

July 7, 2009

Mitsubishi Tanabe Pharma Corporation

**Approval Acquired for a Partial Change of Indications, Dosage and Administration  
for the Anti-Human TNF  $\alpha$  Monoclonal Antibody Agent,  
Remicade<sup>®</sup> Intravenous Drip Infusion 100**

Mitsubishi Tanabe Pharma Corporation (Osaka, President: Michihiro Tsuchiya) hereby announces that the Company obtained approval on July 7th for partial changes of indications, dosage and administration related to rheumatoid arthritis for the anti-human TNF  $\alpha$  monoclonal antibody agent, Remicade<sup>®</sup> Intravenous Drip Infusion 100 (generic name: infliximab; distributed and marketed by Mitsubishi Tanabe Pharma Corporation).

Following the release of Remicade<sup>®</sup> onto the market in Japan in 2002 with an indication for Crohn's Disease, the drug obtained an additional indication for rheumatoid arthritis in 2003. Many physicians have understood the high levels of effectiveness and safety of this drug through a large scale post-marketing surveillance following the acquisition of this indication and at present, 30,000 rheumatoid arthritis patients are receiving administration of this drug.

On the other hand, some patients were unable to obtain sufficient effects with the original dosage and administration, and physicians have requested for changes in the approved dosage and administration (increase of the dosage/shortening of the administration interval). In order to respond to these needs and to enable more and more patients to feel the maximum effect of this drug, we have conducted clinical trial aimed at changes in dosage and administration from 2005. As a result, the effectiveness of this drug with an increased dosage was recognized and a partial change of dosage and administration approved. In addition, the superior effects of this drug in regard to the prevention of structural joint damage, which have already been approved in the U.S. and Europe, were also recognized in Japanese patients in this same trial, and a partial change of indications was approved at the same time.

The Company has taken a new step in the treatment of rheumatoid arthritis due to these partial changes of indications, dosage and administration related to rheumatoid arthritis and will make a greater contribution to the better lives of many patients as a result.

<Product summary>

1) Product name: Remicade<sup>®</sup> Intravenous Drip Infusion 100

2) Generic name: Infliximab

3) Indications/dosage and administration

\*The parts underlined are those that have been added this time.

<p>[Indications]</p> <p>The following diseases for which insufficient effects are obtained with existing treatment</p> <p>Rheumatoid arthritis (<u>including prevention of structural joint damage</u>)</p> <p>Intractable uveoretinitis caused by Behcet's disease</p> <p>Treatment and maintenance treatment of Crohn's Disease presenting either of the following situations.</p> <p>(Limited to cases of insufficient effects with existing treatment)</p> <p>Patients in a moderate to severe active phase</p> <p>Patients with an external fistula</p>
<p>[Dosage and administration]</p> <p>&lt;Rheumatoid arthritis&gt;</p> <p>Normally, administer intravenously via drip infusion at a dose of 3 mg/kg bodyweight. Administer at 2 weeks and 6 weeks after the initial dose and thereafter every 8 weeks. <u>If effects are insufficient or have diminished following administration at 6 weeks, the dosage may be increased or the administration interval shortened. These increases in dosage and shortening of administration interval are to be carried out in incremental steps. If the administration interval is 8 weeks, the upper limit for a dose per 1kg bodyweight is 10 mg and if the administration interval has been shortened, the upper limit for a dose is 6 mg. The shortest administration interval is 4 weeks.</u></p> <p>This drug is used in combination with oral methotrexate therapy.</p> <p>&lt;Intractable uveoretinitis caused by Behcet's disease&gt;</p> <p>Normally, administer intravenously via drip infusion at a dose of 5 mg/kg bodyweight. Administer at 2 weeks and 6 weeks after the initial dose and thereafter every 8 weeks.</p> <p>&lt;Crohn's Disease&gt;</p> <p>Normally, administer intravenously via drip infusion at a dose of 5 mg/kg bodyweight. Administer at 2 weeks and 6 weeks after the initial dose and thereafter every 8 weeks.</p>

4) NHI drug price standard: Remicade<sup>®</sup> Intravenous Drip Infusion 100, 1 bottle ¥100,285