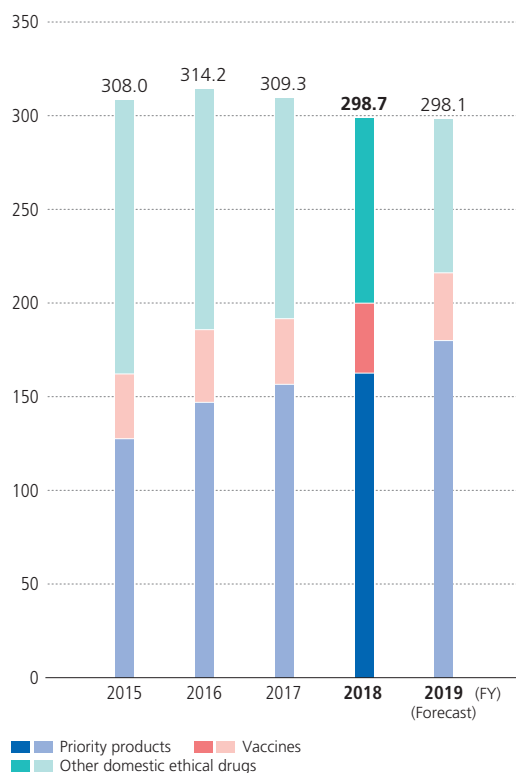


# Overview and Sales Trends of Priority Products



**Domestic revenue of ethical drugs** (Billions of yen)



**Revenue of priority products** (Billions of yen)

	2015	2016	2017	2018 (Forecast)	2019
Remicade	69.4	66.8	64.6	<b>58.8</b>	53.1
Simponi	12.9	24.9	32.1	<b>37.4</b>	43.0
Stelara	–	–	0.3	<b>15.2</b>	21.6
Tenelia	14.1	16.5	17.5	<b>15.2</b>	16.1
Canaglu	0.5	3.4	5.6	<b>6.7</b>	10.9
Canalia	–	–	1.8	<b>7.4</b>	7.6
Lexapro	9.5	11.2	12.7	<b>14.0</b>	15.2
Imusera	4.1	4.9	4.7	<b>4.3</b>	4.2
Rupafin	–	–	0.4	<b>3.4</b>	7.8
<b>Vaccines:</b>					
Influenza vaccine	13.7	12.7	9.9	<b>10.2</b>	10.7
Tetrabik	9.5	9.9	8.7	<b>8.5</b>	10.0
Varicella vaccine	6.3	5.4	5.2	<b>5.1</b>	5.1
Mearubik	4.9	5.9	5.0	<b>6.8</b>	4.8
JEBIK V	3.6	3.9	5.2	<b>5.5</b>	4.5

Note: From fiscal 2016, the Company has voluntarily applied IFRS instead of Japanese GAAP. Figures for fiscal 2015 are also presented in accordance with IFRS.

## Remicade Infliximab



Domestic revenue

**¥58.8 billion**

**Indications** Crohn's disease, RA (including the prevention of structural joint damage), Behcet's disease with refractory uveoretinitis, psoriasis vulgaris, psoriasis arthropathica, pustular psoriasis, erythrodermic psoriasis, ankylosing spondylitis, ulcerative colitis, entero- Behcet's disease, neuro- Behcet's disease, vasculo- Behcet's disease, Kawasaki disease

**Launch** May 2002

**Origin** Janssen Biotech (U.S.)

**Development** Mitsubishi Tanabe Pharma

### Overview

Remicade is the world's first anti-TNF monoclonal antibody. It targets TNF, an inflammatory cytokine. Administered through IV infusion, it is very fast-acting and its efficacy is sustained for eight weeks with a single administration. In Japan, it was launched as a treatment agent for Crohn's disease in 2002 and received an additional indication for RA in 2003. In 2009, approval was received for a change of dosage/administration for RA (increased dosage, shortened administration interval). Furthermore, additional indications for a wide range of inflammatory autoimmune diseases, such as psoriasis and ulcerative colitis, have contributed to growth in sales. In 2012, it became possible to shorten the IV infusion time from the 4th administration if there are no problems with safety. Also, in fiscal 2017 approval was received for a partial change in administration/dosage (shortened administration interval) for Crohn's disease.

