



Mitsubishi Tanabe Pharma

Mitsubishi Tanabe Pharma Corporation Business Briefing

**November 20, 2018
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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

② Strengthening IKUYAKU and Marketing / Reforming Operational Productivity

	Up to fiscal 2018 (including forecasts)	Up to fiscal 2020
<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>	<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>
<p>Reforming Operational Productivity</p> <p>Cost of Sales/SG&A Expenses ¥20.0 billion Reduction</p>	<p>¥19.0 billion reduction (vs. fiscal 2015)</p>	<p>¥30.0 billion reduction (vs. fiscal 2015)</p>

③ Gilenya / Invokana Royalty Revenues Forecast

	Up to fiscal 2018 (including forecasts)	Up to fiscal 2020
Gilenya Royalties	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) The U.S. Patent and Trademark Office (PTAB* ¹) upheld Novartis's U.S. dosage regimen patent Sales favorable, revenue increasing	Anticipate a certain level of royalty revenues for a certain period of time, depending on Gilenya sales
Invokana Royalties	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) Substantially lower than initial expectation	Large-scale clinical trial results expected to contribute to sales growth CANVAS (reduce the risk of MACE* ²) CREDENCE (diabetic nephropathy)
Other Out-licensing Milestones	MT-1303 milestone revenues were expected, but the contract was canceled.	Aiming to select candidates and implement new partnering initiative

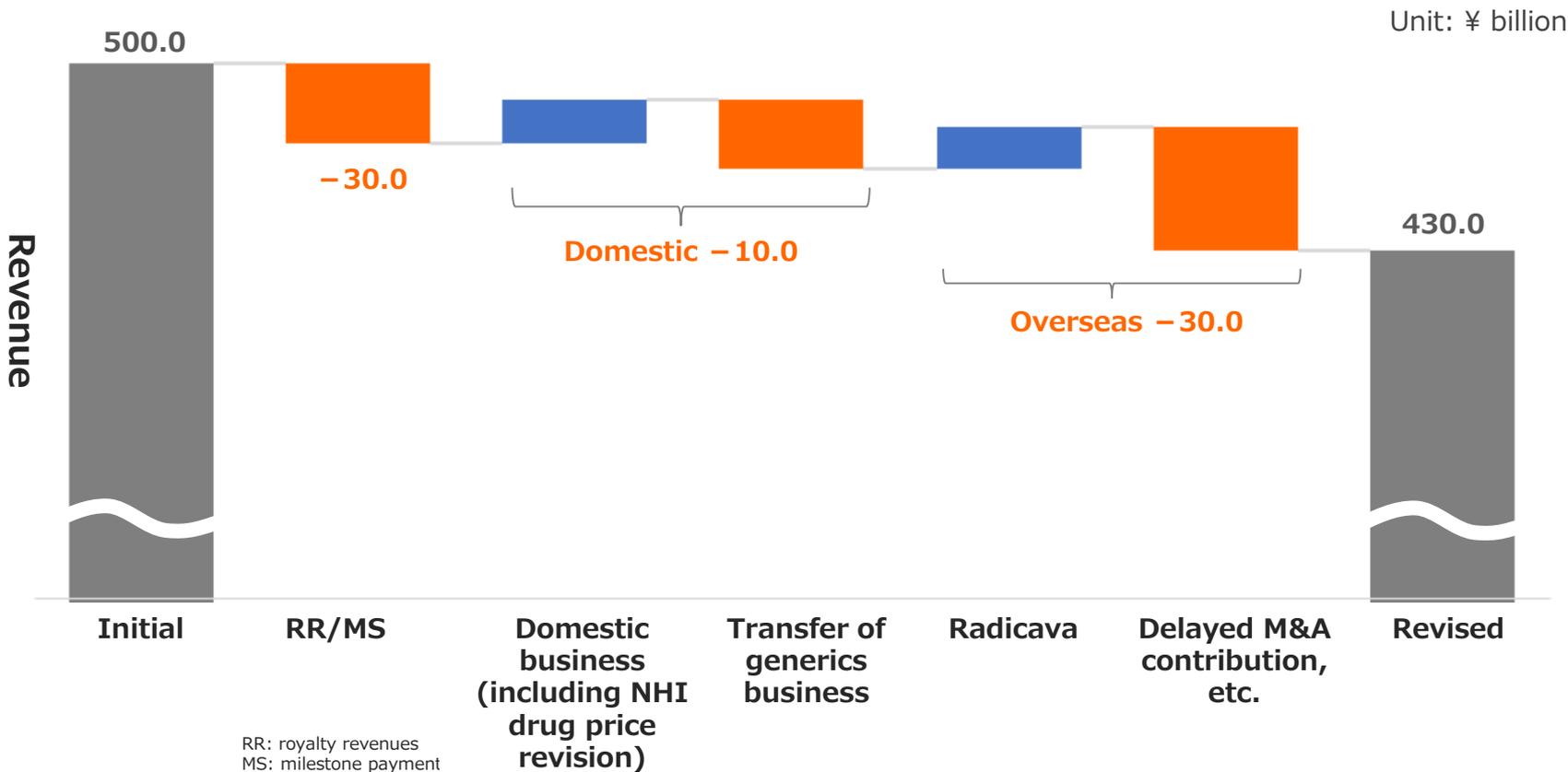
*1 PTAB: Patent Trial and Appeal Board, a part of the U.S. Patent and Trademark Office.

