

# OVERVIEW OF CORE ETHICAL DRUGS AND SALES TRENDS

## Priority Products

### Remicade

Infliximab

Treatment of rheumatoid arthritis (RA), Crohn's disease, and Behcet's disease with refractory uveoretinitis, psoriasis, ankylosing spondylitis, ulcerative colitis (Anti-TNF $\alpha$  monoclonal antibody)



FISCAL 2009 SALES

¥47.2 billion

Launch: 2002

Origin: Centocor Ortho Biotech (U.S.)

Development: Mitsubishi Tanabe Pharma

**Overview:** Remicade is an anti-TNF $\alpha$  monoclonal antibody that targets TNF $\alpha$ , an inflammatory cytokine. It is very fast-acting and its efficacy is sustained for two months with a single administration. In July 2009, a change in usage / dosage was approved for RA (increase in dosage amount, decrease in time interval between administrations) and "prevention of structural joint damage" was approved for inclusion in the indications. In addition, approval was received for indications of psoriasis in January 2010, ankylosing spondylitis in April 2010, and ulcerative colitis in June 2010.

**Sales trend:** Sales in fiscal 2009 were up 26.2%. In fiscal 2010, competition with biological products is expected to intensify in the RA market, but with support from the change in usage / dosage, the Company is forecasting an increase in sales.

### Radicut

Edaravone

Cerebral neuroprotectant  
(Free radical scavenger)



FISCAL 2009 SALES

¥28.0 billion

Launch: 2001

Origin: Mitsubishi Tanabe Pharma

**Overview:** Radicut, which was developed in Japan, is the world's first cerebral neuroprotectant (free radical scavenger) shown to improve neurological symptoms at the acute stage of cerebral infarction, interference with activities of daily living, and functional disability. It inhibits damage to brain cells and protects cerebral blood vessels and cells. It is indicated for the treatment of three major types of cerebral infarction (cerebral lacunar, atherothrombotic, and cardiogenic). Administration is started within 24 hours after onset, and it is not administered for more than 14 days. In May 2010, we launched an additional dosage form, an IV infusion bag formulation.

**Sales trend:** Sales in fiscal 2009 were down 0.3%. Market conditions remain difficult due to an increase in the number of hospitals implementing the DPC system. However, accompanying the aging of the population, the incidence of cerebral infarction is rising about 2% a year. We will launch the highly convenient IV infusion bag formulation, which meets clinical needs, and will strengthen promotions through MRs specialized in the cerebral field.

### Anplag

Sarpogrelate

Anti-platelet agent  
(5-HT<sub>2</sub> blocker)



FISCAL 2009 SALES

¥19.5 billion  
domestic ¥18.4 billion  
overseas ¥1.1 billion

Launch: 1993

Origin: Mitsubishi Tanabe Pharma

**Overview:** Anplag is an oral anti-platelet agent that is used to treat patients with chronic arterial occlusion, such as arteriosclerosis obliterans (ASO). Anplag improves ischemic symptoms associated with chronic arterial occlusion, such as ulcer, pain, and coldness of limbs, through the inhibition of platelet aggregation, vascular contraction, and growth of vascular smooth muscle cells, which are intensified by serotonin. It especially improves blood flow in the collateral circulatory system. In August 2007, approval was received for a small-sized tablet that is convenient for elderly patients.

**Sales trend:** Domestic sales in fiscal 2009 were down 0.5%. In November 2009, a generic competitor was launched, and market conditions are expected to become more challenging. However, accompanying the aging of Japan's population, the ASO market is growing. Utilizing new data that shows effectiveness in improving gait disturbance, we will aggressively promote this product to increase new prescriptions.

### Talion

Bepotastine

Treatment of allergic  
disorders



FISCAL 2009 SALES

¥11.3 billion  
domestic ¥10.6 billion  
overseas ¥0.7 billion

Launch: 2000

Origin: Ube Industries

Development: Co-development with Ube Industries

**Overview:** Talion has a rapid onset of antihistamine (H1) effects and is effective for allergic rhinitis, urticaria, and pruritus accompanying dermatitis. It has minimal incidence of sedation. In July 2007, we launched an additional formulation, orally disintegrating tablets.

**Sales trend:** Domestic sales in fiscal 2009 were up 2.3%, the highest rate of growth in the market for allergic disorder drugs. In fiscal 2010, we will bolster promotion activities in the area of dermatitis, and strive for further growth.

