Translation

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

Bisphosphonate Antiresorptive Agent, Ibandronate Sodium Hydrate Oral Agent, Demonstrates Efficacy in Osteoporosis in Phase III Trial

September 22, 2014 (Tokyo) - Chugai Pharmaceutical Co., Ltd. [Head Office: Chuo-ku, Tokyo; Chairman & CEO: Osamu Nagayama (hereafter, "Chugai")] and Taisho Pharmaceutical Co., Ltd. [Head Office: Toshima-ku, Tokyo; President: Shigeru Uehara (hereafter, "Taisho")] announced today that ibandronate sodium hydrate (generic name) oral agent demonstrated non-inferiority in efficacy of increasing the bone mass of the lumbar spine compared to a comparator, ibandronate sodium hydrate injection [brand name: Bonviva® IV Injection 1 mg Syringe (Bonviva® IV Injection)]. Chugai and Taisho have been co-developing its oral bisphosphonate [Chugai development code: RG484, Taisho development code: CT-064, (hereafter, "RG484/CT-064 oral agent")]. This result is based on a multicenter, randomized, double-blind, comparative Phase III trial for osteoporosis. Detailed study results will be published in medical journals and/or presented at future medical conferences. The application for approval of RG484/CT-064 is planned to be filed in Japan in 2015.

RG484/CT-064 oral agent and Bonviva® IV Injection, bisphosphonate developed by F. Hoffmann-La Roche, Ltd. [Head Office: Basel, Switzerland; CEO: Severin Schwan], demonstrate strong inhibitory effects on bone resorption. Less frequent dosages have been developed with the aim of improving adherence and improving patient outcomes. Currently, once-monthly oral tablet and/or once-quarterly intravenous injection are approved in over 110 countries around the world.

In Japan, 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, by reducing the problems associated with the conventional bisphosphonates, and offer patients more choice of administration routes. Chugai and Taisho Toyama Pharmaceutical Co., Ltd. (Head Office: Toshima-ku, Tokyo; President: Akira Ohira) have been co-marketing Bonviva® IV Injection since August 2013 after Chugai obtained approval for osteoporosis indication in June 2013. The approval of Bonviva® IV Injection, developed ahead of RG484/CT-064 oral agent, was based on some data such as MOVER (MOnthly intraVenous ibandronatE versus daily oral Risedronate) study using sodium risedronate hydrate as a control.

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 bone fractures are awaited.

Chugai and Taisho, having a wealth of experience in the osteoporosis field, will continue to provide new treatment options for osteoporosis patients, and to contribute to the advancement of osteoporosis treatment.

Note

Ibandronate sodium hydrate products 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.