*2 MACE: Major Adverse Cardiovascular Event



④ Fiscal 2020 Management Figures (Revenue)

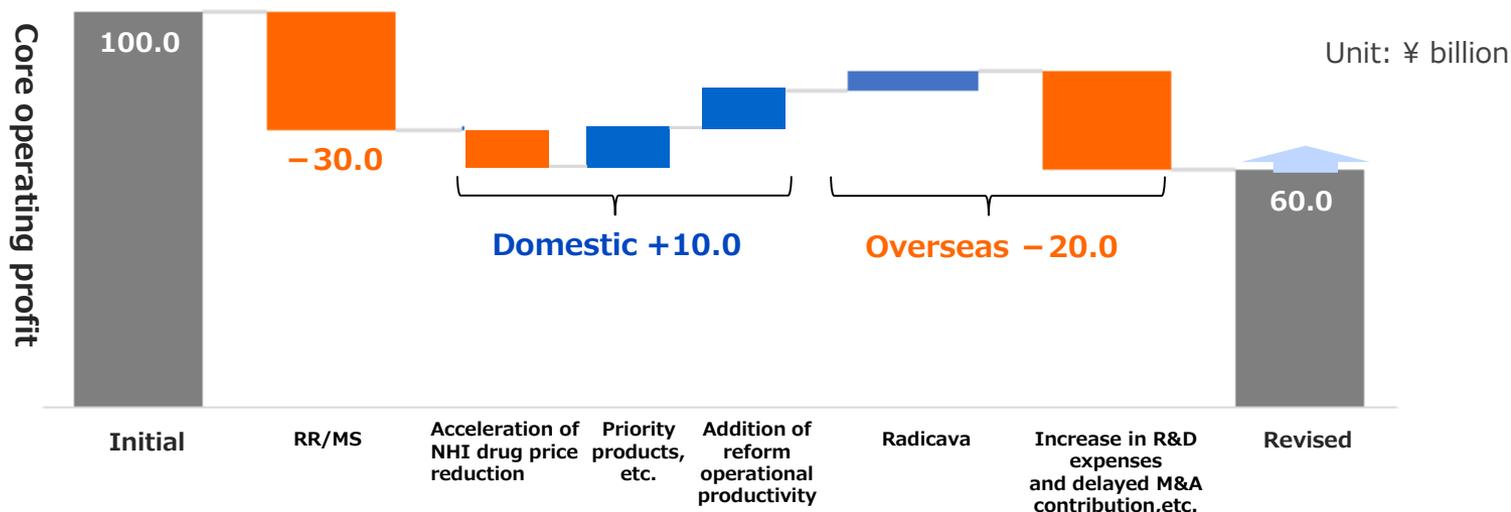
Despite domestic business expansion and higher Radicava sales, forecasting ¥430.0 billion in revenue due to lower Invokana royalty revenues, delayed M&A contribution, etc.



NHI: National Health Insurance

④ Fiscal 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

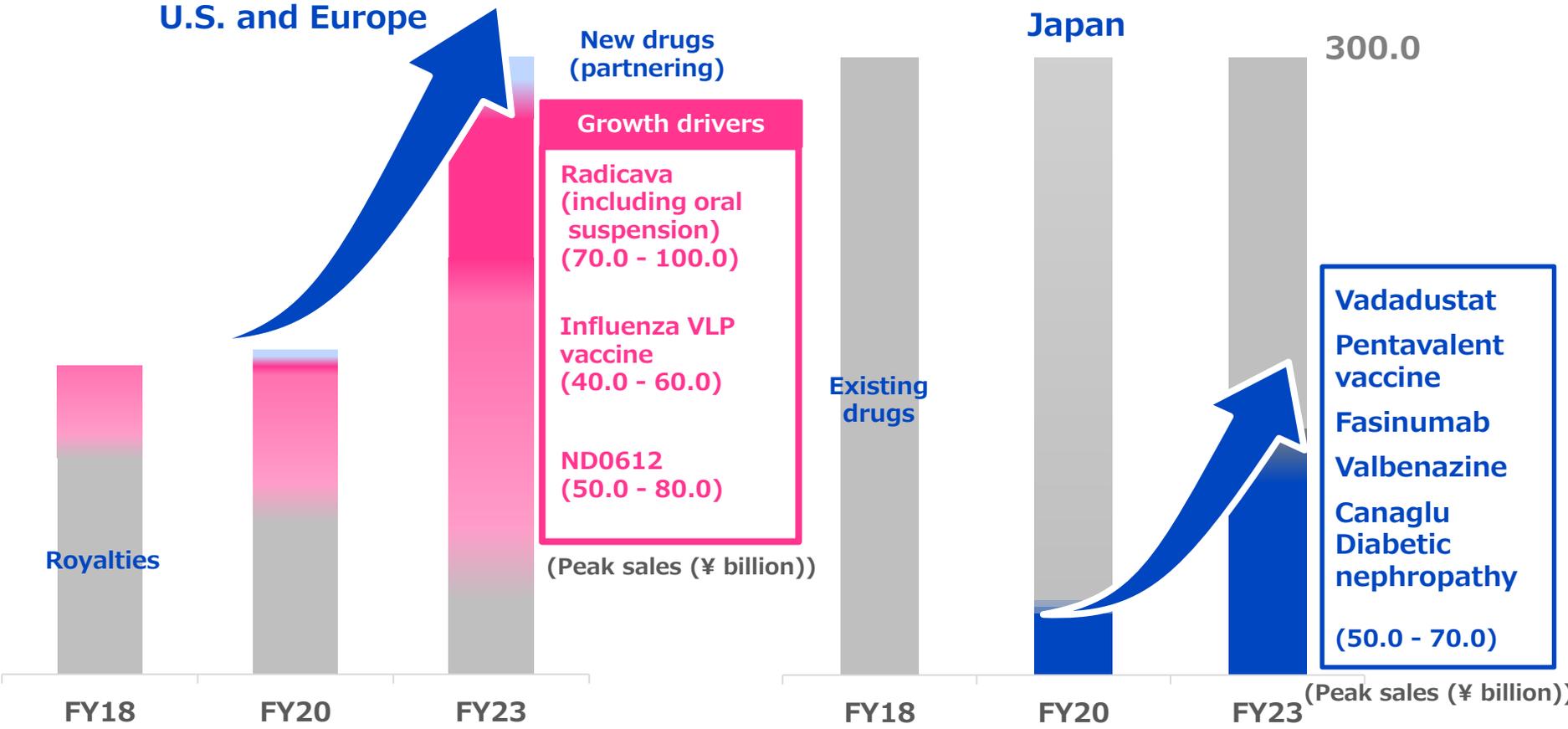
Fiscal 2023

- Revenue **More than ¥500.0 billion**
- Core operating profit **More than ¥100.0 billion**
- R&D investment **¥80.0 billion**

