

Translation

Chugai Pharmaceutical Co., Ltd.

Taisho Pharmaceutical Co., Ltd.

New Agent for Osteoporosis Approved in Japan “Bonviva[®] IV Injection”

June 28, 2013 (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], are announcing today that ibandronate sodium hydrate [brand name: Bonviva[®] IV Injection 1 mg Syringe (Bonviva[®] IV Injection)], a bisphosphonate antiresorptive agent which was developed by F. Hoffmann-La Roche, Ltd. (Roche) [Head Office: Basel, Switzerland / CEO: Severin Schwan] and, in Japan, by Chugai co-developed with Taisho, was approved by the Japanese Ministry of Health, Labour and Welfare (MHLW) for the osteoporosis indication.

On July 18, 2012, Chugai filed a new drug application to the MHLW with the results of the pivotal Japanese studies. The Monthly intraVenous ibandronatE versus daily oral Risedronate (MOVER) registration study, a randomized, double-blind, controlled phase II/III study, has examined the incidence of vertebral fractures and safety profiles in 1,265 Japanese patients with osteoporosis for three years with Bonviva[®] IV Injection (once monthly 1 or 0.5 mg intravenous injection) in comparison with risedronate sodium hydrate (daily oral tablet 2.5 mg). The results showed that the primary endpoint was met by both doses of Bonviva[®] IV Injection demonstrating non-inferiority to risedronate measured by the incidence of vertebral fractures (stratified Cox regression analysis, hazard ratio, 0.88 [95%CI: 0.61-1.27] and 1.09 [95%CI: 0.77-1.54], respectively). The rate of vertebral fractures over three years was 16.1%, 19.9% and 17.6% for Bonviva[®] IV Injection 1 mg, Bonviva[®] IV Injection 0.5 mg, and risedronate, respectively. The increase in bone mineral density of the lumbar spine (percentage of relative change from baseline) after three years was 9.0%, 7.7% and 7.6% for Bonviva[®] IV Injection 1 mg, Bonviva[®] IV Injection 0.5 mg, and risedronate, respectively.

The safety profile was consistent with the previous overseas study results, and Bonviva[®] IV Injection was well tolerated in osteoporotic Japanese patients.

It is estimated that there are more than 12.8 million osteoporosis patients in Japan. The objective of the treatment of osteoporosis 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 bone mass and reduce the risk of bone fractures are awaited. The MOVER trial has demonstrated that Bonviva[®] IV Injection has the effect to increase bone mass and to reduce the risk of bone fractures. It is strongly believed that Bonviva[®] IV Injection offers an additional choice of administration route for patients, improving the adherence, and enhancing the convenience in the clinical practice.

A monthly oral ibandronate formulation is also in development in Japan, and is currently in the phase III development stage.

Through the provision of the new treatment options, Chugai and Taisho will continue their efforts to contribute to optimal osteoporosis treatment.

Note

Overseas, Roche markets the product 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 post menopausal women, and once-monthly oral formulation for the prevention of osteoporosis in post menopausal women in the US.

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