



Briefing on Pharmaceutical Segment

**Business Strategy of KM Biologics**

December 10, 2018

**Meiji Holdings Co., Ltd.**

1. Company Profile of KM Biologics
2. Our Vision
3. Our Business Strategy
4. Outlook for FYE March 2019

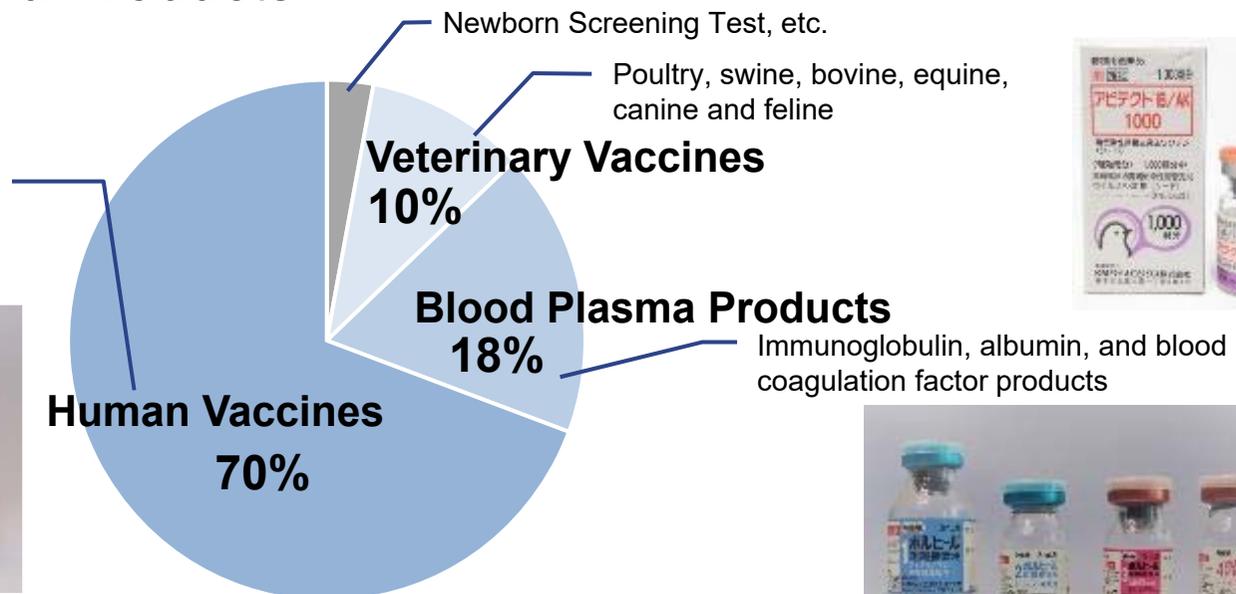
- Information in this material is not intended to solicit sale or purchase of shares in Meiji Holdings.
- Business forecasts and other forward-looking statements are based on information available at the time of the release of this presentation and reasonable assumptions made by the Company. Actual results could differ materially from forecasts due to various factors.
- Although this material includes information concerning pharmaceutical products (including those currently under development), such descriptions are not intended to advertise the products or provide any medical advice.



# 1. Company Profile of KM Biologics

- Company Name                    KM Biologics Co., Ltd.
- Incorporated                    March 7, 2018 (Consolidated on July 2, 2018)
- Net Sales                         JPY 30.0 bn (Outlook for FYE March 2019)
- Operating Income                JPY 3.5 bn (Outlook for FYE March 2019)
- Number of Employees            1,905 (as of July 2018)
- Main Business and Products

Influenza, hepatitis A, hepatitis B, Japanese encephalitis, pertussis, diphtheria, tetanus and poliomyelitis



