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 eldecalcitol [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 eldecalcitol with those of alfacalcidol* in 1,054 patients with osteoporosis (population for safety analysis). In this study, patients received once-daily oral dose of eldecalcitol (0.75µg) or alfacalcidol (1.0µg) for three years. The results demonstrated that the patients who received eldecalcitol 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), eldecalcitol exerted significant preventive effects on bone fractures. Also of note, patients who received eldecalcitol 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 eldecalcitol was similar to that of alfacalcidol. And no new safety signals were identified with eldecalcitol.
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.