September 26, 2011

Press Release

Mitsubishi Tanabe Pharma Corporation

Approval for Additional Indication of Generalized Myasthenia Gravis Venoglobulin® IH 5% for Intravenous Injection, a Human Immunoglobulin Preparation Derived from Donated Plasma

Osaka, Japan, September 26, 2011---Mitsubishi Tanabe Pharma Corporation (President & CEO: Michihiro Tsuchiya) announced that its consolidated subsidiary, Benesis Corporation (Osaka, President: Junichi Watanabe), obtained approval, as of September 26, 2011, of a partial change to the indications of Venoglobulin® IH 5% for intravenous injection, a liquid human immunoglobulin preparation for intravenous injection derived from donated plasma for generalized myasthenia gravis (only in case of insufficient response to steroids or immunosuppressants).

Myasthenia gravis is an autoimmune disease characterized by muscle weakness and fatigability. It occurs in two forms: the ocular type, which presents only ocular symptoms such as blepharoptosis and double vision, and the generalized type, which develops not only with such ocular symptoms, but also with systemic symptoms such as weakness in arms and legs, difficulty in swallowing, and shortness of breath.

Treatment of generalized myasthenia gravis is based on immunosuppressive therapy with steroids or immunosuppressants. In case of a lack of satisfactory effect or rapid exacerbation of symptoms, plasmapheresis is transiently performed as an add-on treatment with the expectation for early amelioration of them.

Because of the involvement of extracorporeal circulation, however, plasmapheresis produces a major physical burden on the patient and is hence considered to be somewhat difficult to perform on pediatric patients, elderly patients, and other patients in poor general condition. Additionally, the necessity for special equipment and a team of highly skilled medical staff poses limitations on the availability of facilities where plasmapheresis can be performed, and other problems arise, such as difficulty with conduct during holiday and night-time. For these reasons, patients and healthcare professionals have been in strong demand for adding generalized myasthenia gravis to the indications of intravenous injection of immunoglobulin preparations that can be conveniently administered by intravenous drip infusion.

In the clinical studies of Venoglobulin® IH 5% for intravenous injection conducted in Japan in patients with generalized myasthenia gravis judged to require plasmapheresis because of

their symptoms difficult to control with existing remedies and therapies, the drug was as effective as plasmapheresis in terms of clinical symptom ratings and the evaluation of basic daily activity movements. As for safety, the drug was not shown to cause any unexpected adverse reactions compared with those of immunoglobulin preparations that have been reported so far.

Since approval was granted on the condition of a drug use investigation (postmarketing all-case surveillance), we are determined to promptly collect data on the safety and efficacy of this product so as to promote its appropriate usage.

Enjoining approval of the expanded indication, we expect Venoglobulin® IH 5% for intravenous injection to contribute to better quality of life for patients with generalized myasthenia gravis as a new option for drug therapy.

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