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## Press Release

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April 28, 2023

Sumitomo Pharma Co., Ltd.

### **Sumitomo Pharma Announces Mid-term Business Plan 2027 (FY2023-FY2027)**

Sumitomo Pharma Co., Ltd. (Head Office: Osaka, Japan; Representative Director, President and CEO: Hiroshi Nomura; Securities Code: 4506, Prime Market of TSE) announced today its Mid-term Business Plan 2027 (FY2023-FY2027) as described below.

Sumitomo Pharma (the “Company”) engages in business in accordance with its Corporate Mission: “To broadly contribute to society through value creation based on innovative research and development activities for the betterment of healthcare and fuller lives of people worldwide.”

As humanity is increasingly being challenged by enduring social issues, including an aging society with fewer children and the pandemic, healthcare needs in the Psychiatry & Neurology and Oncology areas are expected to expand continuously. Meanwhile, healthcare needs keep growing sophisticated, urging the Company to address social expectations for solving healthcare challenges by making the most of diverse modalities as it caters to a lifestyle fused digital and real life and people’s values.

Against this backdrop, the Company has drawn up the Mid-term Business Plan 2027, which will guide the Company through the five years commencing in FY2023, based on the following Vision drawn up in FY2019.

#### I. Vision

“For Longer and Healthier Lives.

We unlock the future with cutting-edge technology and ideas”

With a focus on the Psychiatry & Neurology and Oncology as priority disease areas, Sumitomo Pharma Group (the “Group”) will contribute to the betterment of healthcare and fuller lives of people worldwide through diverse approaches, including pharmaceutical products, regenerative medicine/cell therapy, and non-pharmaceutical solutions. In other areas, too, the Group will leverage its assets to deliver value to patients. With this, the Group aims to establish itself as a Global Specialized Player (“GSP”) by 2033.

In order to promote integrated management of the Group, effective July 1, 2023, the system of philosophies shall be reconfigured to coincide with the combination of Group companies in the U.S; Mission, Values, and the Declaration of Conduct shall

collectively constitute a body of philosophies which will be shared and instilled throughout the Group.

The Company also defines the practice of its Mission that contributes to the realization of a sustainable society and leads to the sustained enhancement of its corporate value as “sustainability management.”

Mission (Sumitomo Pharma’s raison d’être and pledge and commitment to society)

To broadly contribute to society through value creation based on innovative research and development activities for the betterment of healthcare and fuller lives of people worldwide

Values (Value to be shared among all officers and employees)

- Patient First
- Always with Integrity
- One Diverse Team

Declaration of Conduct (Norm of action to be observed in the course of daily business)

1. Follow through the global slogan “Innovation today, healthier tomorrows”
2. Pursue trustworthy corporate activities
3. Positively disclose and properly manage information
4. Improve individual capabilities and collaborate with peers
5. Respect human rights
6. Positively address global environmental issues
7. Build harmonious relationships with society

II. Mid-term Business Plan 2027 (FY2023–FY2027)

1. Basic Strategy: Make a “qualitative transformation” of the business structure and business practices

The Company will transform its business structure by working to establish a revenue base that facilitates sustained growth, with a focus on maximizing the value of the three key products, namely, ORGOVYX<sup>®</sup> (therapeutic agent for advanced prostate cancer), MYFEMBREE<sup>®</sup> (therapeutic agent for uterine fibroids), and GEMTESA<sup>®</sup> (therapeutic agent for overactive bladder), and by engaging in research and development designed to bring the Company’s innovations to fruition. In the meantime, the Company will build a foothold for achieving renewed growth after the expiration of the exclusive marketing period for LATUDA<sup>®</sup> (atypical antipsychotic) in the U.S. and for establishing a position as a GSP. At the same time, the Company will take advantage of the combination of its Group companies in the U.S. to reengineer the Group operating structure and increase the flexibility and efficiency of its business foundation.

## 2. Priority Issues

### (1) Strengthening Business Profitability

- In North America, the Company will concentrate its efforts on the early value maximization of the three key products while steadily moving forward with the combination of Group companies in the U.S. to create synergy.
- In Japan, the Company will focus on maximizing the value of priority products and new products to ensure business revenue while strengthening the Regenerative Medicine/Cell Therapy Business and Frontier Business.
- In China & Asia, the Company will expand the product line while maximizing revenue and profit by launching products in more countries/regions.

### (2) Bringing Own Innovations to Fruition

- The Company will accelerate the development of late-stage assets such as ulotaront (product code: SEP-363856) and allogeneic iPS cell-derived dopaminergic neural progenitor cells (product code: DSP-1083), and work to achieve their successful launches.
- The Company will select priority products from among early-stage assets to accelerate in-house development. At the same time, the Company will seek to maximize the value of its pipeline through adequate measures, including partnerships with external parties, and realize appropriate investment allocation.
- In drug discovery, the Company will forge ahead with its translational research and biomarker research and develop modality technologies to further strengthen its highly unique foundation for drug discovery. The Company will also propel data-driven drug discovery to continuously create candidate compounds that focus on clinical conditions.
- The Company will shift the Regenerative Medicine/Cell Therapy Business and Frontier Business into full gear to make them pillars of its earnings during the next Mid-term Business Plan period beginning from FY2028.
- The Company will promote research and development of drugs to treat antimicrobial resistant bacterial infections and vaccines through partnerships with outside institutions, thus contributing to global health.

### (3) Strengthening Group Governance

- The Company will take advantage of the combination of its Group companies in the U.S. to reengineer the Group operating structure and set about building a management structure that allows the Company to make prompt business decisions optimized for the Group.

### (4) Accelerating Digital Transformation (DX)

- The Company will innovate its organization into one where all of its employees make maximal use of its digital platforms (DrugOME and Digital Innovation) and, following data-driven decisions, make continued autonomous efforts to innovate operations and create value.

### (5) Instilling Corporate Culture and Implementing HR Strategies

- The Company will promote integrated management of the Group through the instillation of the philosophies. The Company will also set about building a global HR management foundation in order to create an HR portfolio that allows members of the Group to work together closely and achieve goals as one.

## 3. Business Goals

### (1) Financial Goals

PL/CF	FY2023	FY2024-FY2027
Revenue	¥362 billion	CAGR 12% or higher (Base year: FY2023)
Core operating profit	¥(62) billion	¥192 billion or higher (For four-year total)
Operating cash flow	¥(130) billion	¥270 billion or higher (For four-year total)
ROIC	(8.5)%	6.5% or higher (For four-year total)
ROE	(21.9)%	8% or higher (For four-year total)

BS	At the end of FY2027
Net D/E ratio	0.5 or lower
Interest-bearing liabilities	¥200 billion or lower
Ratio of equity attributable to owners of the parent to total assets	40% or higher

Forex assumptions: USD1 = JPY130, RMB1 = JPY19.5

All financial goals above are after adjusting for the probability of success.

CAGR: Compound Annual Growth Rate

ROIC = (Core operating profit – Income taxes) / (Equity + Interest-bearing liabilities)

### (2) Long-term ROE Goal

- The Company will aim for an ROE of 10% during the period of the next Mid-term Business Plan starting in FY2028.

### (3) Dividend Policy

- The Company believes it important to distribute surpluses in an appropriate manner reflecting any improvement in its performance. Accordingly, a performance-linked dividend hike will be considered in addition to consistent dividend payout.
- Pursuant to this fundamental policy, during the Mid-term Business Plan 2027 period (FY2023-FY2027), the Company will suspend dividends as negative

core operating profit is forecasted for FY2023 but will resume dividends for FY2024 as core operating profit is expected to return to positive. A consistent dividend payout will be the aim thereafter.

(4) Investment Policy

- Research and development investments in the Company's assets will be prioritized. Resources will be allocated to M&As and in-licensing as well, so long as they do not significantly effect the achievement of financial goals.

For more details, please refer to the attached presentation material.

Disclaimer Regarding Forward-looking Statements

The statements made in this press release contain forward-looking statements based on management's assumptions and beliefs in light of information available as of the day of this release, which involve both known and unknown risks and uncertainties. Actual results of those matters covered in the forward-looking statements including financial forecast may differ materially from those contained in this release, due to a number of factors.

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# Mid-term Business Plan 2027

**Hiroshi Nomura**  
Representative Director,  
President and CEO

**Sumitomo Pharma Co., Ltd.**

**April 28, 2023**

## Disclaimer Regarding Forward-looking Statements

- This material contains forecasts, projections, goals, plans, and other forward-looking statements regarding the Group's financial results and other data. Such forward-looking statements are based on the Company's assumptions, estimates, outlook, and other judgments made in light of information available at the time of preparation of such statements and involve both known and unknown risks and uncertainties.
- Accordingly, forecasts, plans, goals, and other statements may not be realized as described, and actual financial results, success/failure or progress of development, and other projections may differ materially from those presented herein.
- Information concerning pharmaceuticals and medical devices (including compounds under development) contained herein is not intended as advertising or as medical advice.

## Agenda of Mid-term Business Plan (MTBP) 2027 Presentation

»»» Mission and Vision

»»» Review of MTBP 2022

»»» MTBP 2027





# Mission and Vision

## Mission of Sumitomo Pharma<sup>\*1</sup>

**To broadly contribute to society through value creation based on  
innovative research and development activities  
for the betterment of healthcare and fuller lives of people worldwide**

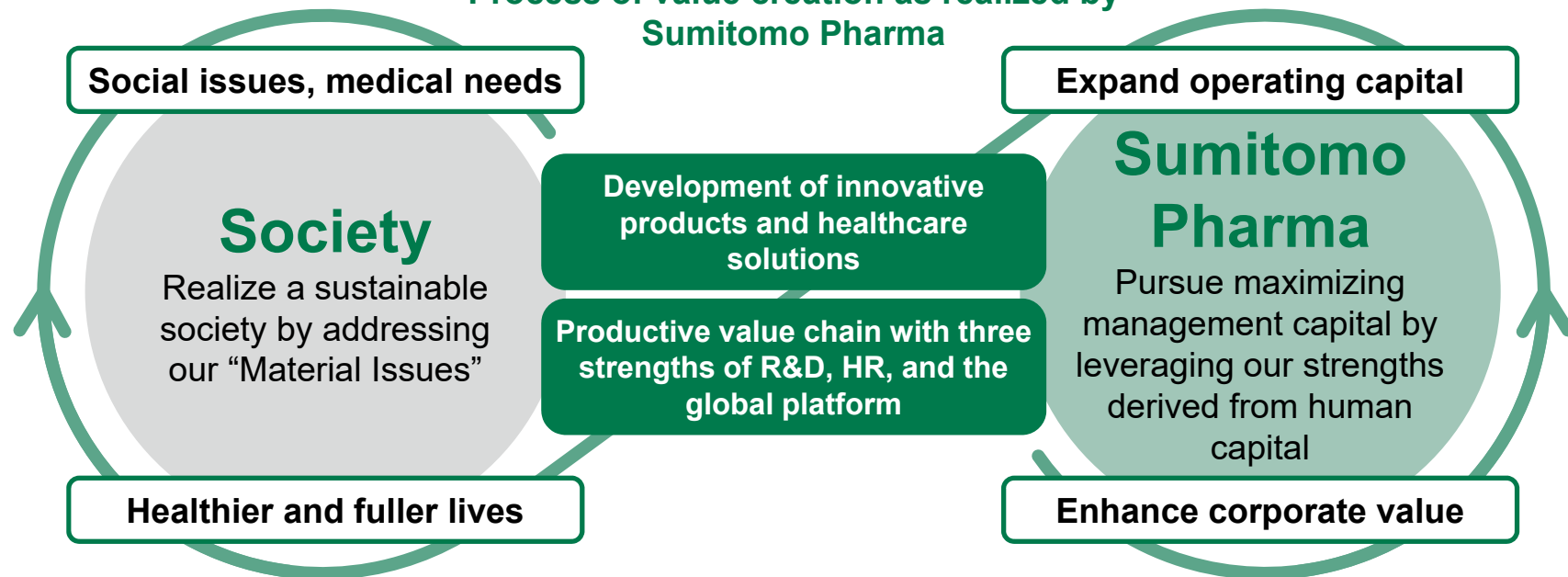
# Sumitomo Pharma's Value Creation Process

Maximize corporate value by contributing to the betterment of healthcare and fuller lives of people worldwide, thus realizing greater social sustainability

## SDGs addressed by Sumitomo Pharma



## Process of value creation as realized by Sumitomo Pharma



## Sumitomo Pharma's Material Issues

“Development of innovative products and healthcare solutions” has been identified as the most important material issue in terms of “expectations from society” and “impact on corporate value enhancement”

<b>Expectations from society</b>	Very large	<ul style="list-style-type: none"> <li>• Stable supply of high-quality pharmaceutical products</li> <li>• Provision of high-quality product information and promotion of proper use</li> <li>• Improving access to medicines and advocacy</li> </ul>	<ul style="list-style-type: none"> <li>• Development of innovative products and healthcare solutions</li> </ul>	
		<ul style="list-style-type: none"> <li>• Respect for human rights</li> <li>• Promotion of environmental initiatives</li> <li>• Enhancement of corporate governance</li> <li>• Strengthening of risk management</li> <li>• Pursuing compliance</li> </ul>	<ul style="list-style-type: none"> <li>• Expansion of human capital and instillment of corporate culture</li> </ul>	
	Large			
	Large	<b>Impact on corporate value enhancement</b>		Very large

# Sumitomo Pharma's Responses to Social Issues and Changes in the External Environment

## Our initiatives

### Development of innovative products and healthcare solutions

Development of innovative pharmaceutical products in the Psychiatry & Neurology and Oncology areas, where the therapeutic effect of drugs is relatively low

Provide new treatment options using diverse modalities such as the Regenerative Medicine/Cell Therapy and non-pharmaceutical solutions (Frontier Business)

Relieving the burden on not only patients but their families and caregivers and improvement of social productivity

## Social issues and changes in the external environment

### Declining birthrate and aging population

- Healthcare needs expanding in the Psychiatry & Neurology and Oncology areas

### Pandemic and conflicts

- More patients in the Psychiatry & Neurology area
- Unstable supply of pharmaceutical products

### Advanced healthcare needs and diversifying modalities

- Clarification of disease mechanisms and enhancement of preventive and interventional measures

### Penetration of value based healthcare

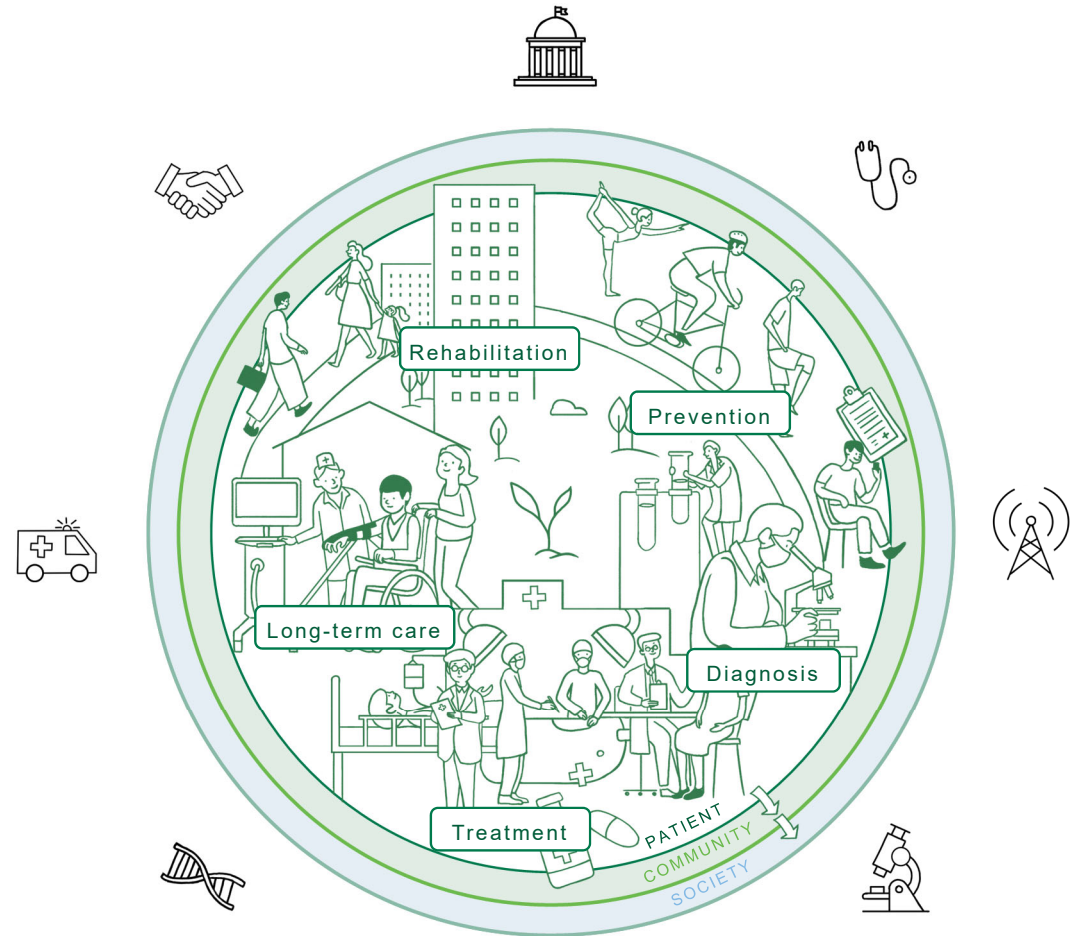
- Sustainable social security

### Lifestyle fused digital and real life, and diversifying values

- Patients' participation in treatment, increase in health management consciousness

