



# Pharmaceuticals Sector

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Director &  
Senior Managing Executive Officer



# VI

## Pharmaceuticals Sector



1

**Business Environment and  
Progress of Action Plan**

**03**



2

**Development of  
Next-generation Businesses**

**11**



3

**Efforts to Prevent the Spread of  
Infectious Diseases**

**17**

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## Environment

### + Opportunities

- Global healthcare and pharmaceutical markets continue to expand
- Emergence of new therapeutic approaches through technological innovation (preemptive, individualized and regenerative medicine)

### - Threats

- Shortage of healthcare finances
- Competition with generic drugs after the loss of exclusivity (Risks: Latuda®, FDG-PET)
- Entry of new players across industries into healthcare business spaces
- Decline in industry-wide R&D productivity



## Group Initiatives

### 1. Offering New Value in Medical Practice through New Technologies

- Regenerative medicine and cell therapy
- Theranostics (fusion of diagnostics and therapeutics)

### 2. Timely Launch of Next-generation Products

- Continuous expansion of promising pipeline through in-house drug discovery and in-licensing

**Drastic reinforcement through strategic alliance with Roivant**

### 3. Improving R&D Efficiency and Increasing the Probability of Success

- Strengthening in-house R&D capability through various approaches, such as digital technology and big data

FY2019-FY2021

## Corporate Business Plan

### Action plan & major issues

- Maintain profitability after Latuda's loss of exclusivity
- Enhance drug discovery capabilities and improve the success rate in R&D
- Strengthen innovation base with new approaches to drug discovery
- Launch new products in oncology
- Explore opportunities in frontier businesses (healthcare solutions)
- Develop theranostics business and strengthen the competitiveness of existing radiopharmaceutical business
- Expand group synergies in the pharmaceutical business
























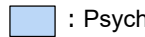
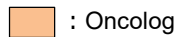

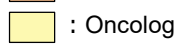
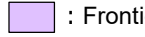
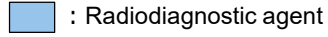
### Progress


- Strategic Alliance with Roivant Sciences
  - ◆ Acquired late-stage assets
    - Post-merger integration is progressing, including development of strategic pipeline and establishment of sales structure utilizing existing North American business bases.
  - ◆ Acquired data science technology platforms, such as "DrugOme," to accelerate digital innovation
- Launched sublingual film for the treatment of Parkinson's disease off episodes
- Continuing clinical trials of napabucasin for colorectal cancer
- Promoting R&D of new healthcare solutions using cognitive activation therapy and biological sensing technology
- R&D site for radiopharmaceuticals will be operational in 2020.
- Establishment of S-RACMO Co., Ltd., a new CDMO company for regenerative medicine and cell therapy, and development of novel drugs for infectious diseases.

# Pipeline for Pharmaceutical Agents and In-vivo Diagnostic Agents

## Product Launch Targets

FY2020	FY2021	FY2022	FY2023	FY2024
		<p>SMC-01 </p> <p>(Mobile App. for management of Type 2 Diabetes)</p>	<p>NMB46 </p> <p>(Vasodilator for coronary arteries)</p>	
<p>KYNMOBI™ </p> <p>(OFF episodes associated with Parkinson's disease)</p> <p>Launched in September</p>		<p>Napabucasin </p> <p>(Colorectal cancer)</p>	<p>Napabucasin </p> <p>(Colorectal cancer)</p>	
<p>LATUDA </p> <p>(Schizophrenia/Bipolar depression)</p> <p>Launched in June</p>	<p>RVT-802 </p> <p>(Pediatric congenital athymia)</p>	<p>Allo iPS cell-derived products </p> <p>(Parkinson's disease) *2</p>	<p>SEP-363856 </p> <p>(Schizophrenia)</p>	<p>NMB58 </p> <p>(PET diagnostics for myocardial perfusion scintigraphy)</p>
<p>Relugolix </p> <p>(Prostate cancer)</p>	<p>Relugolix  </p> <p>(Uterine fibroids)</p>	<p>Allo iPS cell-derived products </p> <p>(Age-related macular degeneration)</p> <p>Launch target under consideration *2</p>	<p>Alvocidib </p> <p>(Myelodysplastic syndrome) *1</p>	<p>Dubermatinib </p> <p>(TP-0903) *1</p> <p>(Solid tumors)</p>
<p>Vibegron </p> <p>(Overactive bladder)</p>	<p>Imeglimin </p> <p>(Type 2 diabetes)</p>	<p>Relugolix </p> <p>(Endometriosis)</p>	<p>TP-0184 </p> <p>(Solid tumors) *1</p>	<p>TP-3654 </p> <p>(Hematologic malignancies) *1</p>

