Translation

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

Agent for Osteoporosis Approved in Japan "Bonviva® Tablet"

January 22, 2016 (Tokyo) - Taisho Pharmaceutical Co., Ltd. (Taisho) [Head Office: Toshima-ku, Tokyo; Chief Executive Officer: Shigeru Uehara] and Chugai Pharmaceutical Co., Ltd. (Chugai) [Head Office: Chuo-ku, Tokyo; Chairman & CEO: Osamu Nagayama] announced today that Chugai obtained approval of ibandronate sodium hydrate tablet [brand name: Bonviva® Tablet 100mg (Bonviva Tablet)], 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 Taisho co-developed with Chugai, from the Japanese Ministry of Health, Labour and Welfare (MHLW) for the osteoporosis indication.

On February 10, 2015, Chugai filed a new drug application to the MHLW with the results of the pivotal Japanese studies. A randomized, double-blind, active controlled phase III study, the Monthly Oral VErsus intravenouS ibandronaTe (MOVEST) registration study, was conducted in 422 patients (55 years old or older) with osteoporosis to assess efficacy and safety of Bonviva Tablet administered once monthly against ibandronate sodium hydrate injection [brand name: Bonviva® IV Injection 1 mg Syringe (Bonviva IV Injection)] administered once monthly as control.
The results showed that the increase rate in bone mineral density of the lumbar spine (L2-L4) (percentage of relative change from baseline) after 12 months, the study's primary endpoint, was 5.22% [95%CI: 4.65 - 5.80] and 5.34% [95%CI: 4.78 – 5.90] for Bonviva Tablet and Bonviva IV Injection, respectively. The difference of change rate between Bonviva Tablet and Bonviva IV Injection was -0.23% (least mean square value, 95%CI: -0.97 – 0.51). It met the requirements of the protocol, Bonviva Tablet demonstrated non-inferiority to Bonviva IV Injection*. In addition, the study's secondary endpoints, the change rate in bone mineral density of femur and bone metabolic markers also showed similar effects between the two groups.
Regarding safety, no new findings were observed in the study. And the safety profile was consistent with the previous overseas study results, and Bonviva Tablet 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 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 bone mass and reduce the risk of fractures are awaited. Taisho and Chugai have been co-developing Bonviva Tablet and Bonviva IV Injection in Japan as new treatment options for osteoporosis that improve adherence to bisphosphonate therapy and offer patients wider choice of administration routes. Taisho Toyama Pharmaceutical Co., Ltd. (Head Office: Toshima-ku, Tokyo; President: Ken-ichi Fujita) and Chugai have been co-marketing Bonviva IV Injection, developed ahead of Bonviva Tablet, since August 29, 2013 after Chugai obtained approval for osteoporosis indication on June 28, 2013.

Through the provision of the new treatment options, Taisho and Chugai 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.

* Nakamura T., et al.: Osteoporosis International Vol.26, Issue 11, p2685-2693, 2015