SanBio
Pioneering Regenerative Medicine

Financial Results for the Fiscal Year Ending January 31, 2021

March 18, 2021

SanBio Company Limited

(TSE Mothers: 4592)

In the beginning...

SanBio observed its 20th Anniversary on February 21st, 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.

Table of Contents

1. Financial Results

Consolidated Income Statement

**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

Consolidated Balance Sheet

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	

Consolidated Earnings Forecast

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

Neurology® Publication of STEMTRA Trial Results (Press Release, Jan. 5, 2021)

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.

STEMTRA Trial Summary

Objective

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

Subject

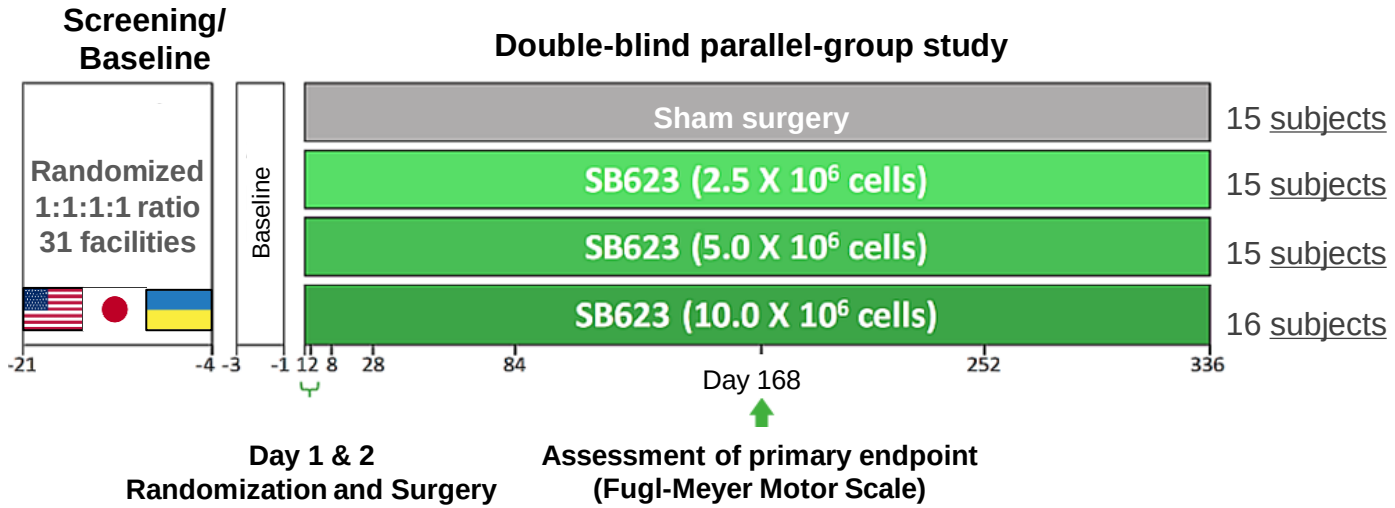
At least 12 months post-TBI, and having chronic motor deficit

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)