# Vision

**For Longer and Healthier Lives**  
**We unlock the future with**  
**cutting-edge technology and ideas**

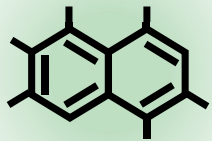


 **Sumitomo Pharma**

# A Global Specialized Player (GSP) as Envisioned by Sumitomo Pharma

Psychiatry & Neurology and Oncology as Priority Disease Areas, contribute to the betterment of healthcare and fuller lives of people worldwide through diverse approaches (pharmaceutical products, regenerative medicine/cell therapy, and non-pharmaceutical solutions), thus establishing a unique position globally

## Small molecule



Molecular design/synthesis based on accumulated experience/know-how

## Regenerative medicine/cell therapy



Know-how acquired by pioneering initiatives



## Non-pharmaceutical (Frontier)

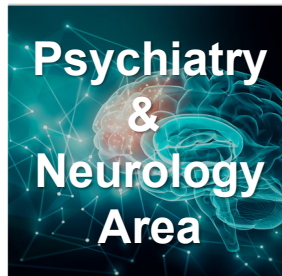


To be developed in the mental resilience area

## Other modalities



Pursuit of optimal modalities



## Psychiatry & Neurology Area

### Diverse approaches to innovate the conventional treatment system

- Our core area
- Accumulated data, experience, and know-how



## Oncology Area

### Distinguished products to innovate standard treatment

- Carefully selected R&D pipeline
- Unique fundamentals for drug discovery



## Other Areas

### Deliver value to patients by leveraging our assets

- Women's health issues, urological diseases, diabetes
- Rare diseases, infectious diseases



# Review of MTBP 2022



## Mid-term Business Plan (MTBP) 2022 in Review

- ✓ Acquired medium- to long-term growth drivers and launched the Regenerative Medicine/Cell Therapy Business and Frontier Business
- ✓ From now on, we will shift to a profit structure through in-house created products and build a business structure that responds to changes

### Establishment of Growth Engine

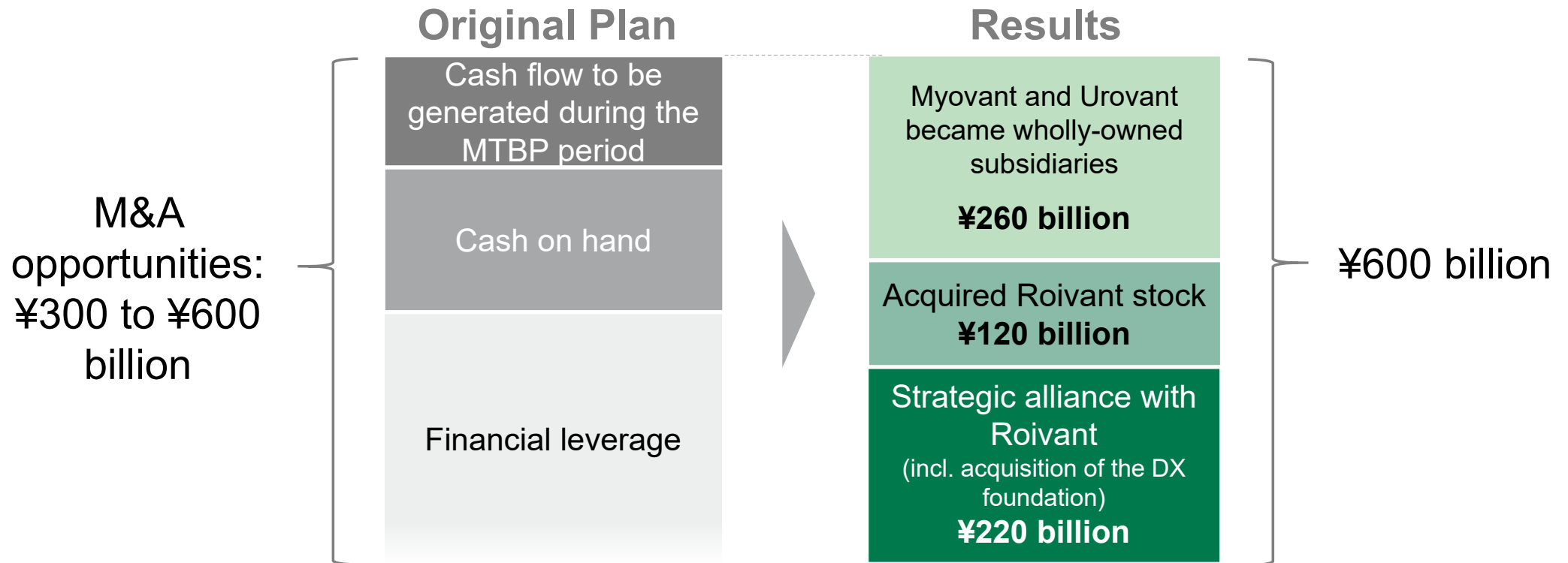
- ◆ **Acquired ORGOVYX<sup>®</sup>, MYFEMBREE<sup>®</sup>, and GEMTESA<sup>®</sup>**  
Strategic alliance with Roivant Sciences Ltd.  
Upfront investment for early recording of sales
- ◆ **Obtained POC for ulotaront and SEP-4199**  
Strategic alliance with Otsuka Pharmaceutical Co., Ltd.
- ◆ **Expanded early pipeline**
- ◆ **Launched new businesses**  
(Regenerative Medicine/Cell Therapy Business and Frontier Business)
- ◆ **Shifted regional strategies**  
(Sold European Business, strengthened the business structure in China & Asia )
- ◆ **Extended LATUDA<sup>®</sup>'s exclusive marketing period by patent strategies**
- ◆ **Revised new product sales forecasts downward**  
KYNMOBI<sup>®</sup>, LONHALA<sup>®</sup> MAGNAIR<sup>®</sup>
- ◆ **Discontinued late-stage development of potential blockbusters**  
napabucasin, alvocidib, DSP-7888, dasotraline

### Building of Flexible and Efficient Organization

- ◆ **Work/compensation systems designed to accelerate the principles of self-discipline, delivering results, and taking on challenges**
- ◆ **Further instilled CHANTO**
- ◆ **Acquired the digital technology foundation**  
DrugOME / Digital Innovation
- ◆ **Sold non-core assets**
- ◆ **Expanded the business foundation in North America in pursuit of business optimization, but the NA business structure became complicated as a result**

## Investment Record

Enabled investment of ¥300 to ¥600 billion for M&As, formed a strategic alliance with Roivant, and made Myovant Sciences (“Myovant”) and Urovant Sciences (“Urovant”) into wholly-owned subsidiaries, thus acquiring three key products\*1 and the foundation for DX (digital transformation)



## MTBP 2022: Goals and Results

- ✓ Despite growth in key products, revenue did not meet the original expectations
- ✓ ROIC and ROE managed to meet the revised goals levels for five-year total, but both ROIC and ROE in the last year turned negative due to impairment loss on intangible assets

	Original Goals (April 2019)	Revised Goals (May 2021, Revised MTBP)	FY2022 Forecasts
Revenue	¥600 billion	¥600 billion	¥555.5 billion
Core operating profit	¥120 billion	¥60 billion	¥16.4 billion
ROIC	10 %	3 %	(3.9)% (2.5% for the 5-year period)
ROE	12 %	3 %	(14.7)% (4.8% for the 5-year period)
Payout ratio	≥20%	≥20%	41.4% (5-year period)
Exchange rate (to the U.S. dollar)	¥110	¥110	¥135.5



# MTBP 2027

# MTBP 2027 Basic Strategy

## Make a “qualitative transformation” of the business structure and business practices

Achieve renewed growth from the “LATUDA® Cliff” and build a foothold for becoming a GSP



“Qualitative transformation”



### Establish a revenue base facilitating sustained growth

Priority Issue 1

- Maximize value of the three key products\*<sup>1</sup> early
- Optimize management resource allocation



### Bring own innovations to fruition

Priority Issue 2

- Launch late-stage development products early
- Develop late-stage products that will underpin the Group’s revenue in the 2030s by accelerating the late-stage development of prioritized products from early-stage development
- Full scale launch of the Regenerative Medicine/Cell Therapy Business and the Frontier Business



### Change to a flexible and efficient business foundation

Priority Issue 3

- Realize integrated management for the Group by reorganizing the global business structure

Priority Issue 4

- Review the cost structure, accelerate DX

Priority Issue 5

- Further instill corporate culture, implement HR strategies

## Financial Goals and Dividend Policy (1)

		MTBP 2022	MTBP 2027	
		5-year total	FY2023	FY2024-FY2027
PL/ CF	Revenue	CAGR 3.5%	¥362 billion	CAGR 12% or higher (Base year: FY2023)
	Core operating profit	¥293.7 billion	¥(62) billion	¥192 billion or higher (For four-year total)
	Operating cash flow	¥273.6 billion	¥(130) billion	¥270 billion or higher (For four-year total)
	ROIC	2.5%	(8.5)%	6.5% or higher (For four-year total)
	ROE	4.8%	(21.9)%	8% or higher (For four-year total)
FX rates	USD (5-year average)	¥115	¥130	
	RMB(5-year average)	¥17.0	¥19.5	

※All financial goals above are after adjusting for the probability of success

CAGR : Compound Annual Growth Rate

ROIC: (Core operating profit – Income taxes) / (Equity + Interest-bearing liabilities)

### Long-term ROE goals:

Aim for ROE of 10% during the next MTBP starting in FY2028

## Financial Goals and Dividend Policy (2)

		At the end of FY2022	At the end of FY2027
BS	Net D/E ratio	0.60	0.5 or lower
	Interest-bearing liabilities	¥334.7 billion	¥200 billion or lower
	Ratio of equity attributable to owners of the parent to total assets	35.8%	40% or higher

※ All financial goals above are after adjusting for the probability of success

### Dividend policy:

In FY2023, the policy is to not pay the dividend as core operating profit is expected to be in the red.

In FY2024, as core operating profit returns to the black, we will resume the dividend, after which we will aim for a consistent dividend payout

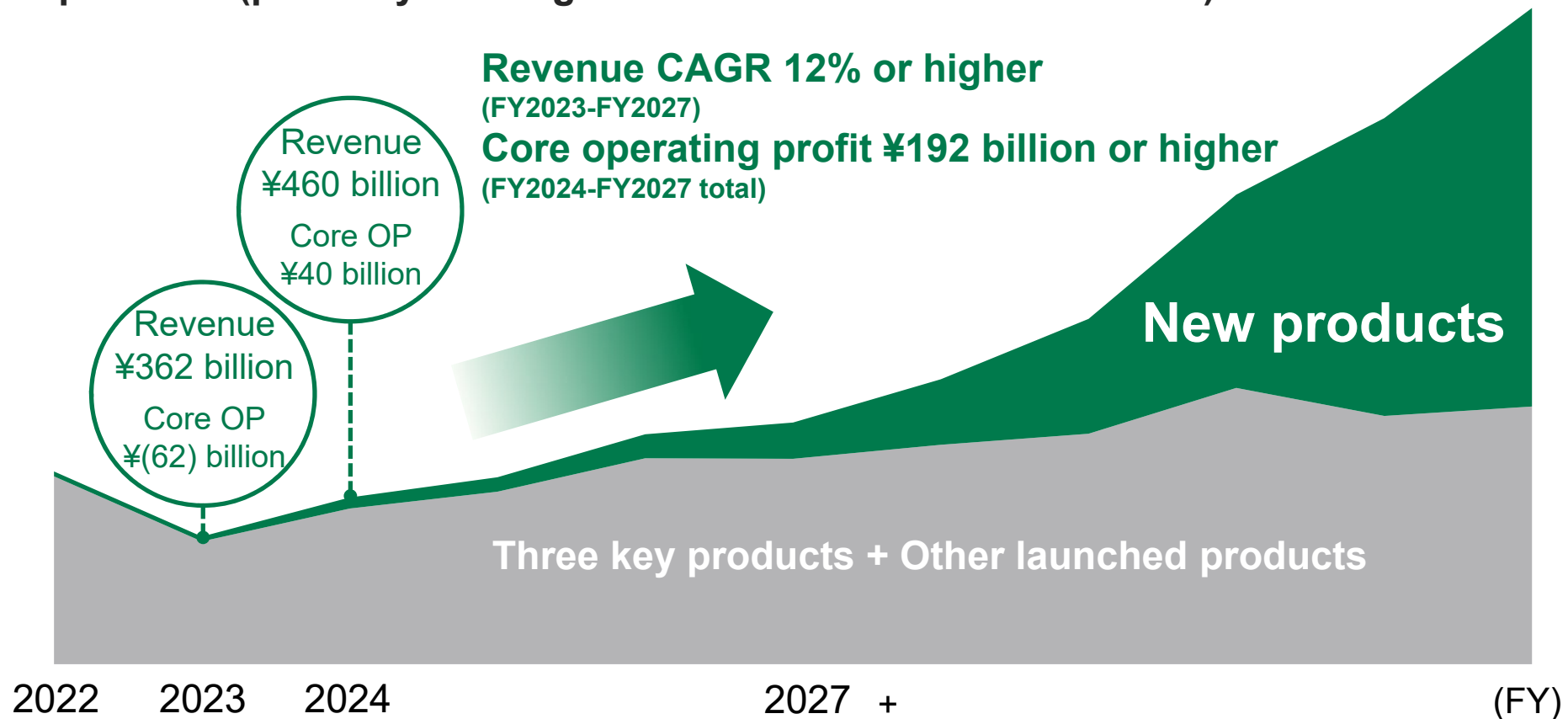
### Investment policy:

R&D investments in own assets will be prioritized.

Resources will be allocated to M&As and in-licensing as well, so long as they do not significantly effect achievement of financial goals

## Renewed Growth Imagined\*1

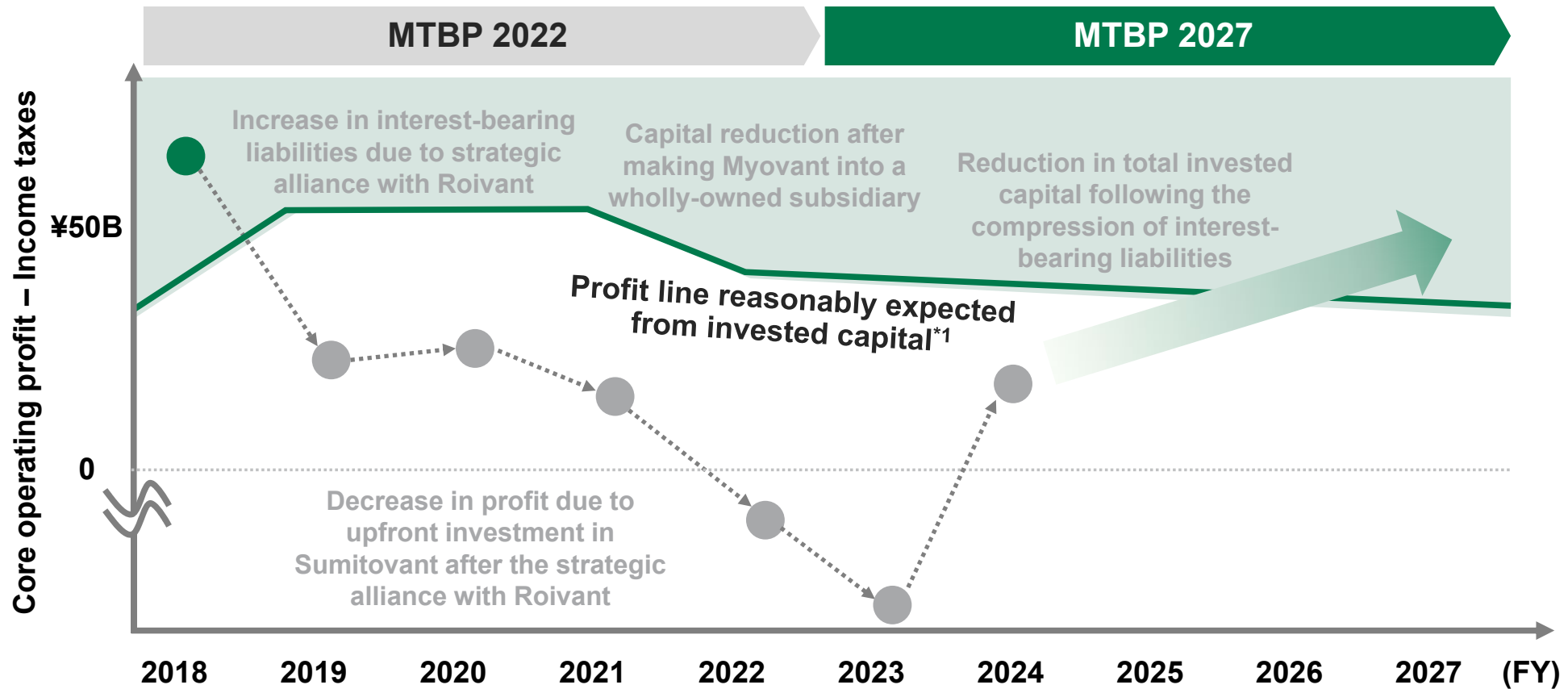
Establish a mid-term revenue base with the three key products and aim for renewed growth with new products (primarily existing Sumitomo Pharma owned assets)





## Invested Capital and Return on Capital

For the four-year period from FY2024, we will seek to secure a level of profit reasonably expected from invested capital and then aim to post a higher profit level during the next Mid-term Business Plan starting from FY2028



\*1. The profit line reasonably required from invested capital (capital + interest-bearing liabilities) is set to be "invested capital x 6.5%" (weighted average cost of capital)

## Priority Issues for the MTBP 2027

- 1 Strengthening Business Profitability**
- 2 Bringing Own Innovations to Fruition
- 3 Strengthening Group Governance
- 4 Accelerating Digital Transformation (DX)
- 5 Instilling Corporate Culture and Implementing HR Strategies

## Strengthening Business Profitability

# Reinvention of the North American Business Structure

Consolidated multiple NA subsidiaries, which had pursued optimization of their business in their respective areas, into a new company

## Sumitomo Pharma America, Inc.

Sumitomo Pharma's wholly-owned subsidiaries (indirectly held)  
 Total headcount: Approx. 1,800  
 Locations: Cambridge, West Coast, etc.