## Urso

Ursodeoxycholic Acid

Agent for improving hepatic, biliary, and digestive functions



FISCAL 2009 SALES

¥16.9 billion  
domestic ¥16.3 billion  
overseas ¥0.6 billion

Launch: 1957

Origin: Mitsubishi Tanabe Pharma

**Overview:** Ursodeoxycholic acid, which is the principal ingredient of Urso, is the source of the effectiveness of black bear gallbladder. It has been used to improve digestive diseases. UDCA, which is one of the bile acids existing in the human body, has a cytoprotective effect on liver cells. It has indications for improvement of liver function in chronic liver disease and in hepatitis C and for the dissolution of gall stones.

**Sales trend:** Domestic sales in fiscal 2009 were up 0.5%. We will continue working to disseminate the treatment objectives under the 2008 chronic hepatitis C treatment guidelines.

## Other Core Ethical Drugs

### Ceredist

Taltirelin

Treatment of spinocerebellar degeneration



FISCAL 2009 SALES

¥16.9 billion

Launch: 2000

Origin: Mitsubishi Tanabe Pharma

**Overview:** Ceredist, developed by the Company, is the world's first oral thyrotropin-releasing hormone (TRH) derivative drug. In June 2009, approval was received for orally disintegrating tablets that are easily taken by patients who have difficulty swallowing due to the progress of spinocerebellar degeneration.

**Sales trend:** Sales in fiscal 2009 were up 4.0%. Spinocerebellar degeneration, for which this drug is indicated, is an intractable neurological disease that has been designated by the Ministry of Health, Labour and Welfare as a special chronic disease. The number of registered patients has been increasing by several percent each year. The usage rate among patients is high. For fiscal 2010, sales are forecast to increase as the number of patients records gradual growth. The Company has developed orally disintegrating tablets for patients who have difficulty swallowing.

## Tanatril

Imidapril

Treatment of hypertension (ACE inhibitor)



FISCAL 2009 SALES

¥12.9 billion  
domestic ¥11.1 billion  
overseas ¥1.8 billion

Launch: 1993

Origin: Mitsubishi Tanabe Pharma

**Overview:** Tanatril shows excellent blood pressure control with effective organ protection as well as minimal incidence of dry cough, a common side effect of ACE inhibitors. With the approval of an additional indication in 2002, it became the first drug in Japan approved for diabetic nephropathy with type 1 diabetes.

**Sales trend:** The size of the market for ACE inhibitors is declining, and in fiscal 2009 domestic sales declined 6.5%. In fiscal 2010, generics will have an influence, but we will utilize evidence for Tanatril in various guidelines and its superiority in terms of its protective effect against coronary artery disease and its effects against hypertension in the elderly.

### Vaccines

FISCAL 2009 SALES\*

¥24.3 billion  
domestic ¥23.0 billion\*  
overseas ¥1.3 billion

The Company sells vaccines produced by BIKEN. In fiscal 2009, JEBIK V, a freeze-dried Japanese encephalitis vaccine, made a contribution to domestic sales of vaccines, which rose 6.9%, to ¥23.0 billion. In addition, the H1N1 influenza vaccine recorded domestic sales of ¥8.8 billion in fiscal 2009.

\* excluding H1N1 influenza vaccine (domestic sales of ¥8.8 billion)

### Mearubik

Freeze-dried live attenuated measles and rubella combined vaccine

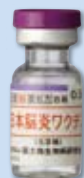


Launch: 2005

**Origin:** This is a combined vaccine for the prevention of measles and rubella. Because vaccination against measles and rubella can be implemented at the same time, it reduces the burden on the patient. The Company will work to foster further education about vaccination and to contribute to an increase in the vaccination rate for measles and rubella.

### JEBIK V

Freeze-dried Japanese encephalitis vaccine (Cell culture derived)



Launch: 2009

**Origin:** This vaccine is a freeze-dried preparation containing inactivated Japanese encephalitis virus derived from cell cultures. It is used in the prevention of Japanese encephalitis. There is no specific method of treatment for Japanese encephalitis. Symptomatic treatment plays the central role. Accordingly, prevention is the most important, and preventive vaccines are one effective method. In April 2010, the government announced that it would reinstate recommendation of vaccination against Japanese encephalitis. Moving forward, the Company will work to foster further education about vaccination and to contribute to an increase in the vaccination rate.