



Mitsubishi Tanabe Pharma

# **Mitsubishi Tanabe Pharma Corporation Business Briefing**

**November 20, 2018  
Masayuki Mitsuka  
President & Representative Director**

## **Content of Today's Presentation**

---

**Today's presentation will cover the progress made to date with the Medium-Term Management Plan 16-20, the revision of our Management Figures, and our initiatives to accelerate growth.**

# Agenda

---

## **1. Progress of Medium-Term Management Plan 16-20 and Revision of Fiscal 2020 Numerical Management Objectives**

- ① Maximizing Pipeline Value / Accelerating U.S. Business Development
- ② Strengthening IKUYAKU and Marketing / Reforming Operational Productivity
- ③ Gilenya / Invokana Royalty Revenues Forecast
- ④ Fiscal 2020 Management Figures
- ⑤ Shareholder Return Policy

## **2. Initiatives Targeting Fiscal 2023**

- ① U.S. / European Market
- ② Japanese Market
- ③ Strengthening Our Platform for Growth

## **3. Open Up the Future**

- ① Creating Pharmaceuticals and Healthcare Services with Differentiated Value
- ② Expanding Drug Discovery Opportunities by Leveraging Modalities

## **4. Targeting the Resolution of Social Issues**

# **1. Progress of Medium-Term Management Plan 16-20 and Revision of Fiscal 2020 Management Figures**

# ① Maximizing Pipeline Value / Accelerating U.S. Business Development

Up to fiscal 2018 (including forecasts)

Up to fiscal 2020

## Maximizing Pipeline Value

Discovery of 10 Late-stage Drug Candidates

Start of late-stage development for 7 drug candidates

CNS: Radicava oral formulation  
Valbenazine

Immuno-inflammatory: Fasinumab

Diabetes and kidney:  
Vadadustat  
Canaglu (diabetic nephropathy)

Vaccines: Influenza VLP vaccine  
Pentavalent vaccine

Start of late-stage development for additional 4 drug candidates

CNS: ND0612, MT-8554

Immuno-inflammatory : MT-7117,  
MT-2990

## Accelerating U.S. Business Development

U.S. Sales Target  
¥80.0 billion

As expected start-up for Radicava

Fiscal 2017: ¥12.3 billion

Fiscal 2018: ¥31.5 billion

Approval in Canada

Influenza VLP vaccine:  
Filing (adults)

ND0612: Development delay in U.S./Europe

Expanding Radicava launch regions

North America: ¥40.0 billion

+ expanded launch countries

Radicava oral suspension filing

Influenza VLP vaccine :Launch (adults)  
Elderly/pediatric filing

ND0612: Steadily advancing P3 trial

# ②Strengthening IKUYAKU and Marketing / Reforming Operational Productivity

	Up to fiscal 2018 (including forecasts)	Up to fiscal 2020
<div><p>Strengthening IKUYAKU and Marketing</p><p>Domestic Ethical Drug Revenue ¥300.0 billion</p><p>New Drug and Priority product revenue ratio: 75%</p></div>	<p>Revenue: ¥296.2 billion Priority products ratio: 70%</p> <p>Immuno-inflammatory: Top share among biologics (40%) Stelara/Rupafin sales</p> <p>Diabetes and kidney diseases: Canalia launch</p> <p>Vaccines: Investment in BIKEN Co., Ltd.</p>	<p>Revenue: Approx. ¥300.0 billion Priority products ratio: up to 75%</p> <p>Immuno-inflammatory: Simponi additional dosage form</p> <p>Diabetes and kidney diseases: Vadadustat launch Expanding in the kidney field</p> <p>Vaccines: Strengthening domestic manufacturing/sales system</p>
<div><p>Reforming Operational Productivity</p><p>Cost of Sales/SG&amp;A Expenses ¥20.0 billion Reduction</p></div>	<p>¥19.0 billion reduction (vs. fiscal 2015)</p>	<p>¥30.0 billion reduction (vs. fiscal 2015)</p>

# ③Gilenya / Invokana

## Royalty Revenues Forecast

	Up to fiscal 2018 (including forecasts)	Up to fiscal 2020
<b>Gilenya Royalties</b>	<p>Fiscal 2016: ¥53.7 billion  Fiscal 2017: ¥57.7 billion  (+¥3.9 billion YoY)  First half fiscal 2018: ¥29.9 billion  (+¥0.4 billion YoY)</p> <p>The U.S. Patent and Trademark Office (PTAB<sup>*1</sup>) upheld Novartis's U.S. dosage regimen patent  <b>Sales favorable, revenue increasing</b></p>	<p>Anticipate a certain level of royalty revenues for a certain period of time, depending on Gilenya sales</p>
<b>Invokana Royalties</b>	<p>Fiscal 2016: ¥18.8 billion  Fiscal 2017: ¥13.9 billion  (-¥4.8 billion YoY)  First half fiscal 2018: ¥4.9 billion  (-¥2.3 billion YoY)</p> <p><b>Substantially lower than initial expectation</b></p>	<p>Large-scale clinical trial results expected to contribute to sales growth  CANVAS (reduce the risk of MACE<sup>*2</sup>)  CREDENCE (diabetic nephropathy)</p>
<b>Other Out-licensing Milestones</b>	<p>MT-1303 milestone revenues were expected, but the contract was canceled.</p>	<p>Aiming to select candidates and implement new partnering initiative</p>

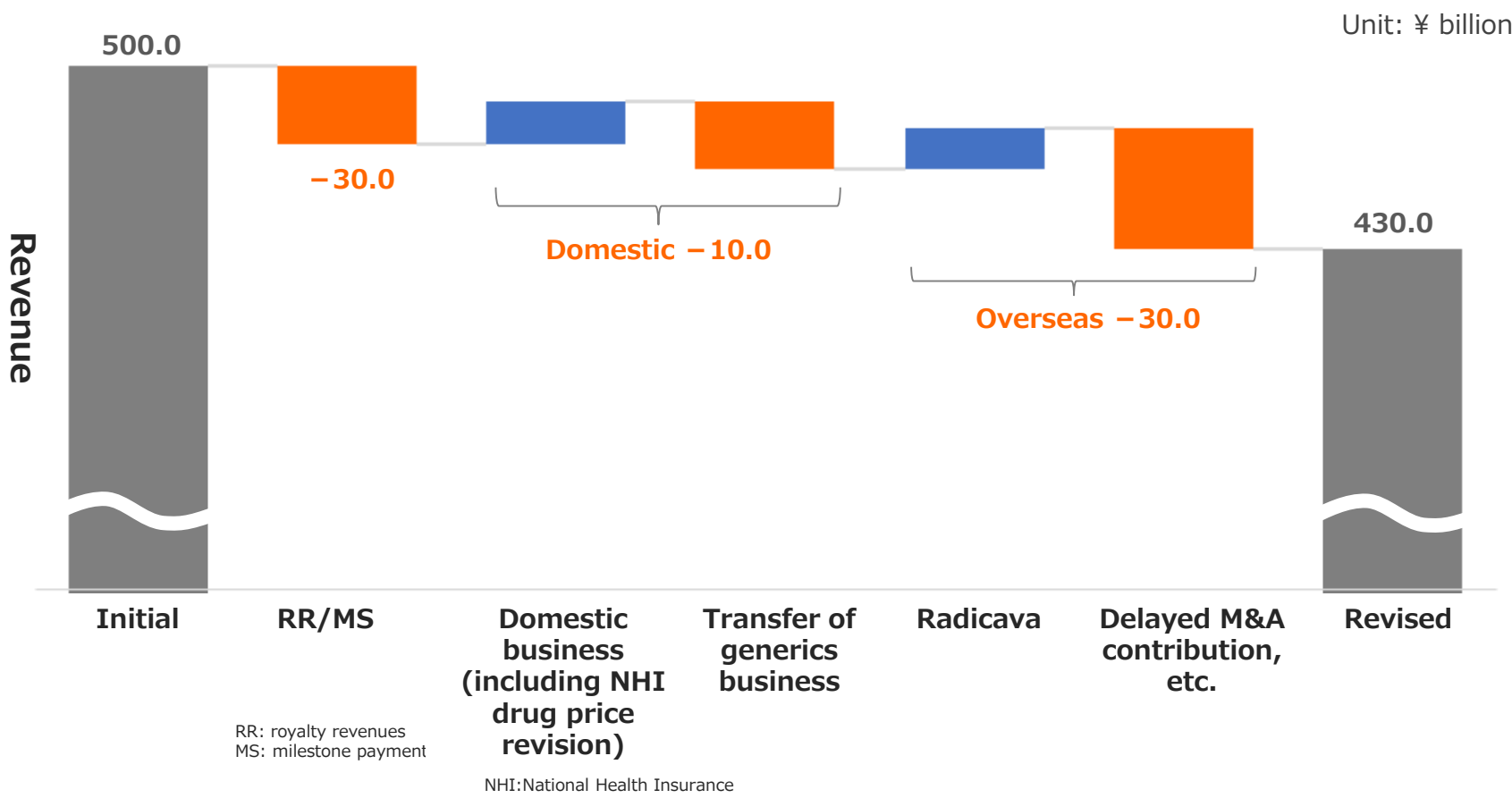
\*1 PTAB: Patent Trial and Appeal Board, a part of the U.S. Patent and Trademark Office.