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

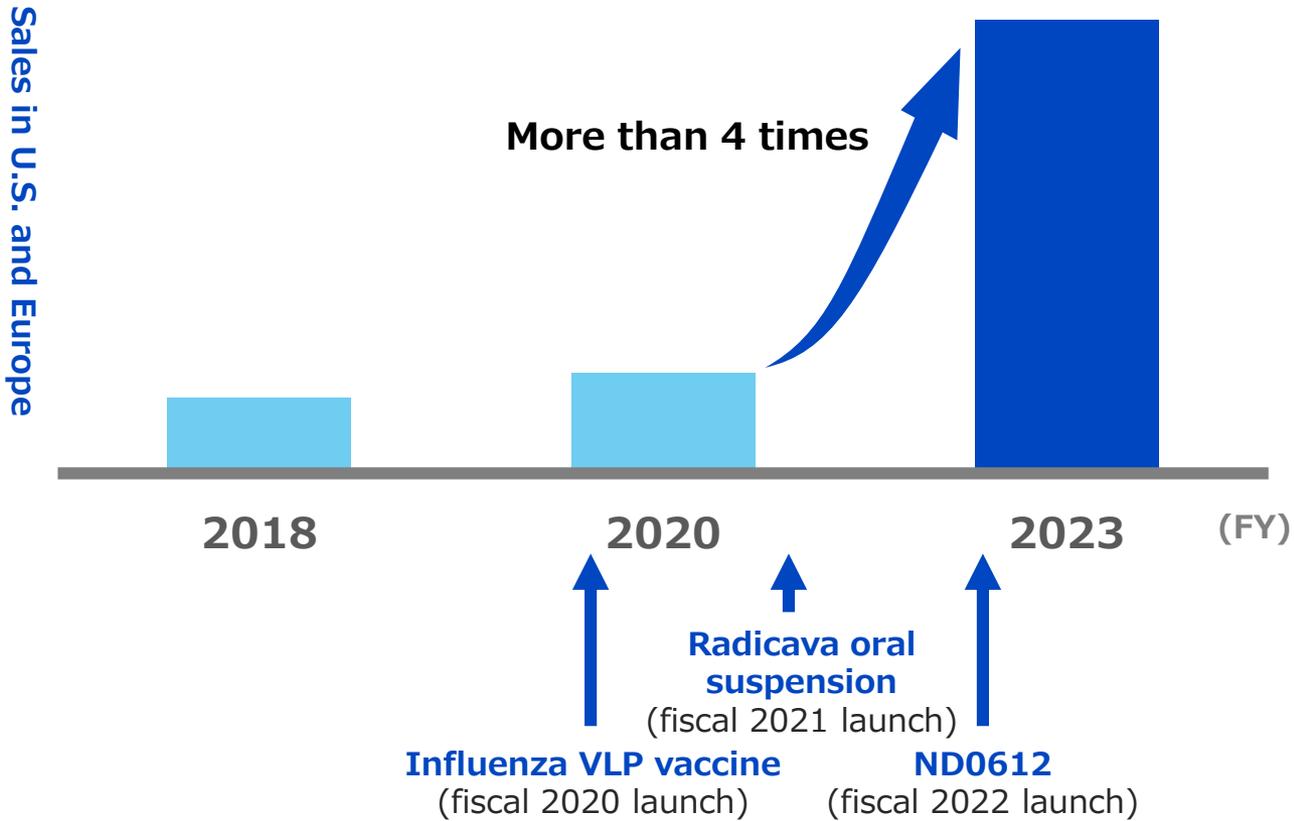
Initiatives in U.S./Europe and Japan

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



① U.S. and European Markets

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

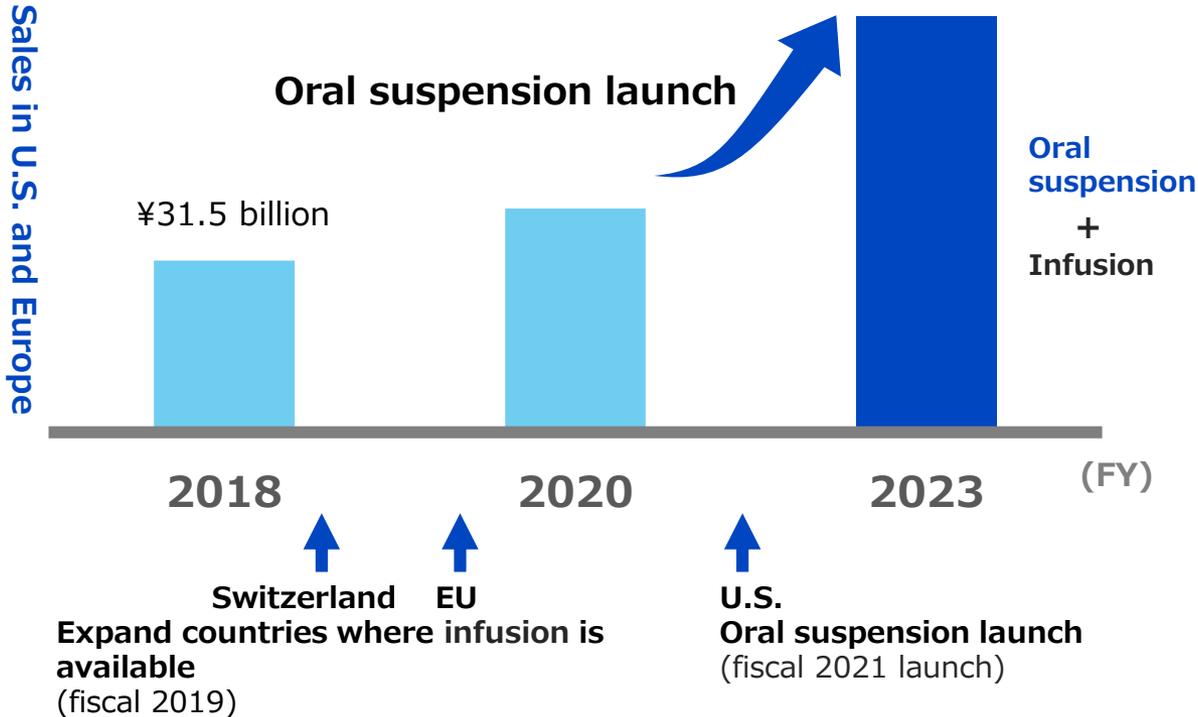


Radicava

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**

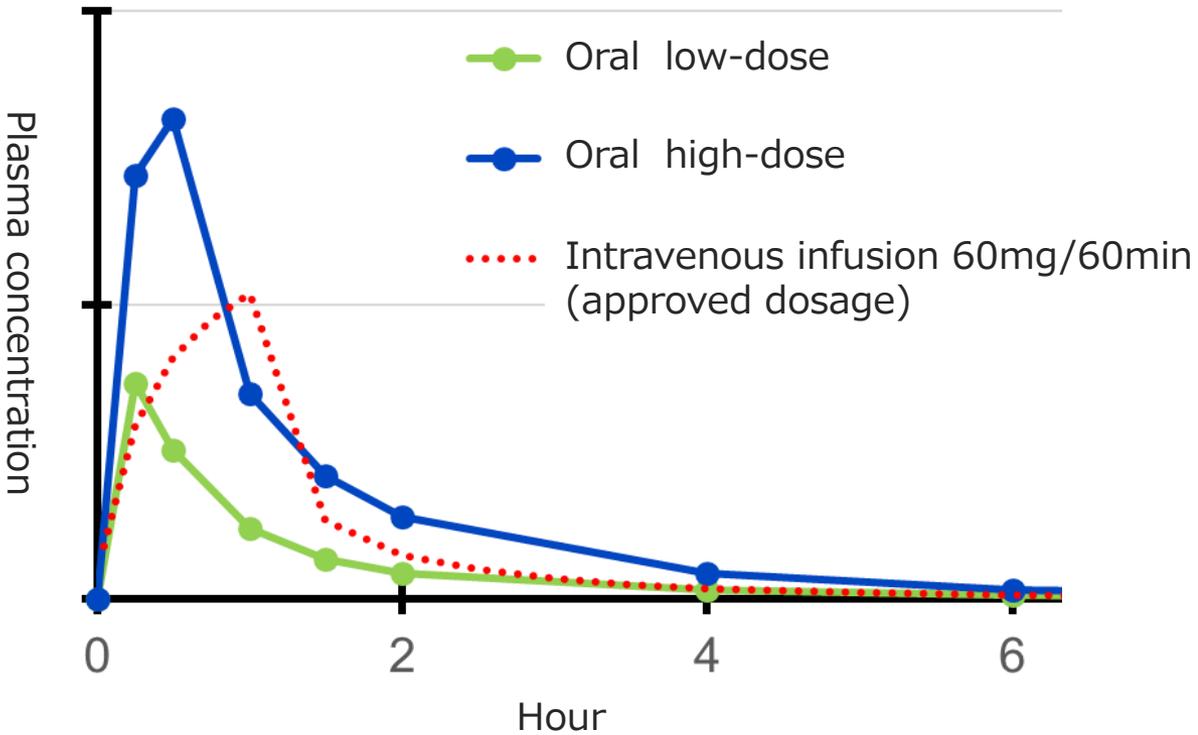
