(TSE Stock Code:4592)

Financial Results for the Fiscal Year ending January 31, 2020

SanBio Company Limited

Representative Director and President
Keita Mori

March 18, 2020

Today's Schedule

1. Financial Results
2. Product approval filing for TBI in Japan
3. Business Update
4. Future Outlook

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Consolidated Income Statement for FY2020.1

R&D cost will move to next year due to postponement of anticipated filing

(Unit : Million yen)

FY2020.1	Forecast(A) *	Actual(B)	(B)-(A)	Factors of Difference
Revenue (Development support fees, etc.)	713	447	-266	Development support fee was lower than in original plan
R&D cost	5,195	4,327	-868	Portion of some R&D and manufacturing-related expenses were not incurred or are expected next fiscal year
Operating expenses	6,601	5,933	-668	
Operating income	-5,887	-5,486	+401	
Net income	-5,395	-5,157	+238	
Yen/US$ exchange rate	110.00	109.08	-	

*Forecast is the figure reported before a revision dated December 13, 2019

Consolidated Balance Sheet as of Jan. 31, 2020

JP¥7.1B equity finance was raised for financial stability

(Unit : Million yen)

	As of January 31, 2019 (A)	As of January 31, 2020 (B)	(B)-(A)
Cash & cash equivalents	12,453	13,646	+1,193
Supplies	-	469	+469
Current assets	13,058	14,626	+1,568
Non-current assets	917	979	+62
Total assets	13,975	15,605	+1,630
Current liabilities	1,066	1,175	+109
Non-current liabilities	4,000	3,500	-500
Total liabilities	5,066	4,675	-391
Net assets	8,909	10,930	+2,021
Total assets and liabilities	13,975	15,605	+1,630

* (off-balance) The amount of Commitment line: JP¥5.3 billion
* Net assets +JP¥2.0 billion due to equity finance (JP¥7.1 billion) and net income (-JP¥5.1 billion)

Financial Forecast for FY2021.1

Plan to promote TBI program both in Japan and globally

(Unit : Million yen)

	FY2020.1 Actual	FY2021.1 Forecast	Outline
Revenue	447	-	
R&D cost	4,327	3,757	FY2020.1: R&D (TBI and Stroke) and manufacturing FY2021.1: Primarily manufacturing
Operating expenses	5,933	5,453	
Operating income	-5,486	-5,453	
Net income	-5,157	-5,544	
Yen=$US	109.08	110.00	

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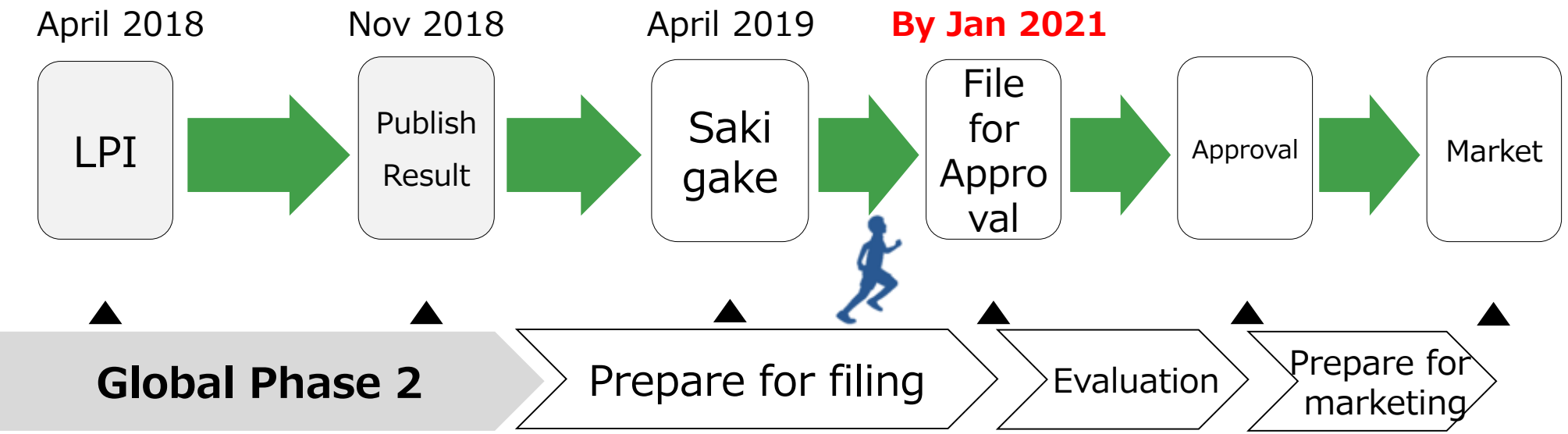
Planned postponement of product approval filing

Change the timing from “By Jan 2020” to “By Jan 2021”



SanBio decided to spend additional time before filing, in order to assure a stable supply system

Change in timing of product approval filing

3Q financial results

- ✓ Regarding the scheduled time of the application, the Group modified its plan in order to spend enough time preparing the production of commercial use products to fulfill its responsibility to ensure a stable supply following their launch. As a result, the Group has decided to make the application during the fiscal year ending January 31, 2021 (from February 2020 to January 2021).

