

September 15, 2011

Press Release

[Mitsubishi Tanabe Pharma Corporation](#)

## **Launch of "SIMPONI<sup>®</sup> (golimumab) Subcutaneous Injection 50mg Syringe" A Treatment of Rheumatoid Arthritis**

**Osaka, Japan, September 15, 2011**--- Mitsubishi Tanabe Pharma Corporation (President & CEO: Michihiro Tsuchiya) announced today, that human TNF- $\alpha$  monoclonal antibody, SIMPONI<sup>®</sup> Subcutaneous Injection 50mg Syringe (generic name: Golimumab (genetical recombination)) for the treatment of rheumatoid arthritis will be launched on September 16, 2011 following the National Health Insurance price listing as of September 12, 2011.

SIMPONI<sup>®</sup> was developed as a treatment for inflammatory autoimmune diseases involving TNF- $\alpha$  such as rheumatoid arthritis, and was first approved in the U.S. and Europe in 2009. As of June 2011, it is approved in more than 40 countries. In Japan, Mitsubishi Tanabe Pharma and Janssen Pharmaceutical K.K. (head office: Chiyoda-ku, Tokyo; president: Toon Overstijns; hereinafter "Janssen") jointly developed SIMPONI<sup>®</sup> for the domestic market from a Phase 2 trial, and Janssen obtained the manufacturing and marketing license for the treatment of rheumatoid arthritis (including prevention of articular structural damage) in cases showing inadequate response to conventional therapies.

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<sup>®</sup> 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. The clinical study showed that it is useful in the regression of signs and symptoms of RA and the improvement of physical function as well as suppressing the progression of joint destruction for the first time, as a subcutaneous injection in Japan.

Mitsubishi Tanabe Pharma and Janssen have started co-marketing SIMPONI<sup>®</sup> on September 16, under the same brand name, and both companies will steadily provide healthcare professionals with information on the proper use of SIMPONI<sup>®</sup> for its safe use in clinical settings. Further, Mitsubishi Tanabe Pharma and Janssen have opened the product website, providing healthcare professionals with information on SIMPONI<sup>®</sup>'s safety and efficacy data. The site is to be enhanced with pages designed for patients and their families to support their daily lives.

With the addition of SIMPONI<sup>®</sup> to its product lineup for rheumatoid arthritis, Mitsubishi Tanabe Pharma further expects to contribute to the treatment of patients suffering from rheumatoid arthritis by expanding their options in biologic treatment.

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