\* Sales composition ratio by business

# Locations

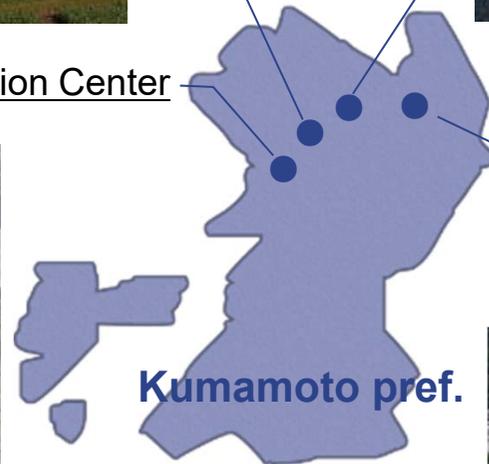
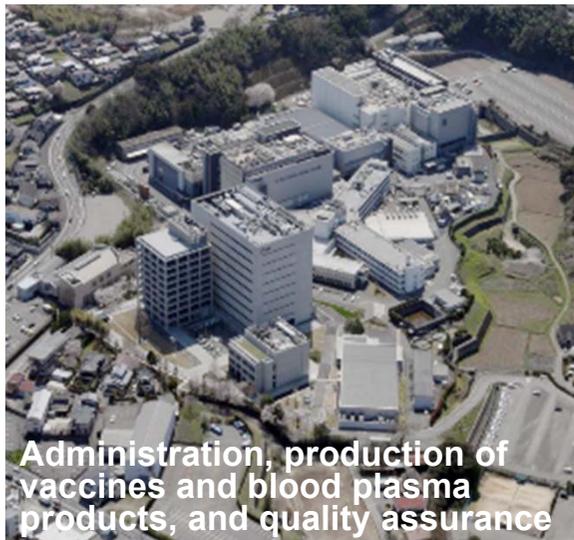
Koshi Production Center  
(103,000m<sup>2</sup>)



Kikuchi Research Center  
(232,000m<sup>2</sup>)



Headquarters & Kumamoto Production Center  
(147,000m<sup>2</sup>)