R&D in  
 Psychiatry &  
 Neurology area  
 (12 pipeline products  
 including ulotaront under  
 development)



Development  
 in the rare  
 diseases area  
 (rodatristat ethyl and  
 SP-101 under  
 development)

R&D in the  
 Oncology area  
 (5 pipeline products  
 including TP-3654  
 under development)

Management of  
 Group companies

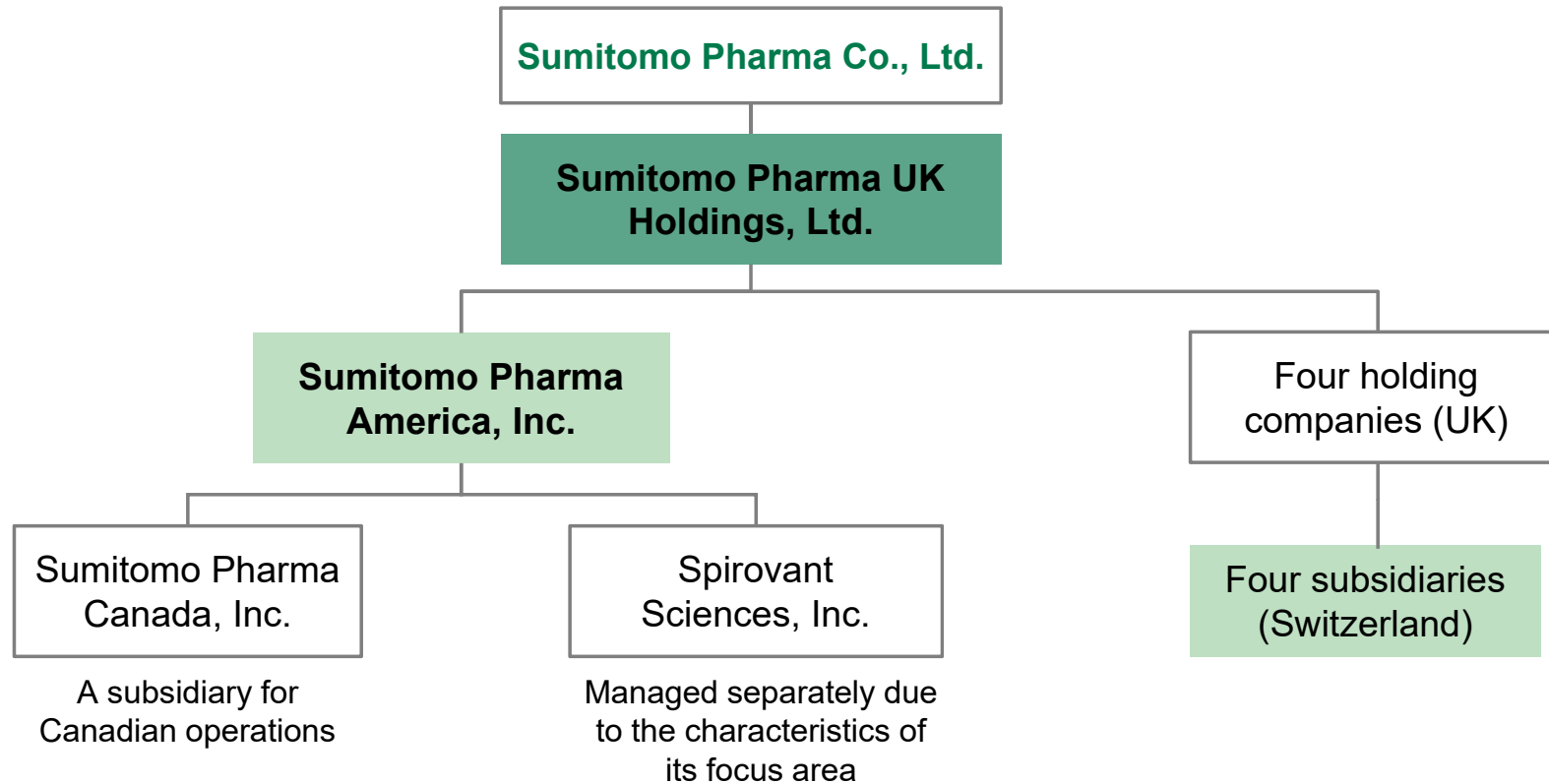
Owns proprietary  
 computing and  
 data platforms  
 ✓ DrugOME  
 ✓ Digital Innovation

Shared  
 service

## Strengthening Business Profitability

# Organizational Structure of the Key Group Companies for the NA Operations

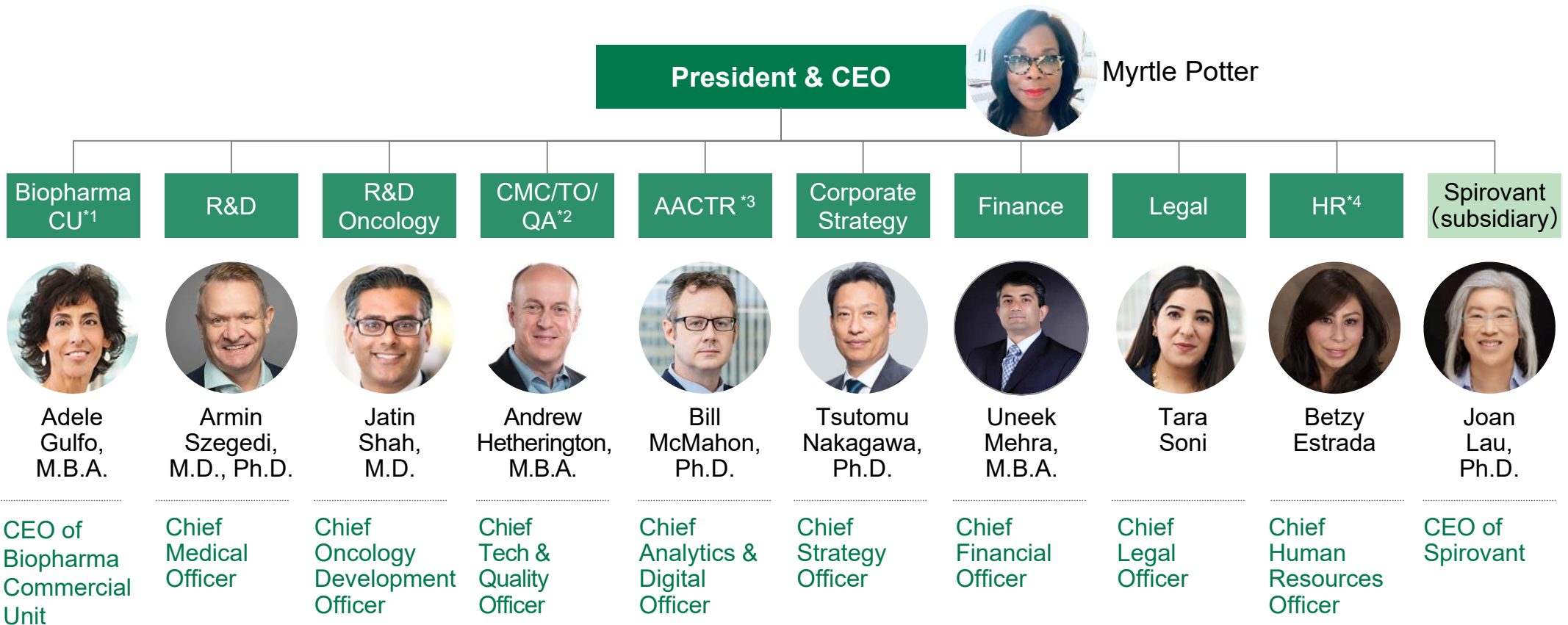
- ✓ Consolidated operational organizations for the NA operations (Sumitomo Pharma America, Inc.)
- ✓ Sumitomo Pharma Directors assume a concurrent directorship at Sumitomo Pharma UK Holdings, Ltd., which is in charge of corporate governance
- ✓ The current framework for intellectual property, which is under the management of Group companies in Switzerland, will be maintained



# Strengthening Business Profitability

## Leadership Team of the North America Operating Company

- ✓ Business of products is managed by top human resource with proven track records
- ✓ Appointed Chief Analytics & Digital Officer, who is responsible for spreading proprietary data utilization technology throughout the Sumitomo Pharma Group



\*1. Commercial Unit, \*2. Chemistry, Manufacturing and Control / Technical Operations / Quality Assurance,

\*3. Advanced Analytics Computational Technology & Research, \*4. Human Resource

## Strengthening Business Profitability

# Further Strengthening of Competitive Advantages in North America

Sumitomo Pharma America with the scale and capabilities to further consolidate the business foundation in NA

### NA to form one team



Integrate corporate philosophies and cultures unique to each entity under the Sumitomo Pharma Group brand and share business objectives

### Lean operating structure

Maximize value of the three key products by Biopharma CU\*1

- ✓ Relugolix (ORGOVYX®, MYFEMBREE®)
- ✓ Vibegron (GEMTESA®)



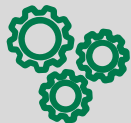
Bringing together top talents to promote R&D  
Make the most of shared functions to realize optimized resource allocation and cost synergy

- ✓ Establish a strategy unit to realize prompt and optimized operations for the Group

### Proprietary data utilization technology to accelerate business and R&D

Advanced analytics teams established within the new company

- ✓ DrugOME (AI, data, and advanced computing ecosystem)
- ✓ Digital Innovation (tailor-made digital platform)



### Solid Growth

~ \$ 1,600<sub>M</sub>

FY2023 revenue forecast

~ \$ 400<sub>M</sub>

Cost synergy



### Expanded pipeline

Approx. 30 clinical studies are currently underway in the Psychiatry & Neurology area, Oncology area, and Other areas

# Strengthening Business Profitability

## Relugolix

Aiming for “Double Blockbusters” by spreading the word about advantages of oral GnRH\*1 agents

Strategy for value maximization

**Biopharma CU\*2 to aggressively expand the GnRH\*1 market**

**Once-daily oral  
GnRH\*1 receptor antagonist**

**ORGOVYX®** Advanced prostate cancer

- Aiming to establish a position of a standard medication for androgen deprivation therapy (used at initial stages)

**Myfembree®** Uterine fibroids,  
endometriosis

- Simple dosing/administration
- Acts without hormonal surge
- Expected to be safe enough to be administered over a long period (24 months or longer)



### Establish a position by gathering new evidence

- Verify efficacy/safety of combination therapy (ORGOVYX®)
- Verify cardiovascular event risks (ORGOVYX®)
- Verify safety during long-term administration (MYFEMBREE®)



### Further strengthen information provision activities

- Provide consistent commercial/medical information from a full-time team
- Apply data analytics approach (successful for the GEMTESA® business) to the relugolix business (Led by the Advanced Analytics teams)



### Facilitate collaborations

- Increase awareness in cooperation with Pfizer, which has a complementary product line
- Branch out to other regions through alliances (Gedeon Richter, Accord)

## Strengthening Business Profitability

### GEMTESA®

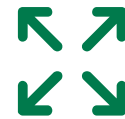
Establish the leading position in the  $\beta 3$  class agonist market to make it a blockbuster

Once-daily oral  $\beta 3$  adrenergic receptor agonist effective for all three major symptoms\*<sup>1</sup>

  
**GEMTESA®** Overactive bladder (OAB)  
(vibegron) 75 mg tablets

- Established evidence for the efficacy against urgency, as well as urge urinary incontinence and urinary frequency
- Hypertensives and elderly patients should find it easy to use as it hardly risks blood pressure increase
- Does not require dose adjustment
- Covered Approx. 90% of Medicare Part D coverage and approx. 60% of commercial coverage

Strategy for value maximization  
**Biopharma CU\*<sup>2</sup> aggressively expands share in the OAB market**



#### Increase the number of indications and market

- Additional indications for OAB+BPH\*<sup>3</sup> (submission scheduled for 2H FY2023)
- Expand to EU (through alliance with Pierre Fabre)
- Expand to other regions (Canada, China, etc.)



#### Gain share in anticipation of the OAB market trends

- Maximize share in the market with the expiration of exclusive marketing period of competing products in mind



#### Further strengthen commercial activities

- Generate sales synergy with relugolix (Urology)
- Strengthen Primary care physician sales
- Conduct data-based marketing activities (Led by the Advanced Analytics teams)



# Strengthening Business Profitability

## Japan Business

Increase adaptability to change and make attempts at new businesses

By changing the product mix and adapting to healthcare policies

### Ensure business revenue in priority areas

#### 1 Maximize value of priority products\*1 and new products

- Maximize product value by leveraging strong sales/marketing base and relations
- Launch new products and expand indications in the Psychiatry & Neurology area and Oncology area
- Increase customer satisfaction by providing information via omni-channels, conduct evidence-based medical activities

#### 2 Strengthen the Regenerative Medicine/Cell Therapy Business and Frontier Business

- Launch products for the Regenerative Medicine/Cell Therapy Business, commence/expand sales in the Frontier Business
- Transform the business structure and enhance competitive advantages

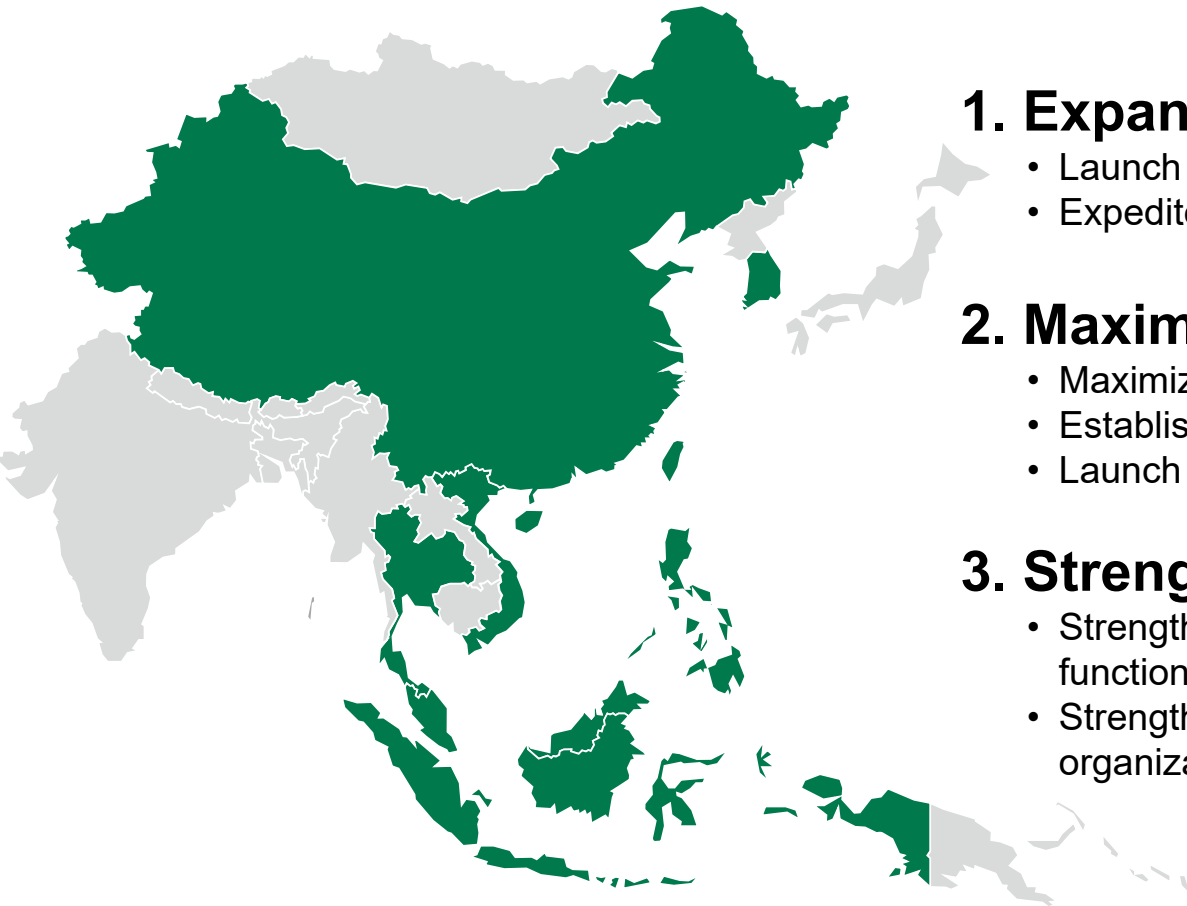
#### 3 Manage business while keeping pace with change

- Shift to an efficient structure commensurate with the business scale and product mix
- Utilize digital technology to change behavior and increase productivity
- Strategic in-licensing and alliances

## Strengthening Business Profitability

### China & Asia Business

Make continued investments in the Asia region to establish a firm profit base, while responding to changes in the business environment



#### 1. Expand the product line

- Launch lefamulin (China)
- Expedite development of vibegron\*<sup>1</sup> (China & Asia)

#### 2. Maximize profit from launched products

- Maximize profits from the MEROPEN<sup>®</sup> business (China & Asia)
- Establish a hybrid sales system using CSO\*<sup>2</sup> (China)
- Launch LATUDA<sup>®</sup> in more countries/regions (Malaysia, etc.)

