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Eldecalcitol, an Active Vitamin D_3 Derivative, Increases Bone Mineral Density of Osteoporosis Patients in Chinese Phase III Study

TOKYO, November 6, 2017 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced today that eldecalcitol, an active vitamin D_3 derivative in development for the treatment of osteoporosis (Japanese brand name: Edirol®), significantly increased the bone mineral density (BMD) of osteoporosis patients compared with alfacalcidol in a Chinese Phase III study. Detailed study results will be published in medical journals and/or presented at future medical conferences.

"The results of the Phase III study are the first step in providing new treatment options to patients with osteoporosis in China," said Dr. Yasushi Ito, Chugai's Senior Vice President, Head of Project & Lifecycle Management Unit. "Chugai will continue discussions with the China Food and Drug Administration and make every effort to submit an import drug license as soon as possible."

Eldecalcitol, an active vitamin D_3 derivative synthesized by Chugai, is an agent with superior effect on bone compared to the existing active vitamin D_3 agents and widely used in Japan since launching in 2011.

This Phase III study, begun in 2015, was a randomized, double-blind, comparative study to compare the efficacy and safety of eldecalcitol with that of alfacalcidol in osteoporosis patients in China. A total of 265 Chinese patients were randomized to receive a once-daily oral dose of either eldecalcitol or alfacalcidol, and the change rate from baseline in BMD of the lumbar spine after 12 months of administration was observed as a primary endpoint. As a result, patients receiving eldecalcitol showed a statistically significant increase of BMD compared to those receiving alfacalcidol. The safety profile was consistent with those seen in previous reports.

China is estimated to have more than 69 million osteoporosis patients*. The objective of osteoporosis treatment is to prevent fractures and disorders of the locomotory apparatus associated with fractures and organ dysfunction. Especially in severe cases, the aim of treatment is to prevent bedridden to maintain and improve patient's quality of life (QOL). Drugs which increase bone mass and reduce the risk of bone fractures have been needed.

Chugai hopes that eldecalcitol will help as many Chinese patients with osteoporosis as possible. Regulatory filing for eldecalcitol is planned for 2018 after the results of the trial have been collated in China.

* THE ASIA-PACIFIC REGIONAL AUDIT Epidemiology, cost & burden of osteoporosis in 2013 IOF

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