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Chugai Obtains Regulatory Approval for Osteoporosis Treatment Eidirol Tablet

TOKYO, August 15, 2022 -- [Chugai Pharmaceutical Co., Ltd.](#) (TOKYO: 4519) and [Towa Pharmaceutical Co., Ltd.](#) announced that Chugai obtained regulatory approval from the Ministry of Health, Labour and Welfare (MHLW) for an osteoporosis treatment Eidirol[®] Tablets 0.5 µg/0.75 µg (generic name: eldecalcitol, hereafter, Eidirol Tablet).

Eidirol is an active vitamin D₃ derivative created based on Chugai's long-standing vitamin D research. The drug was launched in 2011 in a soft capsule formulation as Eidirol Capsule, and has been used as a base drug for the treatment of osteoporosis. Due to the characteristics of the formulation, Eidirol Capsule rolls easily and is hard to grasp with fingers. In addition, patients using Eidirol often take other drugs, too. Considering these points, Chugai developed an alternative tablet formulation for Eidirol that is easier to handle and identify. The regulatory approval for Eidirol Tablet is based on the results of a bioequivalence study comparing the soft capsule and the tablet in 49 healthy adult volunteers.

While Chugai takes responsibilities as a holder of the approval, Towa will be solely responsible for marketing and providing information on appropriate use of Eidirol Tablet. Chugai will manufacture Eidirol Tablet and supply to Towa. Chugai continues to market and provide information on Eidirol Capsule. Towa markets an authorized generic (AG) version of Eidirol Capsule.

“Medication adherence is particularly important in the treatment of osteoporosis as the disease is generally asymptomatic. The approval of Eidirol Tablet will enable patients to select a dosage form that meets their individual needs. We will continue collaborating with Towa so that Eidirol may be utilized further for the treatment of osteoporosis,” said Chugai's President and CEO, Dr. Osamu Okuda.

“We decided to engage in marketing and information provision for Eidirol Tablet as we shared with Chugai the desire to provide better products, following the launch of Eldecalcitol Capsule Towa (AG). We will continue our partnership with Chugai,” said Towa's President Itsuro Yoshida.

Towa will launch Eidirol Tablet after the NHI (National Health Insurance) price listing.

[Reference]

Towa Pharmaceutical Receives Approval for Authorized Generic Version of Chugai's Osteoporosis Agent Ediolol
(Press release issued by Chugai on December 3, 2021)

https://www.chugai-pharm.co.jp/english/news/detail/20211203150000_877.html

About Ediolol

Ediolol is an active vitamin D₃ derivative created by Chugai, which can improve calcium and bone metabolism. In Japan, Ediolol was launched in April 2011 for the treatment of osteoporosis. In Prevention of Osteoporosis and Clinical Practice Guidelines 2015, Ediolol is ranked as grade A as an active vitamin D₃ preparation in the efficacy assessment to validate the increase in bone mineral density and decrease in vertebral fracture.

About Chugai Pharmaceutical

Chugai Pharmaceutical Co., Ltd., headquartered in Tokyo, is a research-based pharmaceutical company with world-class drug discovery capabilities, including proprietary antibody engineering technologies. Chugai is committed to creating innovative pharmaceutical products that may satisfy unmet medical needs. Chugai is listed on the Prime Market of the Tokyo Stock Exchange. While maintaining autonomy and management independence, Chugai is an important member of the Roche Group. Additional information is available at <https://www.chugai-pharm.co.jp/english/>.

About Towa

Towa Pharmaceutical is a comprehensive manufacturer of generic drugs, dedicated to R&D, manufacturing, and marketing, striving for the dissemination of generic drugs that can contribute to reducing the economic burden on patients as well as the financial burden on the country. We are also devoted to R&D of value-added products that are easy to drink and tractable to all people involved in pharmaceuticals. With the company's philosophy "We contribute to people's health. We are dedicated to people's genuine smiles," Towa is also working to newly create health-related businesses. See (<https://www.towayakuhin.co.jp/english/>) for details.

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