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Press Release

[Mitsubishi Tanabe Pharma Corporation](#)

**Approval for "SIMPONI[®] Subcutaneous Injection 50mg Syringe
(Generic Name: Golimumab)" for Treatment of Rheumatoid Arthritis**

Osaka, Japan, July 1, 2011--- Mitsubishi Tanabe Pharma Corporation (President & CEO: Michihiro Tsuchiya) announced today that Janssen Pharmaceutical K.K. (head office: Chiyoda-ku, Tokyo; president: Toon Overstijns; hereinafter "Janssen") obtained the manufacturing and marketing license for human TNF- α monoclonal antibody, SIMPONI[®] Subcutaneous Injection 50mg Syringe (generic name: Golimumab (genetical recombination)) that has been co-developed by Janssen and Mitsubishi Tanabe Pharma for the domestic market, for the treatment of rheumatoid arthritis (including prevention of articular structural damage) in cases showing inadequate response to conventional therapies.

SIMPONI[®] is a human TNF- α monoclonal antibody as a subcutaneous injection. It was discovered and developed by Janssen Biotech, Inc. (former Centocor Ortho Biotech Inc.), USA, as a treatment for inflammatory autoimmune diseases involving TNF- α such as rheumatoid arthritis. It was approved for the treatment of moderately to severely active rheumatoid arthritis, active psoriatic arthritis and active ankylosing spondylitis in the U.S. in April, 2009, and in Europe in October, 2009.

In Japan, Mitsubishi Tanabe Pharma and Janssen have jointly developed SIMPONI[®] from a Phase 2 trial. In a clinical study, where SIMPONI[®] was subcutaneously injected to patients with rheumatoid arthritis every 4 weeks, regression of signs and symptoms of RA, improvement of physical function, and suppression of progression of joint destruction as well as safety have been confirmed. Based on the results, application for manufacturing and marketing of SIMPONI[®] was submitted in June, 2010, and it was approved for the treatment of rheumatoid arthritis including prevention of articular structural damage in patients who showed inadequate response to conventional therapies. Both companies plan to co-market SIMPONI[®] soon after its registration in the NHI price listing, which will be under the same brand name, Mitsubishi Tanabe Pharma will steadily provide healthcare professionals with information on the proper use of SIMPONI[®] for its safe administration in clinical settings.

In most cases, treatment of rheumatoid arthritis is prolonged and requires endurance, and there has been a continuous yearning for drugs that can reduce the patients' burden of frequent hospital visits and administration. SIMPONI[®] is designed to be administered once every 4 weeks; it will reduce the frequency of hospital visits and will also ensure proper

administration, for it can be used only when injected by a physician.

Since 2002, Mitsubishi Tanabe Pharma has been providing REMICADE[®], a TNF- α monoclonal antibody for intravenous drip infusion, which was discovered and developed by Janssen Biotech, Inc., to many patients with rheumatoid arthritis, Crohn's disease, psoriasis, and some other inflammatory autoimmune diseases. Another biological agent, SIMPONI[®] will be added to our product lineup for rheumatoid arthritis, and we expect to make a further contribution to the treatment of patients suffering from rheumatoid arthritis.

<Contact for Inquiries>

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