- Eliminates extended treatment time for patients resulting from intravenous infusion administration
- Eliminates limits on number of administration sites
- Development of suspension that is easy for ALS patients to take



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

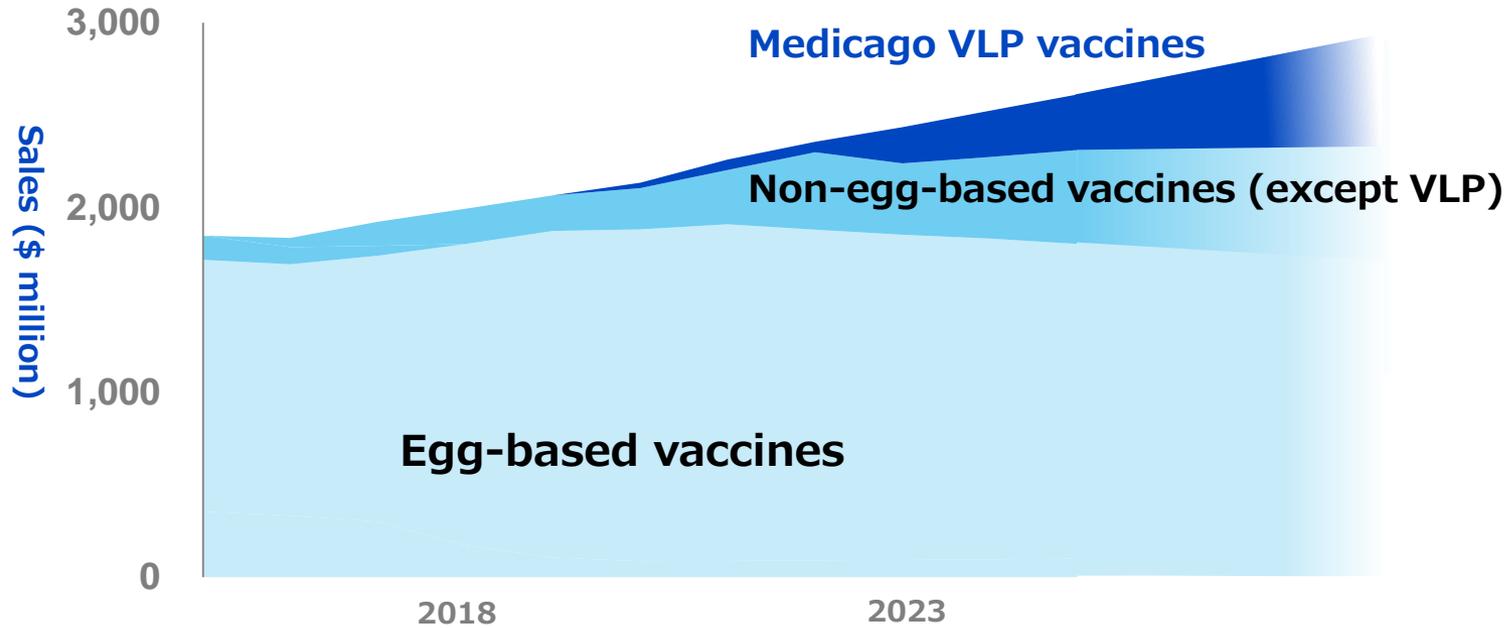
Seasonal Influenza Vaccine Market

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)

