Translation

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

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

February 10, 2015 (Tokyo) - Chugai Pharmaceutical Co., Ltd. (hereafter, "Chugai") [Head Office: Chuo-ku, Tokyo; Chairman & CEO: Osamu Nagayama] and Taisho Pharmaceutical Co., Ltd. (hereafter, "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 oral 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) (hereafter, “RG484/CT-064 oral agent”).

RG484/CT-064 oral agent was developed by F. Hoffmann-La Roche, Ltd. [Head Office: Basel, Switzerland / CEO: Severin Schwan]. In Japan, a Phase III study was conducted in approximately 400 patients with osteoporosis to assess efficacy and safety of RG484/CT-064 oral agent against ibandronate sodium hydrate injection [brand name: Bonviva® IV Injection 1 mg Syringe (Bonviva® IV Injection)]. The study’s primary endpoint, a non-inferiority of RG484/CT-064 oral agent to Bonviva® IV Injection in increasing the bone mass of the lumbar spine at twelve month, has been achieved. Other than lumbar spine, bone mass gains in femur and inhibition on bone metabolic markers also showed similar effects between the two groups. RG484/CT-064 oral agent was well tolerated and its safety profile was consistent with the previously reported data of ibandronate sodium hydrate. Detailed study results will be published in medical journals and/or presented at future medical conferences.

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. Chugai and Taisho have been co-developing RG484/CT-064 oral agent 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 RG484/CT-064 oral agent, since August 29, 2013 after Chugai obtained approval for osteoporosis indication on June 28, 2013.

Following Bonviva® IV Injection, Chugai and Taisho are determined to make efforts to obtain early approval of RG484/CT-064, 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.