July 10, 2006
Ono Pharmaceutical Co., Ltd.
Astellas Pharma Inc.

Application Filed for the Osteoporosis Treatment ONO-5920/YM529 in Japan

Japan, July 10, 2006 - Ono Pharmaceutical Co., Ltd. ("Ono"; headquarters: Osaka; President and Representative Director: Toshiharu Korekane) and Astellas Pharma Inc. ("Astellas"; headquarters: Tokyo; President and CEO: Masafumi Nogimori) today announced that Ono and Astellas submitted an application for marketing approval of ONO-5920/YM529 (generic name: minodronic acid hydrate) for the treatment of osteoporosis on July 7, 2006, jointly developed by the two companies.

In Japan, it is estimated that approximately 2 million patients are under treatment for osteoporosis and the total number of the patients including potential patients would exceed 10 million at present. The number of those patients is expected to increase as the population ages, making it critically necessary for society to establish effective therapeutic treatment for osteoporosis and take effective measures to prevent bone fractures associated with osteoporosis.

In osteoporosis patients, disruption of the balance of bone destruction and bone formation leads to loss of bone mass. Minodronic acid hydrate is one of the most potent bisphosphonates which increases bone mass by suppressing osteoclasts (cells involved in bone destruction). As a result of such effect, this drug reduces the incidence of bone fractures associated with osteoporosis.

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Outline of Phase III trials

- Study on bone mass (double-blind comparative study)

Objective: The efficacy and safety of minodronic acid hydrate were evaluated using an existing bisphosphonate drug as control. The primary endpoint for efficacy was lumbar vertebral bone mass.

Subjects: Patients with involutional osteoporosis

Dosage and administration: Minodronic acid hydrate or control once a day for 48 weeks

Results: Non-inferiority of the efficacy of minodronic acid hydrate to that of the comparator drug was verified. The safety was found to be comparable to that of the comparator drug.

- Study on bone fracture (double-blind comparative study)

Objective: The efficacy and safety of minodronic acid hydrate were evaluated using a placebo as control. The primary endpoint for efficacy was the incidence of vertebral fractures.

Subjects: Involutional osteoporosis patients with a history of vertebral fractures

Dosage and administration: Minodronic acid hydrate or placebo once a day for 104 weeks (2 years)

Results: Superiority of the efficacy of minodronic acid hydrate to that of the placebo was verified. No safety-related problems were found compared to the placebo.