

Translation

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Name of listed company: **Chugai Pharmaceutical Co., Ltd.**
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Name of listed company: **Taisho Pharmaceutical Co., Ltd.**
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An Active Vitamin D₃ Derivative “Edirol[®],” Approved in Japan

January 21, 2011 (Tokyo) - Chugai Pharmaceutical Co., Ltd. ("Chugai") [Head Office: Chuo-ku, Tokyo; President: Osamu Nagayama] and Taisho Pharmaceutical Co., Ltd. ("Taisho") [Head Office: Toshima-ku, Tokyo; Chairman and CEO: Akira Uehara], announced today that eldecacitol [brand name: Edirol[®]], an active vitamin D₃ derivative which was discovered by Chugai and co-developed by the two companies, obtained approval from the Japanese Ministry of Health, Labour and Welfare (MHLW) for the treatment of patients with osteoporosis.

In October 2009, Chugai filed an application for approval with the MHLW based on the results of domestic studies. Especially, the phase III study was a randomized, double-blind, parallel-group, comparative study to compare the three-year incidence of bone fractures and the safety of eldecacitol with those of alfacalcidol* in 1,054 patients with osteoporosis (population for safety analysis). In this study, patients received once-daily oral dose of eldecacitol (0.75µg) or alfacalcidol (1.0µg) for three years. The results demonstrated that the patients who received eldecacitol had a significantly lower three-year incidence of new vertebral fractures. In severe patients (hip bone mineral density T-score -2.5 or less / 2 or more vertebral fractures), eldecacitol exerted significant preventive effects on bone fractures. Also of note, patients who received eldecacitol had a significantly lower three-year incidence in the forearm, which normally is difficult to demonstrate the effect of prevention of fracture.

Overall safety profile of eldecacitol was similar to that of alfacalcidol. And no new safety signals were identified with eldecacitol.

It is estimated that 12 million people have osteoporosis in Japan. It is important to increase bone density and thus reduce the incidence of fractures since osteoporosis-related fractures reduce quality of life, rendering patients bedridden and increase the risk of death. It is strongly believed that “Edirol[®],” as a new active vitamin D₃ derivative that enhances effect to bone, will contribute to significant improvement of the quality of life of the patients.

Through the provision of the new treatment options, Chugai and Taisho will continue its effort to contribute to osteoporosis treatment.

* Alfacalcidol is an active vitamin D₃ prodrug (Chugai brand name: Alfarol[®]) used in Japan to treat osteoporosis.