

## Translation

Taisho Pharmaceutical Co., Ltd.  
Chugai Pharmaceutical Co., Ltd.

### **Bisphosphonate Antiresorptive Agent, Ibandronate Sodium Hydrate Injection, Demonstrates Efficacy in Osteoporosis in Phase II/III Trial**

December 14, 2011 (Tokyo) - Taisho Pharmaceutical Co., Ltd. [Head Office: Toshima-ku, Tokyo; President: Akira Uehara (hereafter, "Taisho")] and Chugai Pharmaceutical Co., Ltd. [Head Office: Chuo-ku, Tokyo; President: Osamu Nagayama (hereafter, "Chugai")] announced today that CT-064 [generic name: ibandronate sodium hydrate; Chugai development code: RG484] injection, a bisphosphonate which Taisho and Chugai are currently co-developing in Japan for osteoporosis indication, has demonstrated non-inferiority in efficacy of reducing the incidence of new vertebral fractures compared to a comparator bisphosphonate agent, sodium risedronate hydrate, in its multicentric, randomized, double-blind, comparative Phase II/III trial for osteoporosis. Detailed study results will be published in medical journals and/or presented at future medical conferences.

CT-064, a bisphosphonate developed by F. Hoffmann-La Roche, Ltd. [Head Office: Basel, Switzerland / CEO: Severin Schwan], demonstrates a strong inhibitory effect on bone resorption. Less frequent dosages have been developed with the aim of improving compliance and improving patient outcomes. Currently, monthly oral tablet and/or quarterly intravenous injection of RG484 are approved in over 110 countries around the world.

In Japan, a phase II/III study has been started in 2006 for monthly injection, involving about 1,200 osteoporosis patients. In the study, patients received either CT-064 or risedronate, and compared the incidence rates of vertebral fractures. The primary endpoint, a non-inferiority of CT-064 to risedronate has been achieved. The safety profile of CT-064 was consistent with the previous overseas trials.

Monthly oral formulation is in development in Japan, and it is currently in phase II development stage.

Since it is estimated that there are more than 12 million osteoporosis patients in Japan, it is becoming increasingly important to develop a drug which increases bone mass and reduces the risk of bone fractures. CT-064 is expected to become a new osteoporosis treatment option in Japan that improves compliance, by reducing the problems associated with the conventional bisphosphonates and offers patients more choice of administration routes.

Taisho and Chugai have been co-developing the compound since 2006. The application for approval of CT-064 for injection is planned to be filed in Japan in 2012 based on the results of this study. Taisho and Chugai will co-market the compound to provide osteoporosis patients with a new treatment option, and will continue its effort to contribute to the advancement of osteoporosis treatment.

#### **Note**

Overseas, Roche markets the product under the brand name Bonviva (Boniva in US) as a once-monthly oral formulation and a quarterly (once-every-three-months) injection formulation for the treatment of osteoporosis in post menopausal women, and once-monthly oral formulation for the prevention of osteoporosis in post menopausal women. Additionally, GSK markets Bonviva in select eastern European countries and Nycomed markets Bonviva in select Asia Pacific countries.