#### 3. Strengthen the organizational foundation

- Strengthen collaborations with global development/production functions (China)
- Strengthen the corporate governance function, optimize organizational management (Asia)

## Priority Issues for the MTBP 2027

- 1 Strengthening Business Profitability
- 2 Bringing Own Innovations to Fruition**
- 3 Strengthening Group Governance
- 4 Accelerating Digital Transformation (DX)
- 5 Instilling Corporate Culture and Implementing HR Strategies

## Bringing Own Innovations to Fruition

Tap into expertise, strengths, and assets built up so far to boost business performance, thus realizing renewed growth over the mid- and long-term

- Achieve successful launches of late-stage assets
- Select priority products from among early-stage assets and bring them to later phases
- Create a distinguished pipeline
- Full-scale launch of the Regenerative Medicine/Cell Therapy Business and Frontier Business
- Initiatives in the infectious diseases area



**Ensure that these initiatives come to fruition and begin boosting business performance**

# Bringing Own Innovations to Fruition

## Product Launch Target (April, 2023)

■ Psychiatry & Neurology 
 ■ Oncology 
 ■ Others

	FY2023	FY2024	FY2025	FY2026	FY2027	
<b>ulotaront</b> (TAAR1 agonist)		<b>Schizophrenia</b> 			<b>Schizophrenia</b> 	Expand indications
<b>Allogeneic iPS cell-derived dopaminergic neural progenitor cells (DSP-1083)</b>		<b>Parkinson's disease</b> 				Development in the U.S.
<b>Allogeneic iPS cell-derived retinal pigment epithelial cells (HLCR011)</b>			<b>Retinal pigment epithelium tear<sup>*1</sup></b> 			Expand indications
<b>DSP-5336</b> (menin and MLL inhibitor)				<b>Acute myeloid leukemia<sup>*2</sup></b> 	<b>Acute myeloid leukemia</b> 	Expand indications
<b>TP-3654</b> (PIM kinases inhibitor)					<b>Myelofibrosis</b> 	Expand sales countries
<b>GEMTESA®</b> (β3-adrenergic receptor agonist)			<b>Overactive bladder with BPH</b> 		<b>Overactive bladder</b> 	
<b>rodatristat ethyl</b> (tryptophan hydroxylase inhibitor)					<b>Pulmonary arterial hypertension</b> 	
<b>lefamulin</b> (antimicrobial agent of pleuromutilin class)		<b>Bacterial community-acquired pneumonia</b> 				

\*1. Launch schedule is based on our goal pending agreement with partners,

\*2. Premise to utilize an application of accelerated approval program (Plan to consult with the FDA)

# Bringing Own Innovations to Fruition

## Ulotaront

Deliver new treatment options that will innovate standard of care in the Psychiatry area

### Target indications

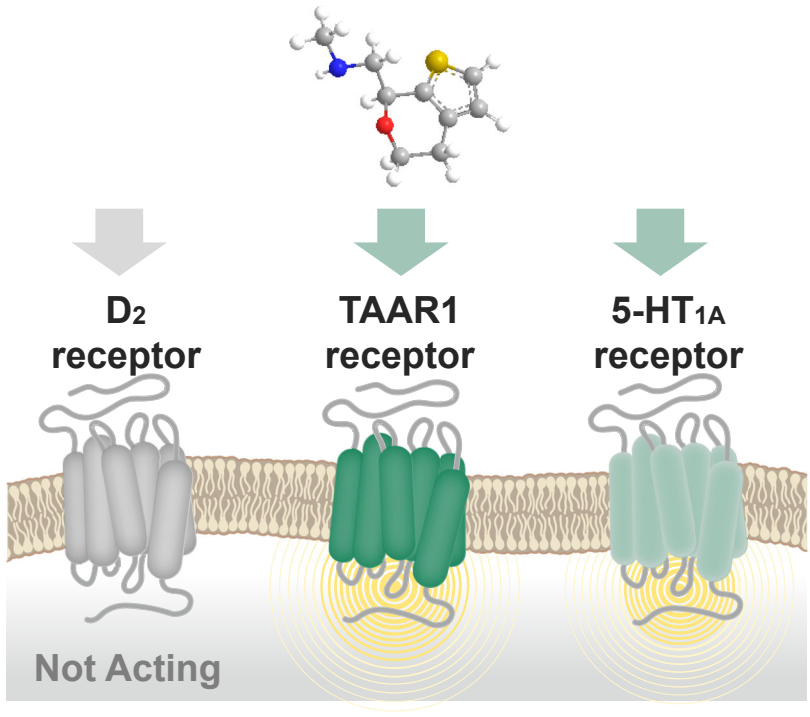
- First indication: Schizophrenia
- Second and third indications: adjunctive Major Depressive Disorder (aMDD), Generalized Anxiety Disorder (GAD)

### Features of the developing compound

- Novel mechanism of action on TAAR1 and 5-HT<sub>1A</sub> receptors (not on dopamine D<sub>2</sub> receptors)
- Potentially fewer extrapyramidal symptoms and metabolic side effects such as weight gain
- Potentially highly effective with positive and negative symptoms
- Aim to achieve early launch and additional indications through joint development with Otsuka Pharmaceutical

### Target timing of launch

- Schizophrenia (  FY2024 ,  FY2027)  
*Outcome of Phase 3 studies (DIAMOND 1 and 2) to be out in 1H FY2023*
- aMDD (under consideration)
- GAD (under consideration)



**With multiple indications, ulotaront is expected to be a blockbuster, with potentially topping LATUDA<sup>®</sup>**

## Bringing Own Innovations to Fruition

# DSP-1083: Allogeneic iPS Cell-Derived Dopamine Neural Progenitor Cells

An innovative treatment option that extends healthy life expectancy by winding back clinical conditions of Parkinson's disease patients



### Target indications

- Parkinson's disease

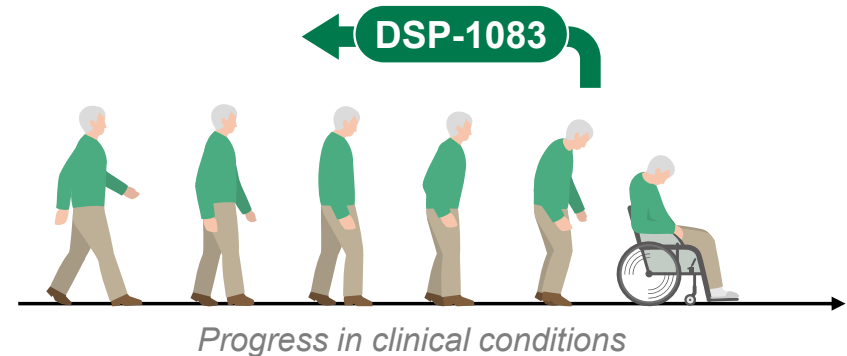
### Features of the developing compound

- High-purity iPS cell-derived dopamine neural progenitor cells
- Evidence of efficacy for cell transplantation
  - Long-term efficacy with embryonic cells\*1
  - Concern of side effects by foreign substances overcome with iPS cells
- Highly efficient cell production realized
  - Concentrate our manufacturing technology and innovative equipment at SMaRT<sup>2</sup>

### Target timing of launch

-  • Investigator-initiated clinical trial underway at Kyoto University Hospital  
Launch scheduled for FY2024 (designated as a "SAKIGAKE")
-  • Clinical study to start in FY2023

Wind back progression of clinical conditions to contribute to longer healthy life expectancy



Expected to be a blockbuster in the 2030s

## Bringing Own Innovations to Fruition

### Oncology Area: TP-3654, DSP-5336

Select pipelines carefully and continue to take on the challenge of creating products with special features

Concentrate resources on TP-3654 and DSP-5336 to launch them early and maximize their value

- Conduct clinical studies in more countries/regions
- Build a stronger relationship with investigators and key opinion leaders
- Early examination and action for expanding lines of therapy and indications

#### TP-3654 (Myelofibrosis)

##### Key features

1. Possibly prevents bone marrow from becoming fibrotic (root cause of the disease)
2. Possibly can be administered to a group of patients with a low platelet count (unmet need of the disease)
3. Possibly contribute to a broad patient group when used in combination with drugs with a different mechanism of action

Target timing of launch: FY2027(🇺🇸)

#### DSP-5336 (Acute myeloid leukemia)

##### Key features

1. Born out of the industry-university collaboration program with Kyoto University. Translational research to be promoted as part of AMED ACT-M\*1 project
2. Clinical POC\*2 confirmed with a competing drug with the same mechanism of action
3. Superior efficacy and safety for a certain patient group expected according to the results of non-clinical studies

Target timing of launch: FY2026(🇺🇸), FY2027(🇯🇵)



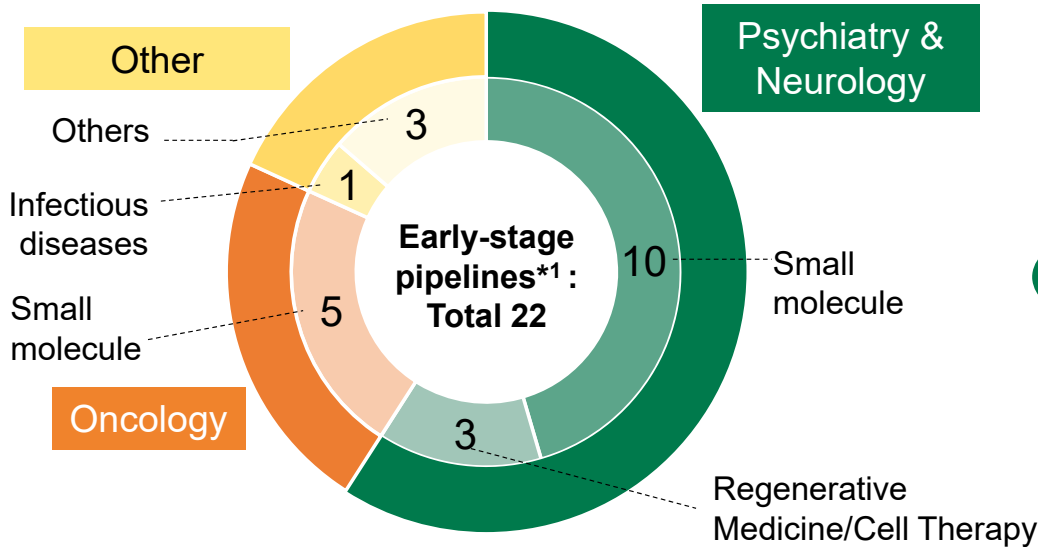
Select priority products from among early-stage assets and bring them to later phases

## Bringing Own Innovations to Fruition

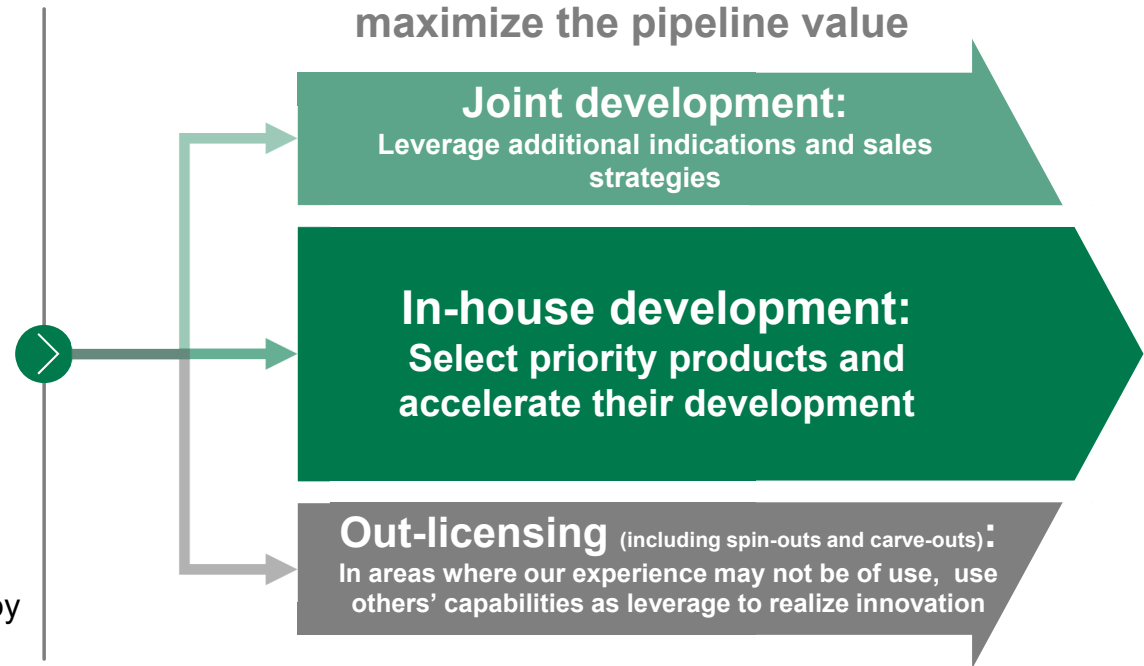
# Selection and Concentration of the Pipeline and Maximization of its Value

Select multiple priority products that will underpin the Group's revenue in the 2030s, and accelerate in-house development while maximizing the value of the pipeline through adequate measures, including partnerships with external parties

Early determination of product value



Allocate investment appropriately and maximize the pipeline value



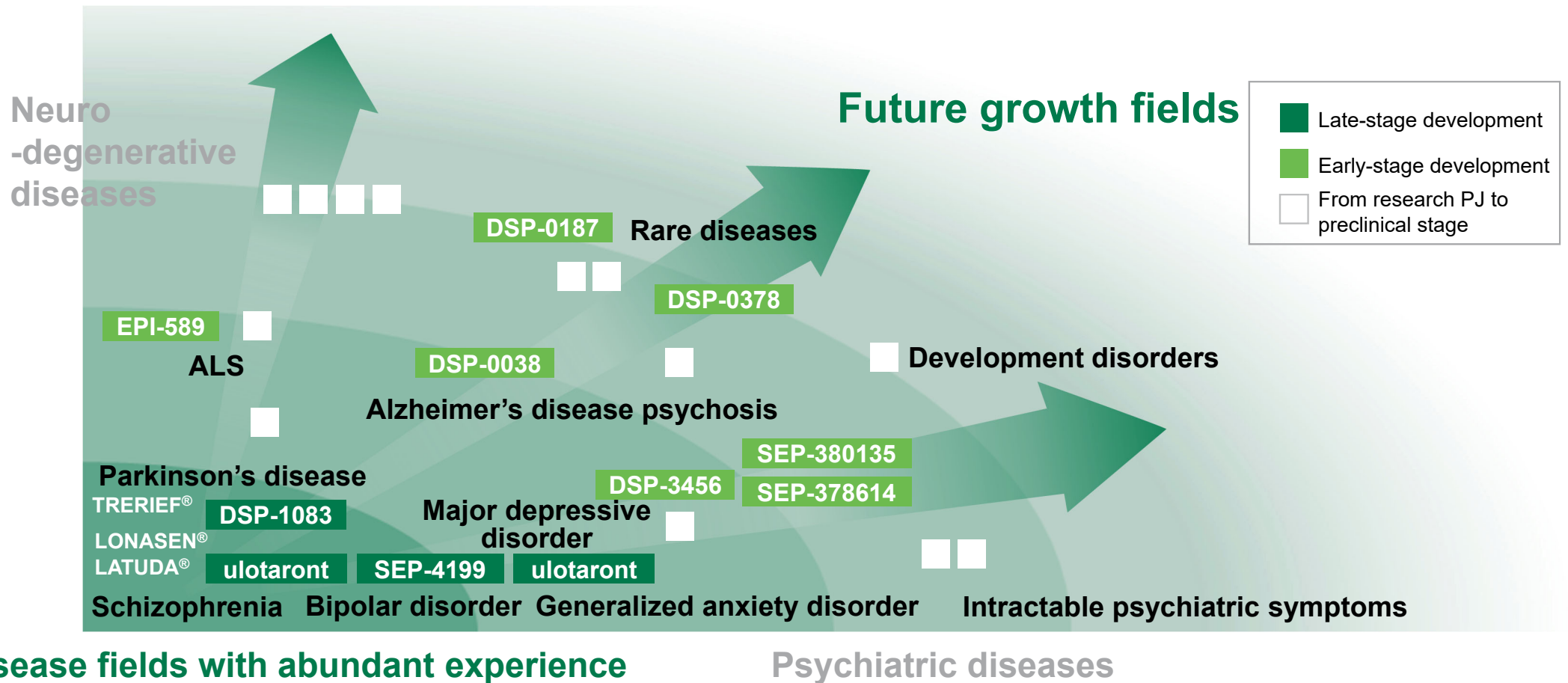
- ✓ Using biomarkers for early clinical studies
- ✓ Conducting small-scale studies with patients early
- ✓ Close examination of business opportunities based on competitive advantages

# Bringing Own Innovations to Fruition

Create a distinguished pipeline

## Future Prospects in Psychiatry & Neurology Area

Dare to branch out to future growth fields from disease fields where we have abundant experience



# Bringing Own Innovations to Fruition

Create a distinguished pipeline

## Drug Discovery Strategies

Continuously create candidate compounds that focus on clinical conditions by leveraging both an advanced translational system and technological innovation

Drug discovery focusing on essences of clinical conditions



### Psychiatry & Neurology

Pursue original targets and mechanisms of action

- TAAR1\*1, activation/suppression balance
- Targets and mechanisms of action with a high probability of success in clinical studies as discovered by data-driven drug discovery