-  : Psychiatry & Neurology
-  : Oncology
-  : Regenerative medicine/cell therapy
-  : Oncology
-  : Frontier field
-  : Radiodiagnostic agent

 Expect peak annual sales to be 50 billion yen or more. (described in first launch)

\*1 Premised on utilizing the accelerated approval program. (consultation with FDA planned)

\*2 Launch schedule is based on our targets, pending agreement with partners.

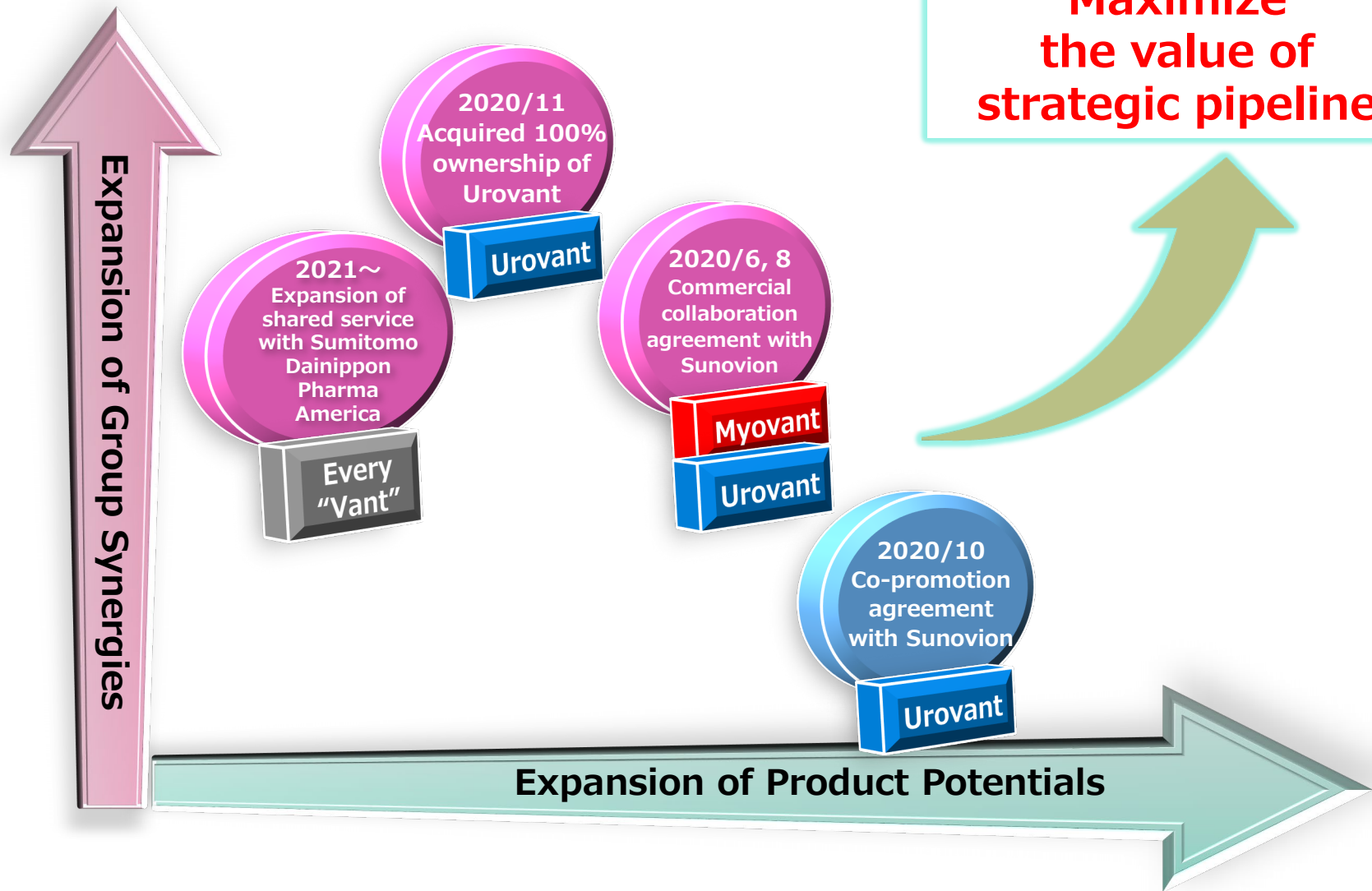
# Progress in Strategic Alliance with Roivant Sciences: Pipeline Development