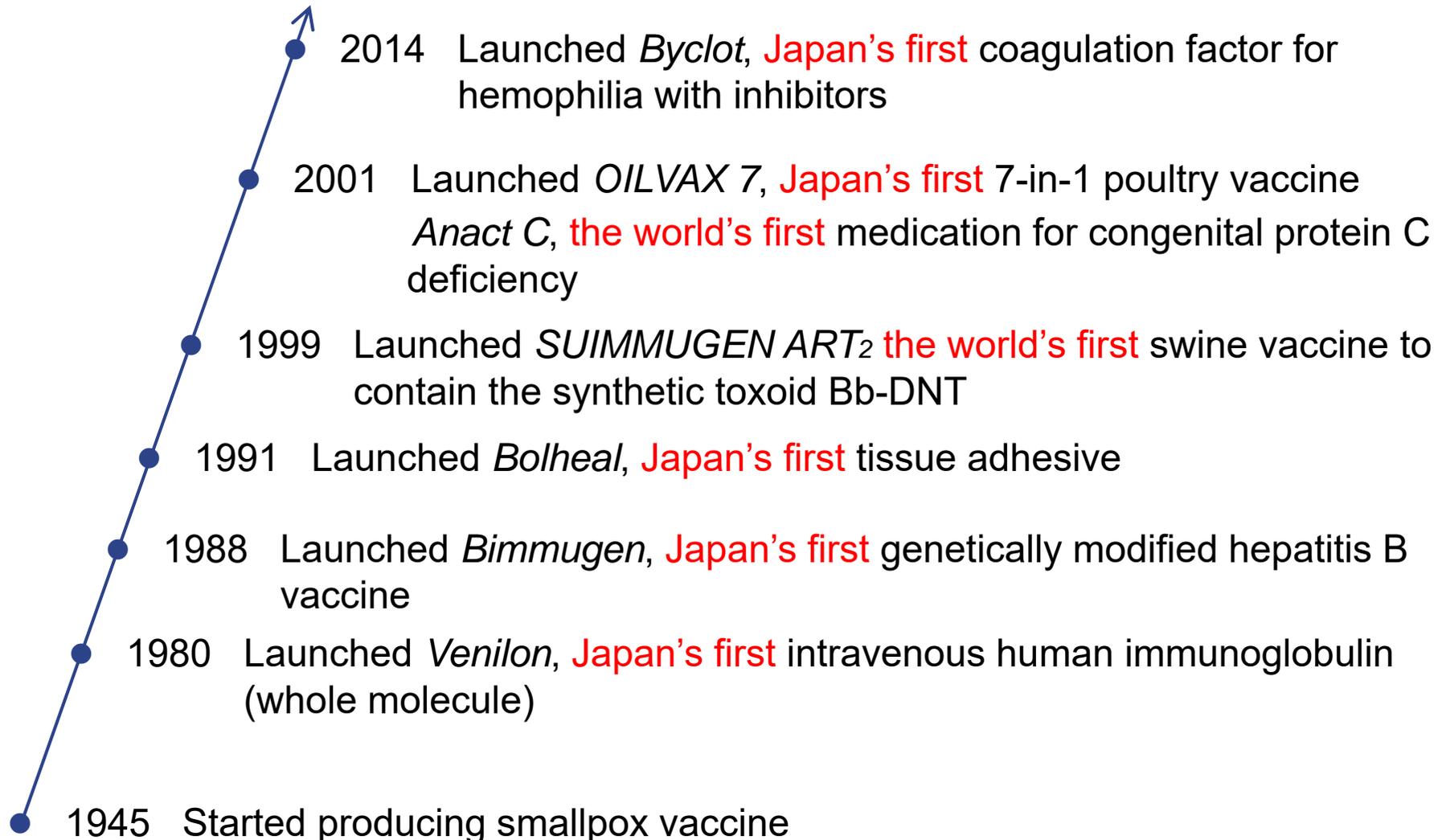


Aso Production Center  
(118,000m<sup>2</sup>)



\*SPF (Specific Pathogen Free) animals

We have produced outstanding innovations that have broken the mold in Japan and the world to prevent infection and treat disease.



First in the world / First Japanese-made

8 products / 21 products

20 products  
can be supplied only by us in Japan

8 orphan drugs  
approved by the MHLW (Japan)

12 million vials of vaccines  
shipped each year

Exciting innovations developed by our

160+ R&D staff

Pandemic influenza vaccines for

57 million people

3+ million newborn babies  
screened since 1977

12+ vaccines  
in development as of Aug. 2018

\*Orphan drugs: The MHLW designates drugs as "orphan drugs" if they meet certain criteria. For example, the target disease must affect fewer than 50,000 individuals in Japan, and there must be a significant medical need for the drug.



## 2. Our Vision

We will explore potentials of biological science and contribute healthier lives of the people in the world as professionals in preventive and therapeutic areas.

- To earn the trust from society, customers and users, we will

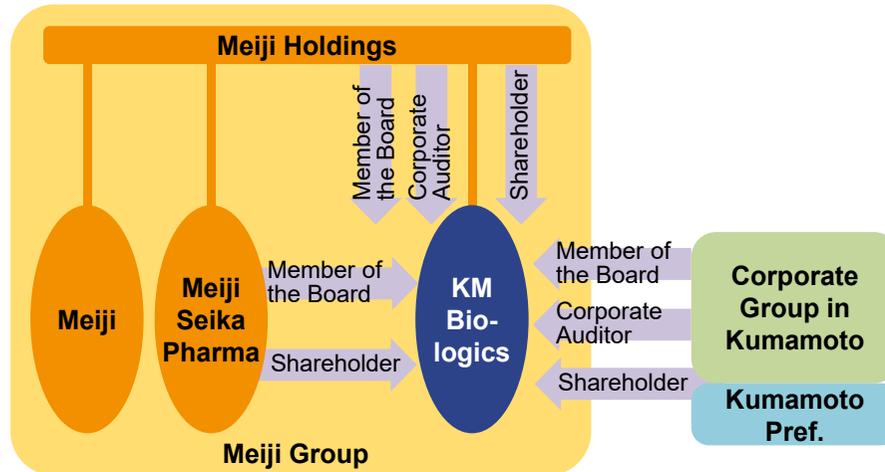
- 1 Establish a corporate governance system