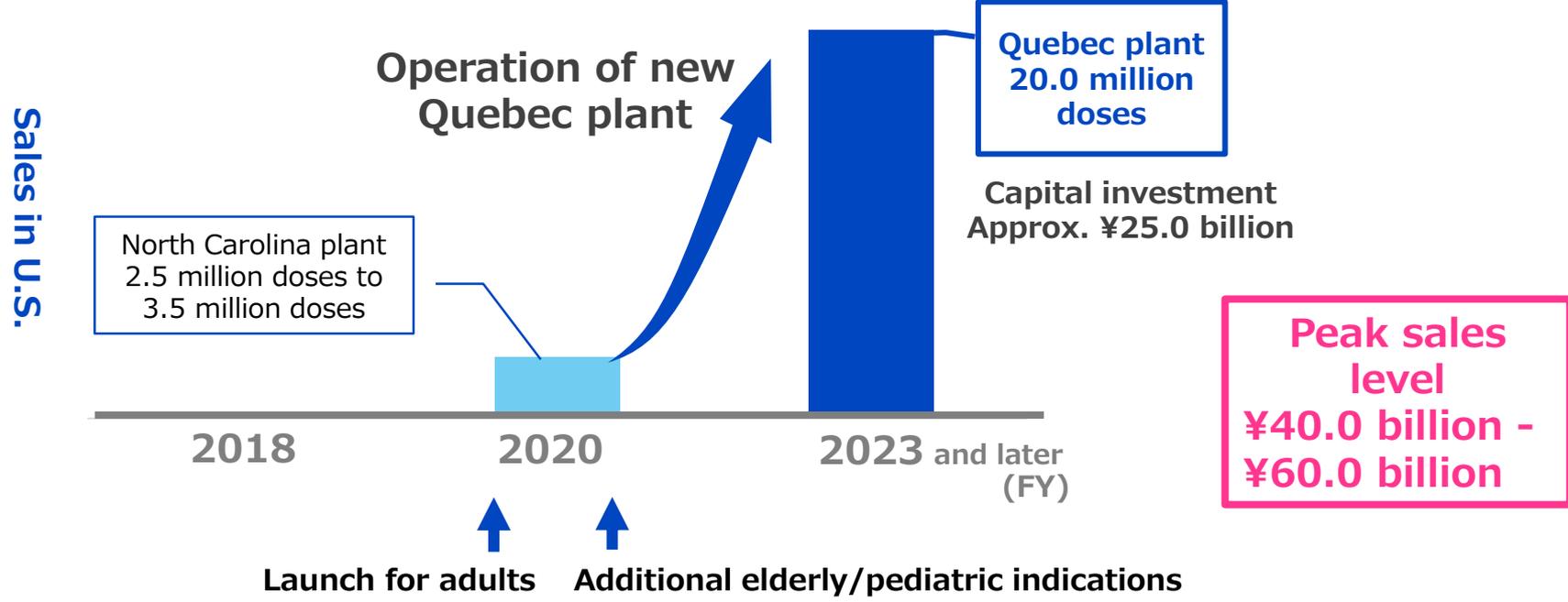
U.S. seasonal influenza vaccine market forecast



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

Before revision

Filing in fiscal 2018

U.S.
PK study
BeyoND trial (long-term safety)

Europe
iNDiGO trial (efficacy)
BeyoND trial (long-term safety)

After revision

Filing in fiscal 2021

Simultaneous development in U.S. and Europe
Efficacy trial
BeyoND trial (long-term safety)

Designing a clinical trial that can better clarify drug action and usage method (505(b)(2) pathway)

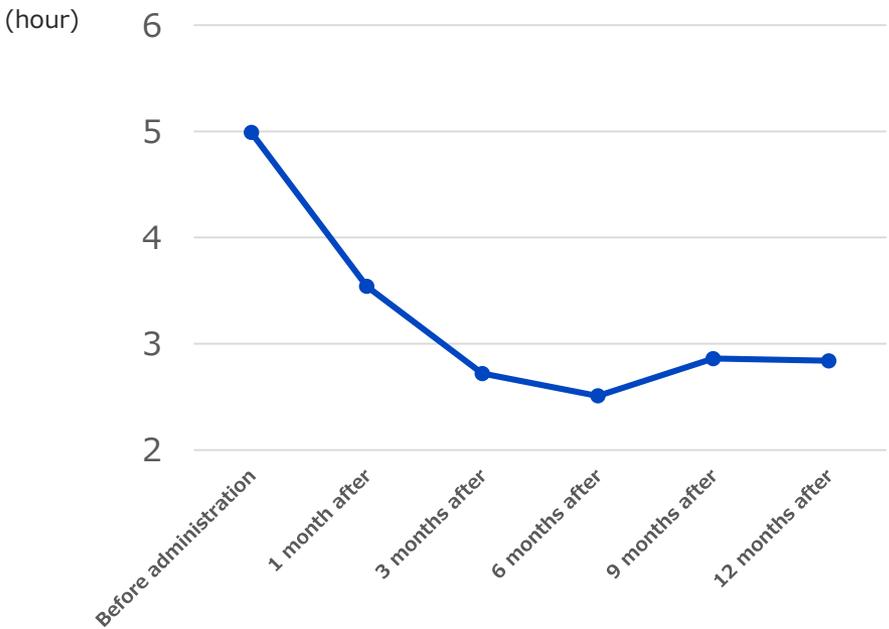
Peak sales level
¥50.0 billion-
¥80.0 billion