### Psychiatry & Neurology

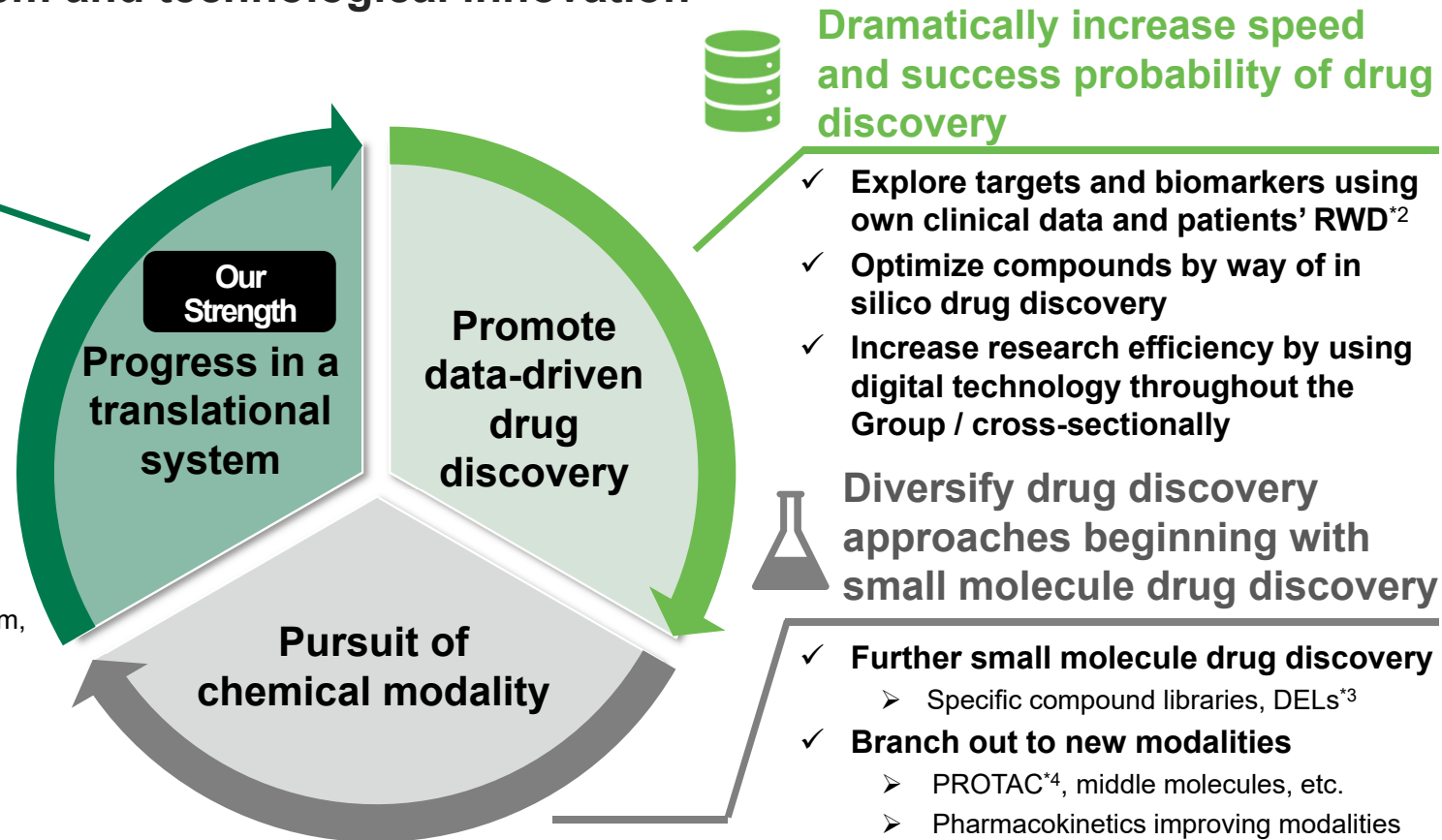
Build a competitive and solid technological foundation

- Patient-derived iPS cell technology
- Neural circuit technology (Electroencephalogram, brain imaging, etc.)

### Oncology

Strengthen collaboration with Academia

- Access to new drug discovery targets and technology
- Build and select an optimal evaluation model using clinical samples



## Bringing Own Innovations to Fruition

Full-scale launch of the Regenerative Medicine/Cell Therapy Business

## Our Strengths and Basic Strategies of the Regenerative Medicine/Cell Therapy Business

Deliver new value that only regenerative medicine can create on a global scale, through the pursuit of advanced industrialization and manufacturing expertise and cutting-edge science, with the open innovation strategy at the core



### Our strengths

#### - Network through open innovation

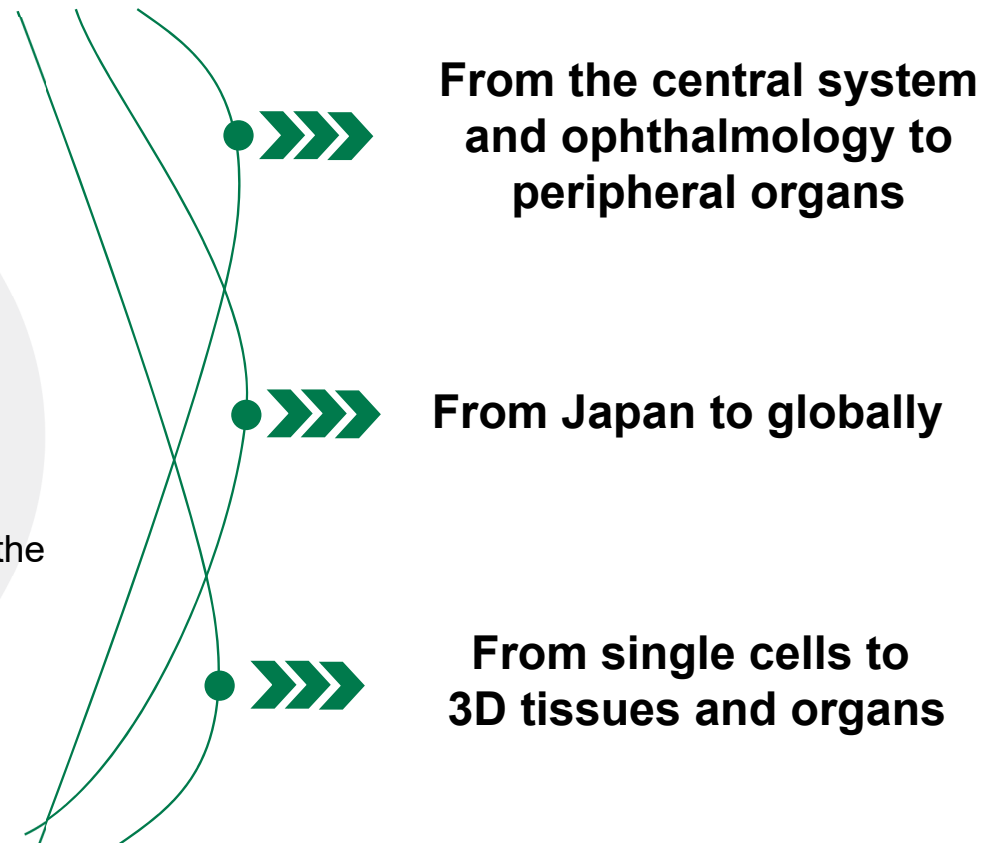
- ✓ Academia, venture businesses
- ✓ Players from different industries (machinery manufacturers, logistics businesses, etc.)

#### - Front-runner in commercializing iPS cells

- ✓ Technology for inducing differentiation from pluripotent stem cells
- ✓ Track records in dealing with authorities in Japan and the U.S.

#### - Manufacturing capabilities

- ✓ Technology and know-how for manufacturing cells and developing manufacturing methods
- ✓ Manufacturing infrastructure and HR

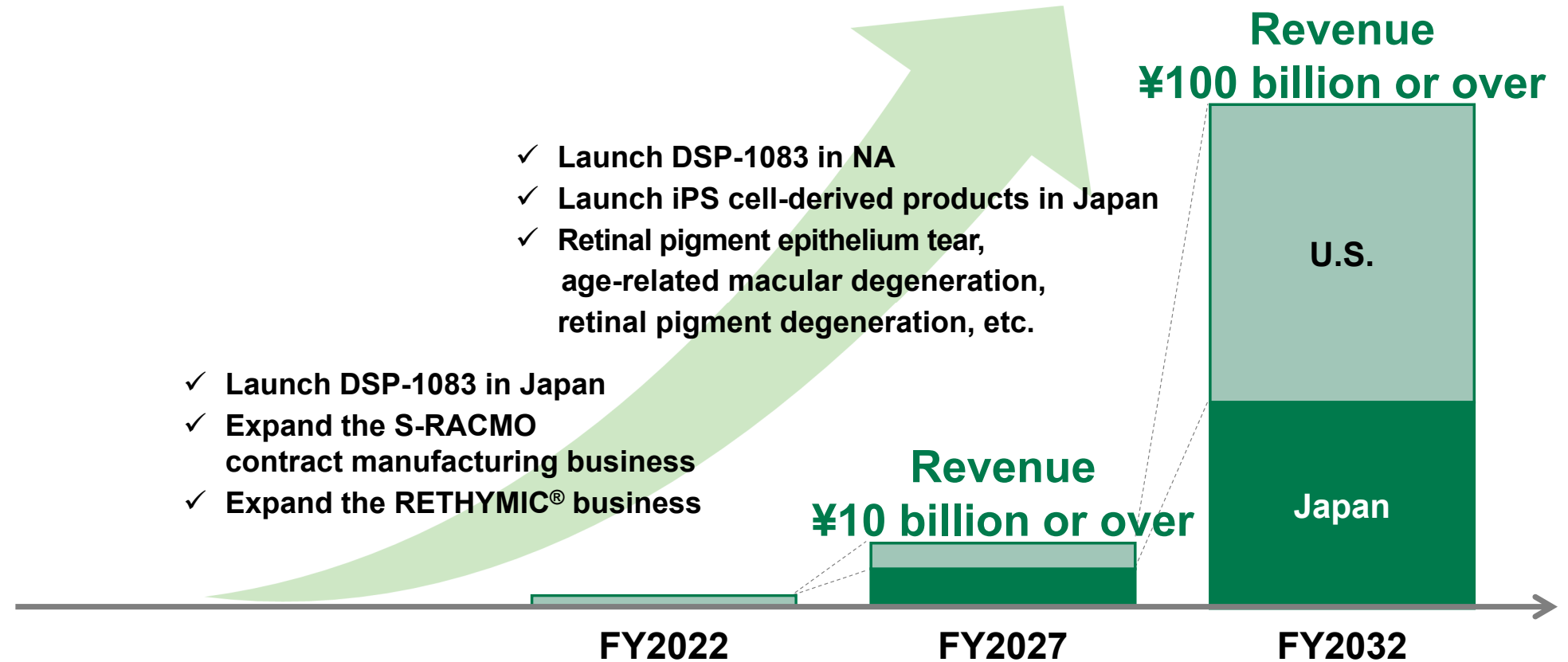


## Bringing Own Innovations to Fruition

Full-scale launch of the Regenerative Medicine/Cell Therapy Business

# Growth Potential of the Regenerative Medicine/Cell Therapy Business

Shift the business into full gear in Japan during the MTBP 2027 period to make it a ¥100+ billion business globally in the 2030s



# Bringing Own Innovations to Fruition

## Vision for the Frontier Business

Full-scale launch of the Frontier Business

Form a medical ecosystem unique to Sumitomo Pharma through integration with the pharmaceutical business

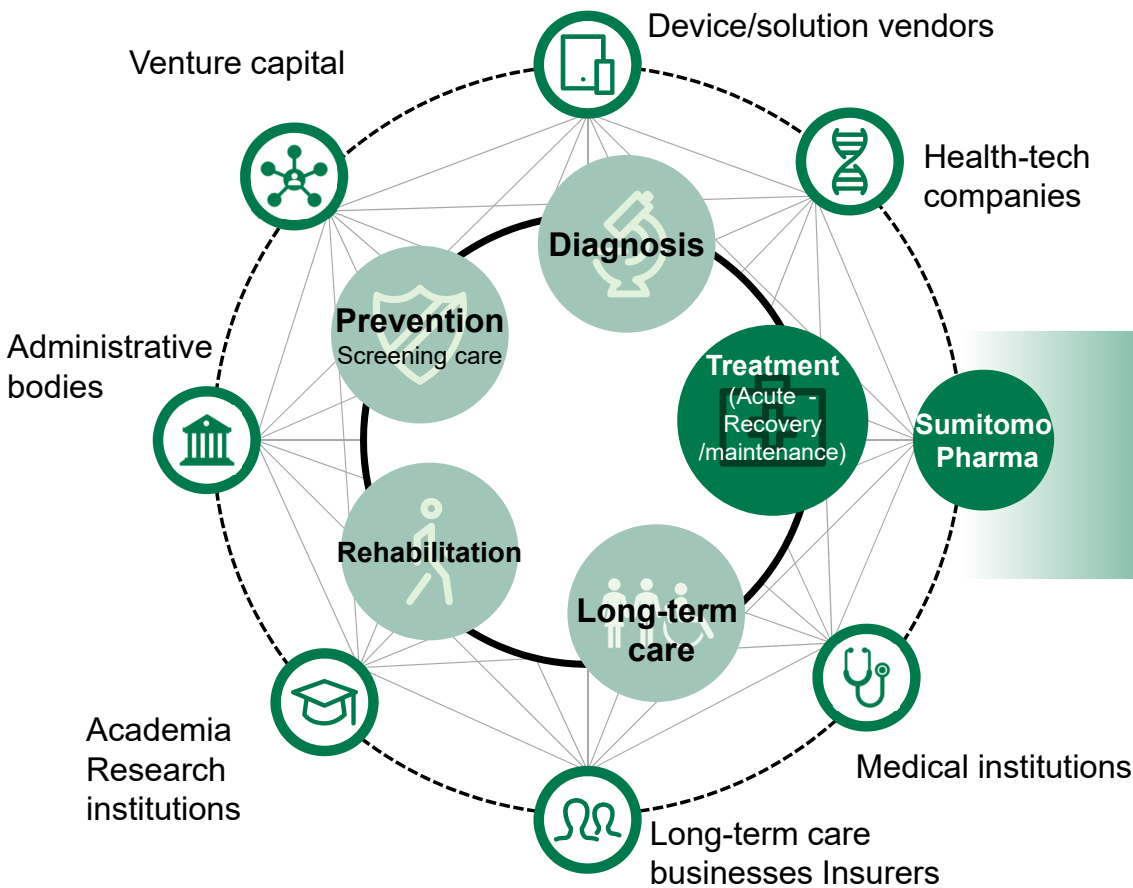
Realize “diverse well-being” that is difficult to attain by the pharmaceuticals business alone

Expand business areas

**Core business area  
(Pharmaceuticals business)**

Expand business areas

**Synergy with the pharmaceuticals business**

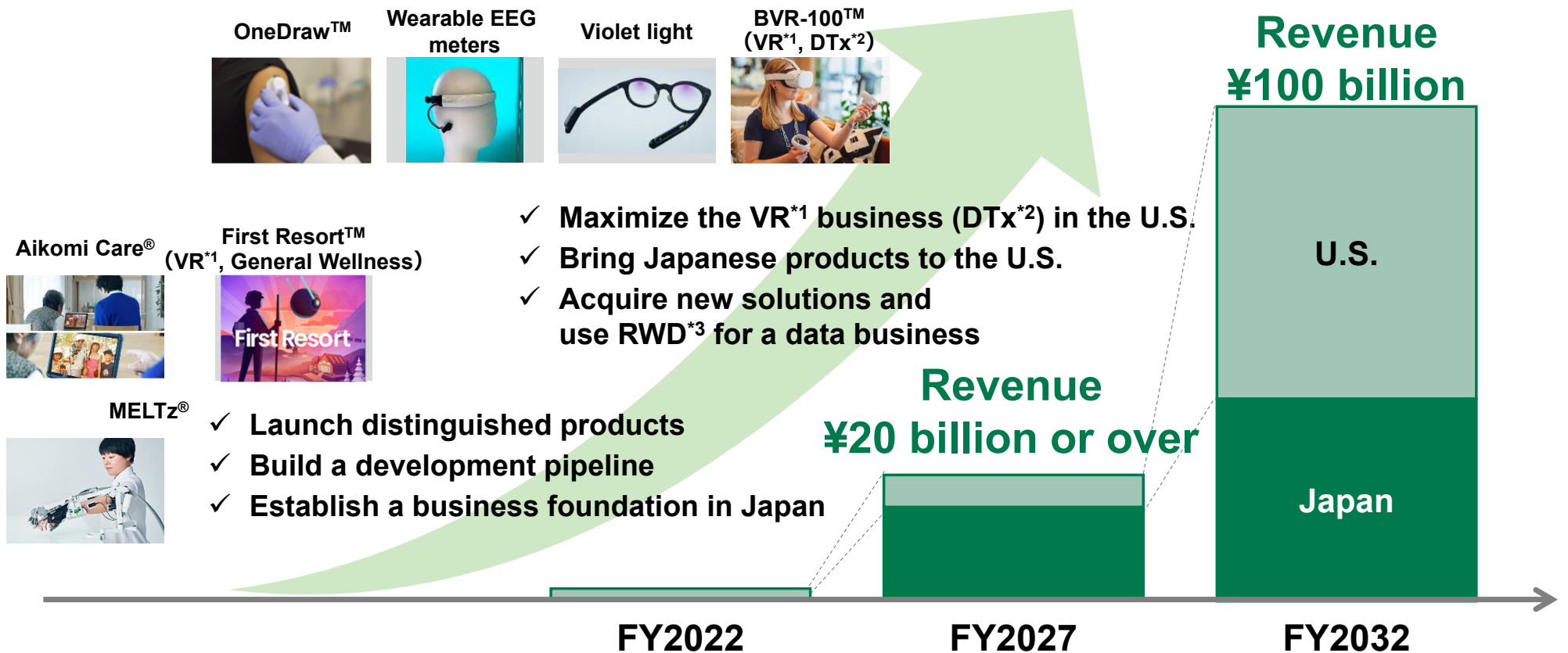


# Bringing Own Innovations to Fruition

Full-scale launch of the Frontier Business

## Growth Potential of the Frontier Business


Aiming to contribute ¥20 billion or over in revenue during the Mid-term Business Plan 2027












