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Towa Pharmaceutical Receives Approval for Authorized Generic Version of Chugai's Osteoporosis Agent Edirol

- Chugai granted Towa Pharmaceutical the license to manufacture and market an authorized generic version of its osteoporosis agent Edirol
- Towa has obtained regulatory approval from the MHLW for the authorized generic. The formulation will be manufactured and supplied to Towa by Chugai

TOKYO, December 3, 2021 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced that Towa Pharmaceutical Co., Ltd. (hereafter "Towa") obtained regulatory approval on December 2, 2021 from the Ministry of Health, Labour and Welfare (MHLW) for "Eldecalcitol Capsules 0.5μg/0.75μg Towa," as an authorized generic (AG) version of Chugai's osteoporosis agent, active vitamin D_3 derivative Edirol® (generic name: eldecalcitol).

Edirol is an active vitamin D_3 derivative created based on Chugai's long-standing vitamin D research and used as a base drug for the treatment of osteoporosis. In light of the maturity of the product life cycle, Chugai has reached an agreement with Towa on the marketing of AG to expand the options for patients and ensure a stable supply of eldecalcitol products. Towa had obtained regulatory approval for a generic version of Edirol in August 2020. Based on the agreement with Chugai, Towa filed an application for partial changes of the prior approval as an AG, and received the approval on December 2, 2021.

"Since its launch in 2011, Edirol has been playing an important role as a base drug for the treatment of osteoporosis," said Chugai's President and CEO, Dr. Osamu Okuda. "With the approval of AG, Chugai will strive to make further contributions to patients by providing a stable supply of high-quality pharmaceuticals with Towa."

Towa will launch the AG after the NHI (National Health Insurance) price listing. Chugai will supply formulation of the product for the time being, while Towa will be responsible for packaging, marketing, and providing information on appropriate use. Going forward, the companies will implement the technology transfer to establish a manufacturing scheme in which Towa will be responsible for drug formulation and subsequent procedures. Chugai will continue to market Edirol and fulfill its responsibilities as a manufacturer of the brand product, including communication of information on appropriate use.

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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.

About Edirol

Edirol is an active vitamin D_3 derivative created by Chugai, which can improve calcium and bone metabolism. In Japan, Edirol was launched in April 2011 for the treatment of osteoporosis. In Prevention of Osteoporosis and Clinical Practice Guidelines 2015, Edirol is ranked as grade A as an active vitamin D_3 preparation in the efficacy assessment to validate the increase in bone mineral density and decrease in vertebral fracture.

About Authorized Generic Drugs (AG)

In general, AG refers to a generic drug that is identical in active pharmaceutical ingredient, drug substance, additive, and manufacturing method, and manufactured and marketed under the authorization of the manufacturer of the brand-name product.

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