taiwan</b>
<b>Number of cases per year<sup>*2</sup></b>	TBI: 4 million people Ischemic stroke: 3.3 million people Hemorrhagic stroke: 1.4 million people	TBI: 160,000 people Ischemic stroke: 86,000 people Hemorrhagic stroke: 51,000	TBI: 70,000 people Ischemic stroke: 36,000 people Hemorrhagic stroke: 16,000 people
<b>Approved regenerative medical products</b>	None	16 products (13 autologous, 3 allogenic)	None
<b>Relevant laws</b>	No legislation specific to regenerative medicine <small>*Priority approval review system is available.</small>	Advanced Biotechnology Act (September 2020)	Cell and Gene Therapy Medicinal Product Management Act (TBD)
<b>Other</b>	By using the Hainan Advanced Zone Ordinance, research projects on cutting-edge medical technology can be developed and the approval time for imported drugs is expected to be shortened.	Domestic and foreign companies are expected to move into cellular and regenerative medicines, and the market is expected to expand in the coming years.	If the law for regenerative medicine is passed, the results of the Phase 2 trials may be used to obtain conditional approval like in Japan.

<sup>\*1</sup> IQVIA survey (conducted in April 2020)

<sup>\*2</sup> World Population Prospects / The Lancet Neurology; Global, regional, and national burden of traumatic brain injury and spinal cord injury / GHDx Healthdata

## 4. Going Forward

# Pipeline: Targeting Areas of Serious Unmet Medical Need

Agent	Indication		Research	Nonclinical	Phase 1	Phase 2	Pivotal	Regulatory Filing
SB623 Chronic Brain Injury	Traumatic Brain Injury	Japan						
		U.S.						
	Ischemic Stroke							
	Hemorrhagic stroke							
SB623 Retinal Diseases	AMD (dry)* <sup>2</sup>		Partnered with OcuMension Therapeutics in China					
	Retinitis pigmentosa* <sup>2</sup>		Partnered with OcuMension Therapeutics in China					





## Other Nonclinical Programs

SB623	Parkinson's disease						
	Spinal cord injury						
	Alzheimer's disease						
SB618	Peripheral nerve damage, etc.						
SB308	Muscular dystrophy						
MSC1	Cancer						
MSC2	Inflammatory disease						
	Optic neuritis* <sup>2</sup>						

\*1 Clinical trials will begin from Phase 2b onward as safety has been confirmed in previous clinical trials for ischemic stroke and TBI programs.

\*2 Co-development with OcuMension (Hong Kong) Limited

## Prioritizing Japan TBI program, followed by Japan clinical trials for ischemic stroke and hemorrhagic stroke programs

	Top priority	
		  
Traumatic brain injury (chronic phase)	Preparing for approval filling	Considering timing for starting clinical trials*
Ischemic stroke	Plan to discuss initiation of clinical trials with PMDA	Planning clinical trials*
Hemorrhagic stroke	Plan to discuss initiation of clinical trials with PMDA	Planning clinical trials*

\*Considering in-house development and partnership options

Management team spearheaded by leaders with proven experience and expertise in their respective fields, fully-equipped with the functions needed to fuel the company's growth

## Executive directors



**Executive  
Chairman  
Toru Kawanishi**



**CEO  
SanBio, Inc. Chairman  
Keita Mori**



**Executive Vice  
President, COO  
SanBio, Inc. CEO  
Akihiro Tsujimura**

## Corporate officers



**CTOO  
(Chief Technical Operations Officer)  
Chris Horan**



**CMO  
(Chief Medical Officer)  
Bijan Nejadnik**



**Business Head  
(Japan/Asia)  
Hiroshi Yamamoto**



**Management  
Administration  
Yoshihiro Kakutani**

## Strengthen the organizational foundation by actively recruiting experienced senior leaders who can support the executive team and lead the business

**Executive Vice  
President, COO  
SanBio, Inc. CEO  
Akihiro Tsujimura**



**Head of Japan Regulatory Affairs and Quality Control  
(Supervisor General of Manufacturing and Marketing)  
Kazumi Sawaguchi**

Ms. Sawaguchi plays a central role in the development of regulatory strategies in Japan and in dealing with authorities related to clinical trial consultations and applications as the Head of Regulatory Affairs in Japan. She became a Supervisor General in February 2021, when the Quality Compliance team and the Quality Assurance team were integrated into the Regulatory Affairs department, and will handle regulatory affairs and quality matters to drive product launches in Japan.

**CMO  
(Chief Medical Officer)  
Bijan Nejadnik**



**Head of Clinical Development  
Hiroyasu Narita**

Mr. Narita is responsible for leading all clinical development activities in Japan in collaboration with key opinion leaders in the central nervous system, stem cell, and regenerative medicine communities in Japan. Together with the CMO, he will play a key role in designing clinical development strategies for each program and long-term strategies for the entire SanBio Group.

**CTOO  
(Chief Technical Operations Officer)  
Chris Horan**



**Head of Quality  
Lesa Valentine**

Responsible for the  
global quality and  
compliance



**Head of Production  
Haruhiko Tsumura**

Responsible for  
production in Japan



**Head of Global  
Supply Chain  
Julia Cher**

Responsible for the  
global supply chain





**Deliver novel therapeutics to patients as rapidly as possible  
and maximize corporate value**

# In business for 20 years

*SanBio observed its 20<sup>th</sup> Anniversary on February 21<sup>st</sup>, 2021.*

*As we all continue to cope with one type of public health challenge, our team at SanBio has been working on cell medicines which are also important to public health, beginning with traumatic brain injury (TBI), chronic stroke, and other central nervous system diseases, with the vision of making regenerative therapeutics a basic modality of modern medicine. Today we believe we are on the verge of our first product approval and launch, and are therefore committing with renewed determination to move our program forward.*

*Obtaining SB623 product approval and executing this market launch is our current top priority. However, we expect soon to broaden our focus to include many additional indications and countries, and to make SB623 widely available globally. Further, to fulfill our mission of pioneering a new category of medicine, we will pursue innovative new drugs including SB623, in fields where there is no effective treatment.*

*Lastly, while we are still on our way to achieving our goal, we would like to thank everyone's support to date, which has enabled us to come this far. We - all of us at SanBio - will continue to strive to bring breakthrough medicines to help patients in need, and we very much appreciate your continued support.*

Keita Mori, CEO



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