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Eldecalcitol, An Active Vitamin D₃ Derivative, Reduces Incidence of New Vertebral Fractures in Osteoporosis Patients in Phase III Clinical Trial

December 16, 2008 (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; President: Akira Uehara], announced today that the active vitamin D₃ derivative being co-developed by the two companies for treatment of osteoporosis (generic name: eldecalcitol; Chugai development code: ED-71, Taisho development code: CT-081) significantly reduced the incidence of new vertebral fractures in osteoporosis patients in a randomized, double-blind, comparative trial. Detailed study results will be published in a medical journal and announced at a medical conference.

Eldecalcitol is an active vitamin D₃ derivative synthesized by Chugai. It is an agent with superior effect on bone compared to the existing active vitamin D₃ agent widely used in Japan. This phase III clinical trial, begun in 2004, was a randomized, double-blind, comparative study to compare the efficacy and safety of eldecalcitol with that of alfacalcidol* in osteoporosis patients. A total of 1,087 patients were randomly allocated to receive a once-daily oral dose of either eldecalcitol or alfacalcidol, and the incidence of new vertebral fractures in both groups was monitored for a period of three years. As a result, patients receiving eldecalcitol showed a significantly lower incidence of bone fractures compared to those receiving alfacalcidol, indicating that eldecalcitol is superior in preventing fractures. The safety profile was similar to that of alfacalcidol, and nothing irregular was observed.

There are an estimated 12 million patients with osteoporosis in Japan. Treatments to increase bone density and quality and thus reduce the incidence of fractures are necessary since osteoporosis-related fractures reduce quality of life, rendering patients bedridden for example, and increase the risk of death. Chugai and Taisho hope that the new drug eldecalcitol will help as many patients with osteoporosis as possible.

Regulatory filing for eldecalcitol is planned for 2009 after the results of the trial have been collated.

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