Overview and Sales Trends of Priority Products in Fiscal 2018

The sales forecasts in this section were announced on May 9, 2018.

Revenue of Priority Products in Fiscal 2018

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<td>Vaccines:</td>
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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, but figures for fiscal 2014 are before the application.
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 2017, revenue was down 3.2%, to ¥64.6 billion. NHI drug prices were revised in April 2018, and the third biosimilar is expected to be launched during fiscal 2018. The circumstances will remain difficult, including competing products. However, in the treatment of RA, we will work to enhance original value by facilitating contributions to the optimization of treatment through the use of blood concentration measurement kits. The forecast for revenue in fiscal 2018 is ¥55.5 billion, a decline of 14.1%.

Overview

Simponi is a human TNFα monoclonal antibody that targets TNFα, 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 other subcutaneous injections, and it is expected to contribute to raising the percentage of patients who continue treatment. In regard to indications, in addition to RA (including the prevention of structural joint damage), in 2017 Janssen Pharmaceutical K.K., with which we are conducting joint development, added an indication for ulcerative colitis.

Sales Trend

In fiscal 2017, revenue rose 29.0%, to ¥32.1 billion. 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 addition, in the ulcerative colitis market, it is used by a growing number of institutions as the third biologic. In April 2018, insurance coverage was extended to include self-administered injections for the treatment of RA, which provides a new treatment option for patients who face difficulties in commuting to medical facilities. In fiscal 2018, new competing products are expected to be launched, and the market environment will be challenging. However, we will leverage our collaborative alliance with Janssen Pharmaceutical K.K. and work to promote the further use of Simponi. The forecast for revenue in fiscal 2018 is ¥35.0 billion, an increase of 9.2%.

Remicade
Infliximab

Domestic Revenue
¥64.6 billion

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

Launch May 2002
Origin Janssen Biotech (U.S.)
Development Mitsubishi Tanabe Pharma

Simponi
Golimumab

Domestic Revenue
¥32.1 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.
Tenelia
Teneligliptin

Indication
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 that has ever been launched. Due to the strength and duration of its action, it can improve post-prandial blood glucose, after 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 of 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
In fiscal 2017, revenue rose 5.8%, to ¥17.5 billion.

Competition in the DPP-4 inhibitors market is intense, but we have implemented joint promotional activities with Daiichi Sankyo and achieved solid increases in the number of administrations. From 2015, to increase efficiency we changed from a joint sales scheme to solo marketing by Daiichi Sankyo. However, we continue to implement joint promotions, and are emphasizing its ease-of-use and strong effectiveness, such as for senior citizens and patients with impaired kidney function. Accompanying the change in the sales scheme, 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 from Tenelia. The forecast for revenue in fiscal 2018 is ¥17.0 billion, a decrease of 2.8%.

Talion
Bepotastine

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

Launch
October 2000

Origin
Ube Industries

Development
Co-development with Ube Industries

Overview
Talion has rapid onset of histamine H1 receptor antagonist effects and quickly displays a high degree of effectiveness for allergic rhinitis, urticaria, and pruritus accompanying dermatitis. It has a low frequency of sedation, which is a side effect of anti-histamines. An orally disintegrating tablet formulation, which makes it easier for patients to take the drug, has been sold since 2007, and a pediatric indication (ages 7 to 15) was approved in 2015.

Sales Trend
In fiscal 2017, sales declined 10.7%, to ¥16.9 billion.

In March 2018, an authorized generic was launched. (An authorized generic is a product that is sold through a subsidiary, affiliate, etc., when that company receives patent usage rights from the pharmaceutical company that manufactures and sells the original product.) In addition, a generic drug was launched in June. However, during the reexamination period we will focus on pediatric applications (ages 7 to 15). The forecast for revenue in fiscal 2018 is ¥7.3 billion, a decrease of 56.6%.
Lexapro

Escitalopram

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).

Launch
August 2011

Origin
H. Lundbeck (Denmark)

Development
Mochida Pharmaceutical

Sales Trend
In fiscal 2017, revenue rose 13.2%, to ¥12.7 billion. Recognition of Lexapro’s efficacy and tolerability has begun to achieve further market uptake, and Lexapro has secured the top share in the SSRI market. With an additional indication for SAD, we will work to promote its use by patients with anxious depression. In addition, for consideration of the pediatric dosage the reexamination period was extended by two years. The forecast for revenue in fiscal 2018 is ¥13.1 billion, an increase of 3.1%.