- 2 Restructure quality assurance and production management system

- 3 Strengthen compliance administration and reform corporate culture

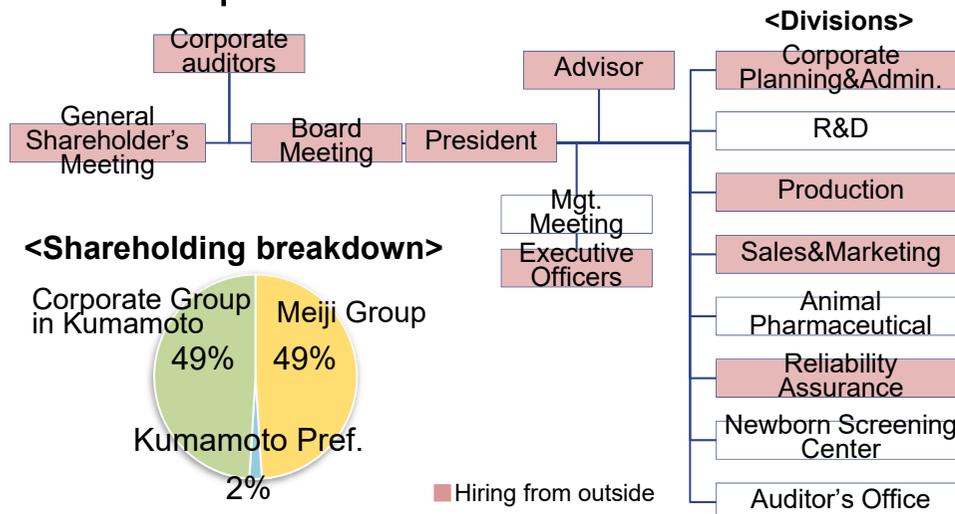
# 1. Establish a corporate governance system

- Improve impartial and transparent management



- Secure compliance and a healthy business  
Instruct, manage and supervise based on Meiji Group's governance system
- Establish impartial and transparent management  
Ensure timely disclosure to our stakeholders; Kumamoto Prefecture and Corporate Group in Kumamoto

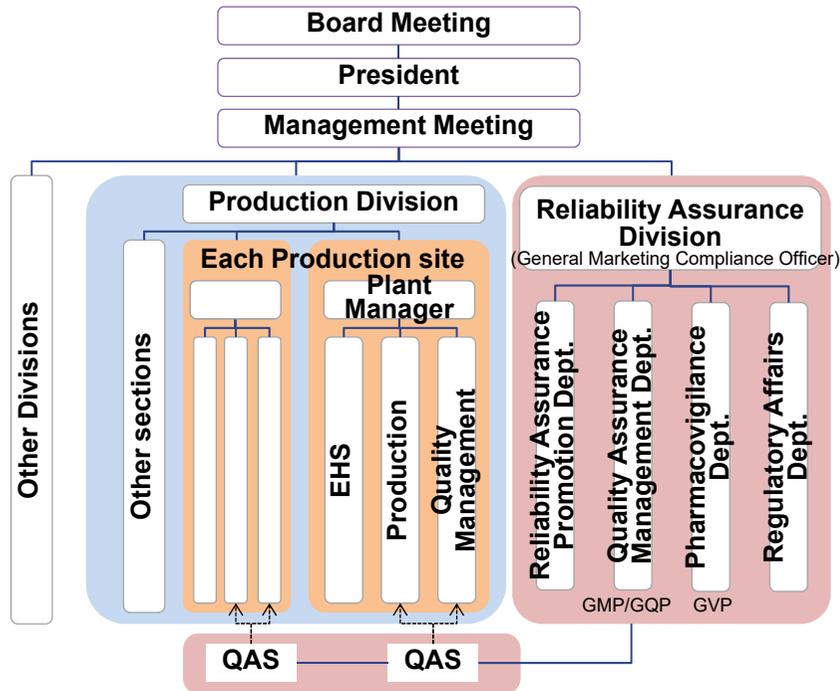
- Place all directors and corporate auditors from the Meiji Group and Corporate Group in Kumamoto



- Build management board wielding a checks-and-balances function and supervision function
- Improve governance, quality assurance and production management for all staff members  
Accept experts from the Meiji Group at middle management posts

## 2. Restructure quality assurance and production management System

- Develop organizational infrastructure



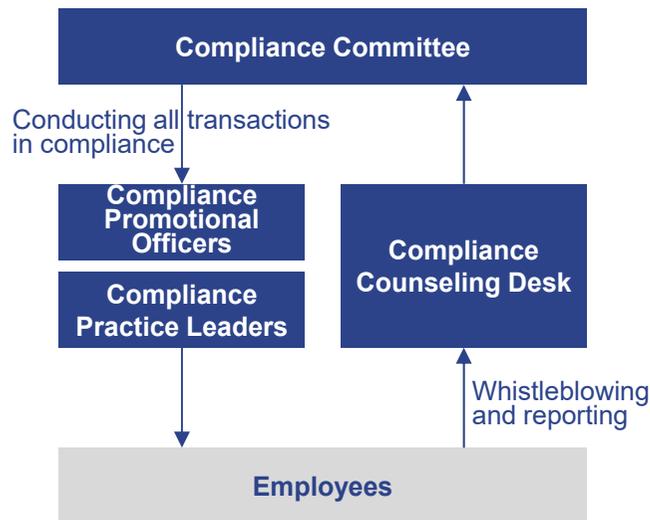
- Clarify duties of general marketing compliance officer
- Assign quality assurance staffs (QAS) at sites to facilitate communication between Production/ Testing Dept. and Reliability Assurance division.
- Introduce Independent Plant Production System in January 2019  
Under this system, the plant manager will be responsible for GMP\* procedures, Kaizen, environment, health and safety (EHS) at work.