### Sales trend

In fiscal 2018, revenue was down 9.1%, to ¥58.8 billion. In fiscal 2018, the third biosimilar and a new competing product for ulcerative colitis were launched and competition further intensified. However, differentiation from competitors for ulcerative colitis led to an increase in revenue in that particular market, mitigating the overall revenue decline. In fiscal 2019, competition is expected to further intensify with market penetration of biosimilars, the impact of new competing products for Crohn's disease and psoriasis, and other factors, but we will continue to collect and provide evidence on the safety and effectiveness of Remicade. The forecast for revenue in fiscal 2019 is ¥53.1 billion, a decline of 9.7% from fiscal 2018.

## Simponi Golimumab



### Autoinjector



Domestic revenue

**¥37.4 billion**

**Indications** RA (including the prevention of structural joint damage), ulcerative colitis

**Launch** September 2011

**Origin** Janssen Biotech (U.S.)

**Development** Co-development with Janssen Pharmaceutical K.K.

### Overview

Simponi is a human TNF monoclonal antibody that targets TNF, an inflammatory cytokine. With simple administration—subcutaneous injection once every four weeks—it has superior efficacy that continues for an extended period of time. Its efficacy and safety are higher than with other subcutaneous injections, and it is expected to contribute to raising the percentage of patients who continue treatment. In regard to indications, in 2017 Janssen Pharmaceutical K.K., with which we are conducting joint development, added an indication for ulcerative colitis, in addition to RA (including the prevention of structural joint damage).

### Sales trend

The convenience of a single administration for a four-week period has been highly evaluated, and Simponi is increasing its share in the RA market. In fiscal 2018, revenue increased 16.7%, to ¥37.4 billion. MRs were very active, resulting in steady acquisition of hospital accounts and prescriptions, and this had a positive effect on revenue growth. In the rheumatism market, prescriptions for seniors are increasing and the scope of patients approved for self-administration is expanding. We have also achieved a steady increase in the number of administrations for ulcerative colitis cases. The forecast for revenue in fiscal 2019 is ¥43.0 billion, an increase of 14.8% from fiscal 2018. The competition will be intense, but we expect a contribution from autoinjector sales, which began in May 2019.

## Overview and Sales Trends of Priority Products

### Stelara Ustekinumab



Domestic revenue

**¥15.2 billion**

- Indications** Psoriasis vulgaris, psoriasis arthropathica, Crohn's disease
- Launch** March 2011
- Origin** Janssen Biotech (U.S.)
- Development** Janssen Pharmaceutical K.K.

#### Overview

Stelara is a human anti-IL12/23p40 monoclonal antibody. It shows a long acting efficacy by subcutaneous injection once every 12 weeks (initial administration, only, by intravenous drip infusion). Additional indication for Crohn's disease was approved in March 2017. Mitsubishi Tanabe Pharma and Janssen Pharmaceutical have jointly promoted STELARA as indicated for Crohn's disease in Japan since April 2017. For the indication for psoriasis, promotion is handled solely by Janssen Pharmaceutical.

#### Sales trend

In fiscal 2018, revenue was ¥15.2 billion. For Stelara, we achieved a steady increase in the number of cases primarily in which anti-TNF- $\alpha$  agents showed diminished effectiveness or that were refractory. The forecast for revenue in fiscal 2019 is ¥21.6 billion, an increase of 42.4% from fiscal 2018. A new competing product for Crohn's disease will enter the market, and competition is expected to intensify, but we intend to promote Stelara's remission maintenance benefits, low immunogenicity, safety and other characteristics and establish its position as a first bio.