# Bringing Own Innovations to Fruition

## Product Launch Target (April, 2023)

Full-scale launch of the Frontier Business

 : Non-medical device

 : Medical device

	FY2023	FY2024	FY2025	FY2026	FY2027
<b>VR*1 contents</b> (BehaVR, Inc.)				<b>Social Anxiety Disorder</b> 	<b>VR*1 contents in other disease area</b> 
<b>MELTz®</b> (MELTIN)			<b>“MELTz® Portable”</b> (finger exercise training system) 		<b>Neurorehabilitation device for hand/fingers</b> 
<b>Wearable EEG meter</b> (NeuroSky Co., Ltd.)		<b>Depression</b> 			<b>Depression</b> 
<b>Violet Light</b> (Tsubota Laboratory, Inc.)			<b>Depression / Dementia</b> 		<b>Depression / Dementia</b> 
<b>Automated blood collection/ stabilization device</b> (Drawbridge Health, Inc.)	<b>Self-management solutions for metabolic diseases*2</b> 				



## Bringing Own Innovations to Fruition

### Infectious Diseases

Expedite R&D through the combination of in-house innovation and external partnerships to contribute to global health

Create drugs to treat antimicrobial resistant bacterial infections, Malaria vaccine and Universal Influenza vaccine

#### 1. In-house innovations

- Antimicrobial agent research: KSP-1007 (joint research with the Kitasato Institute)
- TLR7 research: own TLR7 adjuvant

#### 2. Partnerships with outside institutions<sup>\*1</sup>

- Excellent expertise in the infectious disease and vaccine areas
- Global network



#### 3. Solutions to social issues

- Emergence and prevalence of antimicrobial resistant bacteria
- Measures against malaria (infection, onset, and prevention of transmission)
- Measures against pandemic influenza

## Priority Issues for the MTBP 2027

- 1 Strengthening Business Profitability
- 2 Bringing Own Innovations to Fruition
- 3 Strengthening Group Governance**
- 4 Accelerating Digital Transformation (DX)
- 5 Instilling Corporate Culture and Implementing HR Strategies

## Strengthening Group Governance

# Qualitative Transformation into a Flexible and Efficient Organization

Aim to achieve both integrated management of the Group and prompt response to local needs

1

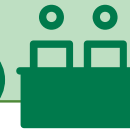


Improve speed and quality  
in global collaboration  
among functional organizations



Gather information efficiently and objectively  
Speedy performance by local members

2



Establish a cross-business/area and  
prompt decision-making system



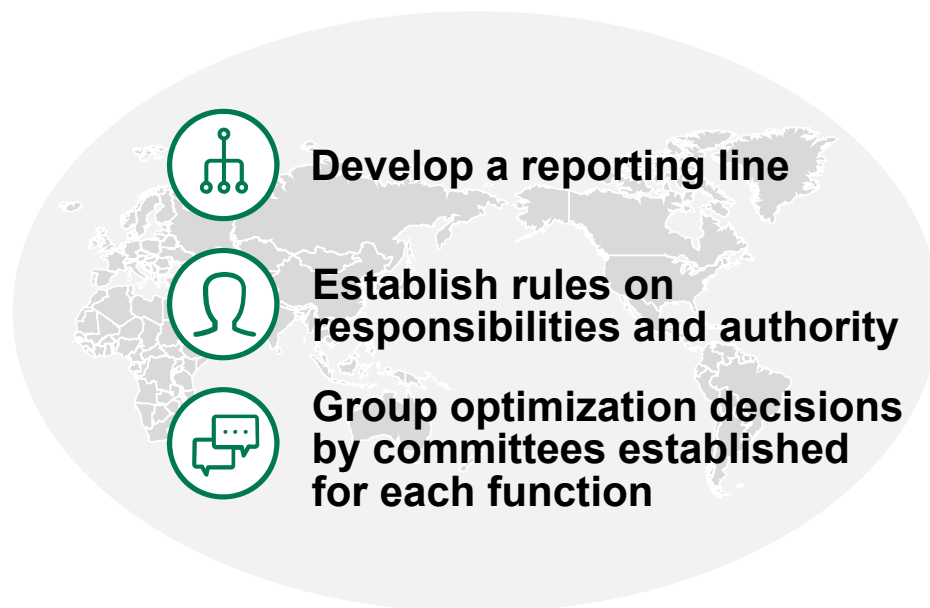
Decisions optimal for the Group  
Timely decision-making

## Strengthening Group Governance

### ① Improve Speed and Quality in Global Collaboration among Functional Organizations

Realize efficient operations by balancing the strengthening collaboration according to characteristics of each function and the transferring of authority

#### Framework for collaboration with the global Head Office



#### Governance policies for each function

Strong collaboration among global strategic functions

- Strategy, Planning, Business Development
- Finance
- R&D, CMC

Timely collaboration with focus on efficiency

- Regulatory Affairs, Regulatory Compliance & Quality, Manufacturing
- IT & Digital
- Legal Affairs, Intellectual Property, Internal Auditing, IR
- HR

Focus on prompt response to local needs

- Sales and marketing

## Strengthening Group Governance

### ② Establish a Cross-Business/Area and Prompt Decision-Making System

In connection with the combination of the NA subsidiaries, establishing a Global Management Committee\*<sup>1</sup> to streamline the decision-making process



**Realize judgements optimized for the Group and timely decision-making**

# Strengthening Group Governance

## ② Establish a Cross-Business/Area and Prompt Decision-Making System (Portfolio Strategy)

Realize a business portfolio optimized for the Group, attested by objective information and high transparency



**A** | The business portfolio and R&D budget will be **overseen by the global head office** and deliberated on by **the Global Management Committee**.

**B** | **By-Business/Area Committees** will carefully discuss scientific appeals, clinical value, feasibility, and risks of the development pipeline.

**C** | **The Strategy Unit** will proactively get involved as a **coordinator facilitating optimal decision-making for the Group**.

**D** | **Maintain high transparency of information for early-stage development pipeline**, which indicates management's future prospects, and utilizes the same for business operation.

**E** | **The Global Research Management Committee\*1**, to which authority has been transferred appropriately, will determine scientific appeal and clinical value of exploratory research compounds.

## Priority Issues for the MTBP 2027

- 1 Strengthening Business Profitability
- 2 Bringing Own Innovations to Fruition
- 3 Strengthening Group Governance
- 4 Accelerating Digital Transformation (DX)**
- 5 Instilling Corporate Culture and Implementing HR Strategies

## Accelerating DX

# Overall Picture of Sumitomo Pharma's DX Initiatives

By implementing a data-driven decision-making process, all value chains will make continued efforts to innovate operations and create value

**A data-driven organization that propels itself autonomously**

Digital data is used as a matter of fact

**Optimal use of in-house technology acquired through strategic investment (DrugOME / Digital Innovation)**

**Corporate Departments orchestrate DX of the Group (GDD\*1 / IDT\*2 / AACTR\*3)**

**Introduce advanced technologies and techniques (web3.0, metaverse, quantum computers, etc.)**



## Accelerating DX

# A Dramatic Increase in Value Created by Digital Technology

Enhance DX into our corporate culture through strengthening the development of core human resources in Japan and Japan-U.S. collaboration

### Citizen Data Scientists\*<sup>1</sup>

Develop 100 persons by FY2024  
(approx. x2 vs FY2022)

### Citizen Developers\*<sup>2</sup>

Develop 150 persons by FY2027  
(approx. x10 vs FY2022)

### Scrum Masters\*<sup>3</sup>

### AACTR\*<sup>4</sup>

Launch 150 or more DX projects of any size per year in Japan and the U.S. combined

Approx. 10% of Sumitomo Pharma's employees will play a core role in DX in initiating efforts to increase operational efficiency and create value

\*1. Personnel initiating data-driven value creation, \*2. Personnel capable of autonomously increasing operational efficiency at the workplace,

\*3. Personnel possessing facilitation coaching skills and promoting instilment of agile minds, \*4. Advanced Analytics Computational Technology & Research

## Accelerating DX

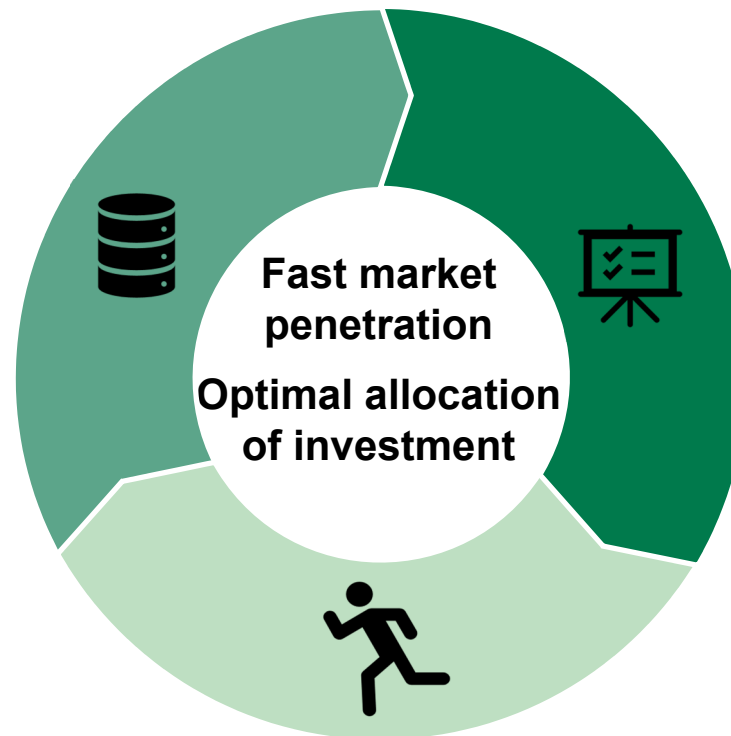
### Data-Driven Marketing: Optimize Promotion in NA

- ✓ Realize industry-leading promotion investment efficiency by prompt decision-making and implementation of actions
- ✓ Apply achievements of GEMTESA<sup>®</sup> to ORGOVYX<sup>®</sup> and MYFEMBREE<sup>®</sup>

1

Visualize market models via exploratory surveys, deep dive analyses

- Integrated data by DrugOME
- Data curation by the advanced analytics teams
- Measure effects of actions taken



2

Create an optimal scenario by model analysis and design a promotion plan

- Analysis, simulation, and scenario planning by the advanced analytics teams

3

Data-driven and quick decision-making and implementation of actions

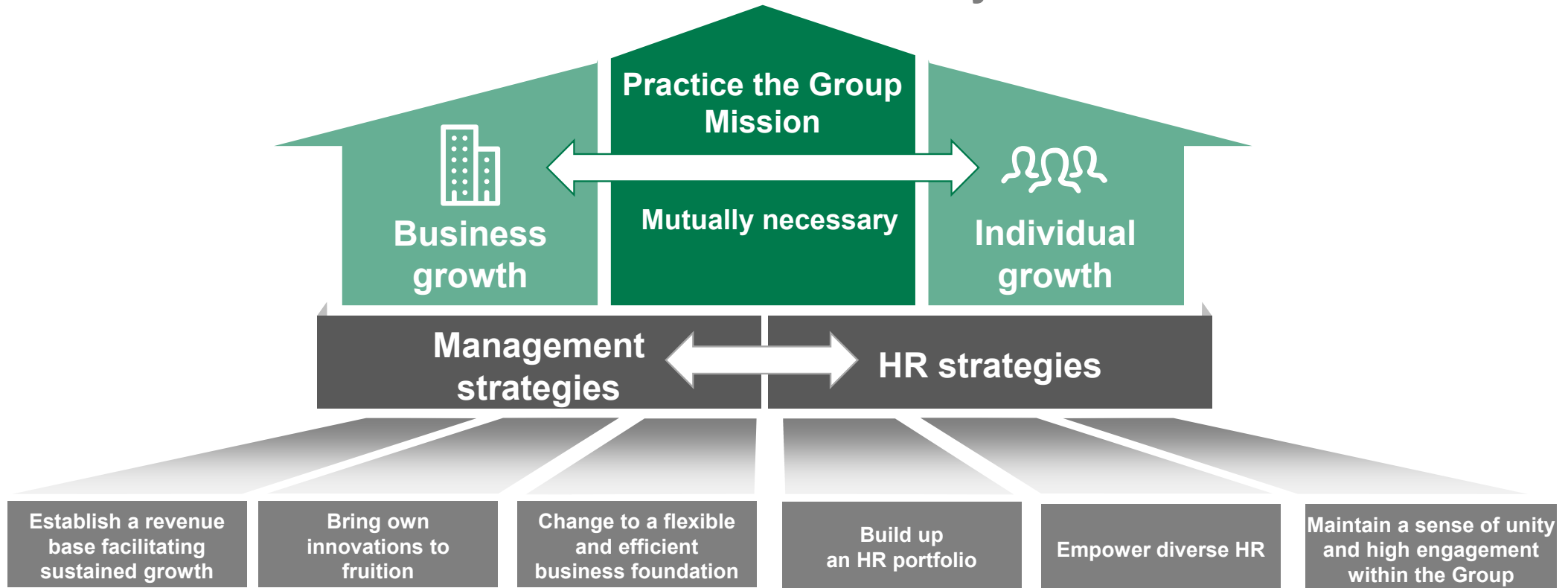
## Priority Issues for the MTBP 2027

- 1 **Strengthening Business Profitability**
- 2 **Bringing Own Innovations to Fruition**
- 3 **Strengthening Group Governance**
- 4 **Accelerating Digital Transformation (DX)**
- 5 Instilling Corporate Culture and Implementing HR Strategies**

# Instilling Corporate Culture and Implementing HR Strategies Working in Tandem with Management Strategies

Realize growth of individuals and business by HR strategies that work in tandem with management strategies and continuously deliver value to society

Deliver value to society



# Instilling Corporate Culture and Implementing HR Strategies

## Basic Policy for HR Strategies

Now that NA operations will be combined, building a global HR management foundation will start, in order to create an HR portfolio that allows members of the Group to work together closely and achieve goals as one

### Build up an HR portfolio

Identify, recruit, develop, and assign persons we need

Visualize/analyze an HR portfolio

Develop leader candidates\*<sup>1</sup> / DX experts\*<sup>1</sup>

Enhance a succession plan

### Empower diverse HR

Everyone aims high and gives their abilities full play

Unify the assessment criteria within the Group

Percentage of male employees taking childcare leave: 100% \*<sup>1</sup>

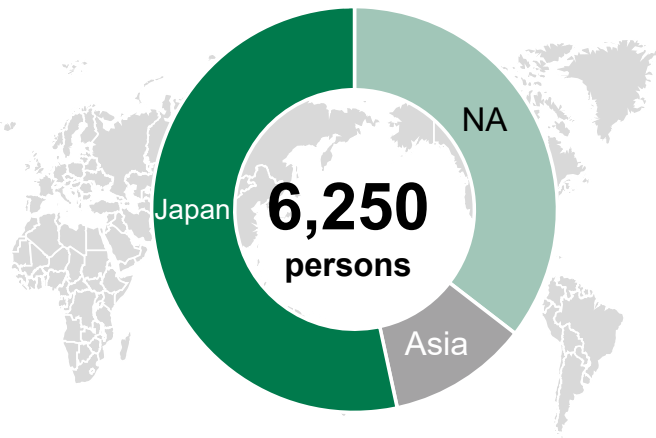
Percentage of female managers: 20% or higher \*<sup>1</sup> (FY2027 target)

### Maintain a sense of unity and high engagement within the Group

Share values and work for value creation with the Group acting as one

Instill our philosophy globally

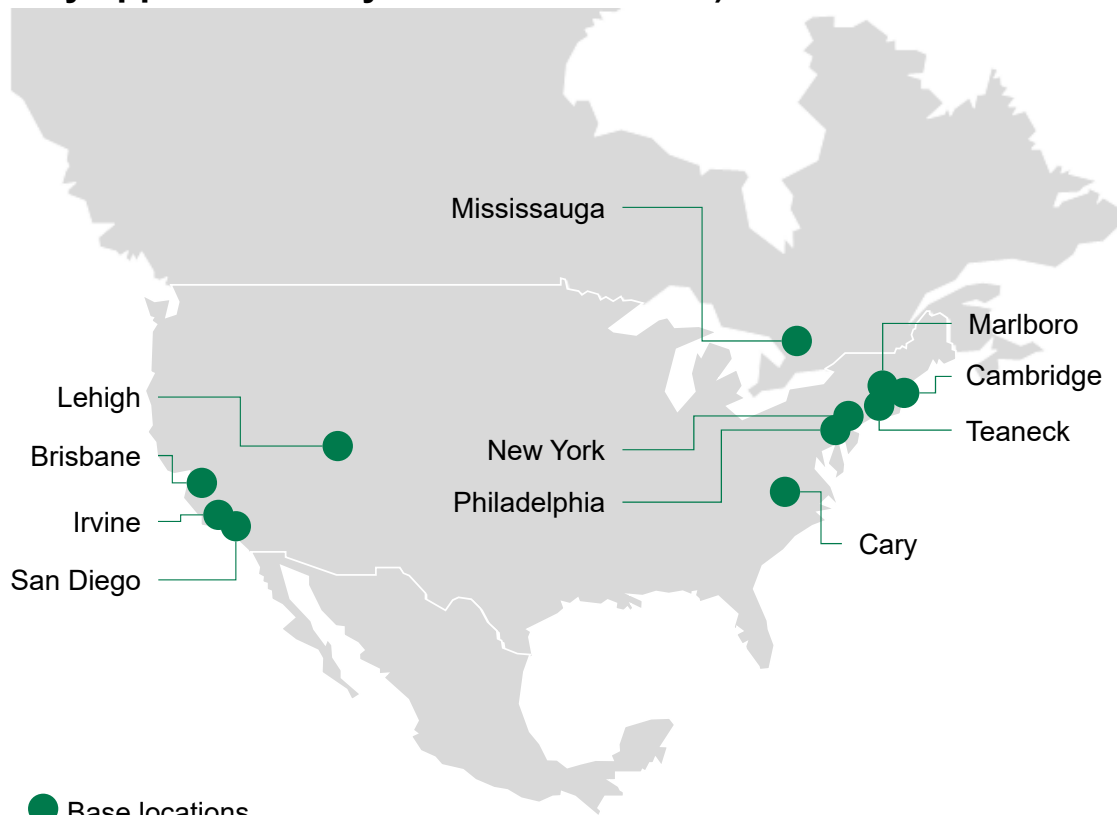
Breakdown of the Sumitomo Pharma Group's personnel by region  
(at the end of FY2022)