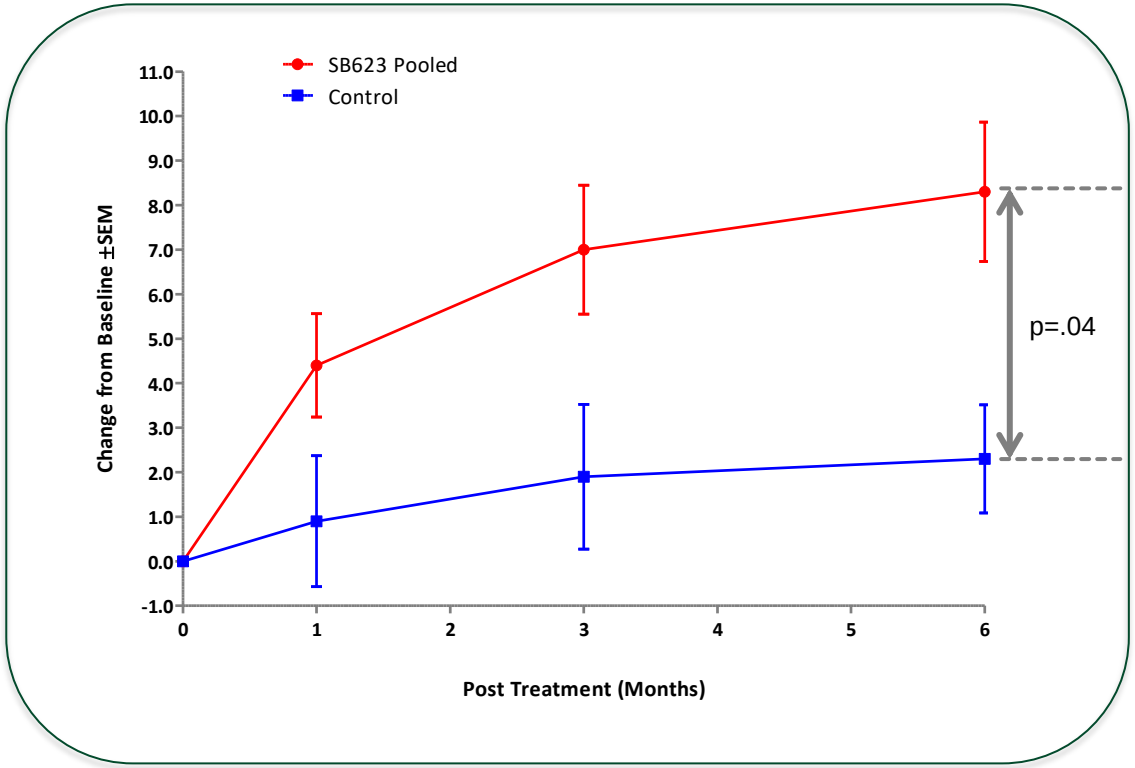
Trial method

- The trial included three SB623-treated groups (2.5×10^6, 5.0×10^6, and 10.0×10^6) 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

Responses to Neurology® Publication

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

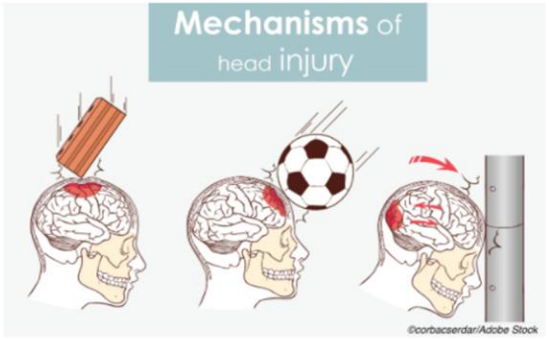
PHYSICIAN'S WEEKLY

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



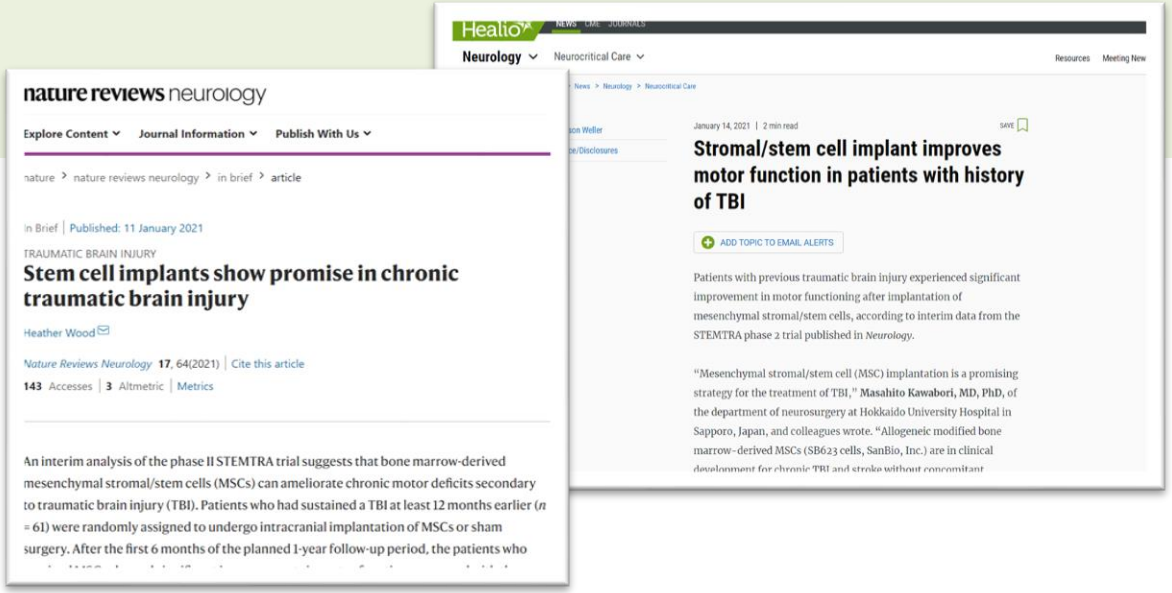
Implanting allogeneic modified bone marrow-derived mesenchymal stromal/stem cells in patients with traumatic brain injury (TBI) met efficacy and safety endpoints in an interim analysis from the phase II randomized controlled STEMTRA trial.