### Tenelia Teneligliptin



Domestic revenue

**¥15.2 billion**

- Indications** Type 2 diabetes mellitus
- Launch** September 2012
- Origin** Mitsubishi Tanabe Pharma
- Development** Mitsubishi Tanabe Pharma

#### Overview

Tenelia is the first dipeptidyl peptidase-4 (DPP-4) inhibitor originating in Japan to ever be launched. Due to the strength and duration of its action, it can improve postprandial blood glucose, after all three meals, with once-a-day oral administration. Furthermore, because it is eliminated from the body via two routes—through the kidneys and the liver—it is not necessary to adjust the dosage for patients with impaired kidney function. In 2013, approval was received for an indication for additional combination for type 2 diabetes mellitus, making it possible to use Tenelia in combination with all oral diabetes mellitus treatment agents and insulin.

#### Sales trend

For Tenelia, the total of the amount of the Company's sales to Daiichi Sankyo and the amount of promotion fees received from Daiichi Sankyo is disclosed as the amount of revenue. In fiscal 2018, revenue decreased 13.3% year on year, to ¥15.2 billion. Among DPP-4 inhibitors, Tenelia can be administered in the standard dosage; the dosage does not need to be reduced even in cases of decreased renal function, so stable treatment can be provided even for seniors and in cases of decreased renal function. In addition, when the effect is insufficient, we propose treatment by switching to Canalia or increasing the dosage to Tenelia 40 mg, and in this way, we are working for continued growth. The forecast for revenue in fiscal 2019 is ¥16.1 billion, an increase of 5.9% from fiscal 2018.

## Canaglu Canagliflozin



Domestic revenue

**¥6.7 billion**

**Indications** Type 2 diabetes mellitus  
**Launch** September 2014  
**Origin** Mitsubishi Tanabe Pharma  
**Development** Mitsubishi Tanabe Pharma

### Overview

Canaglu is an SGLT2 inhibitor that originated in Japan. It has been approved in more than 80 countries around the world, including the U.S., European countries, and Australia. It is based on the SGLT inhibitor T-1095, which was discovered by the Company and is the world's first orally administered SGLT inhibitor. SGLT2 inhibitors promote urinary glucose excretion and blood glucose reduction. In this way, SGLT2 inhibitors have a new mechanism of action that was not previously available and does not work through insulin. In addition to a strong blood glucose lowering effect, SGLT2 inhibitors are expected to have a low hypoglycemia risk in monotherapy. SGLT2 inhibitors also have a weight reduction effect that is not seen with other oral diabetes treatment drugs. In overseas markets excluding Asia, licensee Janssen Pharmaceuticals, of the U.S., received approval in the U.S. in 2013, making this drug the first SGLT2 inhibitor approved in the U.S., and this drug is sold under the brand name Invokana.

### Sales trend

In fiscal 2018, revenue was up 19.9%, to ¥6.7 billion. Since the launch of Canalia, a combination drug that includes a DPP-4 inhibitor and an SGLT2 inhibitor, in September 2017, some patients have switched from Canaglu to Canalia; but the market for SGLT2 inhibitors is growing and we expect prescriptions to increase going forward. Moreover, in April 2019, a large-scale clinical trial (CREDENCE study) for Invokana for type 2 diabetes patients with renal disease was announced, so the overall market is expected to be stimulated and prescriptions of Canaglu to increase. The forecast for revenue in fiscal 2019 is ¥10.9 billion, an increase of 62.1% from fiscal 2018.

## Canalia Teneligliptin/canagliflozin



Domestic revenue

**¥7.4 billion**

**Indications** Type 2 diabetes mellitus  
**Launch** September 2017  
**Origin** Mitsubishi Tanabe Pharma  
**Development** Mitsubishi Tanabe Pharma

### Overview

Canalia is a type 2 diabetes mellitus treatment agent that combines Canaglu and Tenelia. It is the first combination drug launched in Japan that includes a DPP-4 inhibitor and an SGLT2 inhibitor. Canalia has two different mechanisms of action, with the DPP-4 inhibitor promoting the secretion of insulin in accordance with blood glucose level and the SGLT2 inhibitor promoting the excretion of glucose into urine. Accordingly, it is expected to offer good blood glucose control with a single tablet administered once per day. In addition, in clinical trials in Japan targeting patients for whom monotherapy with Tenelia or Canaglu is not sufficiently effective, favorable results have been confirmed in regard to efficacy and safety.

