



# Health Care Domain

In its Health Care domain, the Mitsubishi Chemical Holdings Group not only works to provide treatments for diseases but also products and services that help people around the world live longer and healthier lives.

### Pharmaceuticals business

- We have advanced drug discovery and IKUYAKU (drug fostering and evolution) capabilities.
- We have established a solid presence in priority drug markets, particularly drugs for immuno-inflammatory diseases.

### Life Science business

- Our products target a wide range of applications spanning from sick care to healthcare.
- We have outstanding product development and technological capabilities in regenerative medicine.

Strengths

S

Weaknesses

W

Opportunities

O

Threats

T

### Pharmaceuticals business

- Needs in the healthcare and medical sectors are diversifying.
- The aging of populations in many countries is driving up demand for healthcare.

### Life Science business

- Big data is increasingly being used for healthcare and medical ICT.
- Governments are promoting public health and serious disease prevention to control spiraling healthcare costs.
- People are growing more aware of personal health management, including self-medication.

### Pharmaceuticals business

- Our expansion into global markets has been relatively slow, particularly in North America.

### Life Science business

- We must further diversify our products and services to meet a broad range of customer needs.

### Pharmaceuticals business

- Discovering new drugs is increasingly challenging and stricter drug approval processes result in higher R&D costs.
- Governments are taking various measures to control healthcare expenditures.

### Life Science business

- Economic incentives are lacking for healthcare businesses and services.

## Financial results and main products



FY2019 Sales revenue ¥ **413.1 billion**

FY2019 Core operating income ¥ **14.6 billion**

(Figures do not include results from discontinued operations.)

## Pharmaceuticals business

**Drugs for immuno-inflammatory diseases:** Mitsubishi Tanabe Pharma Corporation has held the No. 1 share in Japan's drug market for immuno-inflammatory diseases by maximizing the respective benefits provided by three products: *REMICADE* (for inflammatory autoimmune diseases such as rheumatoid arthritis), *Simponi* (for rheumatoid arthritis and ulcerative colitis), and *Stelara* (for Crohn's disease, ulcerative colitis, and other indications). Through its leading product, *REMICADE*, in particular, we have secured a steady sales stream and dependable reputation among medical professionals.



REMICADE Simponi Stelara

**Drugs for diabetes and kidney diseases:** Mitsubishi Tanabe Pharma has developed three drugs: *TENELIA*—the first type 2 diabetes mellitus drug developed in Japan—as well as *CANAGLU* and *CANALIA*, and we are working to establish a solid presence in this field by collecting clinical results and expanding sales channels for these three drugs.



TENELIA CANAGLU CANALIA

**Drugs for central nervous system disorders:** Mitsubishi Tanabe Pharma has been obtaining approval for *RADICUT* (*RADICAVA* in the US) as a treatment for amyotrophic lateral sclerosis (ALS) in countries around the world, starting with Japan in June 2015, followed by South Korea, the US, Canada, Switzerland, China, and Indonesia. Evidence has shown that the drug is effective in removing free radicals remaining in the body, thereby protecting motor neurons from damage caused by resultant oxidative stress. This slows the decline of physical functioning and progress of muscle atrophy in ALS patients. The drug is an intravenous infusion, but we are currently developing an oral suspension.



RADICUT

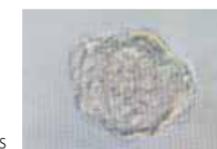
**Vaccines:** Mitsubishi Tanabe Pharma jointly established a company to produce vaccines, BIKEN Co., Ltd., with Osaka University's Research Institute for Microbial Diseases. Since commencing operations in September 2017, the joint venture has been producing in-demand vaccines and helping stabilize the supply of vaccines. We aim to increase total vaccine production capacity by 20 to 30% in the future.



Influenza vaccine TETRABIK Varicella vaccine

## Life Science business

**Next-generation healthcare:** One of our operating companies, Life Science Institute, Ltd., has initiated clinical trials of a formulation (development code CL2020) for treating acute myocardial infarction, ischemic stroke, epidermolysis bullosa, and spinal cord injury based on Multilineage-differentiating stress enduring cells (Muse cells) which were discovered by Professor Mari Dezawa's group at Tohoku University. Meanwhile, our Group's Tonomachi Cell Processing Center obtained a license for manufacturing of regenerative medicine products in August 2019, and is making preparations to launch products to the market.



Muse cells

**Healthcare and medical ICT:** In Japan, the population is aging rapidly and rural areas have increasingly less access to medical care. To address these issues, we are striving to improve the quality of medical care through new products and services. For example, it has been applying digitalization to develop diagnostic support systems that can lessen the workloads of medical doctors, and is currently promoting Open Shared Business (OSB)\* to develop AI-based diagnostic imaging systems.