"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.



nature reviews neurology

Explore Content Journal Information Publish With Us

nature > nature reviews neurology > in brief > article

In Brief | Published: 11 January 2021

TRAUMATIC BRAIN INJURY

Stem cell implants show promise in chronic traumatic brain injury

Heather Wood

Nature Reviews Neurology **17**, 64(2021) | Cite this article

143 Accesses | 3 Altmetric | Metrics

An interim analysis of the phase II STEMTRA trial suggests that bone marrow-derived mesenchymal stromal/stem cells (MSCs) can ameliorate chronic motor deficits secondary to traumatic brain injury (TBI). Patients who had sustained a TBI at least 12 months earlier (*n* = 61) were randomly assigned to undergo intracranial implantation of MSCs or sham surgery. After the first 6 months of the planned 1-year follow-up period, the patients who

Healio

Neurology Neurocritical Care Resources Meeting New

January 14, 2021 | 2 min read

Stromal/stem cell implant improves motor function in patients with history of TBI

ADD TOPIC TO EMAIL ALERTS

Patients with previous traumatic brain injury experienced significant improvement in motor functioning after implantation of mesenchymal stromal/stem cells, according to interim data from the STEMTRA phase 2 trial published in *Neurology*.

"Mesenchymal stromal/stem cell (MSC) implantation is a promising strategy for the treatment of TBI," **Masahito Kawabori, MD, PhD**, of the department of neurosurgery at Hokkaido University Hospital in Sapporo, Japan, and colleagues wrote. "Allogeneic modified bone marrow-derived MSCs (SB623 cells, SanBio, Inc.) are in clinical development for chronic TBI and stroke without concomitant

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

Presented at the Japan Society of Neurotraumatology (Press Release, Mar. 1, 2021)

"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.

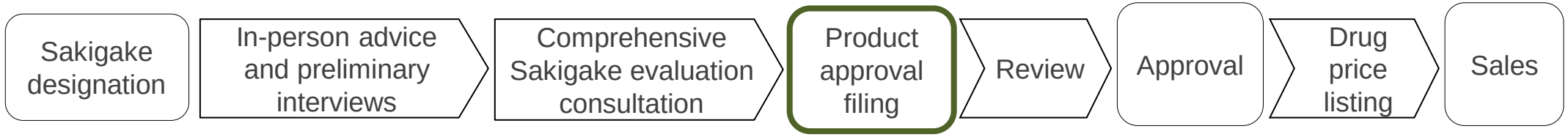
Feb. 26-27 44th Annual Meeting of the Japan Society of Neurotraumatology in Kagawa

- 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

Toward Filing for Japan Product Approval

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



In-person advice and preliminary interviews

- Regulatory agencies provide guidance and advice in response to requests from SanBio

Comprehensive Sakigake evaluation consultation

- Product approval filing will be approved when the authority determines that the review following the submission of the filing can be completed within 6 months

Product approval

- Aiming for early launch by making use of the conditional and time-limited approval system*

NHI drug price listing

- Price is calculated using either the comparable drug method or the cost calculation method, but the method to be used is currently undetermined

Sales

- Preparation underway to promptly market the product after NHI Drug Price listing

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).