Consolidated Financial Results
for the Nine Months Ended October 31, 2019
[Japanese GAAP]

December 13, 2019

Company name: SanBio Company Limited
Stock exchange listing: Tokyo Stock Exchange
Code number: 4592
URL: http://www.sanbio.jp/
Representative: Keita Mori, Representative Director and President
Contact: Yoshihiro Kakutani, Corporate Officer of Management Administration
Phone: +81-3-6264-3481
Scheduled date of filing quarterly securities report: December 13, 2019
Scheduled date of commencing dividend payments: —
Availability of supplementary briefing material on financial results: No
Schedule of financial results briefing session: No

(Amounts of less than one million yen are rounded down.)

1. Consolidated Financial Results for the Nine Months Ended October 31, 2019 (February 1, 2019 to October 31, 2019)

(1) Consolidated Operating Results (% indicates changes from the previous corresponding period.)

	Operating revenue	Operating income	Ordinary income	Net income attributable to owners of parent

Press release on Dec 16, 2019

- ✓ The revised timing stems from changes to the schedule for preparing commercial production, in order to ensure stable supply once the product is on the market. The Company decided it would be best to allow plenty of time for these preparations, having determined that further work was needed to build a stable supply system capable of reliably delivering this much-awaited new drug to all patients.

Message from Representative Director and President, Keita Mori, regarding disclosures made on December 13, 2019

1) **Regarding change in timing of approval filing for regenerative cell medicine SB623 for chronic motor deficit from traumatic brain injury in Japan**

Previously, the Company aimed to file for manufacturing and marketing approval of SB623 for indication of chronic motor deficit from traumatic brain injury (TBI) during FY01/20. However, the Company now will aim to file for approval during FY01/21. We regret to convey this message concerning a timing change, having previously reiterated that preparations were under way with a view to filing during FY01/20.

The revised timing stems from changes to the schedule for preparing commercial production, in order to ensure stable supply once the product is on the market. The Company decided it would be best to allow plenty of time for these preparations, having determined that further work was needed to build a stable supply system capable of reliably delivering this much-awaited new drug to all patients.

Reasons for postponement of product approval filing

- **Delay of technology transfer**
  - Required additional time for technology transfer to New CMO

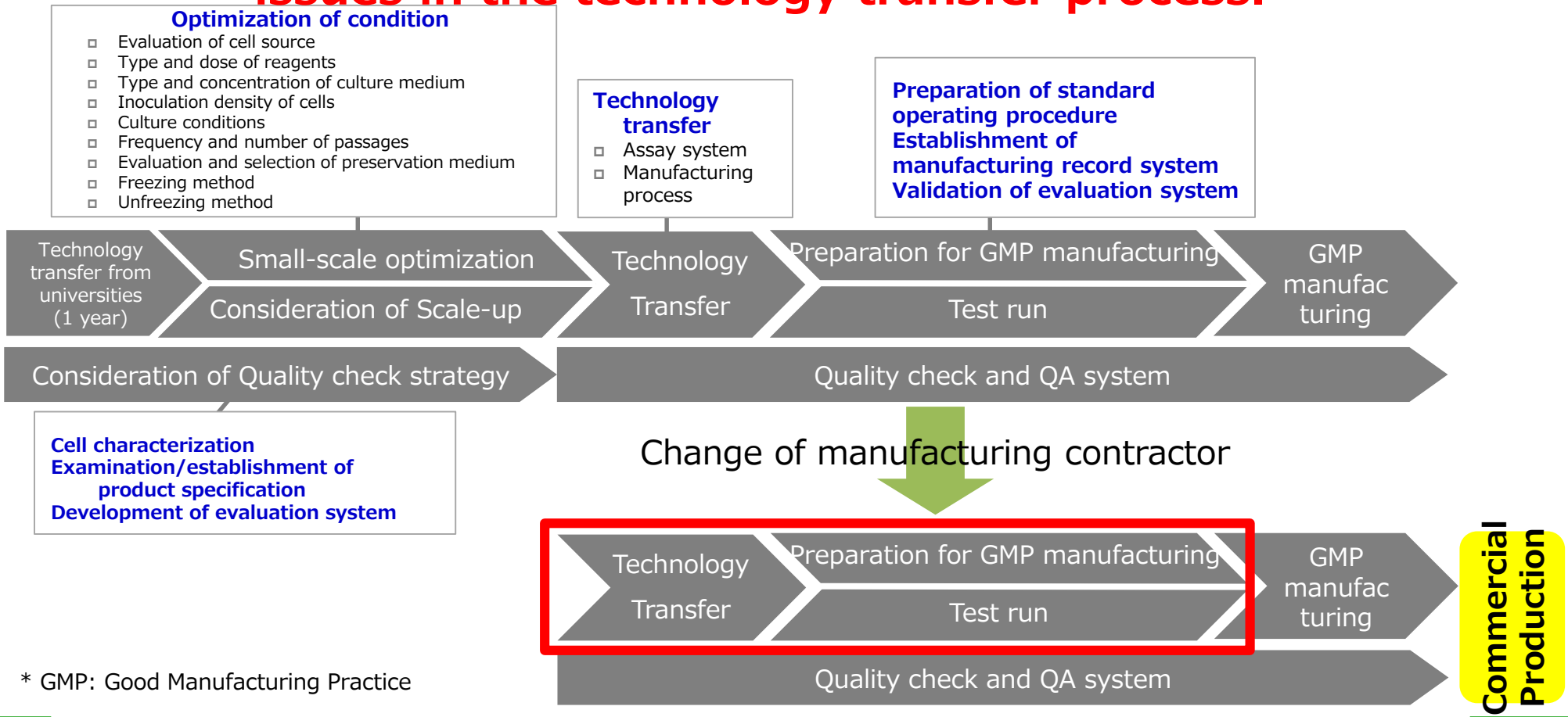
- **Establishment of management system for commercial production**
  - Improve several key processes and adjust interactions among these processes

