

January 21, 2009
Ono Pharmaceutical Co., Ltd.
Astellas Pharma Inc.

Approval for the Osteoporosis Treatment, RECALBON[®] Tablets / Bonoteo[®] Tablets

Japan, January 21, 2009 - Ono Pharmaceutical Co., Ltd. (“Ono”; headquarters: Osaka; President and Representative Director: Gyo Sagara) and Astellas Pharma Inc. (“Astellas”; headquarters: Tokyo; President and CEO: Masafumi Nogimori) today announced that RECALBON[®] Tablets 1 mg (Ono) / Bonoteo[®] Tablets 1 mg (Astellas) (generic name: minodronic acid hydrate) was granted a Japanese marketing approval on January 21, 2009. The drug has been jointly developed by the two companies for the treatment of osteoporosis and its Japanese New Drug Application was filed in July 2006.

Osteoporosis is a systemic bone disease characterized by decreased bone strength leading to an increased risk of bone fractures. It is estimated that over 10 million people, including potential patients, are suffering from the condition in Japan but that the number of patients continues to increase as aging population grows. Elderly osteoporosis patients are liable to vertebral or femoral neck fracture keeping some of them in bed, and therefore measures to tackle the disease by not only therapeutic but social means have been an important issue.

Minodronic acid hydrate is an orally taken bisphosphonate that was first discovered in Japan and exhibits extremely potent inhibition of bone resorption* in the class. It is the first drug that demonstrated significant effect in prevention of bone fractures superior to placebo in Japanese osteoporosis patients in Phase III double blind comparative study.

It is expected that the drug, once approved, can contribute to the improvement of the patients' quality of life by offering an additional therapeutic option for the treatment of osteoporosis.

The drug will be available under the trade name of RECALBON[®] Tablets 1mg by Ono and Bonoteo[®] Tablets 1mg by Astellas respectively.

* Bone resorption: The process by which osteoclasts break down old bone losing elasticity and hardness.

PRODUCT SUMMARY:

Trade name: Ono: RECALBON® Tablets 1mg
Astellas: Bonoteo® Tablets 1mg

Generic name: minodronic acid hydrate, 1mg

Indication: Osteoporosis

Dosage regimen: Normally in adults, 1 mg of minodronic acid hydrate is taken orally together with enough amount of water (180 mL) (or lukewarm water) once a day at the time of awakening. The drug must be taken without lying down at least for 30 minutes before the first food, beverage (other than plain water), and other oral medication.

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