\* Good Manufacturing Practice (GMP) is a system for ensuring that products are consistently produced and controlled according to quality standards.

- Restructure pharmaceutical quality assurance system
  - In compliance with the ICH-Q10 Pharmaceutical Quality System Guideline, clarify management's commitment to, and their accountability for pharmaceutical quality
  - Review quality management by corporate management periodically
- Establish new Quality Policy
- Accomplish the Improvement Plan agreed upon with the MHLW

# 3. Strengthen compliance administration and reform corporate culture **meiji**

## Compliance administration



- Establish Compliance Committee chaired by President
- Assign a compliance promotional officer and a compliance practice leader at every workplace
  - Ensure that compliance awareness permeates throughout company
  - Identify and prevent compliance violations
    - Clarify issues arise in the workplace
    - Address serious issues by middle or top management
- Enhance internal reporting/whistleblowing system
  - Establish external hotline (law firm or hotline agency)
- Organize thorough compliance education to ensure that lessons from past incidents are never forgotten

## Improve corporate culture

- Creating a new Corporate Philosophy and Medium-term Business Plan
  - Engage all employees, particularly the younger generation - who hold the company's future
- Listen to employees' (including part timers) views/issues - hold monthly meetings

## 3. Our Business Strategy

1

Human pharmaceuticals

Strengthen business in Japan and expand overseas

2

Veterinary pharmaceuticals

Expand business

3

Biopharmaceuticals

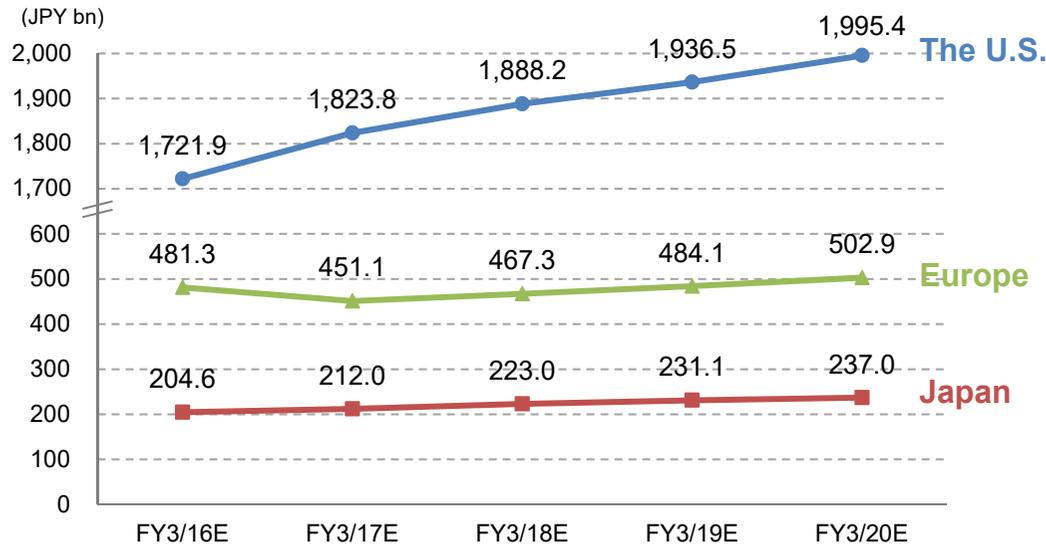
Strengthen research and development

# 1. Human pharmaceuticals

## Strengthen business in Japan and expand overseas



### Human vaccines market



(Source) KM Biologics, based on data from Sogo Kikaku Center Osaka

- **Japan**  
The vaccine development race is heating up
  - Vaccines that the MHLW has prioritized for development
  - Flu vaccines; differentiation and competition with effective flu medicine such as *Tamiflu*, *Relenza* and *Rapivab*
- **Overseas**  
The top 4 mega pharmacy have a combined market share of 90%

