Translation

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

New Drug Application Filed for Ibandronate Sodium Hydrate Injection, Bisphosphonate Antiresorptive Agent

July 18, 2012 (Tokyo) - Chugai Pharmaceutical Co., Ltd. ("Chugai") [Head Office: Chuo-ku, Tokyo; Chairman & CEO: Osamu Nagayama] and Taisho Pharmaceutical Co., Ltd. ("Taisho") [Head Office: Toshima-ku, Tokyo; President: Shigeru Uehara], announced today that Chugai filed a new drug application to the Ministry of Health, Labour and Welfare for the injectable formulation of bisphosphonate antiresorptive agent which was co-developed by the two companies for the indication of osteoporosis (generic name: ibandronate sodium hydrate; Chugai development code: RG484, Taisho development code: CT-064).

RG484/CT-064 was developed by F. Hoffmann-La Roche, Ltd. [Head Office: Basel, Switzerland / CEO: Severin Schwan]. In Japan, a Phase II/III study was performed in approximately 1,200 patients with osteoporosis as a randomized, double-blind, controlled study to assess efficacy and safety of RG484/CT-064 monthly injectable formulation against bisphosphonate agent, sodium risedronate hydrate. As a result, the primary endpoint, a non-inferiority of RG484/CT-064 to risedronate sodium hydrate has been achieved. The safety profile of RG484/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 12.8 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. RG484/CT-064 is expected to become a new osteoporosis treatment option in Japan that has efficacies of increasing bone mass and reducing the risk of bone fractures, as well as improving compliance and offering patients more choice of administration routes.

Chugai and Taisho are determined to make efforts to realize early approval of ibandronate sodium hydrate as the bisphosphonate antiresorptive agent, and supply to patients and healthcare professionals.

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 selected eastern European countries and Nycomed markets Bonviva® in selected Asia Pacific countries.