- **Standard test insufficiency**
  - A common issue in Regenerative Medicine
  - More robust test method must be finalized

Reasons for postponement, 1 ～Technology transfer～

Job proficiency level is not enough, compared with past manufacturing contractor

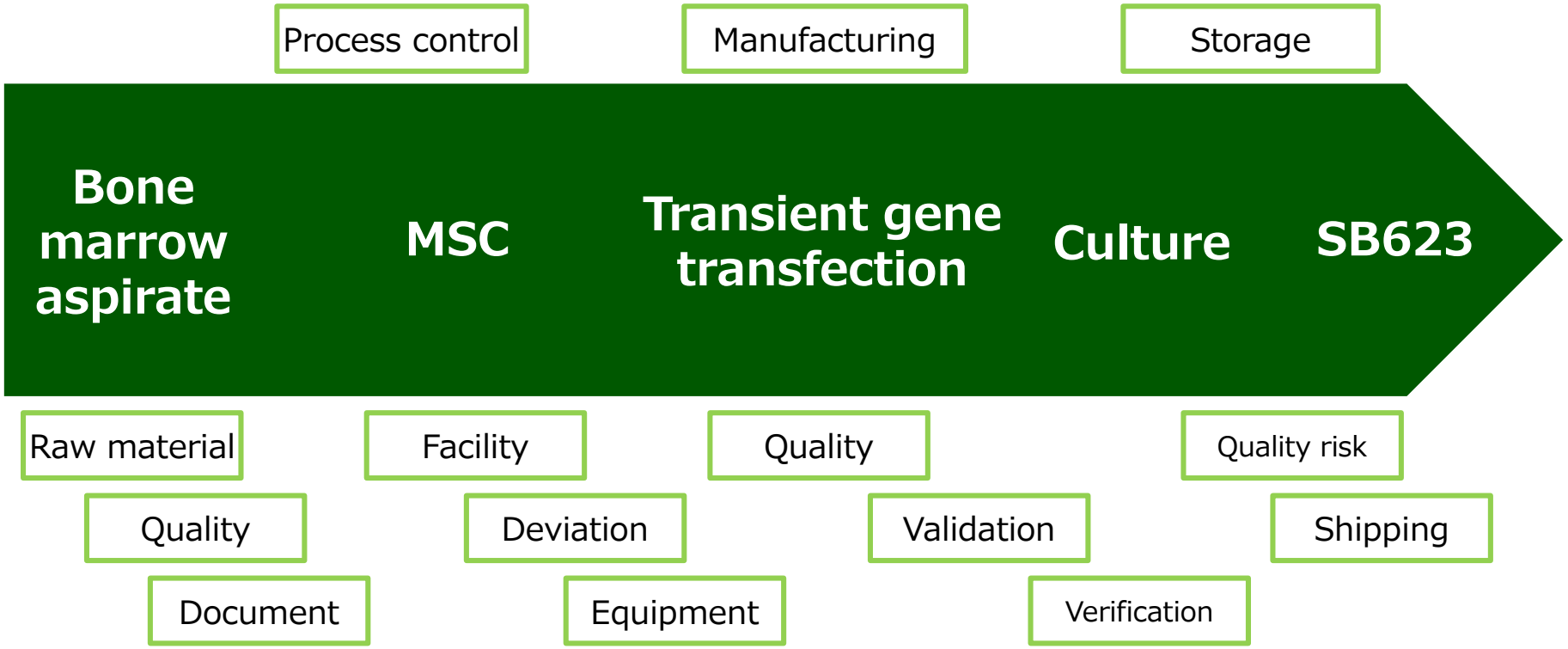
Mass production technology is established, but there remain issues in the technology transfer process.



* GMP: Good Manufacturing Practice

Currently establishing management system for commercial production

Improve several key processes and adjust interactions among these processes

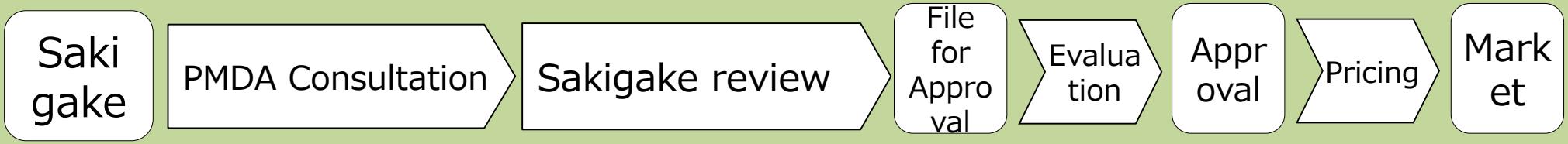


Action items

- **Investigation on issues related to technology transfer**
  -Currently under investigation. So far, no problem has been identified.
  -Areas of issues have been mostly identified.

- **Conduct as a CEO Project**
  - Appointed the person who established manufacturing technology

Standard product approval filing flow



Sakigake designation

・Able to receive incentive treatment

PMDA Consultation

・PMDA provides guidance and advice according to the application from company

Sakigake review

・One of incentives of Sakigake designation
・PMDA reviews 5 parts including Quality, Non-clinical, Clinical, Reliability and GCTP, before the filing for approval.

