

August 10, 2005

Public Relations

Ono Pharmaceutical Co., Ltd.

Tel: +81-6-6263-5670

Fax: +81-6-6263-2950

### **Development status of ONO-2506PO/Cereact® Capsules**

Ono Pharmaceutical Co., Ltd. (“Ono”) announced today that the company obtained the results of Phase II studies of ONO-2506PO/Cereact® Capsules in ALS (Amyotrophic Lateral Sclerosis) patients in Europe. ONO-2506PO/Cereact® was discovered by Ono and is under development both in and outside Japan.

This study was conducted with the aim of evaluating the safety and efficacy of ONO-2506PO/CEREACT on ALS as a double-blind, controlled trial with two groups (placebo and 1200 mg/day).

The study drug was orally administered once daily for a year and it was evaluated as to whether ONO-2506PO/CEREACT can prevent the progression of diseases using changes in respiratory function (SVC) before and after administration as a primary endpoint in accordance with the global standard.

For the entire population of patients, the results showed that the changes in respiratory function were comparable in the placebo and CEREACT groups, with no statistically significant difference between the two groups. The subgroup analyses were performed separately, with the population divided into the subgroup with shorter disease duration of ALS (patients who participated in the study within approximately 1 year after onset) and the subgroup with longer disease duration of ALS. The result of the former population demonstrated that ONO-2506PO/CEREACT was superior to placebo in preventing the deterioration of respiratory function and there was a favorable tendency in other functional tests, which show the status of ALS. The result of the population with longer disease duration of ALS, however, demonstrated that ONO-2506PO/CEREACT was inferior to placebo in efficacy. There was no notable safety concern in the entire population.

After having discussions about these outcomes with medical experts of ALS in Europe, it is considered that ONO-2506PO/CEREACT may have an effect on the population with shorter disease duration of ALS. Therefore, Ono decided to advance discussions on a future clinical development plan.

Note)

“ONO-2506PO/Cereact<sup>®</sup> Capsule” is under development as a drug for the treatment of Parkinson’s disease and Alzheimer’s disease, in addition to ALS. The Phase II clinical study as a drug for Parkinson’s disease is being performed in Japan and the Phase II clinical study as a drug for Alzheimer’s disease, in North America.

(Reference)

· Amyotrophic Lateral Sclerosis: ALS

ALS is a disease characterized by muscle weakness and wasting of the arms and legs, and diminished speech, swallowing and/or breathing. This is, however, not a disease of muscle itself, but a neuromuscular condition due to the death of motor neuronal cells that play a role in muscular movement. The disease is progressive, and once a patient suffers from the disease, the symptoms never improve. Regardless of which part of the body it starts from, it eventually involves the generalized muscles, leads to inability of the respiratory muscles to function, and ultimately results in death due to respiratory failure. The period from onset of the disease until death is approximately 3 to 5 years.

· Compound profile

“Cereact<sup>®</sup> Capsules/ ONO-2506PO”

Cereact<sup>®</sup> Capsule is a drug for neurodegenerative disease having a new mechanism of action to prevent the occurrence and progression of various neurodegenerative diseases such as Alzheimer’s and Parkinson’s diseases, as well as Amyotrophic Lateral Sclerosis (ALS), which are said to be incurable diseases, by improving astrocyte dysfunction.