

Translation

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

Results of Phase III Clinical Trial of Ibandronate Sodium Hydrate Oral Formulation, Bisphosphonate Antiresorptive Agent, in Japanese Patients with Osteoporosis Presented

March 30, 2015 (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 the positive results of Japanese phase III clinical trial (The MOVEST study: Monthly Oral Versus intravenous Ibandronate) of a bisphosphonate antiresorptive agent, ibandronate sodium hydrate oral agent (Chugai Development Code: RG484, Taisho Development Code: CT-064, hereafter, "ibandronate oral formulation"), which is currently co-developed by Chugai and Taisho in Japan for the anticipated indication of osteoporosis, were presented at the World Congress on Osteoporosis, Osteoarthritis and Musculoskeletal Diseases - International Osteoporosis Foundation currently held in Milan Italy (local time, March 27).

The MOVEST study, a randomized, multi center, double-blind, parallel group, controlled study, presented at the congress was conducted in approximately 400 patients (over 55 years of age) with osteoporosis to assess efficacy and safety of ibandronate oral formulation 100mg against ibandronate sodium hydrate injection [brand name: Bonviva[®] IV Injection 1 mg Syringe (ibandronate injection)]. The increase in bone mineral density (BMD) of the lumbar spine (L2-L4) (percentage of relative change from baseline) at twelve month, the study's primary endpoint, was 5.22% [95%CI: 4.65% - 5.80%] for ibandronate oral formulation, and 5.34% [95%CI: 4.78% - 5.90%] for ibandronate injection, respectively. The difference between the rate of change for ibandronate injection group of ibandronate oral formulation group (least squares means) was -0.23 [95%CI: -0.97 - 0.51]. It met the protocol criteria, a non-inferiority of ibandronate oral formulation to ibandronate injection has been demonstrated. The secondary endpoints of BMD gains in femur and inhibition on bone metabolic markers also showed similar effects between the two groups. No new safety signals were observed in the study. The safety profile was consistent with the previous overseas study results, and well tolerability of ibandronate oral formulation in osteoporotic patients was observed. Chugai filed a new drug application to the Ministry of Health, Labour and Welfare in February 2015, based on above and other data.

It is estimated that there are more than 12.8 million osteoporosis patients in Japan. The objective of osteoporosis treatment is to prevent patients from becoming bedridden caused by fractures, thereby maintaining and improving the patients' quality of life (QOL), and the drugs which increase BMD and reduce the risk of fractures are awaited. Chugai and Taisho have been co-developing ibandronate oral formulation and Bonviva[®] IV Injection in Japan as new treatment options for osteoporosis that improve adherence and offer patients wider choice of administration routes in Japan. Chugai and Taisho Toyama Pharmaceutical Co., Ltd. (Head Office: Toshima-ku, Tokyo; President: Akira Ohira) have been co-marketing Bonviva[®] IV Injection, developed ahead of ibandronate oral formulation, since August, 2013 after Chugai obtained approval for osteoporosis indication in June, 2013.

Following Bonviva[®] IV Injection, Chugai and Taisho are determined to make efforts to obtain early approval of ibandronate oral formulation, a monthly oral agent and supply to patients and healthcare professionals.

Note

Ibandronate sodium hydrate are marketed by Roche under the brand name Bonviva[®] (Boniva[®] in the US) as a once-monthly oral formulation and a quarterly (once-every-three-months) injection formulation for the treatment of osteoporosis in postmenopausal women, and once-monthly oral formulation for the prevention of osteoporosis in postmenopausal women in the US.

Bonviva[®] is a registered trademark of F. Hoffmann-La Roche, Ltd.