November 25, 2011

Press Release

Alfresa Holdings Corporation
Mitsubishi Tanabe Pharma Corporation

Approval of Additional Indication for MODIODAL® Tablets 100 mg
a Sleep Disorder Treatment

Alfresa Holdings Corporation (head office: Tokyo, Representative Director & President: Denroku Ishiguro) and Mitsubishi Tanabe Pharma Corporation (head office: Osaka, President & CEO: Michihiro Tsuchiya) announced today that Alfresa Pharma Corporation (head office: Osaka, President & CEO: Kenichiro Iwaya), a subsidiary of Alfresa Holdings engaged in manufacture of pharmaceuticals etc., received approval of a partial change in the indications of MODIODAL® Tablets 100 mg (generic name: modafinil), a sleep disorder treatment, that has been jointly developed in Japan by Alfresa Pharma and Mitsubishi Tanabe Pharma.

Since March 2007, MODIODAL® has been jointly marketed by the two companies as a treatment for excessive daytime sleepiness associated with narcolepsy, a sleep disorder characterized by intolerable daytime sleepiness. The new indication, approved for the first time in Japan, is "excessive diurnal sleepiness accompanied with obstructive sleep apnea syndrome (OSAS) under treatment for airway obstruction by continuous positive airway pressure (CPAP) therapy and the like". The two companies expect MODIODAL® will contribute to improve quality of life of patients whose daily lives would otherwise be disrupted by excessive diurnal sleepiness in OSAS as well as narcolepsy.

MODIODAL® is currently approved in more than 30 countries in the world, and in seven countries, including the US, it is marketed with approval for the new indication.

Alfresa Pharma and Mitsubishi Tanabe Pharma will promptly collect data on the safety and efficacy of MODIODAL® through a post-marketing surveillance, and promote the proper use of this product.

*Note: Obstructive sleep apnea syndrome (OSAS)
OSAS is a sleep disorder such that obstruction of the throat and/or the upper airway frequently stops respiration during sleep, resulting in decreased oxygen content in the blood and brain and increased carbon dioxide levels. Patients with OSAS repetitively experience suffocation during sleep due to an obstructed upper airway, and have a compensatory reaction that obstructs a good night’s sleep. As a result, they may complain of headache or feel fatigue when they wake up. As the symptom progresses, they may suffer from excessive diurnal sleepiness which interferes with daily activities and hence affects the quality of life.

Contact for Inquiries

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