## Current development status of strategic pipeline

Product	Indication	Current development status	Expected schedule for NDA or approval
<b>Relugolix</b> <b>Myovant</b>	Prostate cancer	NDA submitted (US)	PDUFA date Dec. 2020
	Uterine fibroids	NDA submitted (US, EU)	PDUFA date June 2021
	Endometriosis	Phase 3	Plan to submit NDA in FY2020 4Q (at earliest)
<b>Vibegron</b> <b>Urovant</b>	Overactive bladder (OAB)	NDA submitted (US)	PDUFA date Dec. 2020
	OAB in men with benign prostatic hyperplasia	Phase 3	Plan to submit NDA in FY2021 4Q (at earliest)

# Progress in Strategic Alliance with Roivant Sciences: Post-Merger Integration etc.

**Maximize  
the value of  
strategic pipeline**





# FY2020 Performance Forecast

(Released on October 30, 2020)

## Performance Trends

- Sales of pharmaceutical agents remain generally strong regardless of the influence of COVID-19
- On the other hand, the number of laboratory tests for in-vivo diagnostic agents is lower due to the avoidance of medical consultation and restriction of lab tests because of COVID-19
- Higher SG&A and R&D expenses due to the alliance with Roivant, with newly acquired drugs yet to be launched

## Risks and Challenges

- Delay in sales expansion of newly-launched products and in recovery of the number of lab tests, caused by the recurrence or prolonged epidemic of COVID-19
- Delay in determining the results of the Phase 3 clinical trial for napabucasin because of the influence of COVID-19
- Increase in upfront investment in late-stage pipeline for smooth market entry

The impact of acquiring 100% ownership of Urovant announced in Nov. is being examined.

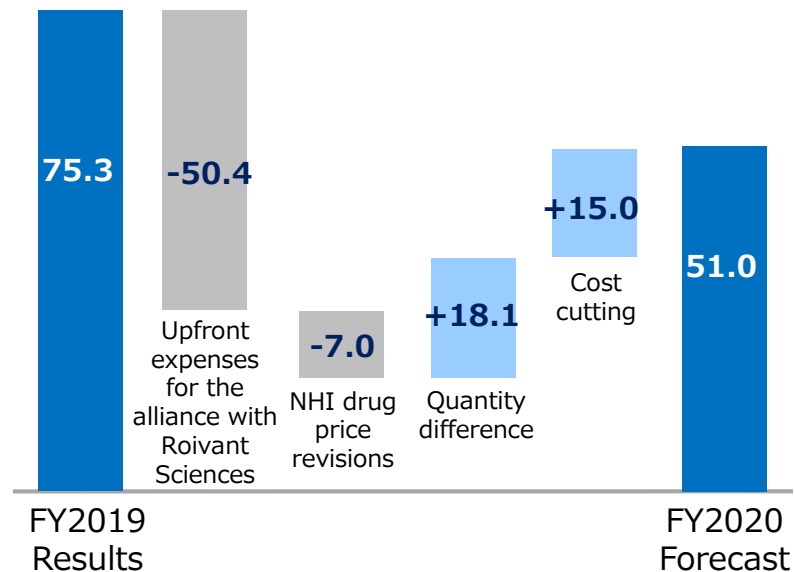
## FY2020 Forecast (Billions of yen)

Sales revenue **535.0**

Core operating income **51.0**

## Variable Factors of Core Operating Income

(FY2019 Results against FY2020 Forecast)



