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PRESS RELEASE

[Mitsubishi Tanabe Pharma Corporation](#)

**Approval for "IMUSERA[®] Capsules 0.5mg"
Japan's First Once-Daily Oral Dosing Multiple Sclerosis Treatment**

Osaka, Japan, September 26, 2011---Mitsubishi Tanabe Pharma Corporation (President & CEO: Michihiro Tsuchiya, hereinafter: Mitsubishi Tanabe Pharma) announced today that the Company obtained the manufacturing and marketing approval for IMUSERA[®] Capsules 0.5mg (generic name: fingolimod hydrochloride) for the indications of prevention of relapse and delay of progression of physical disability in multiple sclerosis (MS).

MS is demyelinating disease of the central nervous system characterized by cyclical relapse and remission of various neurological symptoms, such as paresthesia, optic neuritis, and motor paresis. In Japan, the number of patients with MS is reported about 14,000, and they suffer from physical disabilities, some of them are condemned to a wheelchair. MS is designated as the specified rare and intractable disease by the Ministry of Health, Labour and Welfare.

IMUSERA[®], originally discovered by the Company, is a first-in-class drug that inhibits the receptor function of sphingosine-1-phosphate receptor (S1PR) on the lymphocyte. With this, IMUSERA[®] prevents auto-aggressive lymphocytes from invading the central nervous system, resulting in the control of inflammation in the brain and spinal cord, typical for MS. There has been only injectable drug available for the treatment of MS, and IMUSERA[®] is Japan's first once-daily oral treatment.

In a domestic Phase 2 study, IMUSERA[®] treatment did not only significantly lower annualized relapse rate, but also significantly decreased the proportion of the patients having active lesions, as measured by MRI. In an overseas 2-year placebo-controlled Phase 3 study also showed similar results that the product reduced the relapse rate, suppressed the symptoms, aggravation, and controlled a significant reduction in the risk of physical disability progression. Common side effects in domestic clinical study included abnormal liver functions laboratory values, nasopharyngitis, bradycardia at treatment initiation.

"There has been only interferon β as an approved treatment for prevention of relapse and delay of progression of physical disability in patients with MS in Japan," says Dr. Yasuto Itoyama, Director, National Center Hospital, National Center of Neurology and Psychiatry. "Different from existing drugs, fingolimod hydrochloride has a novel action mechanism and its high efficacy has been confirmed in clinical studies in Japan and overseas. With its convenience of once-daily oral formulation, we expect that fingolimod hydrochloride will become an important treatment option for MS patients."

This product has been jointly developed with Novartis Pharma K.K. (Head Office: Tokyo, Japan; President & CEO: Hiroyuki Mitani) for the domestic development, and both companies plan to co-market the product soon after its registration in the NHI price listing, which will

be under the different brand name. Overseas, our licensee Novartis (head office: Basel, Switzerland) has obtained NDA approvals for this product in more than 50 countries including the U.S., Australia, Canada, EU members, Switzerland and Brazil.

Mitsubishi Tanabe Pharma will contribute to fulfill the expectations of patients as well as medical professionals through developing and marketing pharmaceuticals that satisfy unmet medical needs, and will contribute to the healthier lives people around the world through the creation of pharmaceuticals.

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