\*2 MACE: Major Adverse Cardiovascular Event



# ④Fiscal 2020 Management Figures (Revenue)

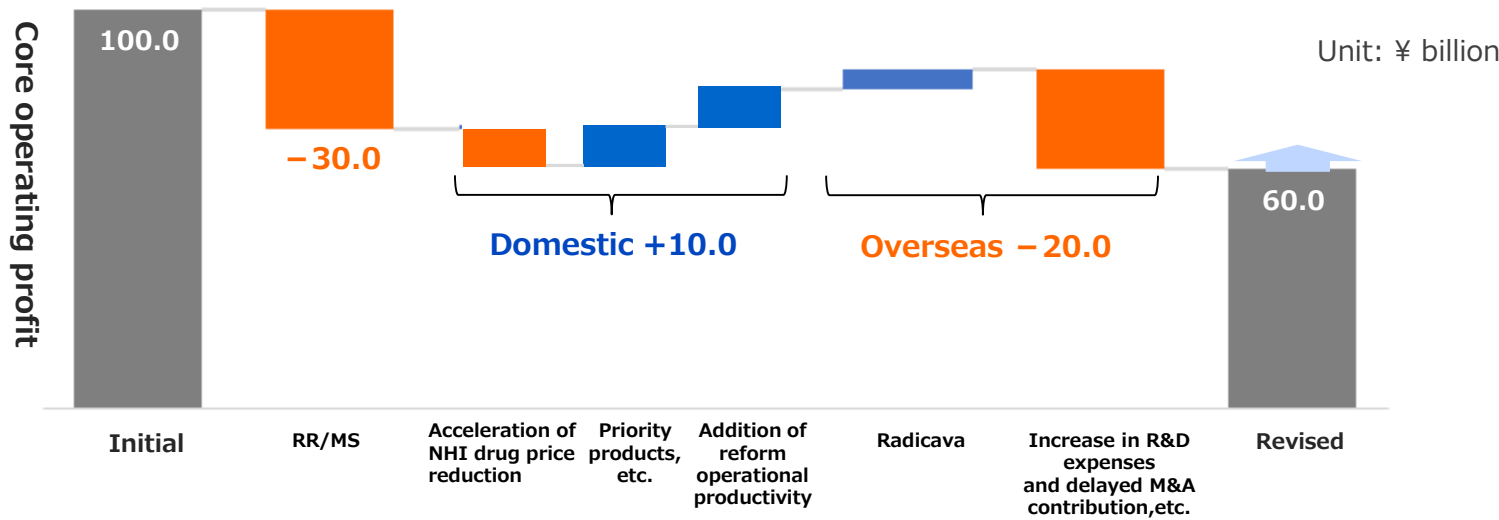
Despite domestic business expansion and higher Radicava sales, forecasting ¥430.0 billion in revenue due to lower Invokana royalty revenues, delayed M&A contribution, etc.





# ④Fiscal 2020 Management Figures (Core Operating Profit)

For future growth, maintain R&D investment at a high level and revise fiscal 2020 core operating profit target to ¥60.0 billion  
Extend target date for achieving revenue of ¥500.0 billion and core operating profit of ¥100.0 billion to three years later



	Initial objective	After revision
Revenue	500.0	430.0
Core operating profit	100.0	60.0

## ⑤ Shareholder Return Policy

---

- Enhance stable, continuous return to shareholders, **targeting a consolidated dividend payout ratio of 50%**
- **Maintain current amount of dividends (annual dividend of ¥56)** during period of Medium-Term Management Plan 16-20

## 2. Initiatives Targeting Fiscal 2023

## Fiscal 2023 Management Figures

---

The target date for achieving revenue of ¥500.0 billion and core operating profit of ¥100.0 billion will be extended to three years later. However, aiming for future growth, we will aggressively implement R&D/strategic investment

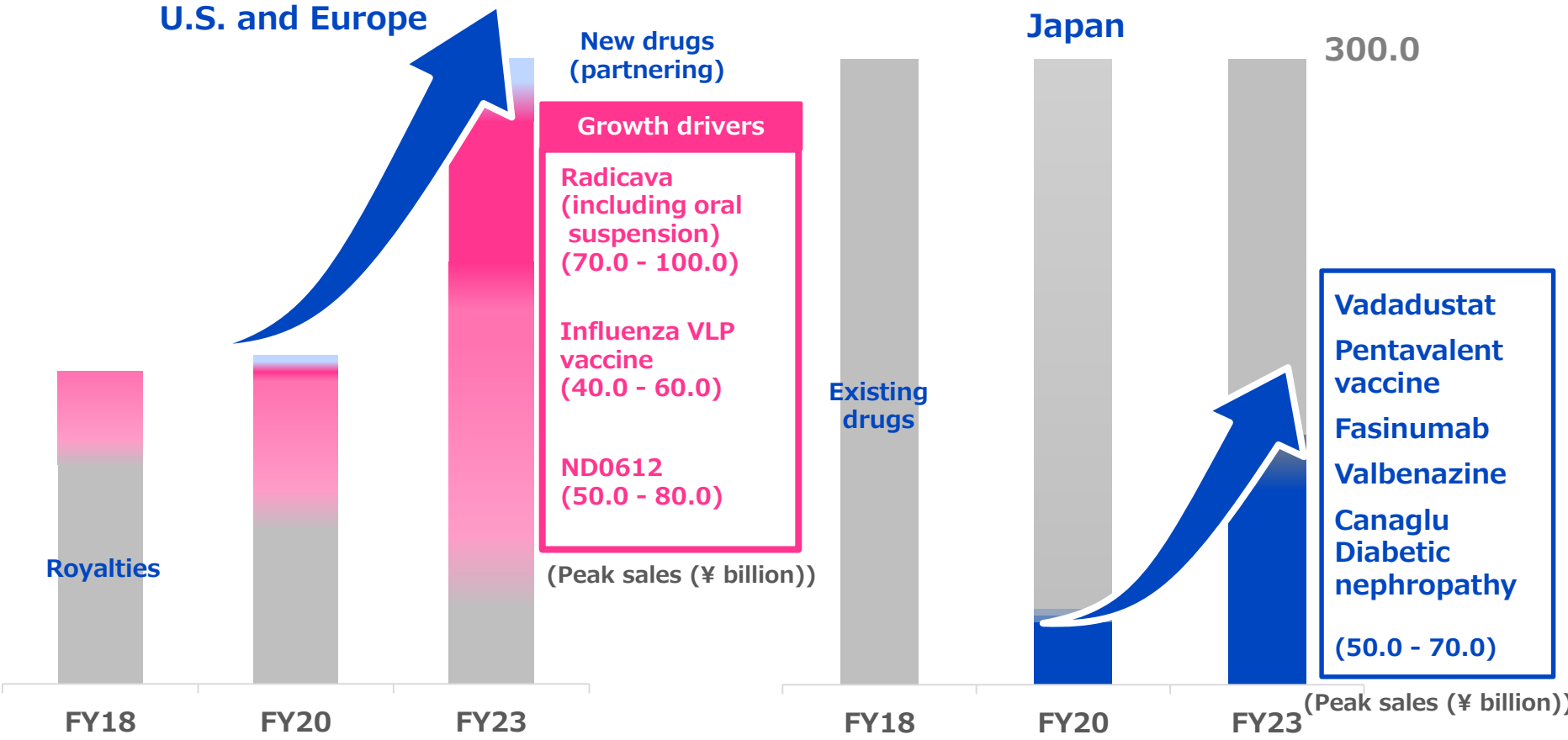
### Fiscal 2023

- |                         |                                 |
|-------------------------|---------------------------------|
| • Revenue               | More than <b>¥500.0</b> billion |
| • Core operating profit | More than <b>¥100.0</b> billion |
| • R&D investment        | <b>¥80.0</b> billion            |