# Mid- to Long-Term Outlook for the Pharmaceuticals Sector

Major changes in the past 6 months

## Initiatives in the Group

### 1 Upward revision of FY2020 results

Core operating income  
37.0 → **51.0** billion yen

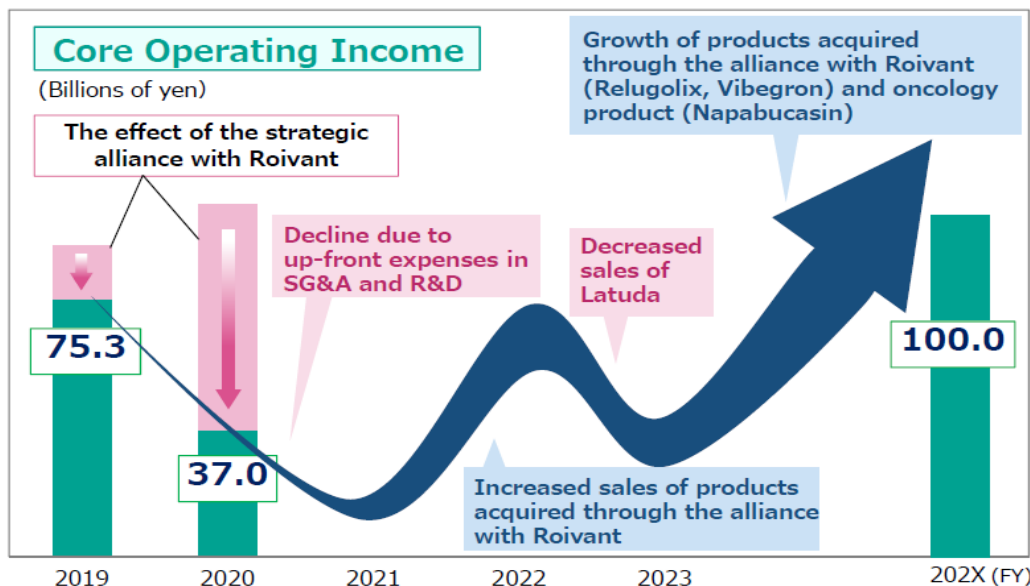
### 2 Promotion of sharing Sunovion's capabilities

Use of Sunovion's distribution channels (Myovant, Urovant)  
Expansion of access to general practitioners (Urovant)

### 3 Acquired 100% ownership of Urovant

Timely provision of operating & growth funds  
Maximize group synergies

## Investors' Meeting for the Current Priority Management Issues and Business Strategy on May 28, 2020



Expecting to overcome the LATUDA cliff and achieve long-term growth, after initial years of increased expenses and lower operating income, due to the investment in the alliance with Roivant

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# Creating New Value through Group Synergies

**Regenerative medicine & cell therapy**

**Theranostics**

**Infectious Diseases Control**

**Frontier Businesses**

Expansion of business scope in regenerative medicine & cell therapy area

Development of novel companion diagnostic & therapeutic agents for cancer using RI

Development of novel vaccines & therapeutic agents against AMR bacteria

Offering healthcare solutions beyond pharmaceutical agents

Fundamental tech. for iPS cells

RI-labeling Tech.

Knowledge about infectious diseases

Digital tech.



R&D capabilities for in-vivo diagnostics



R&D capabilities for pharmaceuticals



Material design tech.



Organic chemistry tech.



Safety assessment tech.



RI Radioisotopes

Red diamond icon Today's topics

## ① Regenerative Medicine and Cell Therapy

Proposed indication, etc.	Partners	Region (planned)	Cell type	Status
<b>Pediatric congenital athymia (RVT-802)</b>	-Duke University	Global	Cultured thymus tissue	Under preparation to resubmit BLA
<b>AMD (Age-related macular degeneration)</b>	-Healios -RIKEN	Global	Allo iPS cell-derived retinal pigment epithelium	In progress: clinical research Preparing to start clinical study (Japan)
<b>Parkinson's disease (Designated as a "SAKIGAKE")</b>	-Kyoto University -CiRA	Global	Allo iPS cell-derived dopamine neural progenitor	In progress: investigator-initiated clinical study (Phase 1/2 study) (Japan)
<b>Retinitis pigmentosa</b>	-RIKEN	Global	Allo iPS cell-derived photoreceptor (3D)	In progress: clinical research
<b>Spinal cord injury</b>	-Keio University -Osaka National Hospital	Global	Allo iPS cell-derived neural progenitor	In progress: clinical research
<b>Kidney failure</b>	-Jikei University -Bios -PorMedTec	Japan, North America	Auto/Allo iPS cell-based differentiation-induced nephron progenitor cells (organ)	In progress: pre-clinical research

