## Launch of "IMUSERA® Capsules 0.5mg" Japan's First Oral Dosing Multiple Sclerosis Treatment with Novel Mode of Action

**Osaka, Japan, November 25, 2011---**Mitsubishi Tanabe Pharma Corporation (President & CEO: Michihiro Tsuchiya, hereinafter: Mitsubishi Tanabe Pharma) announced today that the Company would launch IMUSERA® Capsules 0.5mg (generic name: fingolimod hydrochloride) on November 28, 2011, as a treatment for multiple sclerosis (MS) following the National Health Insurance price listing as of today.

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 (S1P $_1$ R) 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 by 49 % compared to placebo, 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 and in brain atrophy compared to placebo. Common side effects in domestic clinical study included abnormal liver functions laboratory values, nasopharyngitis, bradycardia at treatment initiation.

This drug has been jointly developed with Novartis Pharma K.K. (Head Office: Tokyo, Japan; President & CEO: Hiroyuki Mitani) for the domestic market, and both companies obtained the manufacturing and marketing license for the indication of the prevention of MS relapse and the delay of physical disability progression. Overseas, our licensee Novartis (head office: Basel, Switzerland) has obtained NDA approvals for this drug in more than 50 countries including the U.S., Australia, Canada, EU members, Switzerland and Brazil. More than 20,000 MS patients have been treated with this drug since its launch in the last autumn.

The conditions attached to the IMUSERA® approval to ensure its proper usage include that the drug must be prescribed solely for the cases judged to be appropriate for this therapy, under the supervision by a physician having satisfactory knowledge about this drug's safety and efficacy in addition to treatment experience in MS, and at a medical institution capable of fully coping with an emergency situation.

Mitsubishi Tanabe Pharma will promote the proper use of this drug ensuring safety control; and expects to contribute to improve the QOL of MS patients through providing IMUSERA® that lowers the psychological and physical burden faced by patients being treated with existing self injection treatment.

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