(Strategic investment funds of ¥300.0 billion are planned for fiscal 2019 through fiscal 2023)

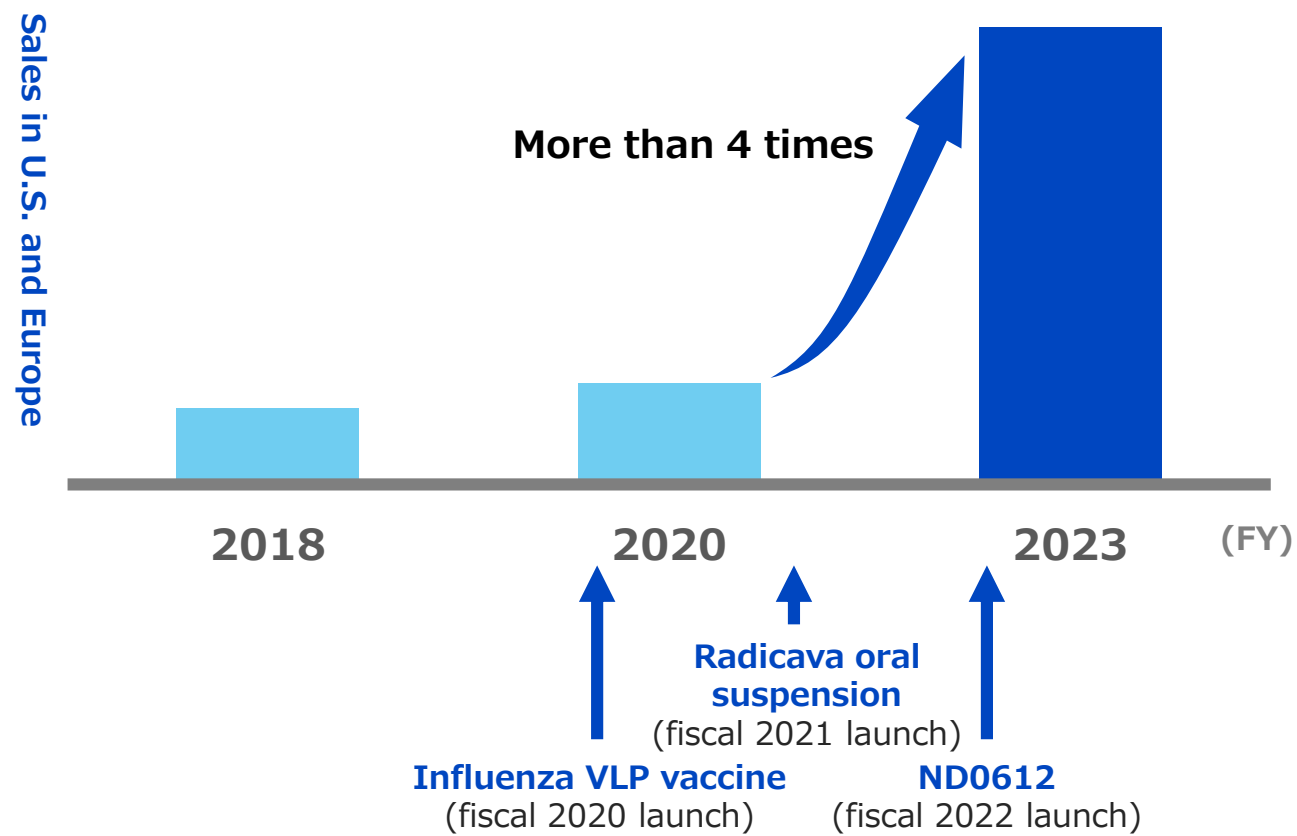
## Initiatives in U.S./Europe and Japan

Accelerate growth in the U.S. and Europe with **3 growth drivers**, maintain revenue of ¥300.0 billion in Japan through new drug launches and IKUYAKU



# ①U.S. and European Markets

Aiming to substantially expand sales by fiscal 2023 with the growth drivers: Radicava oral suspension, influenza VLP vaccine, and ND0612

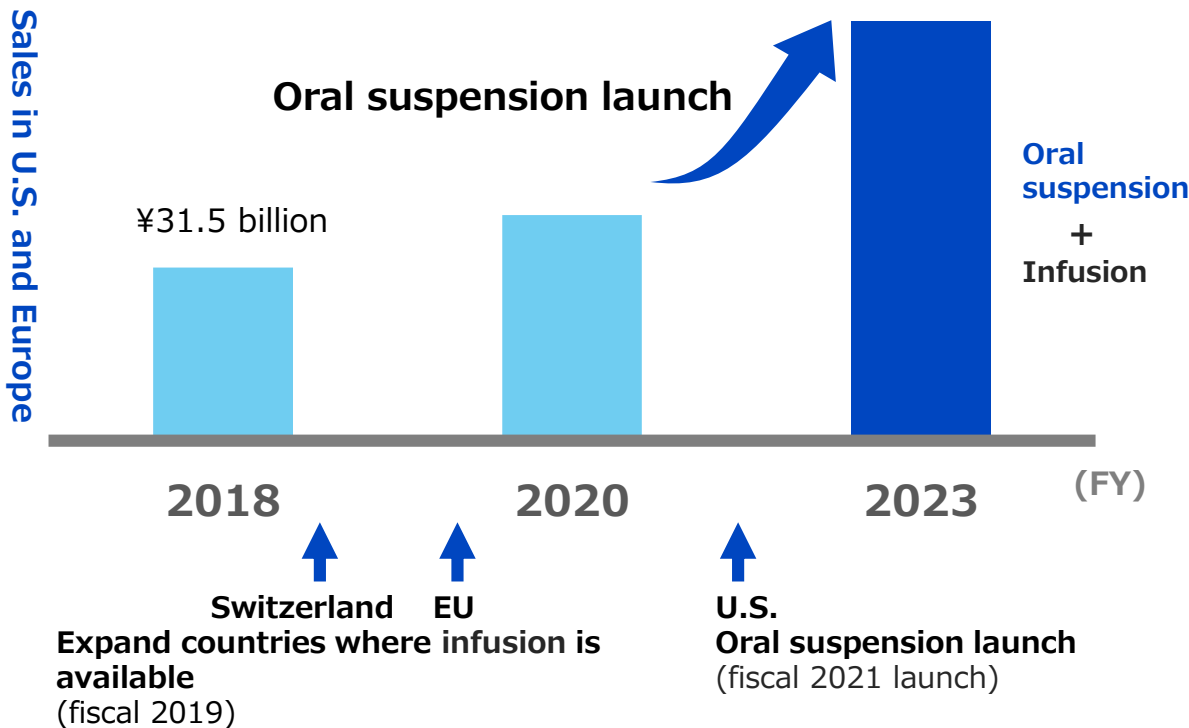


# Radicava

Maximize revenue by successively expanding to other countries, launching oral suspension (MT-1186) in the U.S. in fiscal 2021

advantage of  
Radicava  
oral  
suspension

- Eliminates extended treatment time for patients resulting from intravenous infusion administration
- Eliminates limits on number of administration sites
- Development of suspension that is easy for ALS patients to take