▶ **Planned schedule FY2020**

▶ **Launch schedule FY2022\***

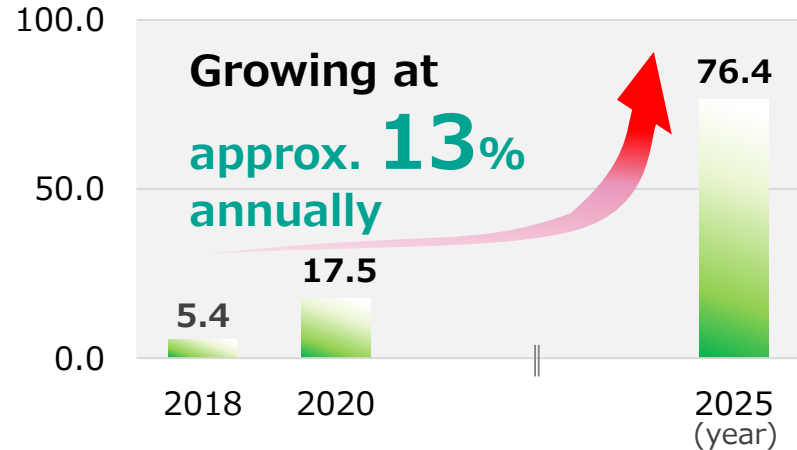
\* Launch schedule is based on our targets, pending agreement with partners

## ② Entry into CDMO Business for Regenerative Medicine and Cell Therapy

### CDMO business for regenerative medicine and cell therapy (Contract Development and Manufacturing Organization)

- Demand for pharmaceutical contract development and manufacturing offers **high growth potential**.
- In the area of regenerative medicine and cell therapy, there are only **a limited number of companies in Japan that have the advanced technologies** required for CDMOs.
- Leverage **the strengths of Sumitomo Chemical and Sumitomo Dainippon Pharma**

### Projection of global demand for regenerative and cellular medicine (\$ Billion) (worldwide)



- Fundamental technology related to ES/iPS cells
- Expertise on CMO business for API
- Analysis and Safety Assessment of the products



- Industry-leading-level expertise on regenerative medicine and cell therapy
- iPS cell-derived cell therapies in development pipeline

**Contributing to Resolving Healthcare Issues by Leveraging Group Synergies  
in the Area of Regenerative Medicine and Cell Therapy**

## ② Entry into CDMO Business for Regenerative Medicine and Cell Therapy



Sumitomo Dainippon  
Pharma



(51%)

(49%)

- Expertise on regenerative medicine and cell therapy
- Lease of existing facilities
- Dispatch of necessary personnel, such as technical staff.

- Investment, Financing
- Providing Services

- Dispatch of necessary personnel, such as technical staff
- Provide industrial technology in the future.

**S-RACMO Co., Ltd.**

Contracts for development of  
manufacturing process and  
product manufacturing

Solutions to  
manufacturing issues

Access to new opportunities for  
cell therapeutics  
(iPSCs & other cell types)

Therapeutic candidates developed by academia & startups  
(Issues: Establishment of manufacturing systems)

\* CorneaGen, Inc.(Washington State, US)and Sumitomo Dainippon Pharma will jointly develop cellular therapeutics with corneal endothelial cells. S-RACMO plans to receive the contract to develop the manufacturing process and to manufacture the product, as its first project.

Theranostics

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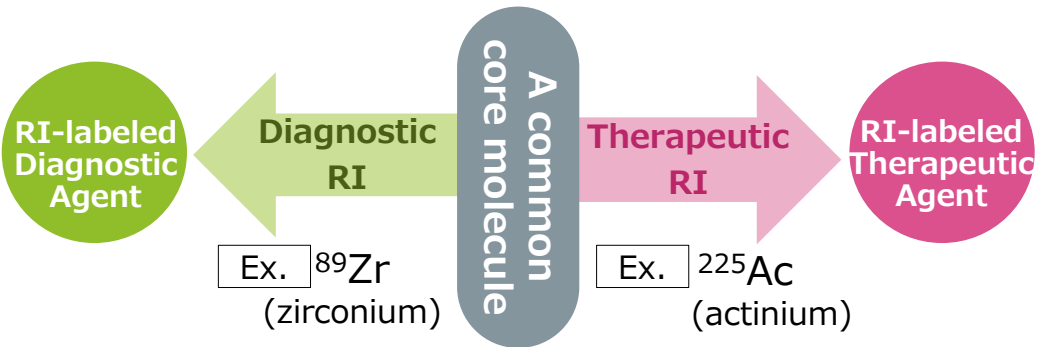
Therapeutics

+

Diagnostics

Fusion of diagnostic and therapeutics

## Basic concept of "Theranostics" executed by Nihon Medi-Physics



Utilize a common core molecule (antibodies, peptides etc.)



