



New Drug Application of Eldecalcitol, an Active Vitamin D₃ Derivative, for the Treatment of Osteoporosis Accepted in China

TOKYO, March 22, 2018 -- [Chugai Pharmaceutical Co., Ltd.](#) (TOKYO: 4519) announced today that the China Food and Drug Administration (CFDA) has accepted for review a New Drug Application (NDA) submitted for eldecalcitol (Japanese brand name: Ediroi®), a Chugai originated active vitamin D₃ derivative for the treatment of osteoporosis in China.

"We are pleased that we could submit data based on the positive results of our Phase III pivotal study conducted by Chugai in China," said Dr. Yasushi Ito, Chugai's Senior Vice President, Head of Project & Lifecycle Management Unit. "Chugai will work closely with CFDA for the early approval to provide eldecalcitol as a new treatment option for osteoporosis patients in China."

This study 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 265 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 who received eldecalcitol showed a statistically significant increase of BMD than those who received alfacalcidol. The safety profile was consistent with those seen in previous reports.

It is estimated that there are approximately 69 million osteoporosis patients in China*. 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, preventing to become bedridden is focused in the treatment to maintain and improve patient's quality of life (QOL) thus drugs which increase bone mass and reduce the risk of bone fractures are in great need.

Chugai will continue to make efforts to provide eldecalcitol to patients with osteoporosis in China as early as possible.

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

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