File for approval

・Needed document : CTD
・CTD consisted below 5 parts
>Module 1: Information of document and attached file
>Module 2: Summary of CTD
>Module 3: Quality
>Module 4: Non-clinical
>Module 5: Clinical

Evaluation

・Normally 6 months needed

Approval

・MHLW decides whether this approval is limited or full.

Pricing

・Pricing is scheduled in Feb, May, Aug and Nov annually.

*This flow is the standard with Sakigake designation for regenerative medicine in Japan.

Product approval filing schedule in Japan

Revised schedule to file by January 2021

April 2019 ▼ Saki gake → PMDA Consultation → Sakigake review → **By Jan 2021** ▼ File for Approval → Evaluation → Approval → Pricing → Market

PMDA Consultation

・Conducted several times so far
・Contents remain undisclosed

Sakigake review

・Plan to start with clinical portion
・SanBio is able to file for product when PMDA thinks evaluation will be complete within 6 months.

Approval

・MHLW decides limited or full approval

Pricing

・Not yet decided whether to use similar efficacy comparison method or cost accounting method

Market

・Preparing marketing to rapidly follow pricing determination

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Product launch activities in Japan

To Do list before launch

- ✓ Build sales structure
- ✓ Build logistics system
- ✓ Create promotional materials
- ✓ Construct R-SAT ™ system
- ✓ Understand market needs
- ✓ Consider regional medical cooperation
- ✓ Conference presentation (Domestic 3 times, Overseas 7 times)
- ✓ Build proper use system
- ✓ Consider medical fees
- ✓ Prepare for HTA
- ✓ Update the SanBio homepage
- ✓ Apply for registration of the SB623 trademark

Preparation for Japan launch, 1

Purpose	Progress Current status	Issues for launch
Build sales structure	70% Conduct marketing surveys for each treatment phase of TBI (3 surveys done to determine medical director and patient needs)	Refine the product strategy based on M.D., facility requirements and market research
	30% Planning sound organization based on M.D. and facility requirements	Build a structure which is able to provide prompt product information and contribute to community medical care
	25% Consider collaboration with medical device manufacturers for understanding of M.D. and facility information	TBD
Build logistics system	80% Building R-SAT™ system	Establish patient registration system including regenerative medicine product traceability
	40% Planning complete logistics system from manufacture to hospital	Build logistics scheme assuring close collaboration with suppliers and community
	70% Plan manufacturing of sub-components and supply chain	Establish manufacturing relationships for sub-components and supply chain
Create promotional materials	50% Advertising agency has already been selected Preparing promotional materials based on product marketing strategy (Website, product information summary, mechanism of action explanation, key visuals, etc)	Finalize promotional materials based on product marketing strategy and video content

Preparation for Japan launch, 2

Purpose	Progress Current status	Issues for launch
Build proper use system	95% Finished collecting recommendations from medical consultants	Further medical information collection for proper use and output
	70% Considering the requirements for cell administration	Build a qualification assessment system with ICT
	50% Exploring collaboration with device maker to assure proper administration	Build the medical structure for proper use after launch (training, communication, monitoring)
Consider medical fees	30% Considering the handling of medical fees for cell administration	Clarification of necessary requirements and public response
Conference presentation	95% Presentations successfully conducted (Domestic 3 times, Overseas 7 times)	Further presentations and publications

Scientific conference presentations (TBI Phase 2)

Area	Date	Conference name	Presenter
Japan	Apr. 2019	14th Korea-Japan Joint Conference on Surgery for Cerebral Stroke (KJJC)	Dr. Kawabori
	Aug. 2019	20th Annual Meeting of the Japan Society of Molecular Neurosurgery (JSMN)	Dr. Karasawa
	Oct. 2019	78th Annual Meeting of the Japan Neurosurgical Society (JNS)	Dr. Imai
USA	Apr. 2019	American Association of Neurological Surgeons (AANS)	Dr. Okonkwo
	Aug. 2019	Military Health System Research Symposium (MHSRS)	Dr. Okonkwo
	Oct. 2019	Congress of Neurological Surgeons Meeting (CNS)	Dr. Chen
	Nov. 2019	American Congress of Rehabilitation Medicine (ACRM)	Dr. Cramer
	Feb. 2020	15th Annual Conference on Brain Injury (ABI)	Dr. Weintraub
EU	Sep. 2019	American Academy of Neurological Surgery Annual Meeting (AANS)	Dr. Steinberg
China	Sep. 2019	World Federation of Neurosurgical Societies (WFNS)	Dr. Yasuhara