Canaglu

Canagliflozin

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.

Launch
September 2014

Origin
Mitsubishi Tanabe Pharma

Development
Mitsubishi Tanabe Pharma

Sales Trend
In fiscal 2017, revenue was up 60.8%, to ¥5.6 billion. Moving forward, we will work to see that Canaglu rapidly catches up to SGLT2 inhibitors that were launched earlier by securing accounts at hospitals and by differentiating it from other drugs in the private practitioner and small hospital market. On a base of abundant evidence for Canaglu, which is the world’s most prescribed SGLT2 inhibitor, we will advance appropriate information provision activities and work to promote the appropriate use of SGLT2 inhibitors while fostering an understanding of the usefulness of this drug. The forecast for revenue in fiscal 2018 is ¥7.6 billion, an increase of 36.5%.
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 BIKEN Foundation and the Company established a joint venture company, BIKEN Co., based on the BIKEN Foundation’s vaccine manufacturing business. On a base of the BIKEN Foundation’s vaccine manufacturing technologies, BIKEN Co., will leverage Mitsubishi Tanabe Pharma’s pharmaceutical production-related systems and management methods and accelerate the reinforcement of the production foundation. In this way, BIKEN Co., will aim to achieve a more stable supply of vaccines.

Sales Trend

In fiscal 2017, overall revenue from vaccines was down 10.0%, to ¥35.0 billion. The Company maintained the top share of the domestic vaccine market in fiscal 2017. For the seasonal influenza vaccine, which accounts for the largest share of the Company’s sales of vaccines, intradermal and cell-culture vaccines have been developed, but their influence on the market is not clear and it is not possible to make specific market forecasts. For the varicella vaccine, the number of children receiving periodic vaccination and the supply both stabilized. Accordingly, from fiscal 2017 we focus on promotions to prevent shingles in people 50 or older. However, the effect on the market has been small because this is a voluntary vaccination. The forecast for overall revenue of vaccines in fiscal 2018 is ¥36.5 billion, an increase of 4.2%.

Imusera

Fingolimod

Domestic Revenue

¥4.7 billion

Indication

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 in more than 80 countries and regions, including countries in Europe and the U.S.

Sales Trend

In fiscal 2017, revenue was down 3.5%, to ¥4.7 billion. New competing product was launched in February 2017, but based on their combined results Imusera and Gilenya have maintained the No. 1 share in the market. Moving forward, we anticipate a shift from injections toward oral drugs, and patients will have a choice of two oral drugs in accordance with their condition. The forecast for revenue in fiscal 2018 is ¥4.9 billion, an increase of 5.4%.

Vaccines

Domestic Revenue

¥35.0 billion
New Products Launched in Fiscal 2017

Canalia
Teneligliptin/canagliflozin

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 mono-therapy with Tenelia or Canaglu is not sufficiently effective, favorable results have been confirmed in regard to efficacy and safety.

Sales Trend
In fiscal 2017, revenue was ¥1.8 billion. Since its launch in September 2017, product recognition and intention to prescribe have been high, and sales have followed a favorable trend. In fiscal 2018, a competing product is expected to be launched, and domestic needs for combination tablets are increasing against a background of declines in the number of tablets taken and in the NHI drug price burden. Accordingly, we will work to foster further uptake in the market by providing information about the characteristics of Canalia. 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. The forecast for revenue in fiscal 2018 is ¥3.2 billion, an increase of 79.6%.

Rupafin
Rupatadine fumarate

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 sneezing and runny nose. By simultaneously controlling PAF and histamine, Rupafin offers strong effectiveness and controls the symptoms of allergic disorders.

Sales Trend
Sales commenced in November 2017, and in fiscal 2017 revenue was ¥0.4 billion. The number of patients with hay fever and other allergic disorders is increasing each year. By simultaneously controlling both PAF and histamine, Rupafin offers dual action that is not available from existing anti-histamine products. Rupafin is a highly effective product, and on that basis we will work to increase its share by implementing sales activities to promote a switch from existing anti-histamine products. The forecast for revenue in fiscal 2018 is ¥6.8 billion, a substantial increase.