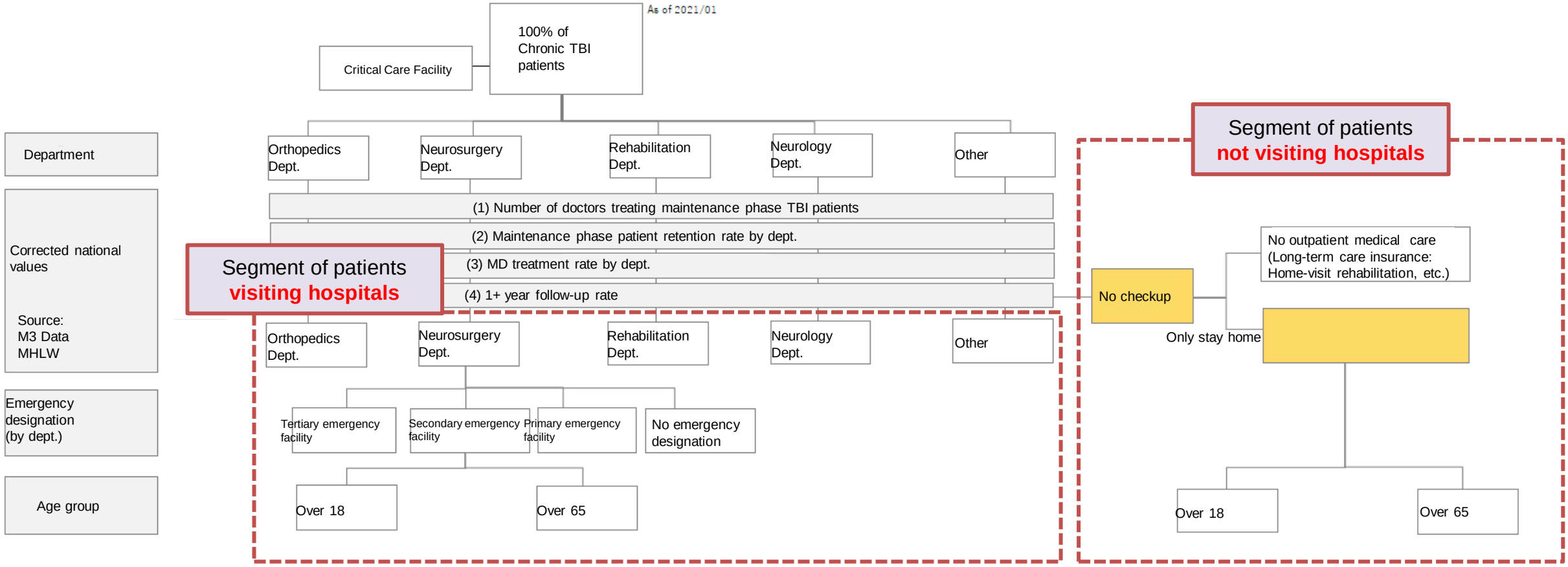
Japan launch preparation status

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)

About Asian Expansion

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

About Regenerative Medicine × Asian Countries[*1]