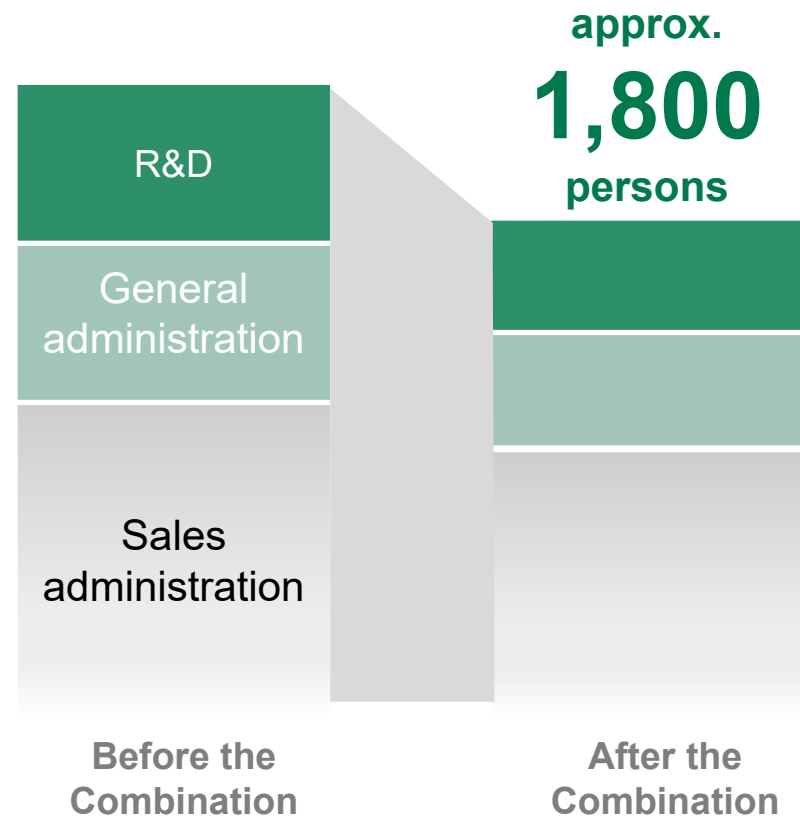
# Instilling Corporate Culture and Implementing HR Strategies

## HR Management Accompanying the Combination of Group Companies in NA

- ✓ Pursuing an operating model that allows diverse HR to share business objectives and work regardless of base or place of residence
- ✓ Integrate overlapping functions to shift to an optimal operating structure (to reduce the total headcount in NA by approx. 500\*1 by the end of FY2023)



● Base locations  
(as of the end of April 2023)



approx.  
**1,800**  
persons

Before the  
Combination

After the  
Combination

# Instilling Corporate Culture and Implementing HR Strategies

## Instilling Corporate Culture

Promote integrated management of the Group through the instillation of globally-shared philosophies

### Sumitomo Pharma group's philosophy<sup>\*1</sup>

#### Mission<sup>\*2</sup>

To broadly contribute to society through value creation based on innovative research and development activities for the betterment of healthcare and fuller lives of people worldwide

#### Values<sup>\*3</sup>

*Patient First  
Always with Integrity  
One Diverse Team*

#### Declaration of Conduct

1. Follow through the global slogan "Innovation today, healthier tomorrows"
2. Pursue trustworthy corporate activities
3. Positively disclose and properly manage information
4. Improve individual capabilities and collaborate with peers
5. Respect human rights
6. Positively address global environmental issues
7. Build harmonious relationships with society

#### Mid-/Long-Term Corporate Strategies

Material issues

#### Vision

What we want our company to be over the mid-/long term

MTBP 2027

#### CHANTO

Conduct Guidelines  
for becoming a GSP

\*1. To enter into force on July 1, 2023, \*2. Renamed from "Corporate Mission" as of July 1, 2023,

\*3. Values that should be shared by all officers and employees



# Appendix



# rodatristat ethyl: Tryptophan hydroxylase (TPH) inhibitor

## Expected to have a disease modification effect approaching the root cause of pulmonary arterial hypertension (PAH)


### Target indications

- Pulmonary arterial hypertension (PAH)  
Pulmonary Hypertension that occurs when intravascular space is narrowed due to intimal or medial hyperplasia

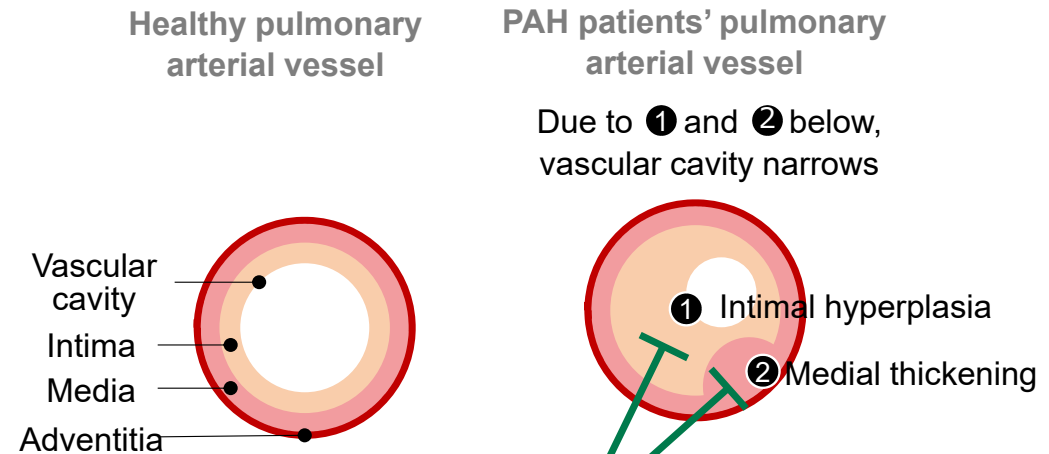
### Features of the developing compound

- Prodrug for TPH inhibitor designed to inhibit peripheral serotonin production (with negligible BBB penetration)
- A concept expected to have a disease modification effect, i.e., restoring vessels to a near normal state by eliminating a cause of vessel walls thickening, unlike symptomatic treatment of expanding the flow path by loosening the entire vascular system
- A new mechanism of action expected to have a disease modification effect
- PoM\*<sup>1</sup> clinically verified (Urinary serotonin metabolite 5-HIAA lowered)

### Target timing of launch

- Phase 2b results should be out by the end of FY2023
-  FY2027

### Concept of rodatristat ethyl



### rodatristat ethyl

Modifying disease by eliminating a cause of vessel walls thickening to restore vessels to a near normal state

Expected to become a blockbuster in global

# TP-3654: PIM1 kinase inhibitor

In addition to monotherapy, the distinct safety profile achieves new opportunities for combination therapy


## Target indications

- Myelofibrosis

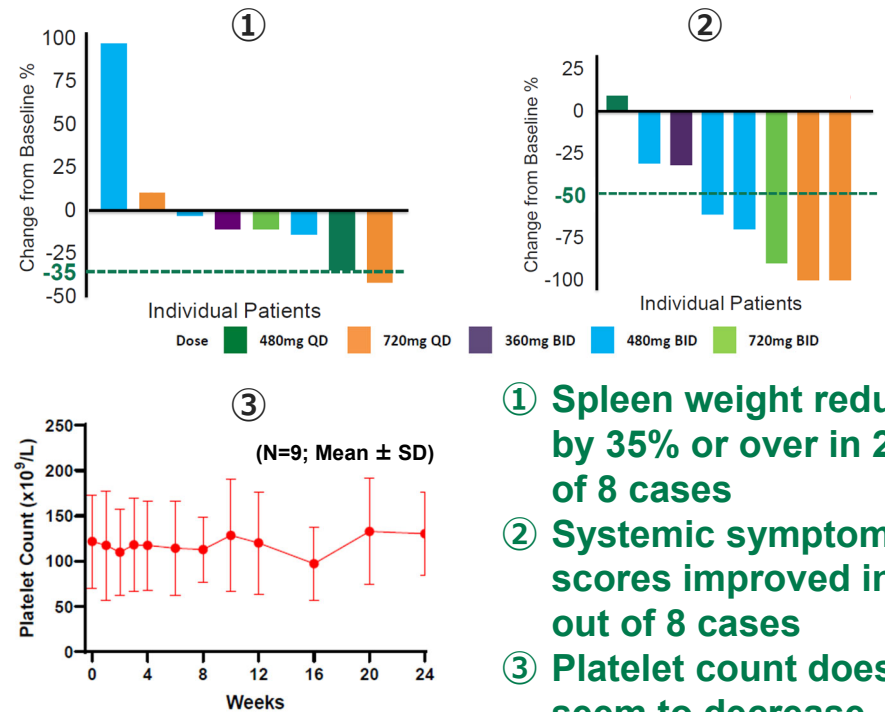
## Features of the developing compound

- Selectively inhibits PIM1 kinases, which are involved in cell multiplication and cancerization, to present antitumor action
- Potentially resolves the unmet need of myelofibrosis
  - Improves fibrotic bone marrow, the root cause of the disease
  - Offers a treatment option to a group of patients with a low platelet count
- Potentially contributes to broad patient groups when used in combination with standard treatments / competing agents with a different mechanism of action

## Target timing of launch

-  FY2027  
(Phase 1 study is underway)

## Phase 1 study interim results\*1



Develop this into a global blockbuster to build our presence in the hematology/oncology area

# DSP-5336 : Menin-MLL interaction inhibitor

Providing a new treatment option for a specific AML patient population with extremely high unmet need



## Target indications

- MLL\*1–rearranged leukemia / NPM1\*2 -mutated AML\*3

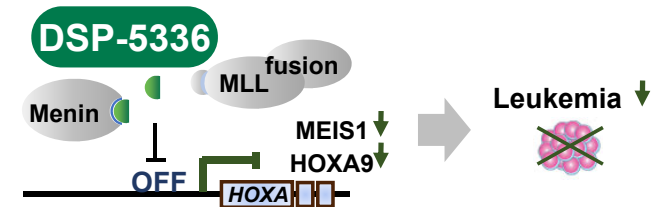
## Features of the developing compound

- Created from an industry-university collaboration program with Kyoto University. Translational research under way as part of the AMED ACT-M\*4 business
- Expected to be a treatment option, especially for MLL-rearranged patients with poor prognosis
- A high probability of clinical success is expected, as clinical POC has been confirmed for a competing agent with the same mechanism of action
- Judging from the results of pre-clinical studies, high efficacy and safety can be anticipated

## Target timing of launch

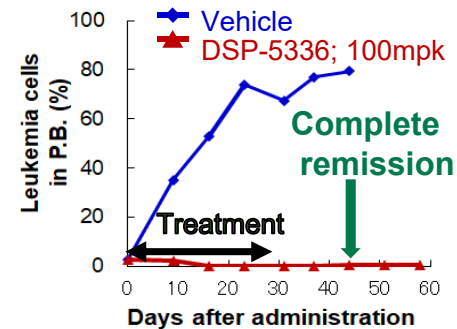
-  FY2026  FY2027  
(Phase 1 study is underway)

## Mechanism of Action of DSP-5336



Inhibits binding between menin protein and MLL protein to present antitumor action

## Efficacy in non-clinical study



Complete remission presented in a model made from tissues of cancer patients\*5

With scope of additional indications to become a major product and building our presence in the hematologic cancer field

\*1. Mixed-Lineage Leukemia, \*2. NucleoPhosmin 1, \*3. Acute Myelogenous Leukemia, \*4. Acceleration Transformative Research for Medical Innovation, Japan Agency for Medical Research and Development (AMED), \*5. American Society of Hematology (ASH) 2021

# DSP-0378 : Gamma-aminobutyric acid (GABA) A receptor positive allosteric modulator

Providing new treatment options for diseases with severe epileptic symptoms

## Target indications

- Dravet syndrome\* and Lennox-Gastaut syndrome\*
- \*Treatment-resistant epilepsy with onset in infancy or early childhood

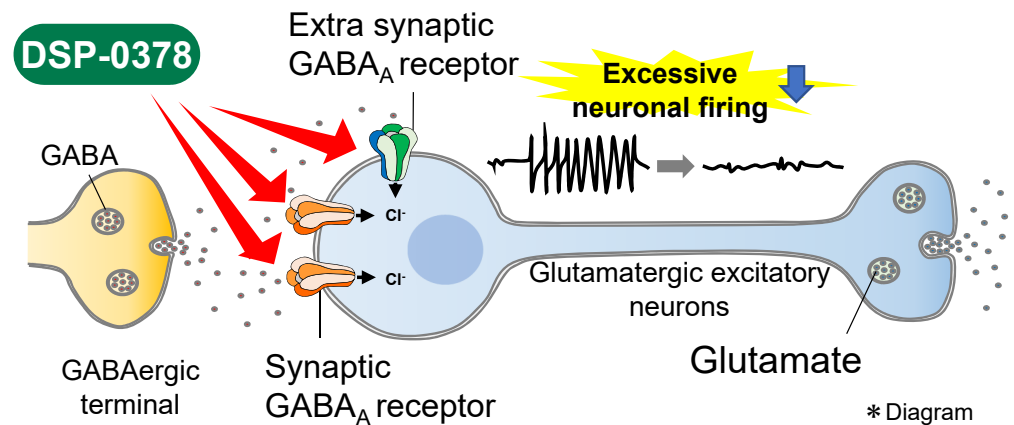
## Features of the developing compound

- To exhibit a potent antiepileptic effect against broad epilepsies through inhibition of excessive neuronal firing via potentiation of various subtypes of GABA<sub>A</sub> receptors expressed in synaptic and extra synaptic regions
- Different mode of action from common GABA<sub>A</sub> receptor potentiators such as benzodiazepines and neurosteroids

## Target timing of launch

- Scheduled to be launched in early 2030s (Phase 1 study is underway in Japan)

## Mechanism of Action of DSP-0378



Expected to become a major product with additional indications

# DSP-3456 : Metabotropic glutamate receptor 2/3 negative allosteric modulator

## Possibility of novel antidepressants showing efficacy against treatment-resistant depression without ketamine-like side effects

### Target indications

- Treatment resistant depression

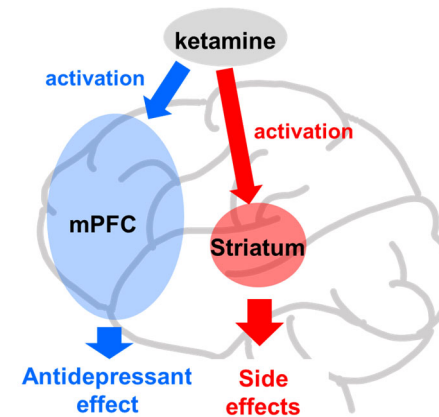
### Features of the developing compound

- DSP-3456 binds to a site different from the binding site of neurotransmitters and inhibits their effects to the receptor
- To exhibit a ketamine-like antidepressant effect through selective activation of the prefrontal cortex by enhancing the glutamate release
- To avoid side effects (psychotic symptoms, cognitive dysfunction) caused by ketamine

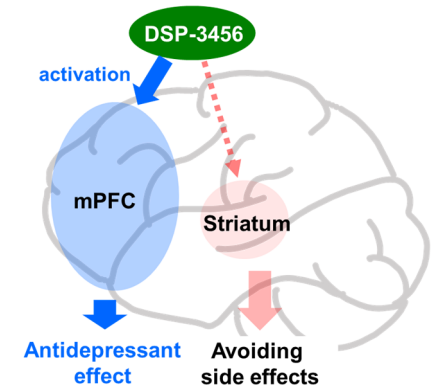
### Target timing of launch

- Scheduled to be launched in early 2030s (Phase 1 study is underway in the U.S.)