### Sales trend

The total of the amount of the Company's sales to Daiichi Sankyo and the amount of promotion fees received from Daiichi Sankyo is disclosed as the amount of the Company's revenue. In fiscal 2018, revenue rose 310.8% year on year, a major increase, to ¥7.4 billion. Since its launch, product awareness and prescription intention have been high and sales have been steady. The revenue share of Canalia in the SGLT2 inhibitor market in fiscal 2018 has grown to approximately 10.8%. The DPP-4 inhibitor has come to be recognized as a standard drug, and the SGLT2 inhibitor market is expanding, so Canalia is expected to continue to grow going forward alongside its competitors. The forecast for revenue in fiscal 2019 is ¥7.6 billion, an increase of 3.7% from fiscal 2018.



## Overview and Sales Trends of Priority Products

### Lexapro Escitalopram



Domestic revenue

**¥14.0 billion**

**Indications** Depression, depressive symptoms, social anxiety disorder

**Launch** August 2011

**Origin** H. Lundbeck (Denmark)

**Development** Mochida Pharmaceutical

#### Overview

Lexapro is a selective serotonin reuptake inhibitor (SSRI). It was launched in 2002 in Europe and the U.S., and is currently approved in approximately 100 countries and regions. Among SSRIs, it has the highest serotonin transporter selectivity. Its superior efficacy for depression and depressive symptoms and good tolerability have been confirmed. In addition, it has simple administration, and as a result it is expected to contribute to the improvement of medication adherence, which is especially important in patients with depression. We have been conducting joint sales activities with Mochida Pharmaceutical since 2011. In 2015, it received an additional indication for social anxiety disorder (SAD).

#### Sales trend

In fiscal 2018, revenue rose 9.7%, to ¥14.0 billion. Growth in the anti-depressant market is slowing, but we propose a patient profile (patients with anxiety) to which Lexapro can contribute and a method of usage, and recognition of Lexapro's exceptional efficacy and tolerability is achieving further market uptake. It has the top share of the SSRI market. In November 2018, the shape of the 10 mg tablet was changed to make it easier to divide, and 20 mg tablets were approved as the new standard. While continuing to promote appropriate use as our basic sales activity, we will utilize the added indication for social anxiety disorder to promote Lexapro's use by patients with anxious depression and focus on its growth while differentiating it from other SSRI and SNRI drugs. The forecast for revenue in fiscal 2019 is ¥15.2 billion, an increase of 9.2% from fiscal 2018.

### Imusera Fingolimod



Domestic revenue

**¥4.3 billion**

**Indications** Multiple sclerosis (MS)

**Launch** November 2011

**Origin** Mitsubishi Tanabe Pharma

**Development** Co-development with Novartis Pharma K.K.

#### Overview

Imusera is a first-in-class drug that controls inflammation in the brain and spinal cord in MS. It inhibits the receptor function of the sphingosine-1-phosphate (S1P) receptor on the lymphocyte, and prevents auto-aggressive lymphocytes from invading the central nervous system. Unlike previous drug treatments for MS, which are limited to injections, it can be administered orally (once daily), thereby lowering the burden on patients. Imusera was discovered by Mitsubishi Tanabe Pharma and developed jointly by Mitsubishi Tanabe Pharma and Novartis Pharma K.K. in Japan. We are marketing this product under the name Imusera, while Novartis Pharma K.K. is marketing it under the name Gilenya. Overseas, Novartis, of Switzerland, which licensed the product, has obtained approval for it in more than 80 countries and regions, including in Europe and the U.S.