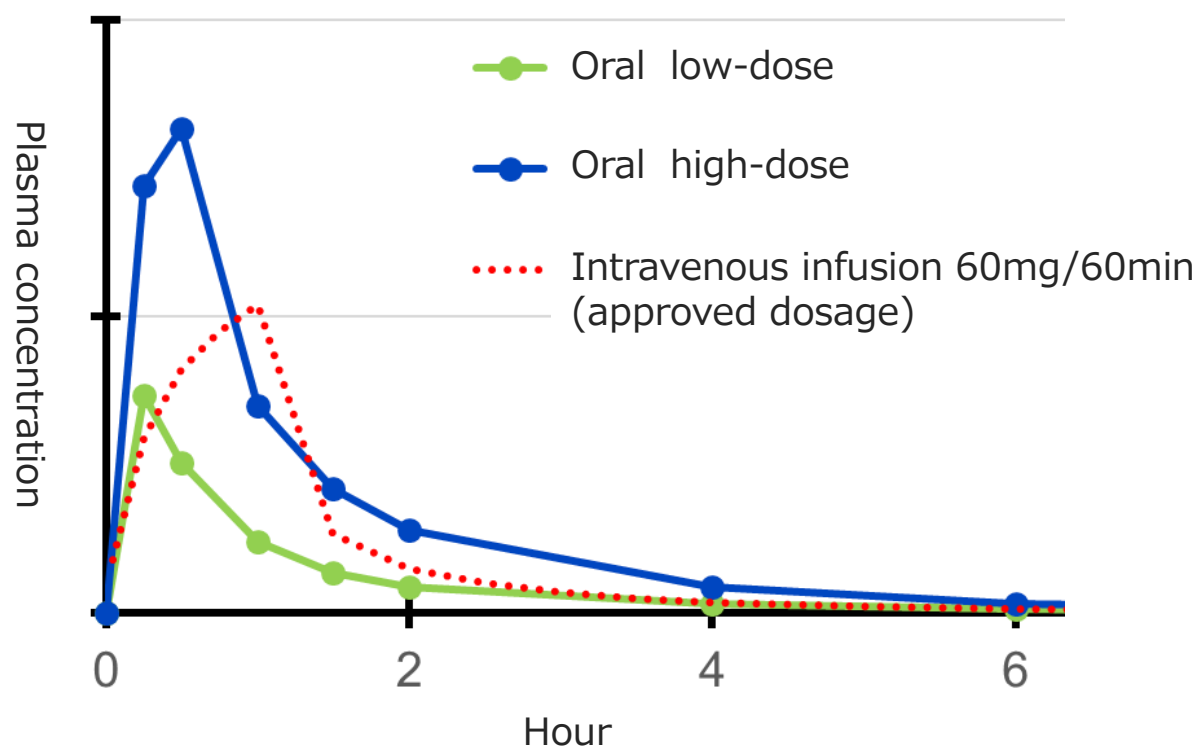


Peak sales  
level  
¥70.0 billion-  
¥100.0 billion

# Accelerating Development of Radicava Oral suspension



The oral suspension has a similar pharmacokinetic profile as the intravenous infusion



Plan to announce details at the International Symposium on ALS/MND (Glasgow, Scotland, December 7-8)

\* ALS : Amyotrophic Lateral Sclerosis  
MND : Motor Neuron Disease



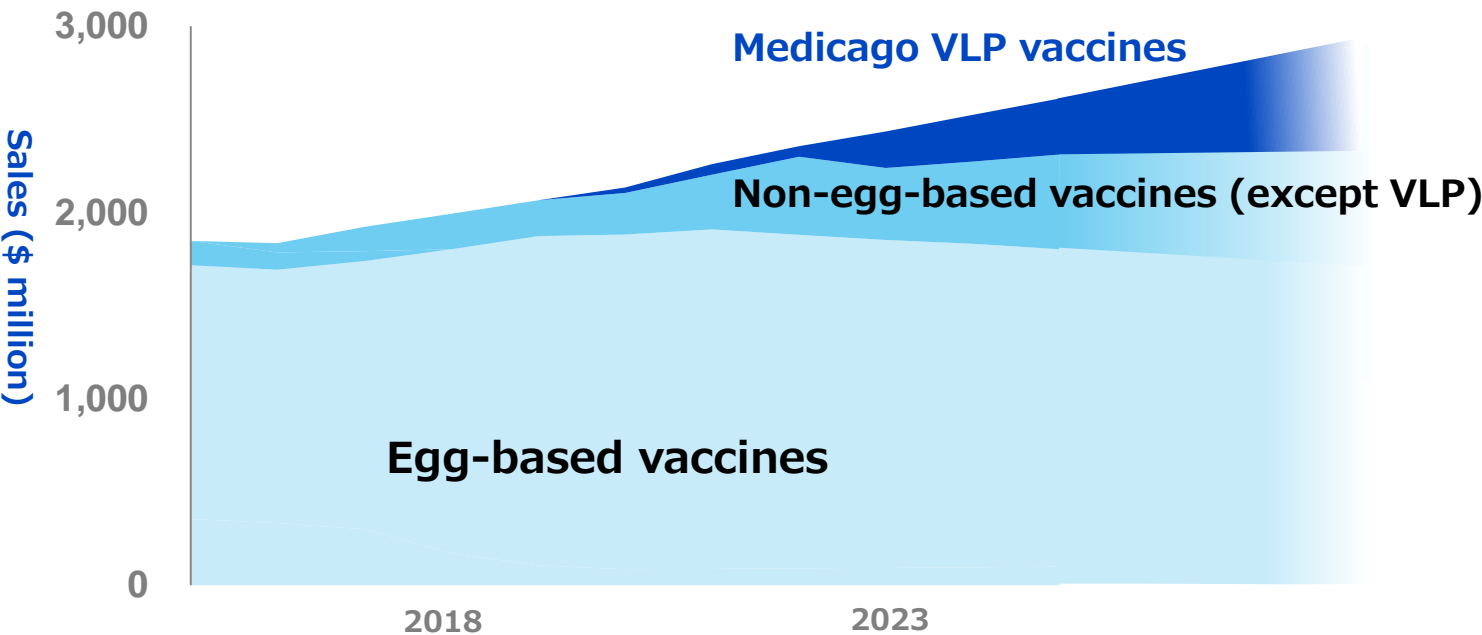
# Seasonal Influenza Vaccine Market

In the U.S. market, non-egg-based vaccines, including Medicago VLP vaccines, are expected to record growth

Medicago  
VLP vaccine  
features

- Shorter time for manufacture
- Matches circulating strains (no egg adaptation)

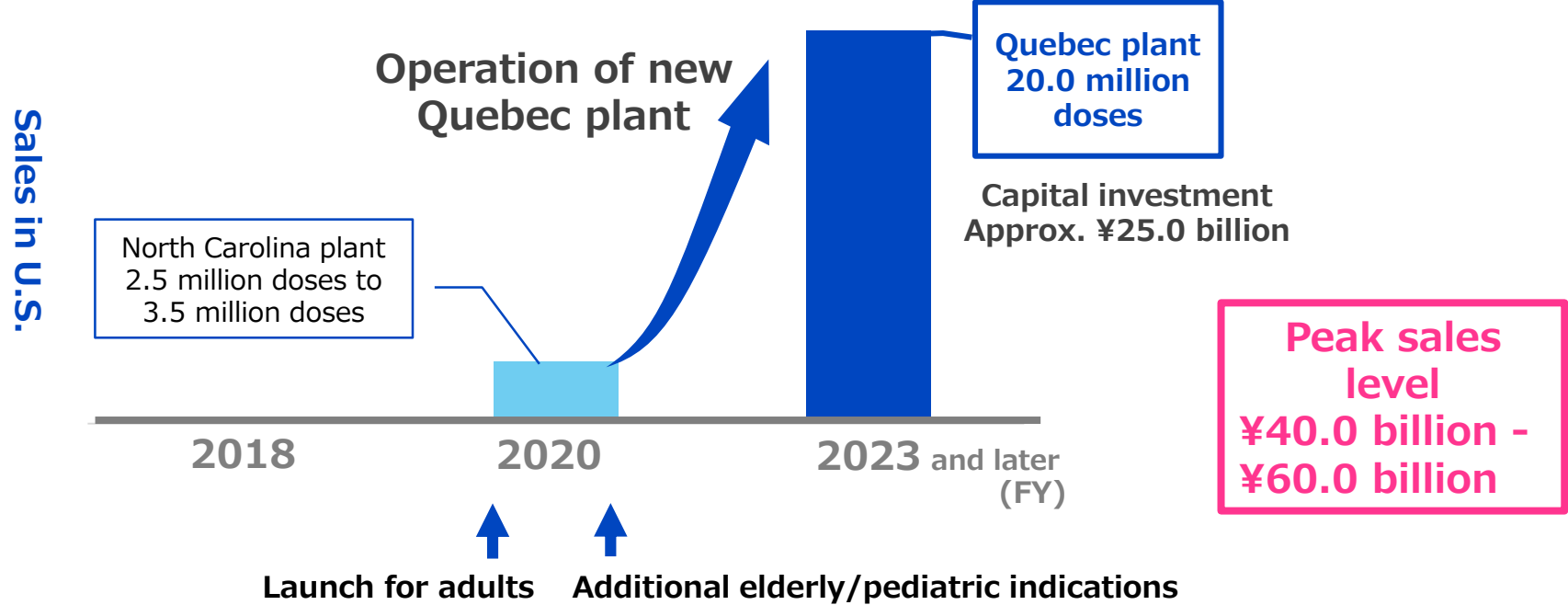
U.S. seasonal influenza vaccine market forecast