Strengths of ND0612

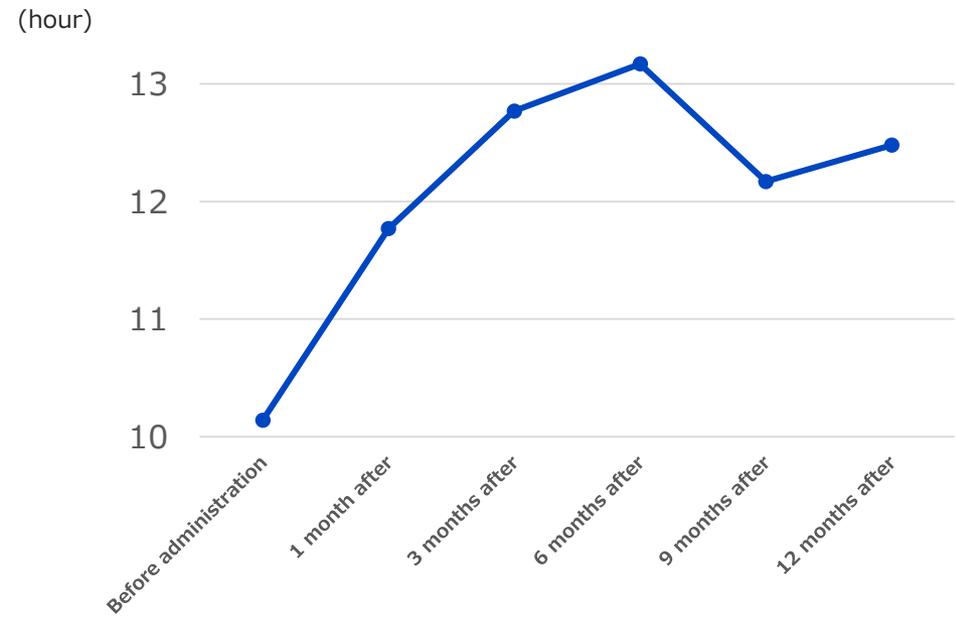
Through continuous subcutaneous administration, the plasma concentration of levodopa stabilized.
→Improvement of motor complications in Parkinson’s disease patients

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

“Off” time, when the drug’s effectiveness wears off and motor function declines



“On” time not accompanied by dyskinesia (involuntary movement) that causes difficulties in daily living



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



② Japanese 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

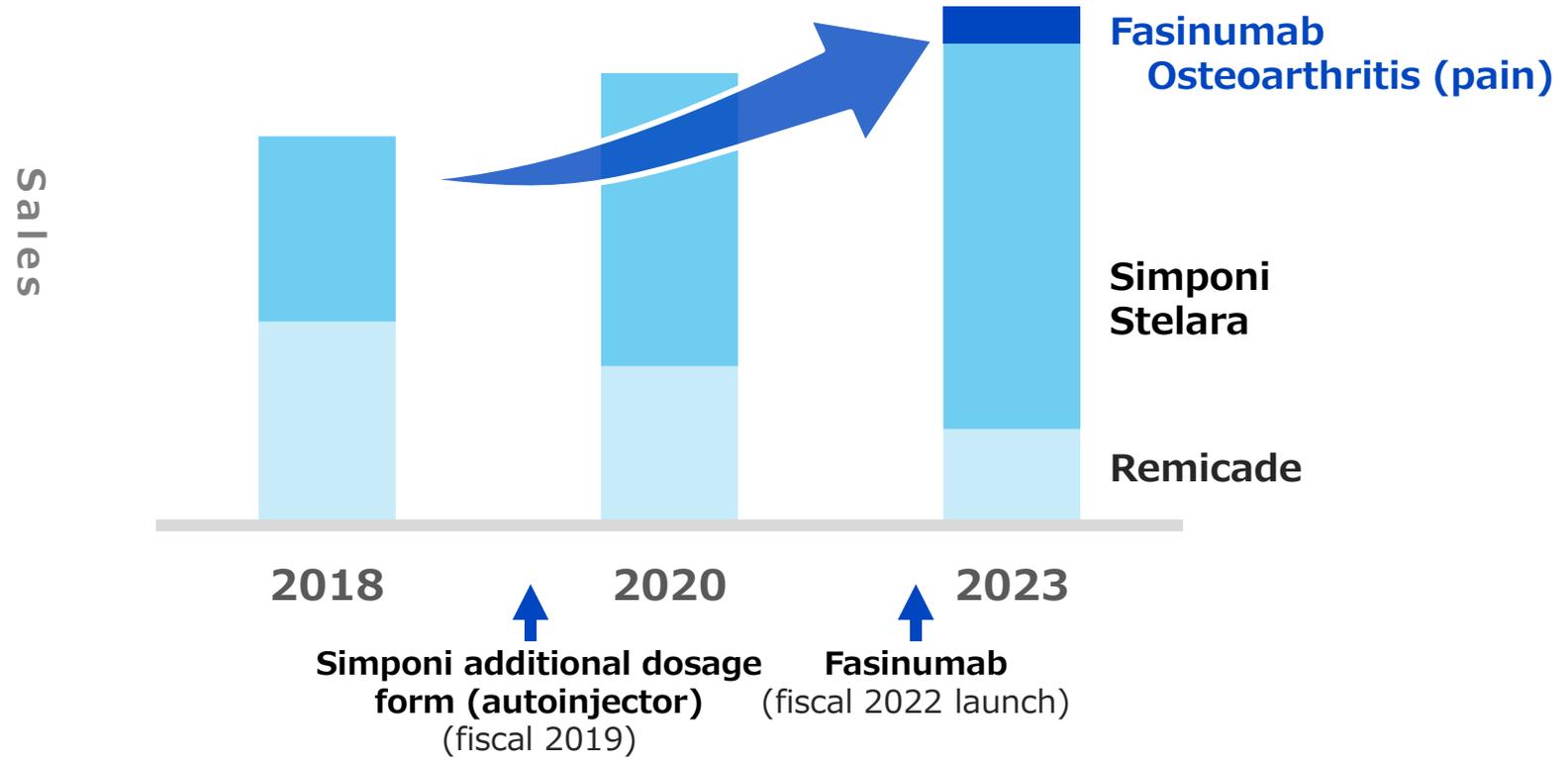
MT-2355(pentavalent vaccine)
Fiscal 2022 launch

