Translation

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

Launch of the New Agent for Osteoporosis "Bonviva® Injection 1 mg Syringe"

August 29, 2013 (Tokyo) - Chugai Pharmaceutical Co., Ltd. [Head Office: Chuo-ku, Tokyo; Chairman & CEO: Osamu Nagayama (hereafter, "Chugai")] and Taisho Toyama Pharmaceutical Co., Ltd. [Head Office: Toshima-ku, Tokyo; President: Akira Ohira (hereafter, "Taisho Toyama")] announced today that they launched the ibandronate sodium hydrate, a bisphosphonate antiresorptive agent [brand name: Bonviva® Injection 1 mg Syringe (hereafter, "Bonviva® IV Injection")], for the indication of osteoporosis on August 29, 2013. "Bonviva® IV Injection" received a manufacturing and marketing approval on June 28, 2013 and was listed on the National Health Insurance (NHI) reimbursement price list on August 27, 2013.

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. A phase II/III, randomized, double-blind, parallel-group study using sodium risedronate hydrate as a control (MOVER Study: MOnthly intraVenous ibandronatE versus daily oral Risedronate) and other studies showed that "Bonviva® IV Injection" was not inferior to existing bisphosphonates in increasing bone mass and reducing the risk of bone fractures when administered once a month. The safety profile was consistent with the previous overseas study results, and "Bonviva® IV Injection" was well tolerated in osteoporotic Japanese patients.

"Bonviva® IV Injection" is expected to enhance adherence by allowing for selection of a route of administration according to the patients' conditions, and moreover, we are confident that its regimen characterized by a once-monthly injection will contribute to improving convenience in clinical settings.

Through the provision of the new treatment options of "Bonviva® IV Injection", Chugai and Taisho Toyama will continue its effort to contribute to osteoporosis treatment and to make efforts for promoting the proper use.

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 a once-monthly oral formulation for the prevention of osteoporosis in post menopausal women in the US.

Drug Information

Product name:	Bonviva® Injection 1 mg Syringe
Generic name:	ibandronate sodium hydrate
Indications:	Osteoporosis
Dosage and administration:	The usual adult dosage is 1 mg as ibandronic acid by intravenous injection once a month.
Date of approval:	June 28, 2013
Date of NHI reimbursement price listing:	August 27, 2013
Date of launch:	August 29, 2013
Shelf life:	3 years
Drug price:	Bonviva® Injection 1 mg Syringe JPY 4,918

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

Package photos