Platform concept for regenerative medicine

SanBio makes it easy to access the Japanese market

Overseas companies

Domestic and overseas bio-ventures

SanBio

- R-SAT system
- Medical team
- PMS
- Pharma-ceutical affairs

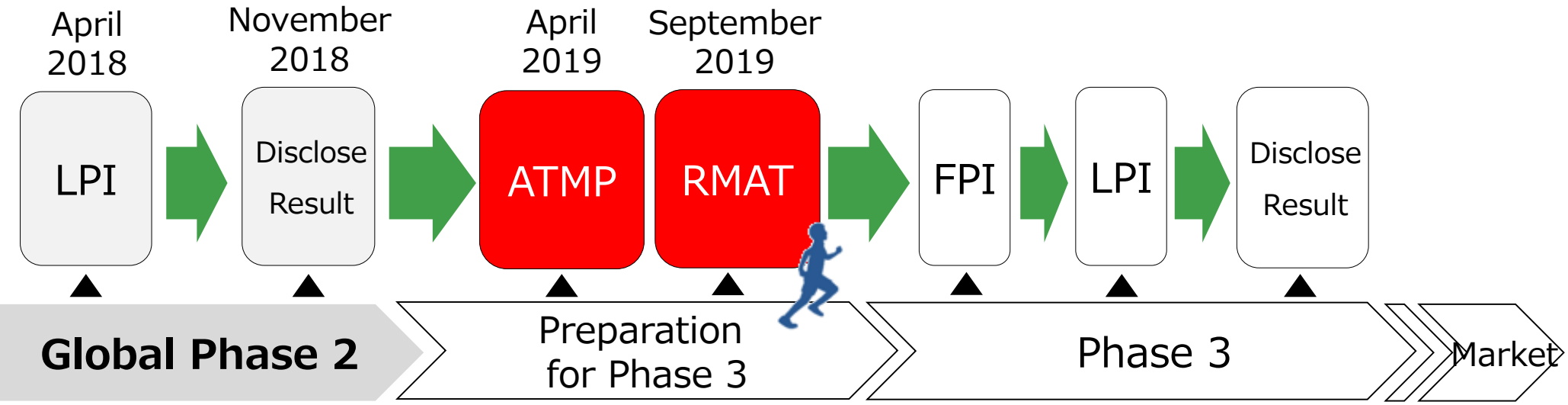
Japan market attracting worldwide attention due to the Regenerative Medicine Safety Assurance Law and the revised Pharmaceutical Affairs Law (November 2014)

Pipeline

Cell drug	Indication		Research	Preclinical	Phase 1	Phase 2	Phase 3
SB623	TBI (chronic)	US					
		JP					
	Stroke (chronic)	US					
	Hemorrhagic (chronic)					(*)	
	AMD (dry)						
	Retinitis pigmentosa						
	Parkinson's disease						
	Spinal cord injury						
	Alzheimer's disease						
SB618	Peripheral nerve damage, etc.						
SB308	Muscular dystrophy, etc.						
MSC1(plan)	Cancer						
MSC2(plan)	Inflammatory disease						

(*) Clinical trials for Hemorrhagic stroke are expected to begin in Phase 2 or Phase 3.

Global development progress



ATMP

・Granted Advanced Therapy Medicinal Product Classification by European Medicines Agency (EMA)