# Seasonal Influenza VLP Vaccine

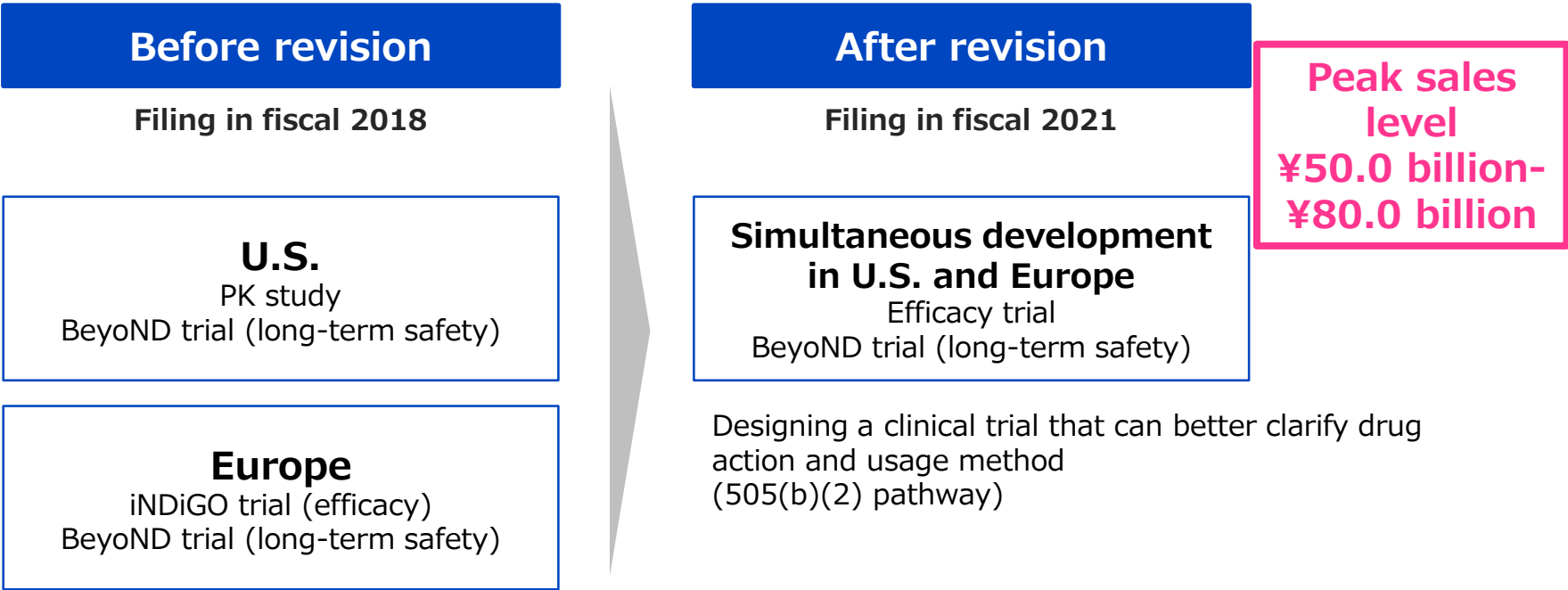
P3 clinical trial for adults completed, preparing for commercialization

- U.S. application (planned for fiscal 2018)
- U.S. sales start (from 2020-2021 season)
- Full-scale supply system through operation of new plant in Quebec (from 2023-2024 season)



# Status of ND0612

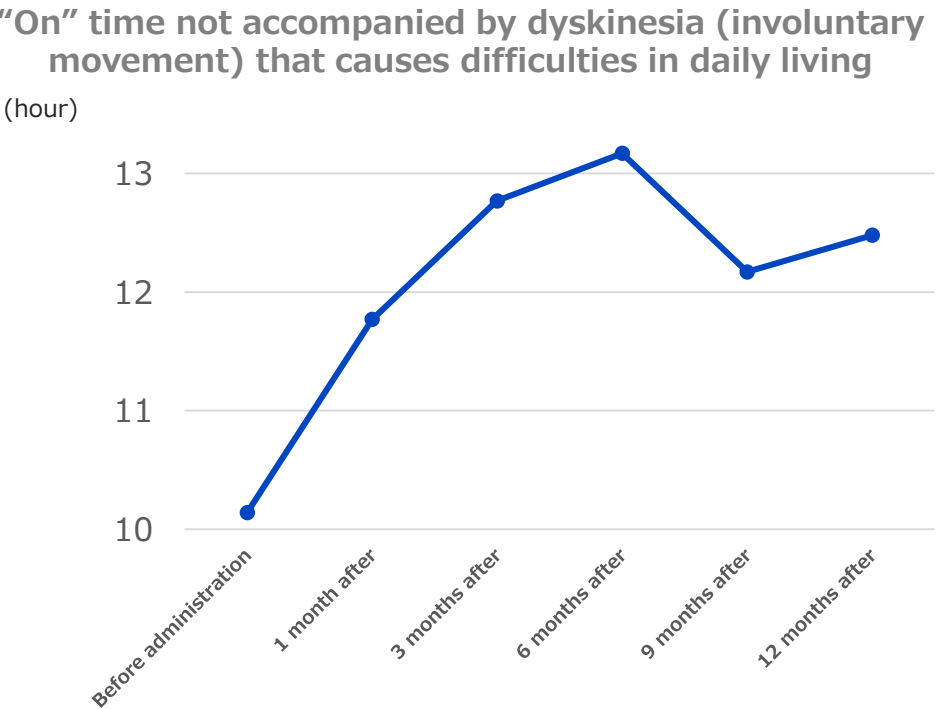
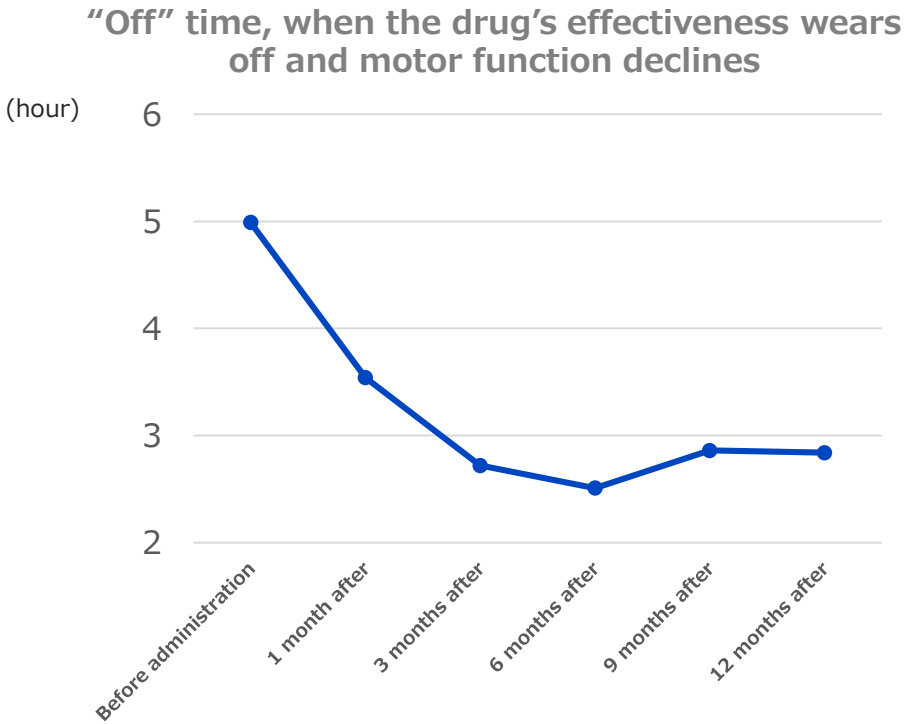
Revision of development plan to establish a global, unified product label through simultaneous development in U.S. and Europe, aiming for fiscal 2022 launches in U.S. and European markets



## Strengths of ND0612

Through continuous subcutaneous administration, the plasma concentration of levodopa stabilized.  
→Improvement of motor complications in Parkinson’s disease patients

Interim results of BeyoND trial (long-term safety)  
— When ND0612 is administered for 24 hours —



Note: This is interim data, and it could be different from final results accordingly.

