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New Drug Application Filed for Eldecacitol, An Active Vitamin D3 Derivative

October 22, 2009 (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; CEO: Akira Uehara], announced today that a New Drug Application was filed to the Ministry of Health, Labour and Welfare for the active vitamin D₃ derivative which was discovered by Chugai and co-developed by the two companies for the indication of osteoporosis (generic name: eldecacitol; Chugai development code: ED-71, Taisho development code: CT-081).

It is estimated that 12 million people have osteoporosis in Japan. Treatments to increase bone density and thus reduce the incidence of fractures are necessary since osteoporosis-related fractures reduce quality of life, rendering patients bedridden and increase the risk of death. In the clinical trial, eldecacitol was shown to improve the bone and calcium metabolism, increase the bone density and inhibit fracture in the osteoporosis patients. Therefore, it is expected that eldecacitol will contribute to significantly improve the quality of life of the patients.

Chugai and Taisho are determined to make efforts to realize early approval of eldecacitol as a new active vitamin D₃ derivative that enhances effect to bone, and supply to patients and healthcare professionals.

[Reference: Outline of Phase III Clinical Study in Japan]

In Japan, a Phase III clinical study was performed in patients with osteoporosis as a randomized double-blind alfacalcidol*-controlled study to assess efficacy and safety of eldecacitol. A total of 1,087 patients were randomly assigned to the eldecacitol treatment group and the alfacalcidol treatment group and the incidence of new vertebral fractures in both groups was monitored for a period of three years. As a result, patients receiving eldecacitol showed a significantly lower incidence of bone fractures compared to those receiving alfacalcidol, indicating that eldecacitol is superior in preventing fractures. The safety profile was similar to that of alfacalcidol, and nothing irregular was observed.

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