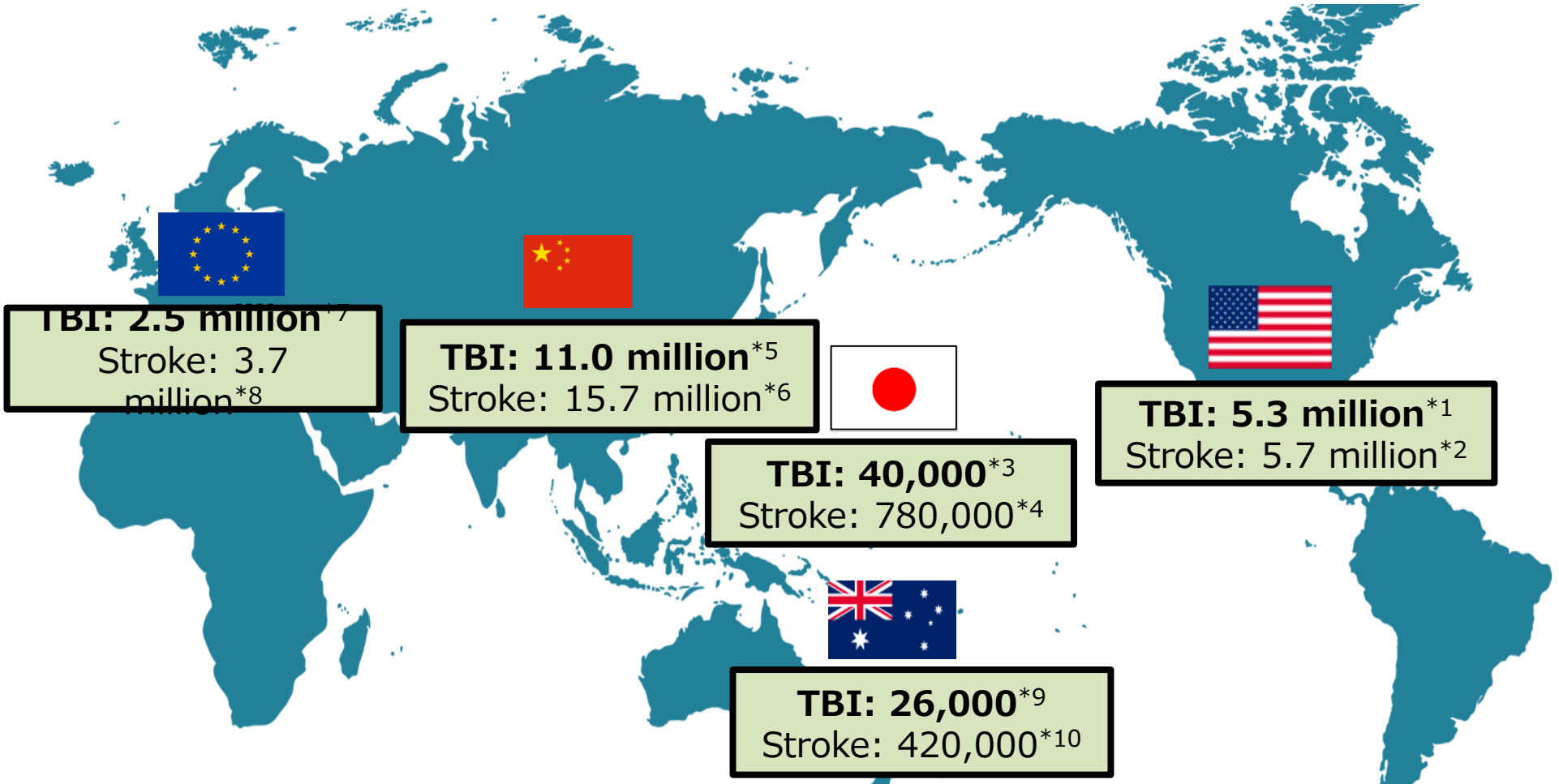
RMAT

・Granted Regenerative Medicine Advanced Therapy by Food and Drug Administration (FDA)

Phase 3

・Plan to initiate a Phase 3 trial for TBI by the end of the fiscal year ending January 31, 2021
・Have begun discussing study design and development details with FDA

TBI - Number of Patients



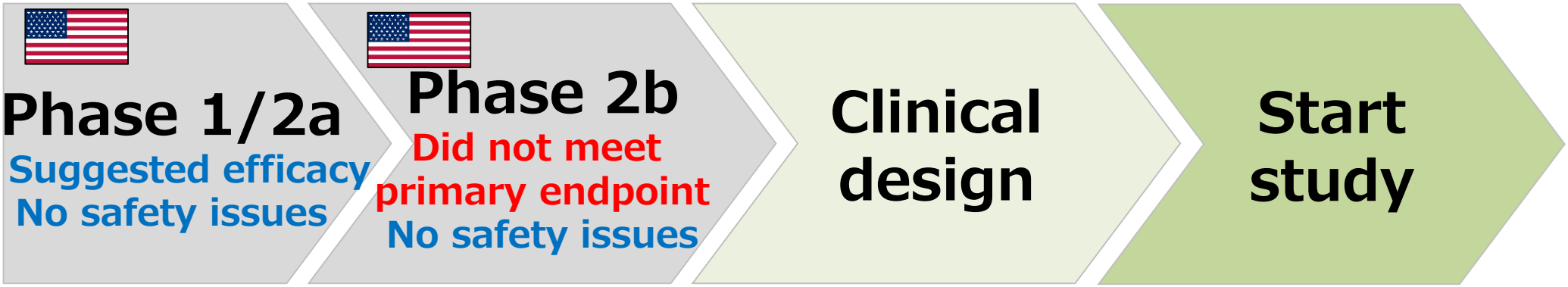
*1:Traumatic Brain Injury In the United States: Epidemiology and Rehabilitation (US Centers for Disease Control and Prevention)
*2:Heart Disease and Stroke Statistics, 2016 update
*3:Japanese Ministry of Health, Labour and Welfare 2017 (The total number of cerebrovascular disease patients)
*4:Japanese Ministry of Health, Labour and Welfare 2017
*5:Arch Neurol. 1986;43(6):570-572 (Wang et al.)
*6:Circulation. 2017;135:759–771 (Wang et al.)
*7:Center-TBI HP (https://www.center-tbi.eu/)
*8:The burden of stroke in Europe (The stroke Alliance for Europe)
*9:Australian Family Physician, Volume 43, No.11, November 2014 Pages 758-763
*10:Australia's health 2018 (Australian Institute of Health and Welfare)

Competitive drugs are few and mostly for acute TBI

Agent	Company	Phase	Mechanism	Key Details
VAS-203 (Ronopterin)	vasopharm	**III**	Nitric Oxide Synthase Inhibitor	• Vasopharm's European Phase III trial is testing VAS-203, a neuroprotective agent, in acute TBI patients to improve clinical outcomes at 6 and 12 months
CEVA-101	Cellvation	**II**	Autologous Bone Marrow-derived Mononuclear Cells	• This cell-based product requires autologous harvesting, isolation and processing, and is intravenously infused within 48 hours of injury
NNZ-2566 (Trofinetide)	neuren pharmaceuticals	**II**	Neurotrophic Peptide Analogue	• IV-trofinetide has received Fast Track Designation from the FDA for TBI, Fragile X, and Rett Syndrome and collaborates with the U.S. Army for TBI. Acute TBI.
NA-1 Tat-NR2B9c	NONO CHANGE EVERYTHING	**I**	PSD95 Inhibitor	• NoNo Pharma's lead candidate promotes cell survival and disrupts toxic cell signals following damage to neurons, in both TBI and ischemic stroke
itMSCs	STEMEDICA	**IND**	Allogeneic Bone Marrow-derived ischemia-tolerant mesenchymal stem cells	• Compared to other MSCs, Stemedica's MSCs secrete higher levels of growth factors usually associated with angiogenesis and healing. • No updated information has been identified after company received IND approval from FDA in May 2016.