# New Drug Launches

## Original drugs from in-house research driving further growth

Product	Indication (Development stage)	Features	Expected peak sales
MT-8554	Vasomotor symptoms, etc. (P2)	Non-hormonal treatment with new mechanism of action that is expected to eliminate need for hormonal treatment and offer a high level of safety	>¥100.0 billion
MT-7117	Erythropoietic protoporphyria (P2)	Oral, small-molecule treatment agent for prevention of photosensitivity(fast-track designated)	>¥20.0 billion
MT-1303	Inflammatory bowel disease, etc. (P2)	Next-generation S1P receptor functional antagonist with low risk of bradycardia manifestation	>¥50.0 billion
MT-3995	Nonalcoholic steatohepatitis, etc. (P2)	Mineralocorticoid receptor antagonist that is expected to have limited cardiovascular action and high efficacy.	>¥100.0 billion
MT-3921	Spinal cord injury, etc. (pre-clinical)	Humanized anti-RGMa antibody that promotes neuron regeneration (Discovered jointly with Osaka University)	>¥100.0 billion

RGMa: Repulsive Guidance Molecule a



②Japanese Market Newly Launched Products

Work to maintain domestic sales of approximately ¥300.0 billion through new drug launches in 4 priority disease fields (total amount of peak sales: ¥50.0 billion to ¥70.0 billion)

Diabetes and kidney

Vadadustat (renal anemia)  
Fiscal 2020 launch

Canaglu (diabetic nephropathy)  
Fiscal 2023 additional indication

Immuno-inflammatory

Fasinumab (osteoarthritis)  
Fiscal 2022 launch

Simponi (autoinjector)  
Fiscal 2019 additional dosage form

Vaccines

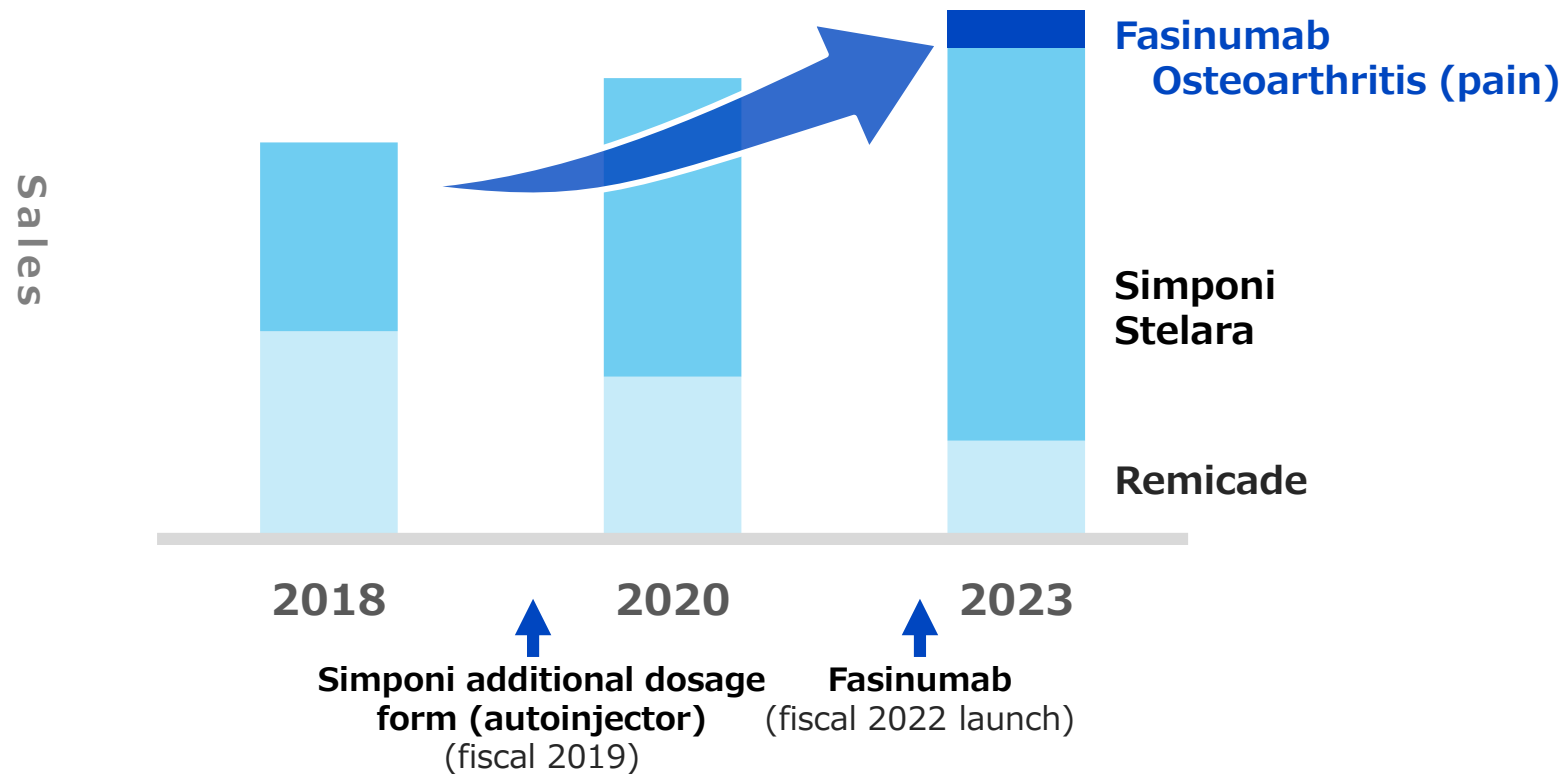
MT-2355(pentavalent vaccine)  
Fiscal 2022 launch

CNS

Valbenazine (tardive dyskinesia)  
Fiscal 2022 launch

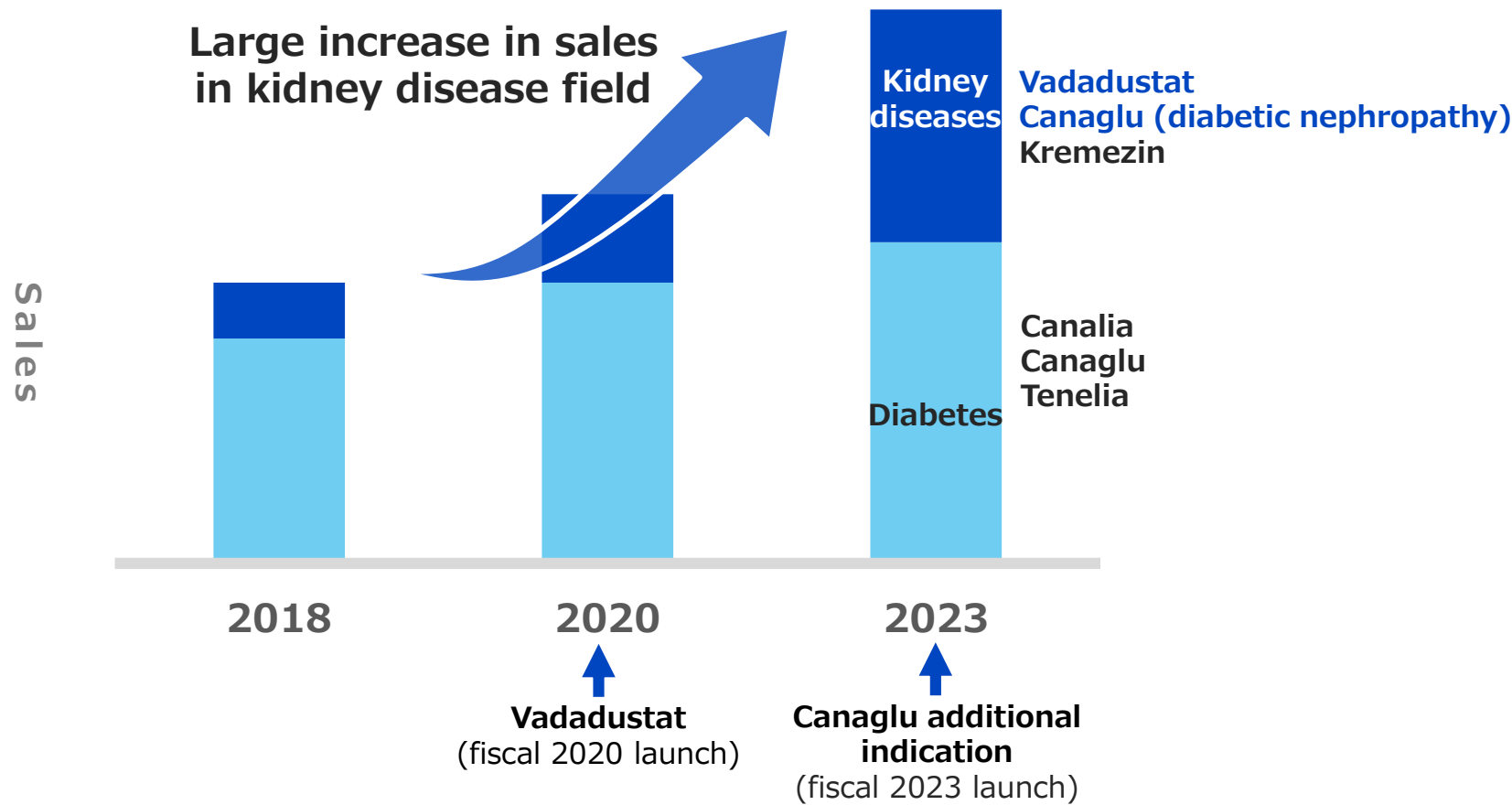
# Immuno-Inflammatory

Through launch of Simponi / Stelara and Fasinumab, maintain top share among biologics in the Immuno-inflammatory field