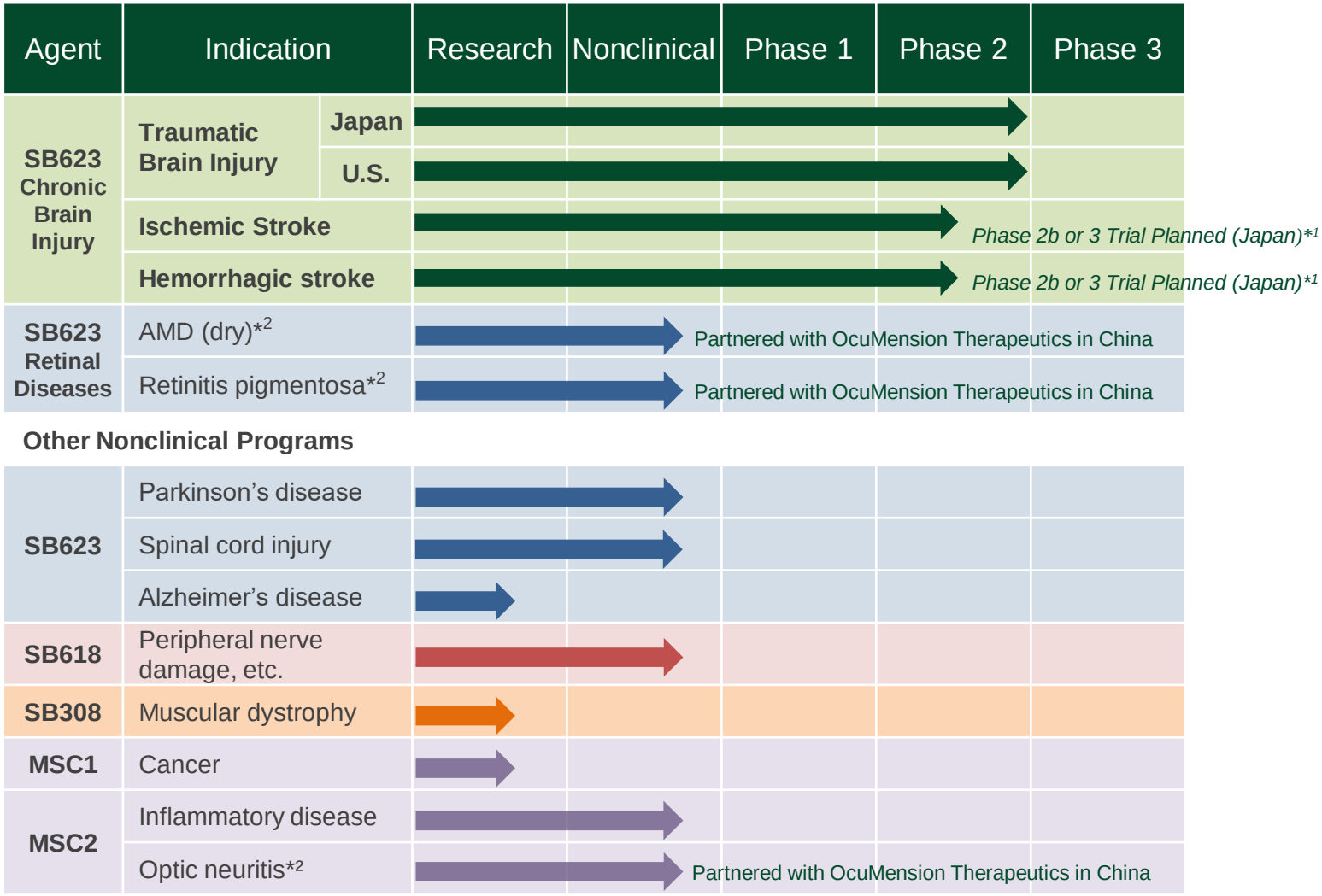
We will introduce products at an appropriate time while checking the relevant laws for regenerative medicine in each country

	China	Korea	Taiwan
Number of cases per year[*2]	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
Approved regenerative medical products	None	16 products (13 autologous, 3 allogenic)	None
Relevant laws	No legislation specific to regenerative medicine *Priority approval review system is available.	Advanced Biotechnology Act (September 2020)	Cell and Gene Therapy Medicinal Product Management Act (TBD)
Other	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.

*1 IQVIA survey (conducted in April 2020)
*2 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



*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

SB623 Development Plans

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

SanBio Taking on the Challenges for Transition: Becoming a Global Leader

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

SanBio Taking on the Challenges for Transition: Enhancing Senior Leadership

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

Becoming a Global Leader in Regenerative Medicine

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

In business for 20 years

SanBio observed its 20th Anniversary on February 21st, 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

SanBio
Pioneering Regenerative Medicine

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.

SanBio cautions you that actual results may differ substantially from those discussed in this material due to various factors. We do not guarantee the accuracy or completeness of the information herein. Unless otherwise stated, estimates or forecasts are solely those of our company and subject to change without notice. We accept no liability whatsoever for any direct or consequential loss arising from any use of this report.

SanBio Company Limited

Management Administration

Contact: info@sanbio.jp


SanBio
Pioneering Regenerative Medicine