\* OSB (Open Shared Business) is the original framework of Mitsubishi Chemical Holdings Corporation for working with organizations outside the Group. We promote collaboration in both R&D and business and build a distinctive value chain by using the OSB framework.



**Pharmaceutical development solutions:** Our Life Science business manufactures active pharmaceutical ingredients and intermediates. It has also manufactured high-quality, high-performance hard-shelled capsules, including the world's first hypromellose capsules made from plant-derived materials. The business has also applied its capsule manufacturing technology and expertise to supply pharmaceutical processing equipment (PPE). (The capsules and PPE businesses were transferred to the High Performance Chemicals Business Domain of Mitsubishi Chemical Corporation in July 2020.)



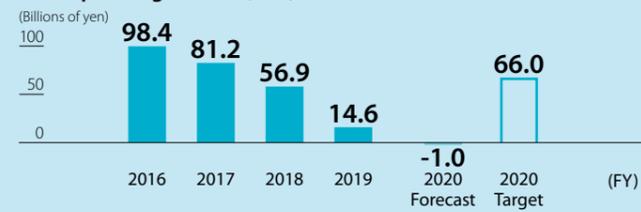
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- Policies**
- Enable global growth of the Pharmaceutical business
  - Establish and improve the healthcare and medical business utilizing ICT and regenerative medical products
- Key strategies**
- Accelerate expansion of the Pharmaceutical business globally, particularly in the US.
  - Strengthen drug discovery capabilities
  - Bolster IKUYAKU (drug fostering and evolution) and marketing to maximize the value of new drugs and priority products
  - Expand the healthcare and medical business utilizing ICT
  - Expand the regenerative medicine business
  - Improve profitability and global expansion of the business for pharmaceutical capsules

### Planned investment from FY2016 to FY2020

Total investment **¥460 billion** Investment in R&D **¥440 billion**

### Core operating income (loss)



(Note) The figure for fiscal 2019 does not include results from discontinued operations.

## Growth strategies in the Pharmaceutical business

Mitsubishi Tanabe Pharma has set forth four challenges for achieving its goals in its medium-term management plan, Open Up the Future, which ends in March 2021. One of these challenges is maximizing pipeline value. As part of these efforts, the company filed for approval of Vadadustat (generic name) for the treatment of renal anemia in Japan and entered into a licensing agreement for the introduction of Inebilizumab (generic name) for the treatment of optic neuromyelitis-related diseases in fiscal 2019.

On a global level, Mitsubishi Tanabe Pharma revised its development plan in the United States based on the results of a Phase 3 clinical trial of a plant-derived virus-like particle (VLP) vaccine (development code MT-2271) for the prevention of seasonal influenza. The company has confirmed a certain level of efficacy in comparison with a placebo and a control (vaccine grown in chicken eggs). Considering the merits of the plant-derived VLP platform technology, it is investigating the development of a seasonal influenza vaccine with an adjuvant\* to further improve the efficacy of the vaccine compared to the current formulation.

\* An adjuvant is a substance used in combination with a vaccine to enhance or supplement the effectiveness of pharmaceuticals, and it can be expected to improve immunogenicity.

## Growth strategies in the Life Science business

### Developing Muse cell-based products in response to unmet medical needs

One of our operating companies, Life Science Institute, is developing a Muse cell-based formulation (development code CL2020), which is a regenerative medicine product, with the aim of becoming a truly unique healthcare solutions company.

Muse cells were discovered by Professor Mari Dezawa's group at Tohoku University in 2010. These pluripotent stem cells have the capacity to differentiate into a range of human cells. Muse cells are considered as non-tumorigenic, and they naturally exist in the connective tissue of the human body. Moreover, they do not need to be induced to differentiate into target cells, and can be simply administered intravenously to accumulate and engraft injured tissues for repair.