## Diabetes and Kidney Diseases

Accelerate growth in kidney disease field through launch of vadadustat and additional indication for Canaglu





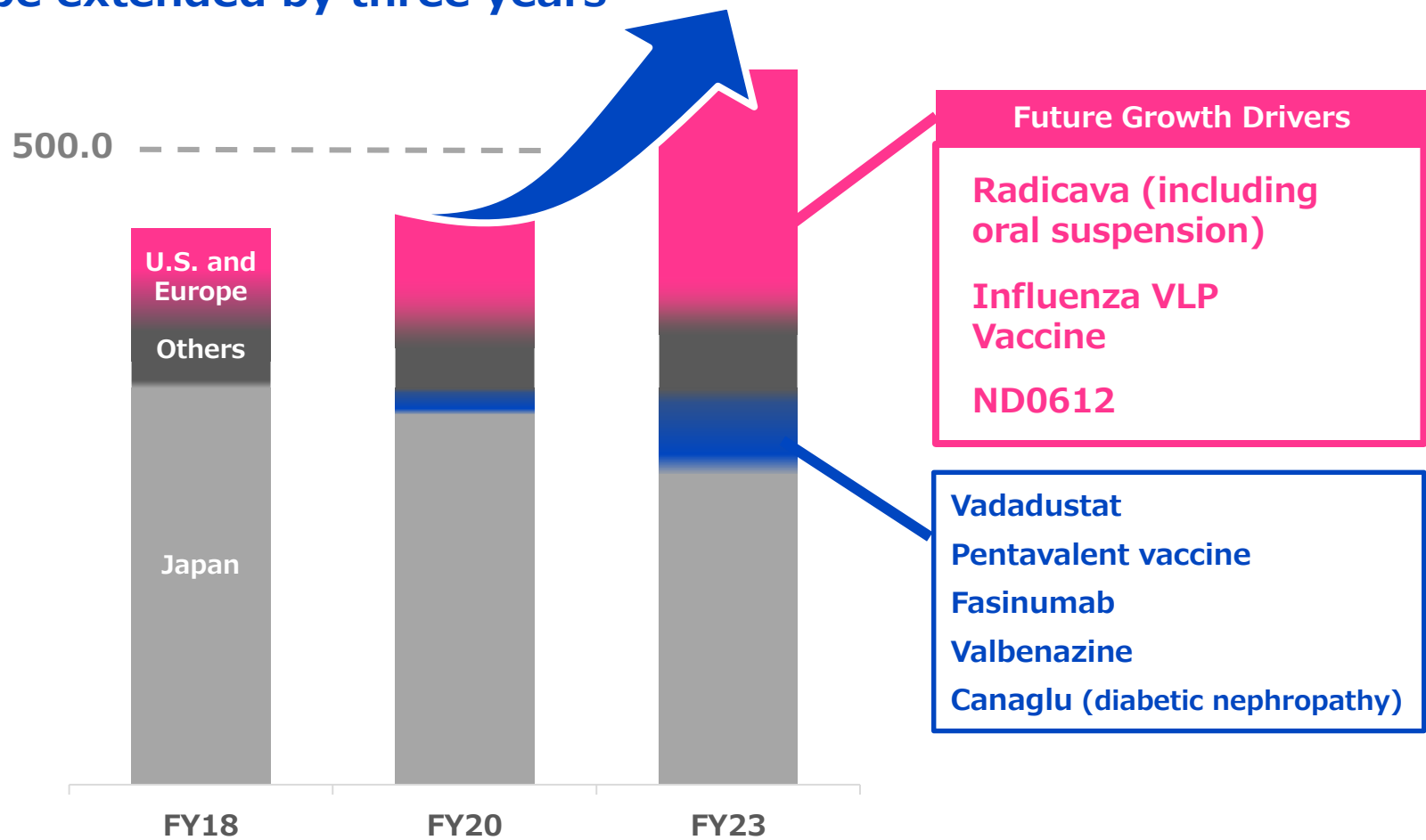
### ③Strengthening Platform for Growth

Work to optimize and increase efficiency of global management system and to strengthen functions by reallocating management resources (workforce / technologies / information, etc.)

Basic Policy	Issues	Countermeasures
1 R&D System Reforms	<ul style="list-style-type: none"><li>➤ Reform to <b>highly diverse, agile research structure</b></li><li>➤ Make transition to <b>global development system</b></li></ul>	<ul style="list-style-type: none"><li>➤ Aggressive use of external collaboration Reorganize/consolidate research functions</li><li>➤ Move toward an organization that puts priority on U.S. launches</li></ul>
2 Strengthen/ Develop Marketing and Production Systems	<ul style="list-style-type: none"><li>➤ Reinforce <b>domestic sales capabilities</b> (earnings power)</li><li>➤ Reinforce <b>supply chain based on manufacturing capabilities</b></li></ul>	<ul style="list-style-type: none"><li>➤ Track market needs and increase efficiency through effective use of ICT, including both MR &amp; supporting staff</li><li>➤ Increase production efficiency through the use of new technologies Reorganize/consolidate production and technology functions</li></ul>
3 Reinforce Corporate Platform Functions	<ul style="list-style-type: none"><li>➤ Reinforce <b>global strategy functions</b></li><li>➤ Reinforce <b>shared business platforms</b></li></ul>	<ul style="list-style-type: none"><li>➤ Reorganize/consolidate head quarter functions</li><li>➤ Promotion of the duties efficiency by the RPA utilization</li></ul>

## Accelerating Growth

Revenue of more than ¥500.0 billion and core operating profit of more than ¥100.0 billion will be achieved in fiscal 2023, even though the target date for achievement of the objectives will be extended by three years