### Blood plasma products market

- Demand continues to grow, but there are issues

- Ig demand will increase  
(converted to plasma volume)
  - 2017 1,150 thousand liter
  - ↓
  - 2025 1,400 thousand liter (MAX)
- To accommodate the growing demand for Ig therapy for autoimmune disease:
  - Secure sufficient amount of plasma (Blood donation)
  - Increase globulin production yields (Pharmaceutical companies)
- Unused non-globulin intermediates are piling up; we should find their use

# 1. Human pharmaceuticals

## Strengthen business in Japan and expand overseas



### Our actions

- Improve production and quality assurance systems to ensure stable production and supply with human vaccines and blood plasma products
- Improve usability/convenience and facilitate obtaining evidence
- Improve supply chain management to maximize profits
- Develop systems for expanding overseas business
- Boost Newborn Screening Test business
- Use Meiji Seika Pharma's business base

### Japan

- Use strong relationship with infectious disease specialists (e.g., paediatricians, internists)
- Increase presence in infectious disease sector further with broad product mix - from vaccines to therapeutic medicine

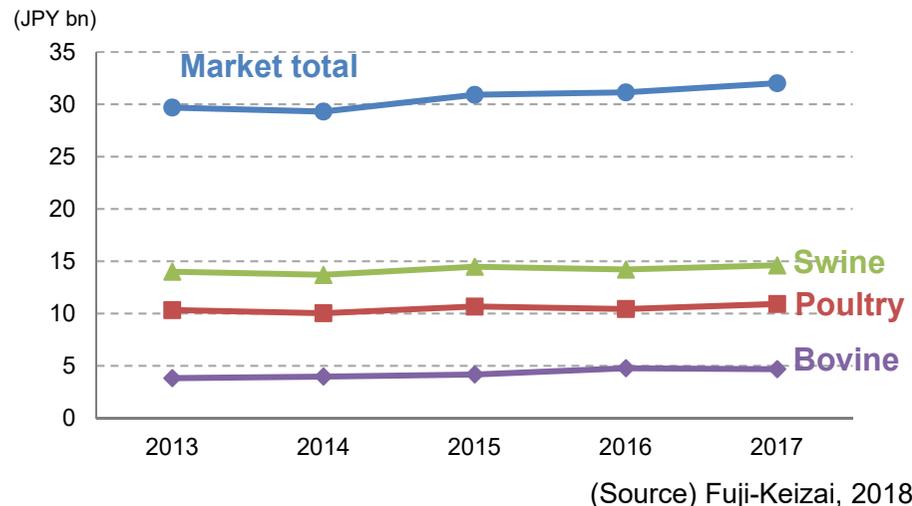
### Overseas

- Develop new vaccine businesses overseas, primarily in South East Asia

## 2. Veterinary pharmaceuticals Expand business



### Livestock vaccines market in Japan



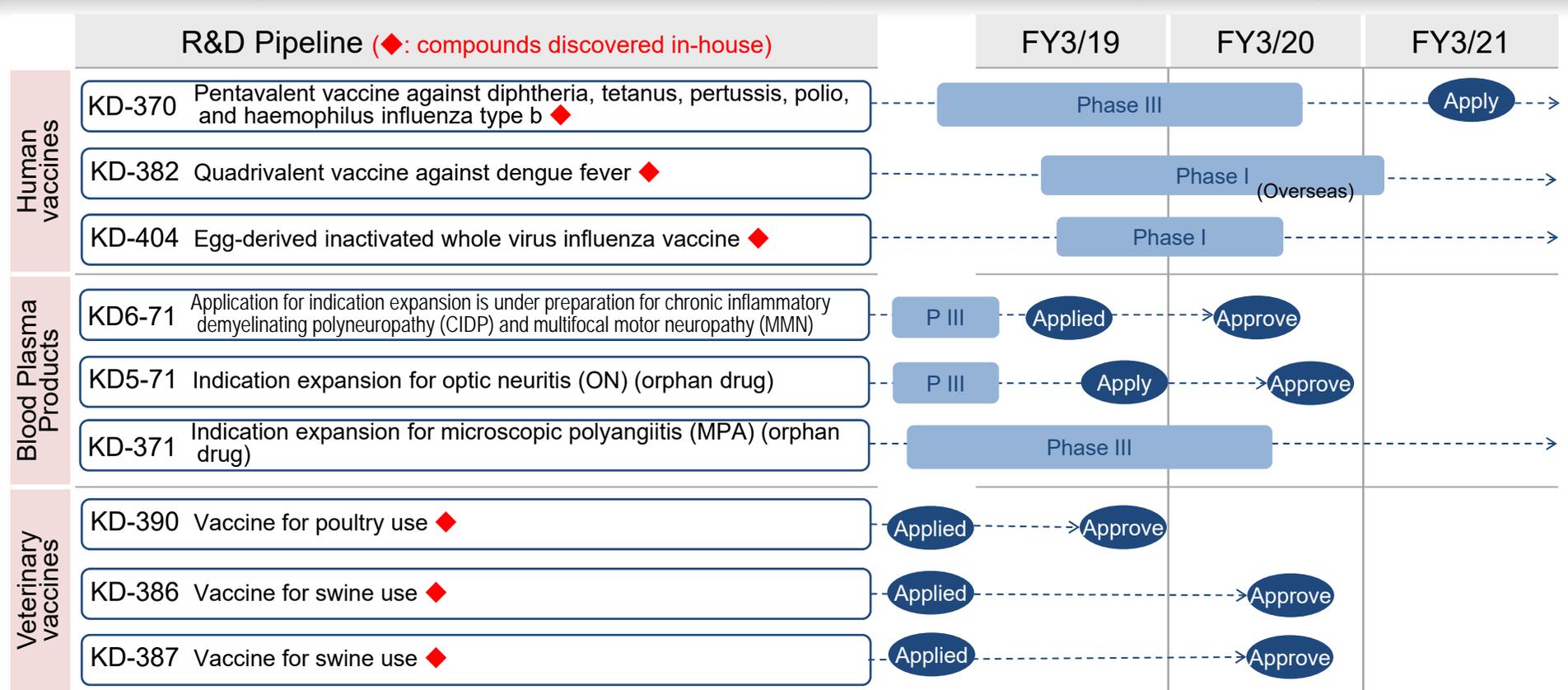
- The livestock vaccine market has been leveling off
- The three major vaccine manufacturers, including us, specialize in a different sector
- Overseas manufacturers gain presence in the swine and bovine sectors