Stroke program

Continue development to aim for rapid launch



◆ **Termination of a Joint Development and License Agreement with Sumitomo Dainippon Pharma (Dec 2019)**

- Sumitomo Dainippon Pharma determined to discontinue joint development of SB623 after evaluating SDP's strategic priorities, taking into account detailed analysis of the results of the Phase 2b study. SanBio and SDP concurred that the Agreement should be terminated.
- The rights to SB623 in North America will be returned to SanBio.

Expanding our pipeline

Promoting joint research with academia

Institution	Research Contents	Target
Nippon Medical School (Prof. Yokobori)	Goal is to obtain the data required for progressing to clinical trials, by evaluating the therapeutic effects of SB623 in subacute TBI disease model animals	SB623-embedded dural matrix (stem cell-embedded collagen-based dural matrix)
Juntendo University (Prof. Okazaki)	Goal is to obtain the data required for progressing to clinical trials, by evaluating the therapeutic effects of SB623 in type 1 diabetes disease model animals	Pancreatic Beta Cells of Bone Marrow-Derived Mesenchymal Stem Cells (Direct Reprogramming)
Asahikawa Medical University (Prof. Yanagi)	Goal is to obtain the data required for progressing to clinical trials, by evaluating the therapeutic effects of SB623 in retinal disease model animals	SB623

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Challenge of “brain regeneration”

Pursue “brain regeneration,” which was considered impossible for 100 years

Santiago Ramón y Cajal

Neuroanatomist

1906 Nobel Prize in Physiology and Medicine

Damaged central nervous system of living mammals does not regenerate
⇒ This became “common sense” for about 100 years thereafter

Prof. Hideyuki Okano

(SanBio Founding Scientist)

Keio University School of Medicine

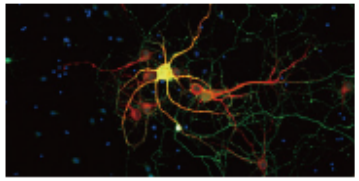
2009 Purple Ribbon award in neuroscience

Discovered that neural stem cells exist in the adult brain in 1998
⇒ Possibility of regeneration

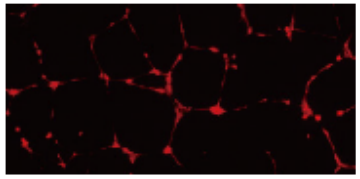
SB623 stimulates the brain's regenerative capability

SB623

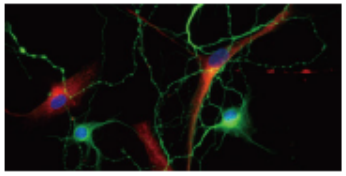
Produced by mass culture of mesenchymal stem cells derived from bone marrow of healthy donor



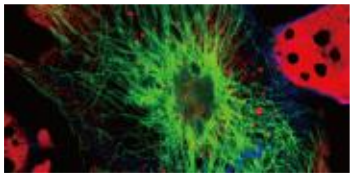
▲Creates nerve cells



▲Creates blood vessels

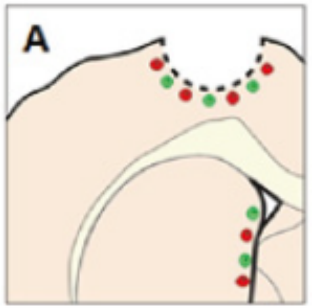


▲Protects nerve cells



▲Reduces inflammation

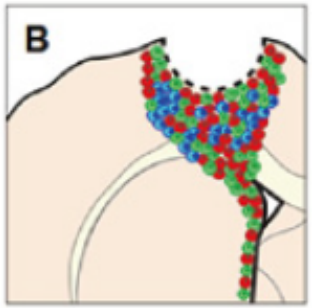
Biobridge



Damage site

X Normally, neural cells can't reach the damage site

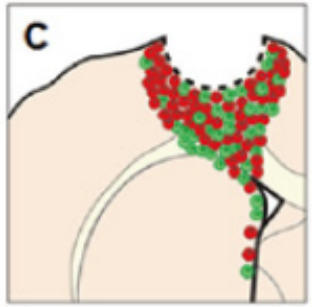
Neural stem cells



Damage site

Transplanting SB623 allows the patient's own neural stem cells to reach the damage site

Neural stem cells



Damage site

The effect persists even if SB623 cells disappear

Neural stem cells

Pursuing central nervous system diseases which represent vast unmet medical needs