### Mechanism of Action of DSP-3456



Ketamine shows efficacy for treatment-resistant depression, but side effects are problems due to activation of the striatum



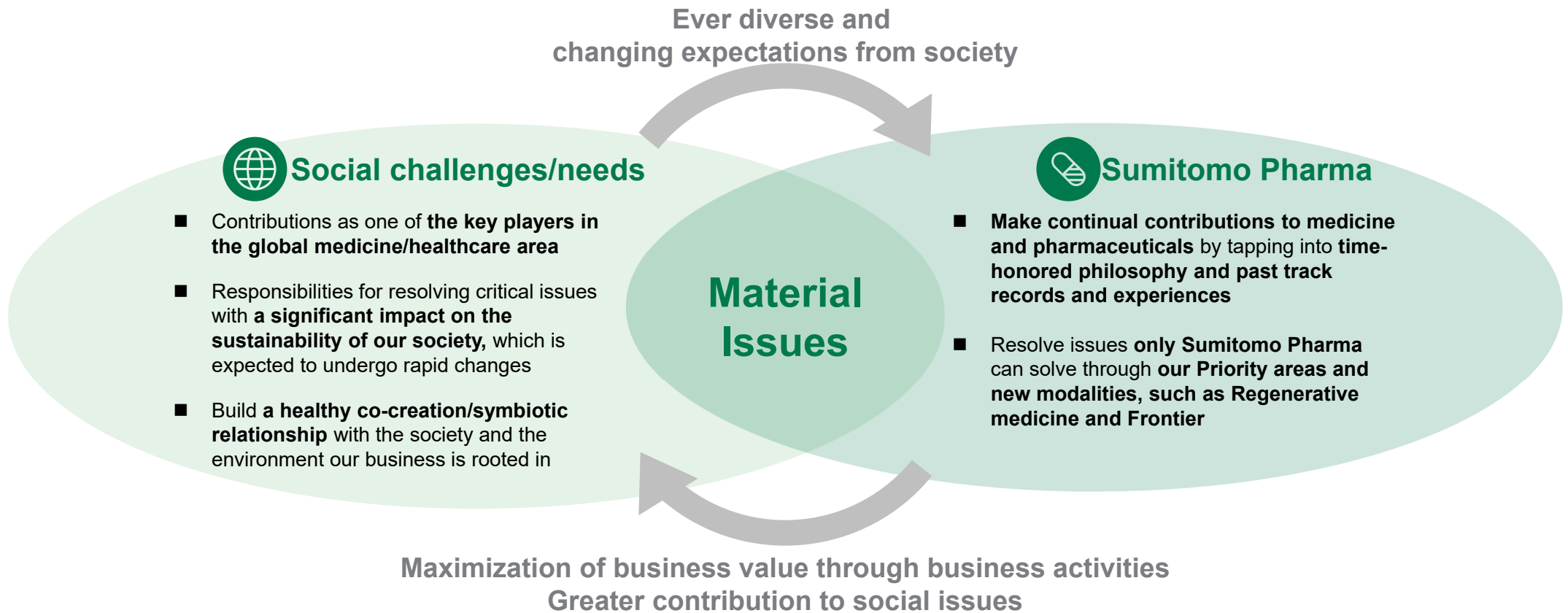
DSP-3456 is expected to be effective against treatment-resistant depression while avoiding side effects

\*mPFC: medial prefrontal cortex

Expected to become a major global product

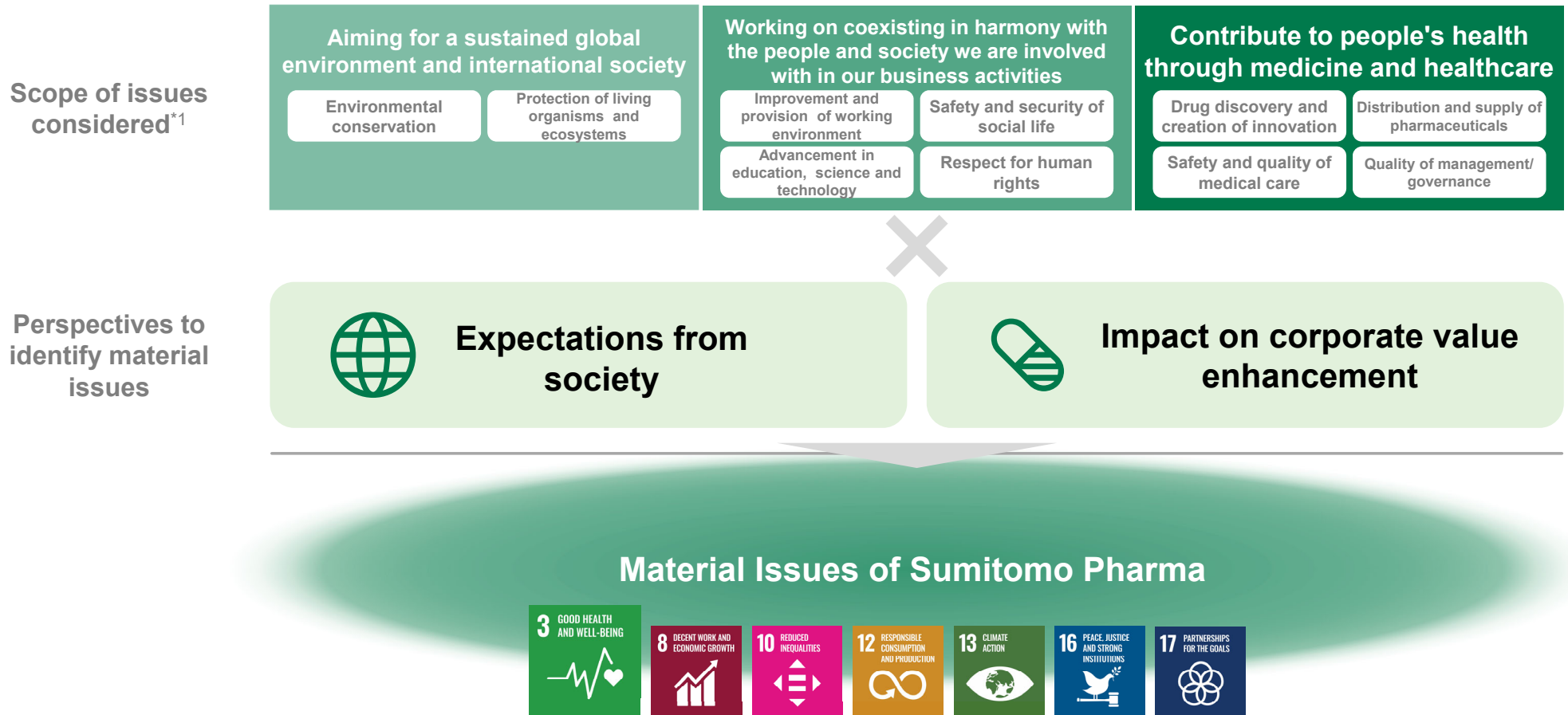
## Thoughts behind Material Issues

Our responsibility as a corporate member of a global society, we aim to realize the sustainability of society and our company through the creation of value that only Sumitomo Pharma can create







# Approach to Identifying Material Issues

Based on the perspectives of “Expectations from society” and “Impact on corporate value enhancement”



\*1. In addition to the SDGs set by the UN, the issues that Sumitomo Pharma places particular emphasis on among the issues raised by the SASB, GRI, and the WORLD ECONOMIC FORUM

# Targets and KPIs for Material Issues




Material Issues	Targets	KPIs	Targets of KPIs
<p>Development of innovative products and healthcare solutions</p>  	<p>Support the betterment of healthcare and fuller lives of people worldwide by continually creating innovative products and healthcare solutions that respond to diverse medical needs, including predictive, preventive, personalized, and patient-participated medicine (i.e., solutions that enable optimization of the conventional therapeutic systems and radical cures), as we always stay close to patients</p>	<ol style="list-style-type: none"> <li>Number of products launched</li> <li>Number of products in the development pipeline</li> <li>Work motivation of research &amp; development staff</li> </ol>	<p>Target number of products launched by FY2027</p> <ul style="list-style-type: none"> <li>Psychiatry &amp; Neurology: 7 products (including 2 regenerative medicine/cell therapy and 4 non-pharmaceutical solutions)</li> <li>Oncology: 2 products</li> <li>Others: 3 products (including 1 non-pharmaceutical solutions)</li> </ul> <p>Number of products that have achieved phase transition by FY2027</p> <ul style="list-style-type: none"> <li>Phase 3 transition: 4 products</li> <li>Phase 2 transition: 6 products</li> <li>Start of corporate clinical studies for regenerative medicine/cell therapy: 5 products</li> <li>Start of corporate clinical studies for DTx: 5 products</li> </ul> <ul style="list-style-type: none"> <li>Use SMP Opinion<sup>*1</sup> to maintain/increase their satisfaction<sup>*2</sup> with work motivation<sup>#</sup></li> <li>(FY2022: Authority/discretion: 3.9, CSR: 4.1, Growth opportunities: 3.8, Work appropriateness: 3.9)</li> </ul>
<p>Stable supply of high-quality pharmaceutical products</p>  	<p>Continuously work to nurture a quality-oriented culture and, under the appropriate quality assurance and manufacturing and quality management, build a resilient supply chain through cooperation with our plants and business partners, thus realizing the stable supply of high-quality products. Work on product design, quality management, and development of efficient processes with the entire product life cycle of diverse modalities in mind, thus providing new value to patients</p>	<ol style="list-style-type: none"> <li>Findings subject to administrative action in regulatory inspections related to our products</li> <li>Number of product recalls</li> <li>Investment in new manufacturing/quality technologies</li> </ol>	<ul style="list-style-type: none"> <li>0</li> <li>0 in any year</li> <li>Number of new technology investments of ¥10 million or over: at least 5 each year</li> </ul>

#. Targets of KPI for Sumitomo Pharma non-consolidated \*1. Company-wide questionnaire using Qualtrics Employee XM by Qualtrics, Inc.



\*2. Average score out of 5 points in the research & development departments



# Targets and KPIs for Material Issues

Material Issues	Targets	KPIs	Targets of KPIs
<p>Provision of high-quality product information and promotion of proper use</p> 	<p>Provide information on the safety and efficacy of our products based on scientific objectivity and ethics in a way that best suits target customer groups, in an effort to ensure that healthcare professionals, patients, and their families can always use our products with confidence and peace of mind.</p> <p>At the same time, gather information on the safety of our products accountably to ensure the safety of patients</p>	<ol style="list-style-type: none"> <li>1. Assessment by doctors in focus areas</li> <li>2. Ensure appropriateness of sales information provision activities</li> <li>3. Education on safety information collection</li> <li>4. Education on harmful incident concerning pharmaceuticals</li> </ol>	<ul style="list-style-type: none"> <li>• Rated number one in the focus areas of diabetes and schizophrenia in our own survey conducted by an external organization<sup>#</sup></li> <li>• Number of guidance from the Ministry of Health, Labour and Welfare's monitoring program for sales information provision activities: 0 in any year<sup>#</sup></li> <li>• At least four times a year for MRs and once a year for all employees to raise employee awareness of safety information collection<sup>#</sup></li> <li>• Number of delayed adverse drug reaction reports to regulatory authorities: 0<sup>#</sup></li> <li>• Annual educational program for all employees to form and maintain a mindset that does not cause harmful incident concerning pharmaceuticals</li> </ul>
<p>Improving access to medicines and advocacy</p>  	<p>Attempt to improve access to medicines by promoting disease awareness from patient-centered perspectives, which is expected to reduce illness stigma and facilitate early treatment, and by working to lessen a drug lag, which will increase treatment options for patients.</p> <p>Contribute to the betterment of the healthcare system in countries/regions that struggle with equal access to necessary healthcare, by developing healthcare professionals, raising awareness of the public, and making policy recommendations through collaboration with the industry, governments, and NPOs/NGOs</p>	<ol style="list-style-type: none"> <li>1. Further increase in health literacy of the public, including patients</li> <li>2. Number of products, and policy recommendations contributing to access to medicines</li> <li>3. Number of partnerships contributing to improvement in healthcare access in developing countries</li> </ol>	<ul style="list-style-type: none"> <li>• Number of public lecture participants by FY2027 cumulative total of 10,000 since FY2023<sup>#</sup></li> <li>• Total annual visits to schizophrenia and bipolar disorder disease awareness website (Kokoro Share) 40% increase over FY2022 by FY2027<sup>#</sup></li> <li>• Responding to requests for development of unapproved and off-label drugs of high medical necessity<sup>#</sup></li> <li>• Continued participation in policy recommendations<sup>#</sup></li> <li>• Constantly two or more</li> </ul>




# Targets and KPIs for Material Issues

Material Issues	Targets	KPIs	Targets of KPIs
<p>Expansion of human capital and instillment of corporate culture</p> 	<p>Consider employees' knowledge and potential as "capital" to invest in them and instill corporate culture linked to the provision of value, thus realizing sustained enhancement of corporate value</p>	<ol style="list-style-type: none"> <li>Employee engagement scores</li> <li>Percentage of female managers</li> <li>Number of participants in selective training</li> <li>Number of career consultations</li> <li>Number of digital experts and data scientists</li> <li>Amount of investment in HR development</li> <li>Instillment of CHANTO</li> </ol>	<ul style="list-style-type: none"> <li>Maintain/improve engagement scores in SMP Opinion (FY2022: 68%<sup>*1</sup>)</li> <li>Lower the percentage of departments whose engagement scores are less than 63%<sup>*2</sup> (FY2022: 24%)<sup>#</sup></li> <li>Increase the ratio to 20% or over by FY2027<sup>#</sup></li> <li>80 every year<sup>#</sup></li> <li>200 every year<sup>#</sup></li> <li>100 citizen data scientists by FY2024</li> <li>150 citizen developers by FY2027</li> <li>Maintain the amount of investment per person<sup>#</sup></li> <li>Implement measures contributing to employees' change of behavior every year in a bid to establish position as GSP<sup>#</sup></li> </ul>
<p>Respect for human rights</p> 	<p>Identify human rights risks throughout the Group's business activities to prevent and mitigate them while asking business partners and other parties concerned to understand and support such initiatives, thus respecting human rights throughout the value chain</p>	<ol style="list-style-type: none"> <li>Implementation of human rights education and training (including e-Learning) for all employees</li> <li>Implementation of human rights due diligence in the value chain, including business activities of each Group company</li> </ol>	<ul style="list-style-type: none"> <li>Implement education and training at least once a year to instill the human rights policy and raise awareness of human rights</li> <li>Increase in cumulative number of due diligence and outreach to key business partners</li> <li>Realization of zero occurrence of serious human rights violations</li> </ul>



#. Targets of KPI for Sumitomo Pharma non-consolidated \*1. Percentage of positive responses to engagement questions answered on a 5-point scale,

\*2. Average Engagement Score of Japanese Companies Benchmarked by Qualtrics, Inc. © Sumitomo Pharma Co., Ltd. All Rights Reserved. 68

# Targets and KPIs for Material Issues

Material Issues	Targets	KPIs	Targets of KPIs
<p>Promotion of environmental initiatives</p>  	<p>Conserve the global environment, which serves as the foundation for health of people worldwide, by working to prevent environmental pollution, mitigate climate change, and circulate resources, to hand it over to future generations</p>	<ol style="list-style-type: none"> <li>Greenhouse gas (GHG) emissions (Scope 1+2)</li> <li>Water withdrawal</li> <li>Recycling rate of waste</li> <li>Final disposal rate of waste</li> </ol>	<ul style="list-style-type: none"> <li>Reduce GHG emissions (Scope 1+2) to zero by FY2050</li> <li>Reduce GHG emissions (Scope 1+2) by 42% vs. FY2020 by FY2030</li> <li>Reduce water withdrawal by 12% vs. FY2018 by FY2030</li> <li>Maintain the recycling rate at 80% or higher and increase the rate to 85% or higher by FY2030<sup>#</sup></li> <li>Maintain the final disposal rate below 1% and lower the rate to below 0.5% by FY2030<sup>#</sup></li> </ul>
<p>Enhancement of corporate governance</p> 	<p>Strive to achieve sustained growth and enhance corporate value by continuously seeking to build a highly effective corporate governance system. In so doing, work to further improve the Board of Directors' functions, protect the interests of minority shareholders, and manage Group Companies appropriately</p>	<ol style="list-style-type: none"> <li>Implementing evaluation of the effectiveness of the Board of Directors and working on priority issues based on the evaluation results</li> <li>Strengthening of Group governance</li> <li>Conducting appropriate transactions between Group Companies with consideration to protecting the interests of minority shareholders</li> </ol>	<ul style="list-style-type: none"> <li>Maintain a good level of quantitative evaluation results in the effectiveness evaluation</li> <li>Rebuild a group governance system, including the streamlined North American group companies</li> <li>The Supervisory Committee for Conflict of Interests in Transactions between Group Companies meets not only periodically (once a year) but also on an as-needed basis</li> </ul>

# Targets and KPIs for Material Issues

Material Issues	Targets	KPIs	Targets of KPIs
<p>Strengthening of risk management</p> 	<p>Develop/promote a risk management system capable of appropriately responding to risks that could seriously impact business activities, by building an effective BCP and strengthening information security</p>	<ol style="list-style-type: none"> <li>1. Implementing risk assessment and implementing appropriate countermeasures based on assessment results</li> <li>2. Rebuilding and implementing of training and drills of business continuity management (BCM) and business continuity plans (BCPs)</li> <li>3. Provision of education and training for proper information management</li> <li>4. Events that have a significant impact on business activities</li> </ol>	<ul style="list-style-type: none"> <li>• All departments implement risk assessments every fiscal year</li> <li>• Provide education and training at departments with priority operations and update BCP at least once a year<sup>#</sup></li> <li>• Provide necessary education and training at least once a year for enhancement of knowledge and awareness concerning information management</li> <li>• Number of serious accidents: 0 in any year</li> <li>• Number of serious information leaks and other incidents: 0 in any year</li> <li>• Number of serious information technology security incidents: 0 in any year</li> </ul>
<p>Pursuing compliance</p> 	<p>Strive to nurture a mindset in everyone that urges them to unflinchingly seek consultation when in doubt about education and training designed to keep high awareness of compliance high or compliance itself and, as a member of the life science industry that requires high ethical standards, conduct transparent and fair corporate activities with a strong commitment to ethical behavior, thus further consolidating trust of stakeholders</p>	<ol style="list-style-type: none"> <li>1. Implementation of compliance education and training</li> <li>2. Level of awareness and understanding of the whistle-blowing system</li> <li>3. Number of serious compliance violations</li> </ol>	<ul style="list-style-type: none"> <li>• Provide training designed to enhance the latest knowledge and raise compliance awareness at least once a year</li> <li>• Awareness: Maintain current level (FY2022 98%)<sup>#</sup></li> <li>• Understanding: Increase to the same level as awareness by FY2027 (FY2022 78%)<sup>#</sup></li> <li>• 0 in any year</li> </ul>

