

July 1, 2011
Ono Pharmaceutical Co., Ltd.
Astellas Pharma Inc.

Approval for RECALBON[®] Tablets 50mg/ Bonoteo[®] Tablets 50mg,
Once per 4 weeks Oral Osteoporosis Treatment in Japan

Osaka and Tokyo, Japan, July 1, 2011 - Ono Pharmaceutical Co., Ltd. (“Ono”; headquarters: Osaka; President and Representative Director: Gyo Sagara) and Astellas Pharma Inc. (“Astellas”; headquarters: Tokyo; President and CEO: Yoshihiko Hatanaka) today announced that ECALBON[®] Tablets 50mg (Ono) / Bonoteo[®] Tablets 50mg (Astellas) (generic name: minodronic acid hydrate) was granted a Japanese marketing approval on July 1, 2011. The drug has been jointly developed by the two companies for the treatment of osteoporosis and its Japanese New Drug Application was filed in September 2010.

Minodronic acid hydrate is an oral bisphosphonate that has been discovered by Astellas and has been co-developed by Ono and Astellas. This drug increases the bone mineral density and the strength by inhibiting osteoclastic bone resorption. RECALBON[®] Tablets 1mg / Bonoteo[®] Tablets 1mg, a daily formulation of this drug, demonstrated a significant efficacy in bone fractures prevention, and launched in April, 2009 in Japan.

RECALBON[®] Tablets 50mg / Bonoteo[®] Tablets 50mg, once per 4 weeks formulation of this drug, demonstrated non-inferiority to the daily formulation 1 mg in average bone mineral density change in lumbar spines, the primary endpoint in a Phase 2 / 3 study in Japan. Furthermore, based on the safety results in the Phase 2 / 3 study, once per 4 weeks formulation 50 mg appeared to be safe, and the incidence of side-effects was low and comparable to the daily formulation 1 mg. Therefore, once per 4 weeks formulation 50mg is expected to have an equivalent effect in bone fractures prevention to the daily formulation and boost the patients’ convenience by reducing the dose frequency.

Since the launch of RECALBON[®] Tablets 1mg / Bonoteo[®] Tablets 1mg in Japan, Ono and Astellas have contributed to the improvement of the quality of life of the patients suffering from osteoporosis through the prevention of bone fractures. The both companies expect to provide a new therapeutic option to the current osteoporosis treatment in addition to RECALBON[®] Tablets 1mg / Bonoteo[®] Tablets 1mg, and believe to contribute further to the patients by introducing RECALBON[®] Tablets 50mg / Bonoteo[®] Tablets 50mg into the Japanese market.

PRODUCT SUMMARY

Product name: Ono: RECALBON® Tablets 50mg
Astellas Bonoteo® Tablets 50mg

Generic name: minodronic acid hydrate, 50mg

Indication: Osteoporosis

Dosage regimen Normally in adults, 50mg of minodronic acid hydrate is taken orally together with enough amount of water (180ml) (or lukewarm water) once per 4 weeks 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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