Approval of additional indication of Venoglobulin[®] IH 5% I.V., human immunoglobulin G for the treatment of polymyositis and dermatomyositis

Osaka, Japan, October 27, 2010---Mitsubishi Tanabe Pharma Corporation (President & CEO: Michihiro Tsuchiya) announced today that its consolidated subsidiary Benesis Corporation (President: Junichi Watanabe) received, as of October 27, 2010, approval of a partial change to the indications for Venoglobulin[®]-IH 5% I.V., a human immunoglobulin preparation derived from donated plasma, for improvement of muscle weakness associated with polymyositis or dermatomyositis (only in case of insufficient response to steroids).

Polymyositis and dermatomyositis are chronic systemic inflammatory conditions of unknown etiology, categorized as connective tissue diseases. Clinical symptoms include muscle pain and weakness resulting from muscle inflammation and damage, and may be accompanied by joint symptoms and damage to organs such as the lungs, heart and gastrointestinal tract.

These conditions are treated mainly with medication, steroids being the first-line therapy. Some cases, however, are resistant to steroids, and therefore they do not show sufficient improvement.

Domestic clinical studies for Venoglobulin[®] IH, with poor steroid responder patients of polymyositis or dermatomyositis, revealed significant post-treatment improvement from baseline, as determined by muscle strength testing of major muscles and scoring of daily life activities. In addition, the safety of this product was shown to be comparable to that of existing therapies.

Approval was granted on the condition of post-marketing all-case surveillance. We shall promptly collect safety and efficacy data so as to promote proper use of this product.

With approval for the expanded indication, we expect Venoglobulin[®] IH to contribute to better quality of life for patients with polymyositis or dermatomyositis, as a new treatment option for the diseases.

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