Since central nerves do not regenerate…

…these are diseases for which no cure exists

Stroke

Alzheimer's disease

TBI

Parkinson's disease

Unmet Medical Needs

Hemorrhagic

Retinitis Pigmentosa

Spinal cord injury

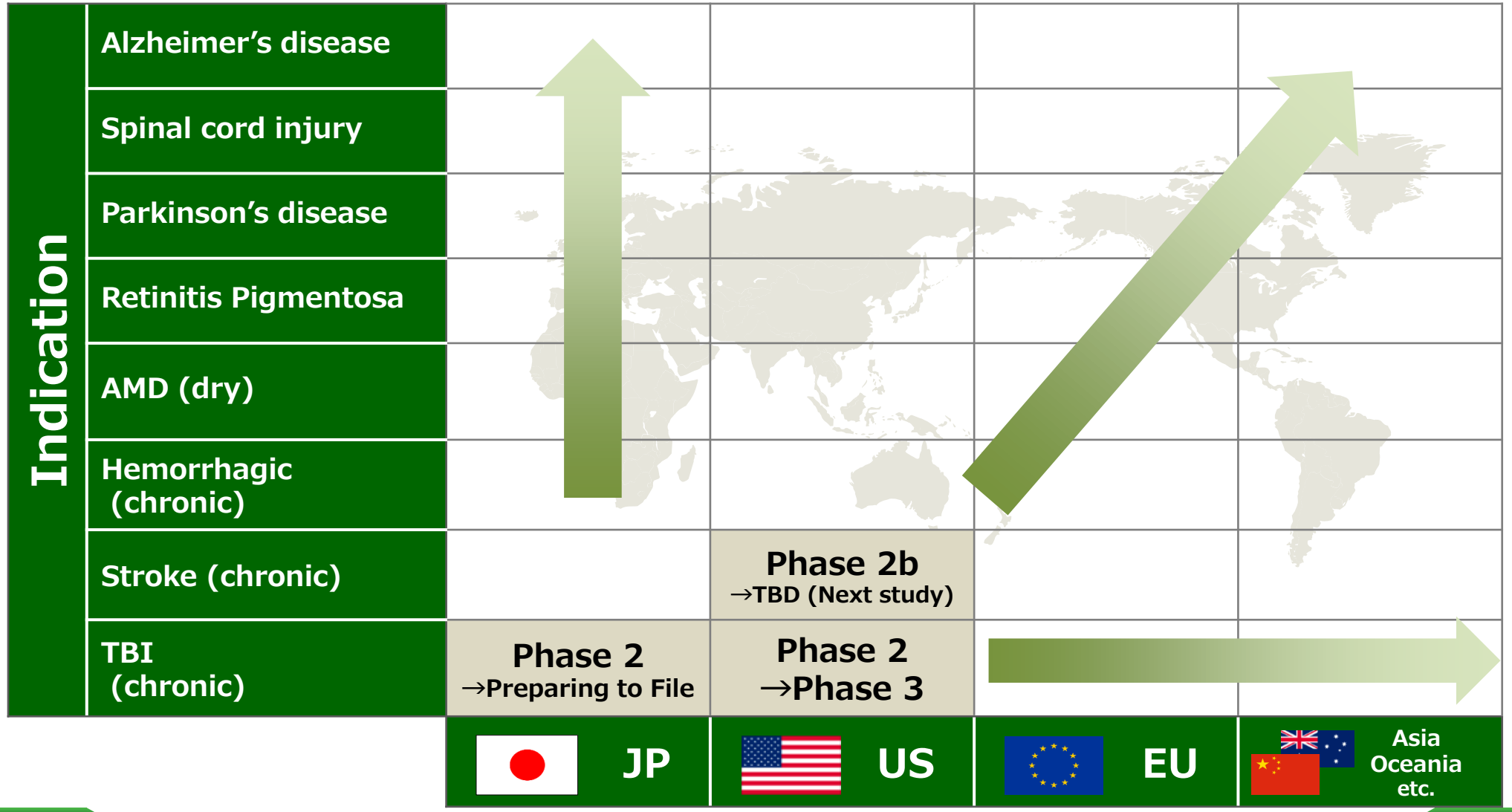
AMD (dry)

Current Indications

Future Indications

Becoming a global leader

Grow by expanding into new indications and geographies



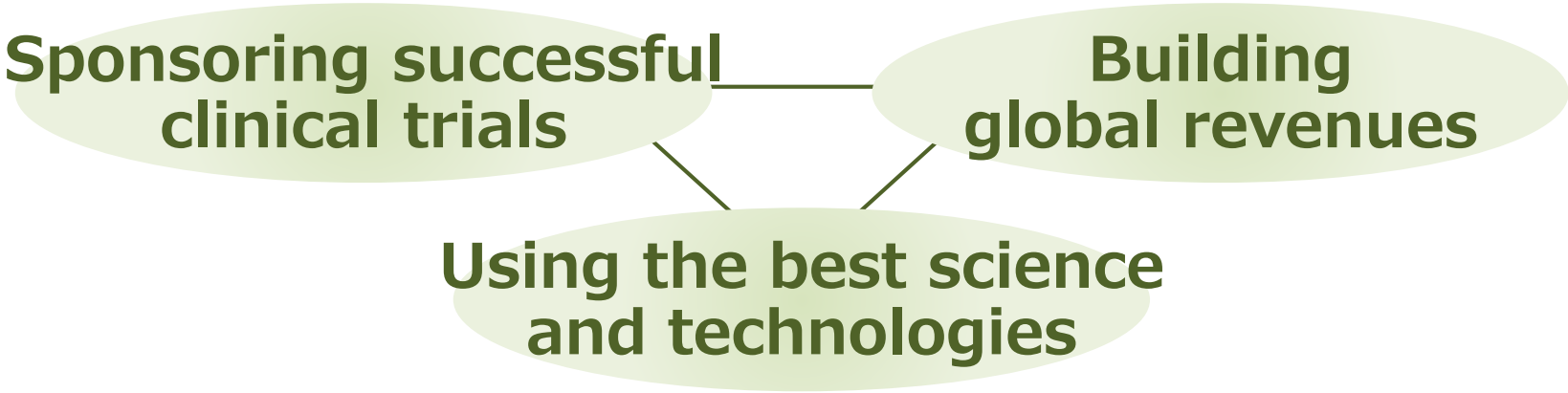
Company Mission and Business Objective

Our Mission Statement

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

Our Business Objective

Achieve global leadership in the regenerative medicine field:



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SanBio
Pioneering Regenerative Medicine