

Targeting the Discovery of New Growth Drivers

The Company is working to advance the discovery of new growth drivers for the period after the current management plan, and those efforts are steadily showing results. This section reports on the progress of our major development projects, centered on the key development projects outlined in the Medium-Term Management Plan 08–10.



Promising New Drug Candidate Compounds

FTY720 Sphingosine-1-phosphate receptor modulator (Multiple sclerosis treatment)

Multiple sclerosis (MS) is a disease that causes white matter lesions in such areas as the brain, the spinal cord, and the optic nerve. The cyclical relapse and recurrence of neurological symptoms is a frequent characteristic of the disease. The cause is unknown. The number of MS patients worldwide is estimated to be about 2.5 million. Currently, MS drugs are used in injection formulations, and there is a lack of satisfactory treatments. We are aiming to launch FTY720 as the world's first oral drug for the treatment of MS. It shows great promise in regard to unmet medical needs for MS treatment, where treatments with greater efficacy and safety are needed. As a first-in-class drug, it is expected to become a major product. The Company has licensed FTY720 to Novartis Pharma. Novartis Pharma is developing the drug in the U.S. and Europe, where NDAs were filed in December 2009. As a result of its usefulness, FTY720 was granted priority review status in the U.S. in February 2010, and in June 2010 the FDA advisory committee recommended approval. In Japan, the Company and Novartis Pharma are moving ahead with co-development of FTY720, and we plan to file an NDA in 2010.

MP-424 NS3-4A protease inhibitor (chronic hepatitis C)

MP-424 is the most advanced new treatment for hepatitis C in the world. We licensed MP-424 from Vertex Pharmaceuticals, of the U.S., in June 2004. It is administered orally, and is a selective inhibitor of the hepatitis C virus (HCV) NS3-4A protease, thereby resulting in suppression and clearance of HCV RNA. For patients with viral genotype 1 virus,

the standard treatment of combination therapy administration of two drugs—pegylated interferon and ribavirin—is not sufficiently effective. We are collecting data to demonstrate that concomitant administration of three drugs, through the addition of MP-424, results in shorter treatment periods and superior effectiveness. MP-424 is also drawing attention from liver specialists, and is expected to be positioned as the “gold standard” in hepatitis C treatment. In Japan, the drug administration period of the phase 3 trials has completed, and we are aiming to file an NDA in 2011.

TA-7284 SGLT2 inhibitor (diabetes mellitus)

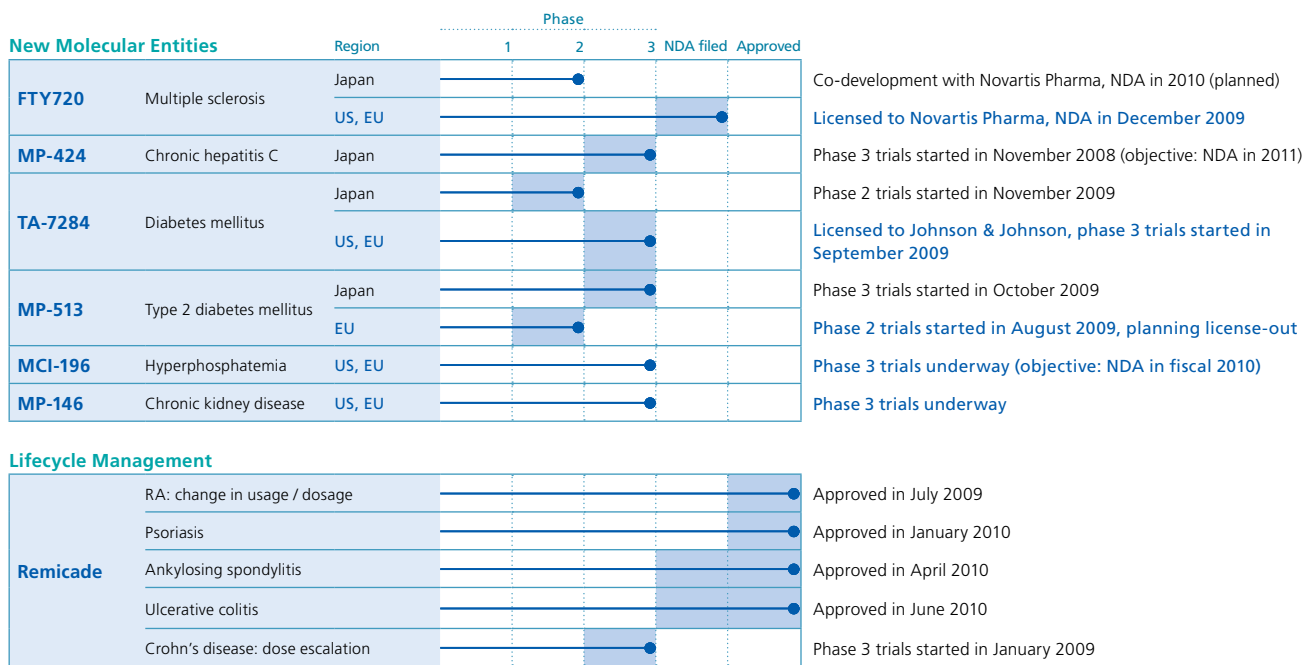
TA-7284 controls renal tubular reabsorption of glucose and promotes its excretion in the urine, thereby having the effect of controlling blood glucose levels. It has an entirely different mechanism from conventional diabetes treatments in the strong excretion of sugar, and is also expected to have a weight-loss effect through calorie loss. We are moving forward with development of TA-7284, targeting best in class. In Japan, we started phase 2 trials in November 2009. Development in the U.S. and Europe is being conducted by Johnson & Johnson, which has licensed TA-7284 from Mitsubishi Tanabe Pharma. Phase 3 trials were started in September 2009. In June 2010, the blood glucose-lowering effect and the weight-loss effect were reported at the American Diabetes Association's annual meeting.