### Our actions

- Enhance production and sales systems to increase market share in Japan
- Establish business infrastructure for overseas expansion in South East Asia
- Use Meiji Seika Pharma's business base
  - Synergic effects with Meiji Seika Pharma; product mixes and sales resources
  - Competitive advantage: KM Biologics; poultry and Meiji Seika Pharma; swine
  - Improve market presence: broad product mix from vaccines to antimicrobial agents
  - Gather information and forge sales channels using overseas network

### 3. Biopharmaceuticals

## Strengthen research and development of biological drug



- Facilitate R&D with selection and concentration strategies
- Develop new vaccines considering overseas markets
- Increase market share by improving existing vaccines
- Synergic effects with Meiji Seika Pharma:
  - Use technical expertise in biopharmaceuticals
  - Improve technological competitiveness expanding the personnel exchange programs

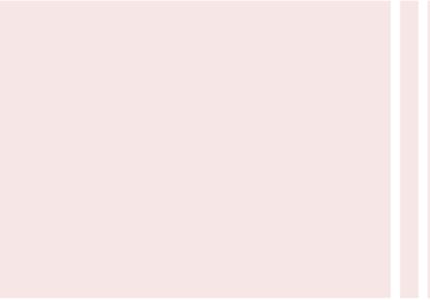


## 4. Outlook for FYE March 2019

(JPY bn)		First Half Results	Second Half Plan (as of Nov. 7)	Full Year Plan (as of Nov. 7)
Non-consolidated	Net sales	9.9	20.0	30.0
	Operating income	1.6	1.8	3.5

(Note) Eliminations are recorded when calculate consolidation of KM Biologics.

- Sales and profit are disproportionately weighted in the 2nd and 3rd quarters.  
Human vaccines, particularly flu vaccines, constitute a large proportion of overall sales.
- Earnings are largely as planned.  
The flu vaccines, mainstay product, were produced and delivered on time though some vaccines were delivered late.



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