#### Sales trend

In fiscal 2018, revenue was down 8.2%, to ¥4.3 billion. In March 2018, the prescription period limit for a competing product was lifted and prescriptions of it increased significantly. As a result, though Imusera (and Gilenya) maintained the top share of the market, the competing product closed the gap. The multiple sclerosis treatment market is shifting from injections (interferons) to oral drugs. In addition, in the MS and NMO Clinical Guidelines 2017 (Japanese Society of Neurology), an ideal case for fingolimod\* (multiple sclerosis patients with high disease activity) is advocated. Going forward, we will continue to promote prescriptions of Imusera for this ideal case in accordance with the guidelines while promoting the convenience of oral administration. The forecast for revenue in fiscal 2019 is ¥4.2 billion, a decrease of 1.4% from fiscal 2018.

\* The general name for Imusera (Gilenya)

## Rupafin

### Rupatadine fumarate



Domestic revenue

**¥3.4 billion**

**Indications** Allergic rhinitis, urticaria, pruritus accompanying skin disease (eczema, dermatitis, cutaneous pruritus)

**Launch** November 2017

**Origin** J. Uriach Y COMPANIA (Spain)

**Development** Teikoku Seiyaku

### Overview

Rupafin is an oral allergy treatment agent that has a new mechanism of action. In addition to anti-PAF (platelet activating factor) action, it also has anti-histamine action. Launched in 2001 in Spain, it is currently approved in more than 80 countries and regions. Like histamine, PAF is a chemical transmitter that is closely involved in the pathology of allergic disorders. PAF induces vasodilation, vascular permeability enhancement, sensory nerve stimulation, and white blood cell activation. As a result, it brings about such symptoms as itchiness, sneezing and runny nose. By simultaneously controlling PAF and histamine, Rupafin offers strong effectiveness and controls the symptoms of allergic disorders (rhinitis, dermatosis).

### Sales trend

In fiscal 2018, revenue was ¥3.4 billion. With the limit on the dosing period lifted on December 1, 2018, we reinforced activities to position it as the drug of choice for the 2019 pollen season, and, as a result, the number of advertisements and presentations were No. 1 among all pharmaceuticals, which led to increases in both hospital accounts and prescriptions. Market share increased to 8.8% from a share of 2.0% prior to the dosing limit being lifted. In fiscal 2019, the antihistamine market is projected to contract slightly due to inroads made by generics, but we intend to achieve a share of 11% by establishing Rupafin as the drug of choice for rhinitis and dermatosis patients. The forecast for revenue in fiscal 2019 is ¥7.8 billion, an increase of 128.9% from fiscal 2018.

## Vaccines



Domestic revenue

**¥37.3 billion**

### Overview

The Company sells vaccines developed and produced by the Research Foundation for Microbial Diseases of Osaka University (BIKEN Foundation). In May 2017, aiming for a stable supply of high-quality vaccines that are competitive in Japan and overseas, the Company and the BIKEN Foundation established a joint venture company, BIKEN Co. Taking the BIKEN Foundation's vaccine manufacturing technologies as its base, BIKEN Co., will leverage Mitsubishi Tanabe Pharma's pharmaceutical production-related systems and management methods and accelerate the reinforcement of the production base. In this way, BIKEN Co. will aim to achieve a more stable supply of high quality vaccines.

### Sales trend

In fiscal 2018, overall revenue from vaccines rose 6.4%, to ¥37.3 billion. The Company maintained the top share of the domestic vaccine market. In fiscal 2018, Mearubik benefited from an increase in voluntary inoculation demand due to measles and rubella outbreaks, and JEBIK V from an increase in demand for periodic vaccination for children at the end of fiscal 2017, and these both contributed greatly to revenue. For the seasonal influenza vaccine, which accounts for the largest share of the Company's vaccine sales, we worked to ensure stable supplies through the collaboration with BIKEN Foundation and the company it merged with, BIKEN. For the chickenpox vaccine, a competing product is expected to be launched this fiscal year, so while activities to promote awareness of shingles inoculation are likely to intensify, it is a voluntary vaccination, so the impact on the market is unclear. The forecast for revenue in fiscal 2019 is ¥36.2 billion, a decrease of 2.9% from fiscal 2018.