MP-513 DPP4 inhibitor (type 2 diabetes mellitus)

MP-513 inhibits dipeptidyl peptidase 4 (DPP4), which breaks down GLP-1, which promotes the secretion of insulin. In this way, MP-513 promotes insulin secretion. It is less likely to cause problems associated with conventional diabetes treatments, such as hypoglycemia

PROGRESS IN MAJOR DEVELOPMENT PROJECTS

Progress from fiscal 2008



and weight gain. Due to MP-513's strong DPP4 inhibition and sustained action, we expect it to have the effect of improving blood glucose with once-a-day, low-dose oral administration. MP-513's renal excretion rate is low, so it is possible that it will not be necessary to adjust the dosage, even for patients with impaired renal function. MP-513 has great promise as a next-generation diabetes treatment, and we are proceeding with development, targeting best in class. In Japan, phase 3 trials were started in October 2009, and in Europe, phase 2 trials were started in August 2009. In the U.S. and Europe, we are also moving ahead with negotiations regarding alliances.

Steady Progress in Overseas Development of Drugs for Renal Diseases

MCI-196 Non-absorbed phosphate binder (hyperphosphatemia)

MCI-196 promotes the absorption of phosphate in the digestive tract and its excretion, thereby improving the hyperphosphatemia of renal disease patients. In Japan, it is marketed for the treatment of hypercholesterolemia under the brand name Cholebine. It is currently in phase 3 trials for hyperphosphatemia in dialysis patients in a number of regions, such as the U.S. and Europe, with the objective of filing NDAs in fiscal 2010.

MP-146 Uremic toxin adsorbent (chronic kidney disease)

MP-146 is a spherical adsorbent that adsorbs uremic toxins produced in the digestive tract and promotes their excretion. Mitsubishi Tanabe Pharma licensed MP-146 from Kureha, of Japan, in 2006. Aiming to follow up MCI-196 with approval for MP-146 in the U.S. and Europe, MP-146 is in phase 3 trials for chronic kidney disease patients (moderate to severe), with the objective of filing an NDA.

Aggressively Promoting Lifecycle Management

Remicade Anti-TNF α monoclonal antibody

Remicade is an anti-TNF α monoclonal antibody that is effective against a wide range of inflammatory autoimmune diseases. In 1993, we licensed Remicade from Centocor Ortho Biotech, of the U.S. It has received indications for Crohn's disease, RA, and Behcet's disease complicated with refractory uveoretinitis that does not respond to conventional therapies. In July 2009, the Company received approval for a partial change of usage / dosage for RA and for a partial change of indications to include the prevention of structural joint damage. In addition, approval was received for indications of psoriasis in January 2010, ankylosing spondylitis in April 2010 and ulcerative colitis in June 2010. Currently, we are conducting phase 3 trials in preparation for the filing of an application for a change in usage / dosage for Crohn's disease.