Translation

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

Results of Phase II/III Clinical Trial of Ibandronate Sodium Hydrate Injection, Bisphosphonate Antiresorptive Agent, in Japanese Patients with Osteoporosis Presented

April 19, 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], announced today that the positive results of the phase II/III clinical trial (MOVER Study) of a bisphosphonate antiresorptive agent, ibandronate sodium hydrate injection (Chugai Development Code: RG484, Taisho Development Code: CT-064, hereafter, "ibandronate injection"), which is currently co-developed by Chugai and Taisho in Japan for the anticipated indication of osteoporosis, were presented at the European Congress on Osteoporosis and Osteoarthritis 13-International Osteoporosis Foundation currently held in Rome, Italy (local time, April 18).

The phase II/III clinical trial presented at the congress was a randomized, double-blind, controlled study in which the incidence of vertebral fractures and safety profiles were examined in 1,265 Japanese patients with osteoporosis for three years with ibandronate injection (once monthly 0.5 or 1 mg) in comparison with risedronate sodium hydrate (daily oral tablet 2.5 mg). As a result, the primary endpoint was met by both doses of ibandronate injection demonstrating non-inferiority to risedronate sodium hydrate measured by the incidence of vertebral fractures (stratified Cox regression analysis, hazard ratio, 1.09 [95%CI: 0.77-1.54] and 0.88 [95%CI: 0.61-1.27], respectively). The rate of vertebral fractures over three years was 19.9%, 16.1% and 17.6% for ibandronate injection 0.5 mg, ibandronate injection 1 mg, and risedronate sodium hydrate, respectively. The increase in bone mineral density of the lumbar spine (percentage of relative change from baseline) after three years was 7.7%, 9.0% and 7.6% for ibandronate injection 0.5 mg, ibandronate injection 1 mg, and risedronate sodium hydrate, respectively. The safety profile was consistent with the previous overseas study results, and well tolerability of ibandronate injection in osteoporotic patients was observed.

Chugai filed a new drug application to the Ministry of Health, Labour and Welfare in July 2012, based on above and other data. Monthly oral formulation is also in development in Japan, and it is currently in phase III development stage.

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' QOL, and the drugs which increase bone mass and reduce the risk of bone fractures are becoming increasingly more important. This phase II/III clinical trial has demonstrated that ibandronate injection has the effect to increase bone mass and to reduce the risk of bone fractures. It is expected to become a new osteoporosis drug which offers excellent clinical efficacy and more choice of administration routes, and improves the adherence.

Chugai and Taisho are determined to make efforts to realize early approval of ibandronate injection, a new bisphosphonate antiresorptive agent, and provide 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.