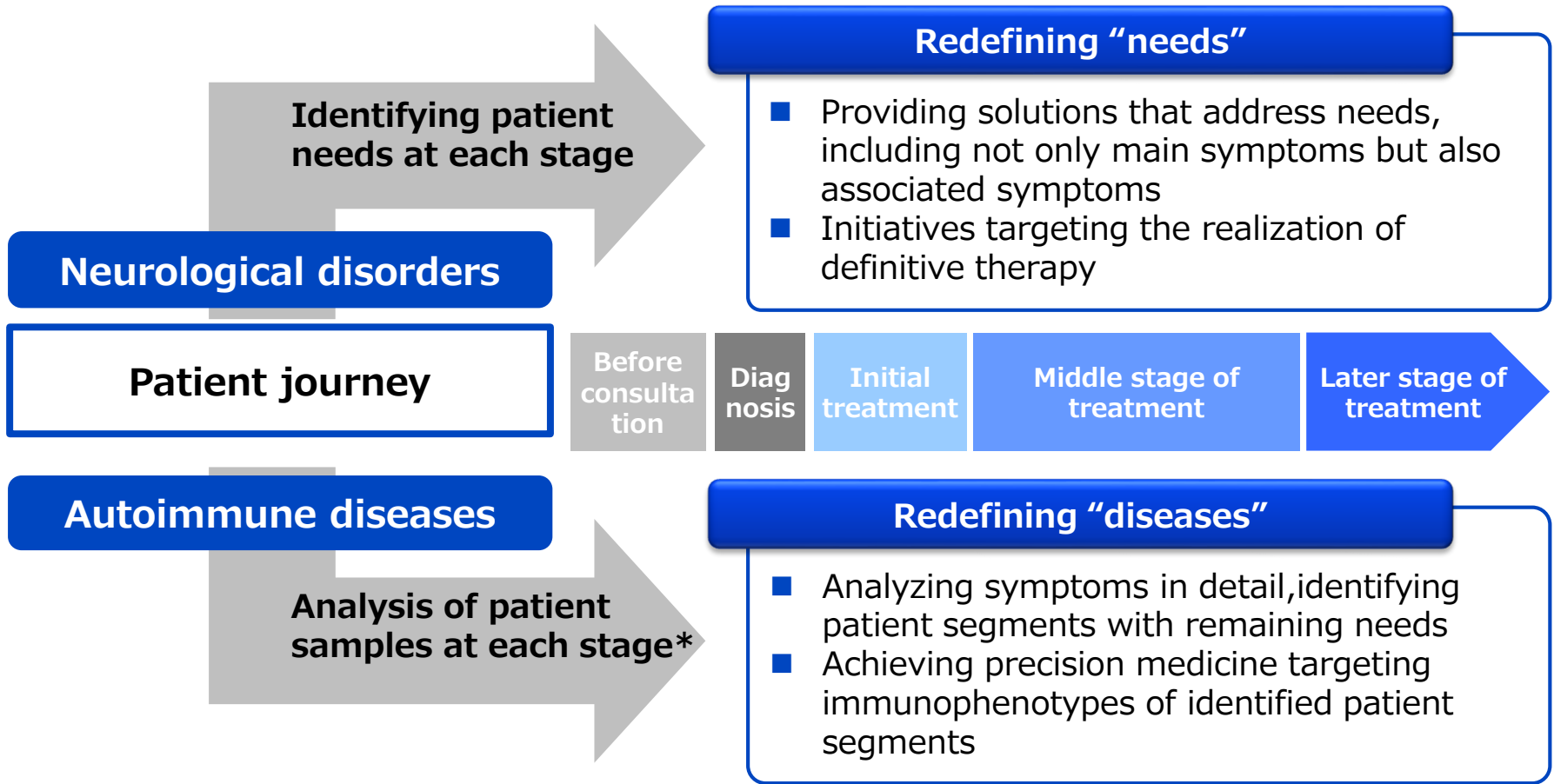


### ***3. Open Up the Future***



# ① Pharmaceuticals and Healthcare Services with Differentiated Value

Throughout the patient journey, figuring out what the patient is feeling, thinking, and doing. Taking steps to meet patient needs

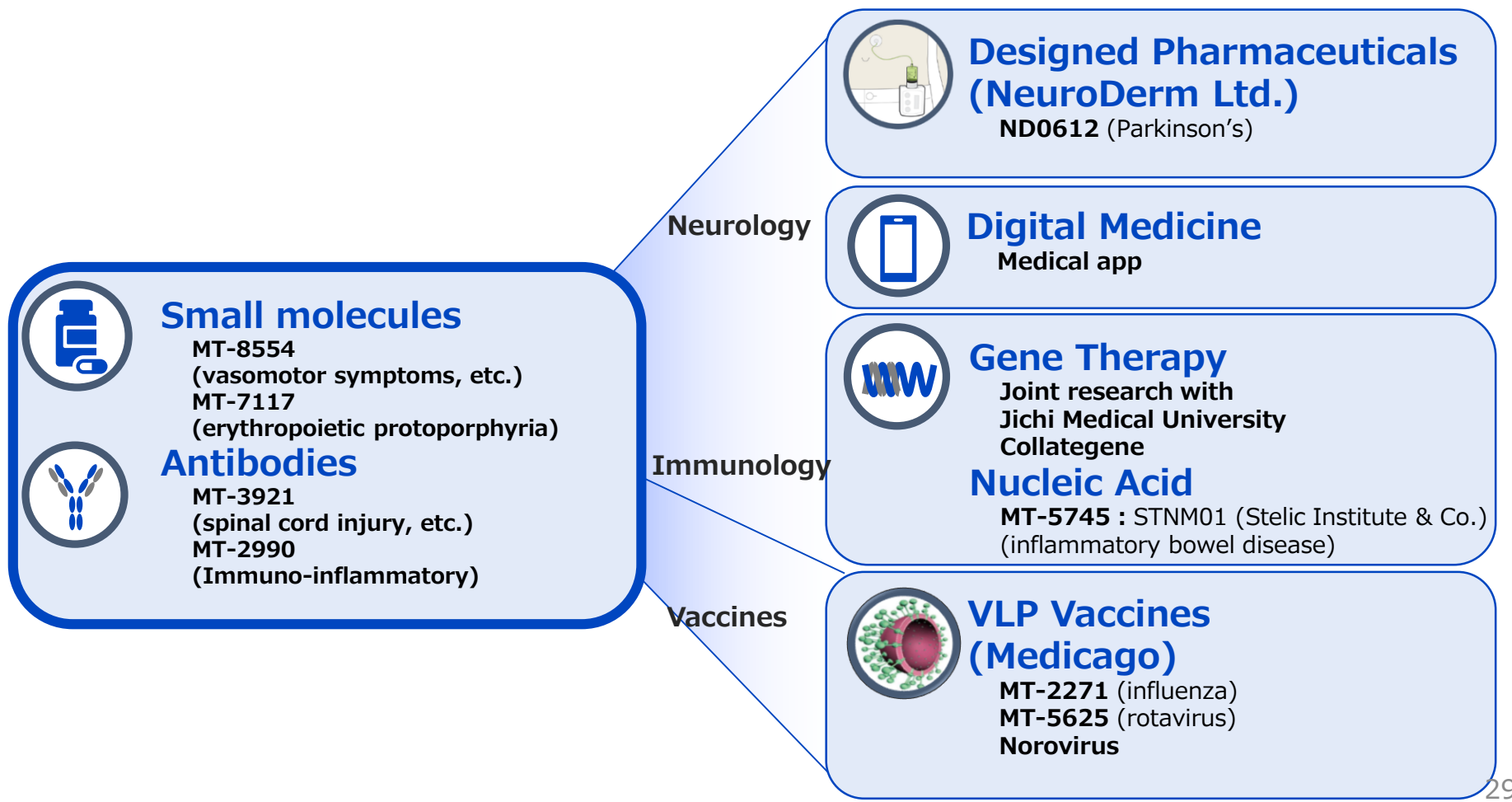


\* Joint research with Keio Research Park, Immune-Mediated Inflammatory Diseases Consortium for Drug Development, etc. 28

# ② Expanding Drug Discovery Opportunities by Leveraging Modalities

To meet needs, focusing on the following modalities in addition to ongoing focus on small molecules and antibodies

For new modalities, utilize partnering to accelerate the process of meeting needs



## 4. Targeting the Resolution of Social Issues

## **OUR PHILOSOPHY**

**We contribute to the healthier lives of people around the world through the creation of pharmaceuticals.**

## **OUR VISION**

**We strive to be a global research-driven pharmaceutical company that is trusted by communities.**

## Targeting the Resolution of Social Issues

We will work to fulfill our social duty by taking steps to address seven material issues (materiality) and will strive to contribute to the extension of healthy lifespan.

### Material Issues

Pharmaceuticals and healthcare services with differentiated value

Reliable products and sustainable supply

Appropriate use of products

Ethics, fairness and sincerity in business practices

Stakeholder engagement

Employee health, diversity and inclusion

Social contribution activities for health

SUSTAINABLE  
DEVELOPMENT  
GOALS

Extend healthy lifespan

Fulfill our social duty

SDGs: Sustainable Development Goals  
Adopted by the UN for achievement by 2030.



# *Open Up the Future*

Becoming a company that works with a sense  
of speed and is the first to deliver differentiated value



Mitsubishi Tanabe Pharma

## **Cautionary Statement**

The statements contained in this presentation is based on a number of assumptions and belief in light of the information currently available to management of the company and is subject to significant risks and uncertainties.

# Appendix

An abstract graphic featuring several overlapping, flowing shapes in various shades of blue and pink. The shapes originate from the left side of the page and curve towards the right, creating a sense of movement and depth. The colors range from a deep navy blue to a light sky blue, with a vibrant pink accent.

## Fiscal 2020: Management Figures

¥ billion

	Fiscal 2020: Initial	Fiscal 2020: revised
<b>Revenue</b>	<b>500.0</b>	<b>430.0</b>
<b>Japan</b>	<b>300.0</b>	<b>300.0</b>
<b>U.S.</b>	<b>80.0</b>	<b>40.0</b>
Royalty/milestone revenues	80.0	50.0
Others	40.0	40.0
<b>Core operating profit</b>	<b>100.0</b>	<b>60.0</b>
<b>Net profit attributable to owners of the Company</b>	<b>70.0</b>	<b>40.0</b>
<b>R&amp;D expenses</b>	<b>80.0</b>	<b>85.0</b>
<b>Overseas sales ratio</b>	<b>40%</b>	<b>30%</b>

<b>R&amp;D investment</b>	<b>400.0</b>	<b>400.0</b>
<b>U.S. strategic investment</b>	<b>More than ¥200.0</b>	<b>(currently, ¥130.0)</b>

Fiscal 2016 to  
fiscal 2020

## Dividends

- Enhance stable, continuous return to shareholders, targeting a consolidated dividend payout ratio of 50%
- Maintain current level of dividends (annual dividend of ¥56) during period of Medium-Term Management Plan 16-20

