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

Launch of the Agent for Osteoporosis "Bonviva® Tablet 100 mg"

April 21, 2016 (Tokyo) - Taisho Toyama Pharmaceutical Co., Ltd. (Taisho Toyama) [Head Office: Toshima-ku, Tokyo; President: Ken-ichi Fujita] and Chugai Pharmaceutical Co., Ltd. (Chugai") [Head Office: Chuo-ku, Tokyo; Chairman & CEO: Osamu Nagayama] announced today that they launched the ibandronate sodium hydrate, a bisphosphonate antiresorptive agent [brand name: Bonviva® Tablet 100 mg (Bonviva Tablet)], for the indication of osteoporosis on April 21, 2016. Chugai obtained a manufacturing and marketing approval on January 22, 2016 and Bonviva Tablet was listed on the National Health Insurance (NHI) reimbursement price list on April 20, 2016.

The efficacy of Bonviva Tablet of once a month administration has been confirmed in a phase III study using ibandronate sodium hydrate injection [brand name: Bonviva® IV Injection 1 mg Syringe (Bonviva IV Injection)] as a control (The MOVEST Study: Monthly Oral VErsus intravenouS ibandronaTe).
Regarding its 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 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 in the clinical settings. Bonviva Tablet that starts selling from today and Bonviva IV Injection that has been sold since August, 2013 are the drugs of the same administration frequency of once a month with the same brand. They are only treatment options for osteoporosis that provide the choice of two administration routes to patients in Japan.

Through the provision of the new treatment options, Taisho Toyama and Chugai 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® Tablet 100 mg
Generic name:	ibandronate sodium hydrate
Indications:	Osteoporosis
Dosage and administration:	The usual adult dosage is 100 mg as ibandronic acid once a month, taken by mouth with plenty of plain water (approximately 180 mL) when the patient gets out of bed. For at least 60 minutes after taking BONVIVA, patients should not lie down and should avoid food or drink (except water) and other oral drugs.
Date of approval:	January 22, 2016
Date of NHI reimbursement price listing:	April 20, 2016
Date of launch:	April 21, 2016
Shelf life:	3 years
Drug price:	Bonviva® Tablet 100 mg JPY 2,790/Tablet