

April 17, 2012

ONO PHARMACEUTICAL CO., LTD.

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Code No.: 4528 at the 1st section of the Tokyo / Osaka Stock Exchange
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ONO-4641 Met Primary Endpoint of Phase II Study in Multiple Sclerosis Patients

Ono Pharmaceutical Co., Ltd. announced today that the global Phase II study (DreaMS*) of ONO-4641 in development for the indication of multiple sclerosis (MS) was completed and met the primary endpoint.

The study was a double-blind placebo-controlled study conducted in 11 countries including North America, Europe and Japan in patients with relapsing-remitting multiple sclerosis. A total of 407 patients between the ages of 18 and 55 with relapsing-remitting MS were randomized to receive placebo or one of 3 active doses of ONO-4641 once daily for 26 weeks.

Patients were included in the study if they had two or more relapses in the two years prior to the study, one or more relapses within the year prior to the study or one or more new MS-related brain lesions, also known as Gd-enhancing lesions, detected on MRI within three months prior to the study. For the primary endpoint of the study, MRIs were performed every four weeks from 10 to 26 weeks, 5 times.

At the end of the study, patients taking 0.05, 0.10, or 0.15 mg of ONO-4641 had 82 percent, 92 percent and 77 percent fewer Gd-enhancing brain lesions (all $p < 0.0001$), respectively, compared to placebo.

Adverse events appeared to be generally dose related. Of note was a slower heartbeat and atrioventricular blocks associated with the initiation of treatment, which were asymptomatic, transient and did not require ONO-4641 discontinuation. Other notable adverse events included liver enzyme elevations. In addition, Grade 4 lymphopenia, which is an abnormally low level of lymphocytes in the blood, occurred in 4 percent of patients receiving the 0.15 mg dose of ONO-4641 and in 1 percent of those receiving the 0.10 mg dose.

Detailed data will be presented at the [American Academy of Neurology's](#) 64th Annual Meeting in

New Orleans April 21 to April 28, 2012.

Ono has granted Merck KGaA, Darmstadt, Germany, an exclusive license for development and commercialization of ONO-4641 in countries around the world except Japan, Korea and Taiwan under the agreement entered into October, 2011.

* DreaMS: Drug Research EvaluAtion for Multiple Sclerosis

<Reference>

About ONO-4641

ONO-4641 is a sphingosine-1-phosphate (S1P) receptor agonist which keeps lymphocytes in lymph nodes and thereby inhibits the infiltration of lymphocytes into lesions. The compound is therefore expected to be a drug for the treatment of auto-immune diseases such as multiple sclerosis, which is regarded as an intractable disease.

About Multiple Sclerosis

Multiple sclerosis is a chronic neurological disorder accompanying by diverse and severe neurological symptoms such as paralysis and numbness of limbs, gait disorders, visual disorders, and dysuria. Although there are no specific factors known to be responsible for the onset and relapses of the disease, it is thought to be an autoimmune disease that, because of some triggers, one's own body is improperly recognized as foreign and is attacked by lymphocytes, which have an essential role in the immune system for protection from foreign substances such as viruses and bacteria. Most patients are diagnosed between the ages of 20 and 40, and women tend to suffer disproportionately more from this disease compared to men. In Japan, around 14,500 people suffer from this disorder. It is estimated that there are at least 350,000 MS patients in the US and about 2.5 million globally.