

April 6, 2009  
Ono Pharmaceutical Co., Ltd.  
Astellas Pharma Inc.

### **Launch of the Osteoporosis Treatment, RECALBON<sup>®</sup> Tablets / Bonoteo<sup>®</sup> Tablets**

Japan, April 6, 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<sup>®</sup> Tablets 1mg (Ono) / Bonoteo<sup>®</sup> Tablets 1mg (Astellas) (generic name: minodronic acid hydrate) will be launched on April 7, 2009 in Japan. The drug has been jointly developed by the two companies and was granted a Japanese marketing approval for the treatment of osteoporosis on January 21, 2009.

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 in particular 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 launched, 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 brand name of RECALBON<sup>®</sup> Tablets 1mg by Ono and Bonoteo<sup>®</sup> Tablets 1mg by Astellas respectively.

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

## PRODUCT SUMMARY:

Brand name: Ono: RECALBON<sup>®</sup> Tablets 1mg  
Astellas: Bonoteo<sup>®</sup> Tablets 1mg

Generic name: minodronic acid hydrate

Indication: Osteoporosis

Dosage and administration: 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.

- Distinctive features:
1. Minodronic acid hydrate is a bisphosphonate that was first discovered in Japan.
  2. It is also the first bisphosphonate that demonstrated significant effect in prevention of bone fractures superior to placebo in Japanese osteoporosis patients.
  3. It shows an excellent effect in increment of bone mineral density (BMD).
  4. It also exhibits potent reduction of a bone resorption marker from the beginning of the treatment with the drug.
  5. It exhibits extremely potent inhibition of bone resorption (*in vitro* and in rats).
  6. The drug is in an easy-to-administrated small film coated tablet (6.6 mm in diameter, 3.0 mm thick.)
  7. Incidence of adverse reactions (side effects) was observed in 18.6% (206 out of 1,108 patients) including abnormal laboratory test values, and those include stomach and abdominal discomfort in 35 patients (3.2%), abdominal pain in 27 patients (2.4%), decrease in blood calcium level in 22 patients (2.0%), and gastritis in 15 patients (1.4%). Disorders in upper gastrointestinal tract such as duodenal ulcer and gastric ulcer were reported as clinically significant adverse reactions.

Packaging: RECALBON<sup>®</sup> Tablets 1mg: 100 tablets (blister packaging and bottle)  
Bonoteo<sup>®</sup> Tablets 1mg: 100 tablets (blister packaging) and 500 tablets (bottle)

NHI reimbursement prices: 135.50 yen / 1 mg tablet

Date of NHI price listed: March 13, 2009

Date of launch: April 7, 2009

\* 140 tablets (14T×10) and 700 tablets (14T×50) in blister packaging will be available around June.

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