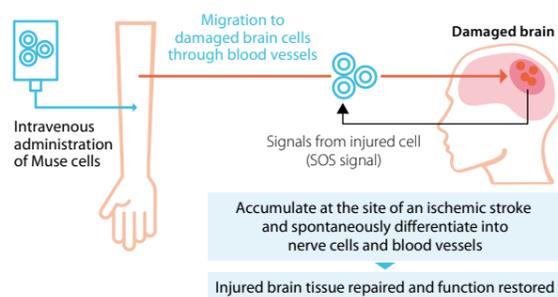
Life Science Institute is currently conducting clinical trials on CL2020 as a treatment for acute myocardial infarction, ischemic stroke, epidermolysis bullosa, and spinal cord injury. Of these

### Four objectives for creating future possibilities

1 Maximize pipeline value	Late-stage development target <b>10 drug discoveries</b> 5-year cumulative R&D investment <b>¥400 billion</b>	FY2019 results Started late-stage development of 9 candidates
2 Strengthen IKUYAKU (drug fostering and evolution) and marketing	Japan sales revenue target <b>¥300 billion</b> Sales ratio of new drugs and priority products target <b>75%</b>	FY2019 results ¥313.9 billion 74.6%
3 Accelerate expansion in the US	US sales revenue target <b>¥40 billion</b> Export <b>RADICAVA</b> to more countries Strategic investment from FY2019 to FY2023 <b>¥300 billion</b>	FY2019 results ¥23.1 billion RADICAVA approved in 6 countries
4 Raise productivity	Reduction of the cost of sales and SG&A expense reduction target <b>¥30 billion</b> Maximum workforce target <b>5,000</b>	FY2019 results ¥32 billion reduction Workforce cut to 4,782 employees
FY2020 targets Sales revenue of <b>¥430 billion</b> Core operating income of <b>¥60 billion</b>		
FY2020 forecasts Sales revenue of <b>¥383.5 billion</b> Core operating income of <b>¥10 billion</b>		

clinical trials, the exploratory clinical trial for acute myocardial infarction and the clinical trial for ischemic stroke have met expectations in terms of preliminary results.

The company aims to commercialize CL2020 as soon as possible in order to meet the expectations of the many patients and their families who have expressed interest in it.



## Focus

### Applying digitalization in healthcare

As a group, we have established a unique healthcare platform that leverages chemistry, biotechnology, and digital technologies. We have also introduced AI to streamline and improve operations.

### Shift from treatment to prevention and disease avoidance

The focus of the Japanese government's healthcare policy has shifted from treatment to prevention and disease avoidance. There is also a growing awareness of the importance of health management by individuals. For the lifestyle-related disease of diabetes, prevention of an increase in severity is a pressing issue in order to avoid rising medical expenses.

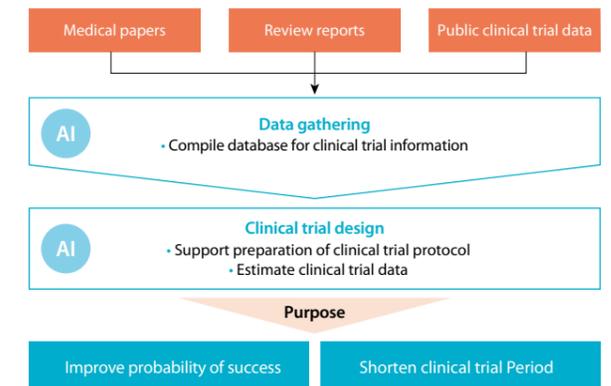
The TOMOCO diabetes care app developed by Mitsubishi Tanabe Pharma in collaboration with Habitus Care Inc. encourages daily recording of diet, exercise, medication, and blood glucose levels, and follows up with a plan of action developed by an instructor. In doing so, the app supports efforts to prevent diabetes from becoming more severe by encouraging behavior change in addition to medical care.



### Operational streamlining and improvements by IKUYAKU (drug fostering and evolution) and marketing

Clinical trials are an important process that determines the success or failure of new drug development. They aim to verify the efficacy and safety of new drug candidates. This is why clinical trials require elaborate implementation plans, as well as

considerable time and know-how based on the knowledge and experience of skilled human resources. Mitsubishi Tanabe Pharma is working together with Hitachi, Ltd., to combine AI that supports information and data collection and AI that supports clinical trial design. The companies have confirmed that it is possible to reduce the time required to collect information by approximately 70% compared to conventional work that relies on the know-how of skilled personnel. Together, we will continue to work toward reducing the time and cost of new drug development and improving the probability of success.



Mitsubishi Tanabe Pharma's marketing teams are working to improve the efficiency of operations through the establishment of a system that accumulates and analyzes data on activities such as the history of physician visits and the details of inquiries from physicians, derives efficient patterns for sales activities, and automatically sends papers and other content of interest to physicians via email.

## Solutions for environmental and social issues

### Development of a VLP vaccine for COVID-19

Medicago Inc., a subsidiary of Mitsubishi Tanabe Pharma, began Phase 1 clinical trials of a plant-derived VLP vaccine for COVID-19 in July 2020. The company is committed to steadily advancing the development of the vaccine so that, if approved, it can be delivered to the public as soon as possible in order to contribute to the prevention of COVID-19, an urgent public health issue.