CNS

Valbenazine (tardive dyskinesia)
Fiscal 2022 launch

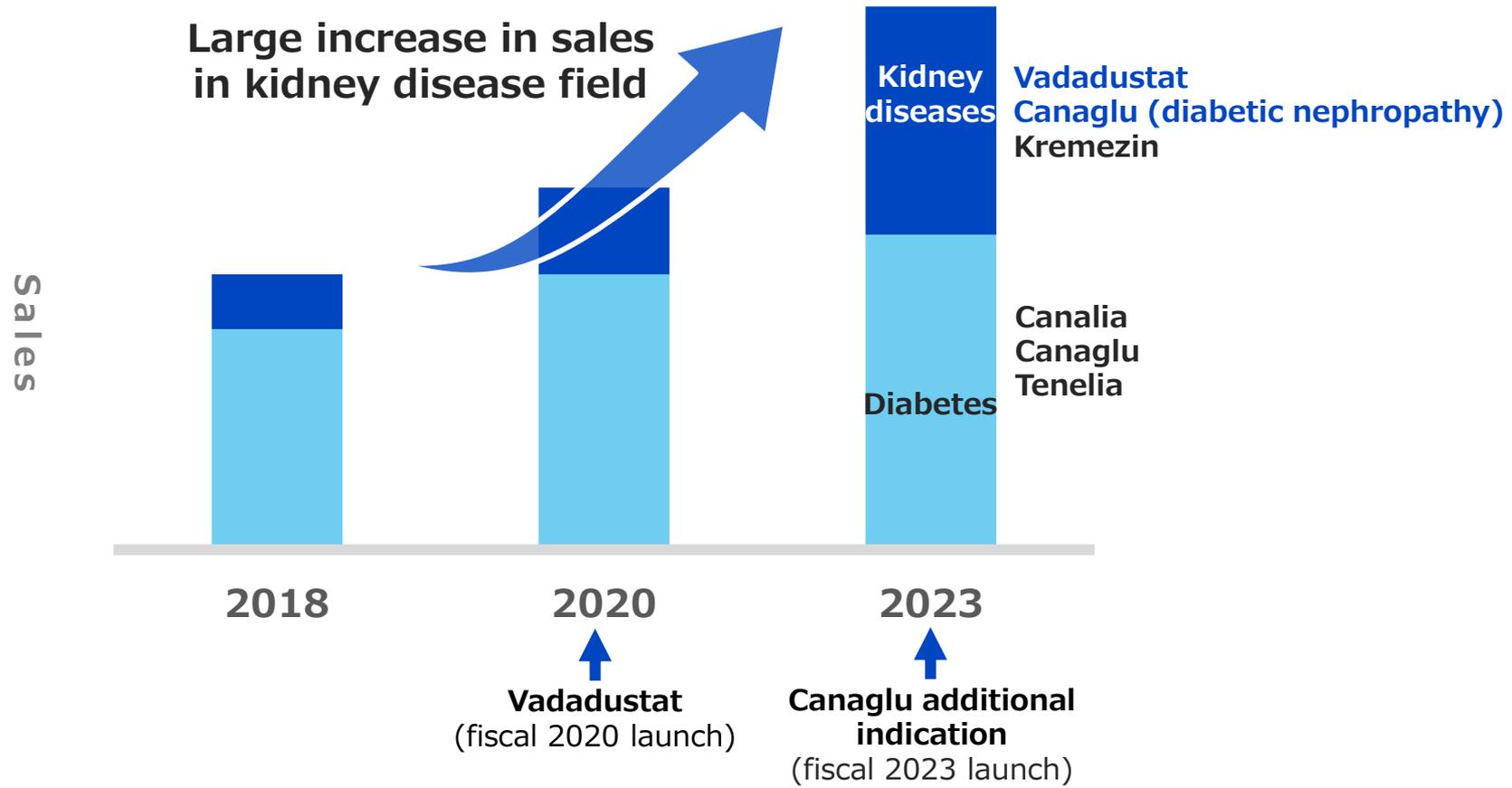
Immuno-Inflammatory

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



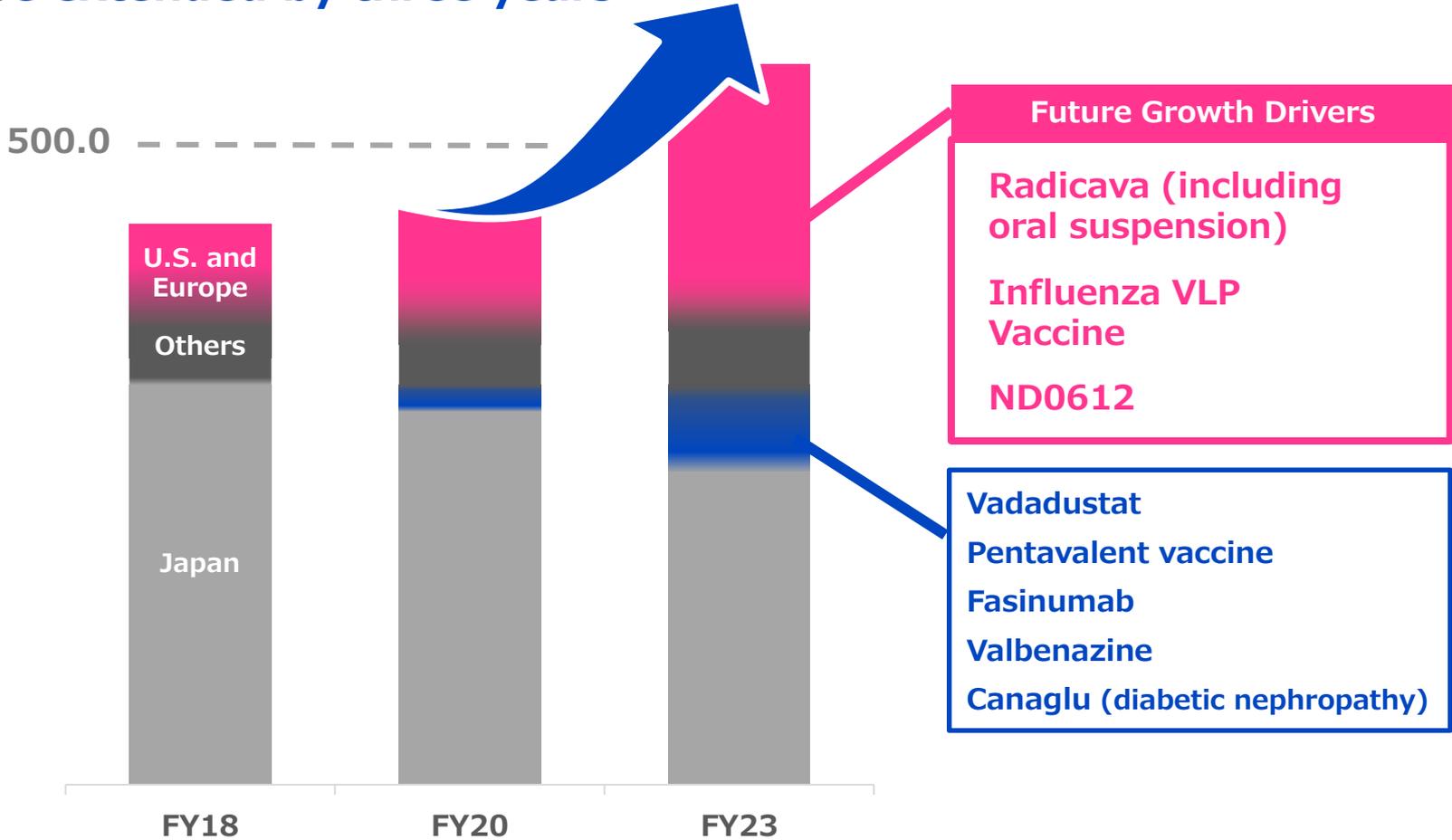
③ Strengthening Platform for Growth

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

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

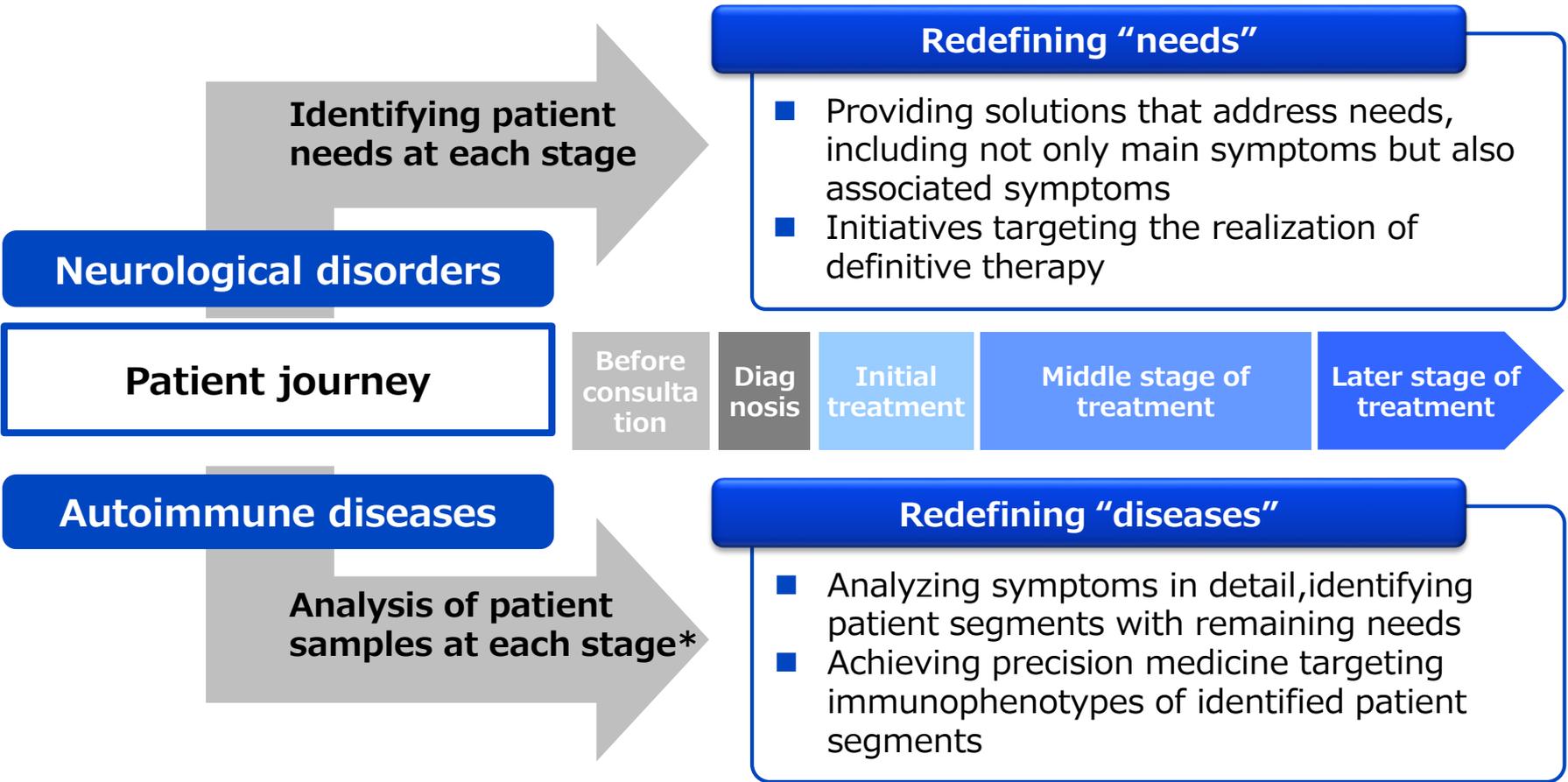


3. Open Up the Future



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

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

 **Small molecules**
 MT-8554 (vasomotor symptoms, etc.)
 MT-7117 (erythropoietic protoporphyria)

 **Antibodies**
 MT-3921 (spinal cord injury, etc.)
 MT-2990 (Immuno-inflammatory)

Neurology



Designed Pharmaceuticals (NeuroDerm Ltd.)

ND0612 (Parkinson's)



Digital Medicine

Medical app



Gene Therapy

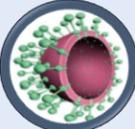
Joint research with Jichi Medical University
Collategene

Nucleic Acid

MT-5745 : STNM01 (Stelic Institute & Co.)
(inflammatory bowel disease)

Immunology

Vaccines



VLP Vaccines (Medicago)

MT-2271 (influenza)
MT-5625 (rotavirus)
Norovirus

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



Extend healthy lifespan

Fulfill our social duty

Open Up the Future

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



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



Fiscal 2020: Management Figures

¥ billion

	Fiscal 2020: Initial	Fiscal 2020: revised
Revenue	500.0	430.0
Japan	300.0	300.0
U.S.	80.0	40.0
Royalty/milestone revenues	80.0	50.0
Others	40.0	40.0
Core operating profit	100.0	60.0
Net profit attributable to owners of the Company	70.0	40.0
R&D expenses	80.0	85.0
Overseas sales ratio	40%	30%
R&D investment	400.0	400.0
U.S. strategic investment	More than ¥200.0	(currently, ¥130.0)

} 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