Selectively deliver RI-labeled diagnostic or therapeutic agents to target organ

Adopted by AMED\*1 as CiCLE\*2

## Aims of Theranostics Project

### 1 Offering new value in medical practice through nuclear medicine

- Development of companion diagnostic and α-emitting therapeutic agents for cancer using radioisotopes (RI) originated in Japan
- Expecting approval and launch in the second half of the 2020s through open innovation within and outside the Group

### 2 Building a new earnings base

- As the pillar for next-generation businesses following FDG-PET
- Expanding the ratio of new products to approximately 30% by 2030, along with new PET diagnostic agents under development

\* 1 AMED: Japan Agency for Medical Research and Development  
 \* 2 CiCLE: Cyclic Innovation for Clinical Empowerment



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Besides COVID-19, the following issues remain to be solved regarding infectious diseases.

\* As for COVID-19, we participate in the US COVID-19 Research-Database, donate to the Kitasato Institute's Project for COVID-19 and provide medical protective equipment.

## Global Health Issues

- Threats of periodic **pandemics by new strains of influenza viruses.**
- **The target for developing new vaccines has shifted to diseases for which vaccines are more difficult to develop, such as mycobacterium tuberculosis, malaria and HIV,** although the number of infected patients is large.

## Spread of Antimicrobial- Resistant (AMR) Bacteria

- Since the 2010s, AMR bacteria have been recognized as a global issue.
- If no measures are taken, **in 2050 an estimated 10 million people will die** worldwide, and it is considered the **next threat after COVID-19.**

We aim to create **(I) Novel Vaccines (Universal Influenza and Malaria)** and **(II) Therapeutic agents for AMR bacteria**, by utilizing our accumulated knowledge in R&D in the area of infectious diseases.

# Development of Novel Vaccines and Therapeutic Agents against AMR Bacteria

## Development of Vaccines


**NIID 国立感染症研究所**  
NATIONAL INSTITUTE OF INFECTIOUS DISEASES  

**NIBIOHN** 国立研究開発法人  
 医薬基盤・健康・栄養研究所  
National Institutes of Biomedical Innovation, Health and Nutrition

**Universal Influenza Vaccine**

The next-generation vaccine that protects against various subtypes of flu viruses incl. pandemic ones



**愛媛大学**  
EHIME UNIVERSITY

**Malaria Vaccine**

Novel Malaria Vaccine

Joint Research

Joint Research


**Sumitomo Dainippon Pharma**

Novel Vaccine Adjuvant

Accumulated knowledge in drug discovery in the area of infectious diseases.


Possibility of adjuvant manufacturing in Sumitomo Chemical in the future

## Therapeutic agents against AMR bacteria


**北里研究所**  
THE KITASATO INSTITUTE

A long tradition and track record in infectious disease research over 100 years.

Joint Research

Research scientists at Sumitomo Dainippon Pharma  Drug discovery group led by Dr. Ohmura (Nobel Prize Winner) in Kitasato University

➡ Aim to overcome global issues on AMR bacteria

### Cautionary Statement

Statements made in this document with respect to Sumitomo Chemical's current plans, estimates, strategies and beliefs that are not historical facts are forward-looking statements about the future performance of Sumitomo Chemical. These statements are based on management's assumptions and beliefs in light of the information currently available to it, and involve risks and uncertainties.

The important factors that could cause actual results to differ materially from those discussed in the forward-looking statements include, but are not limited to, general economic conditions in Sumitomo Chemical's markets; demand for, and competitive pricing pressure on, Sumitomo Chemical's products in the marketplace; Sumitomo Chemical's ability to continue to win acceptance for its products in these highly competitive markets; and movements of currency exchange rates.