



FOR IMMEDIATE RELEASE

August 31, 2021

Eisai Co., Ltd.
FUJI YAKUHIN CO., LTD.

**Eisai and FUJI YAKUHIN Conclude License Agreement Concerning
the Development and Distribution of Dotinurad, a Treatment for Hyperuricemia
and Gout, in Five ASEAN Countries**

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, “Eisai”) and FUJI YAKUHIN CO., LTD. (Headquarters: Saitama, CEO: Masayuki Takayanagi, “FUJI YAKUHIN”) announced today that they have concluded a license agreement concerning dotinurad (generic name), a treatment for hyperuricemia and gout discovered by FUJI YAKUHIN, for development and distribution in five ASEAN (Association of Southeast Asian Nations) member states: Indonesia, Malaysia, Myanmar, the Philippines, and Thailand. This agreement conclusion will lead to an expansion into Southeast Asia of an agreement regarding dotinurad in China concluded by Eisai and FUJI YAKUHIN in February 2020.

Based on this agreement, Eisai will acquire exclusive development and marketing rights for dotinurad in the said five countries from FUJI YAKUHIN. FUJI YAKUHIN will retain responsibility for manufacturing the formulation of dotinurad, and supply to Eisai. Eisai will be responsible for New Drug Applications for dotinurad in the said five countries and pay FUJI YAKUHIN an upfront payment and sales milestones.

Hyperuricemia is known to be associated with various diseases in the urinary system, endocrine system, metabolic system, cardio-cerebrovascular system etc., including gout. Furthermore, it is estimated that currently in Southeast Asia, the number of hyperuricemia and gout patients is approximately 2.83 million.¹ It is expected that the number of patients will further increase in the near future due to changes in lifestyle and dietary preferences in accordance with socioeconomic development in Southeast Asia.

Dotinurad is a new therapeutic medicine for gout and hyperuricemia discovered by FUJI YAKUHIN. Dotinurad suppresses uric acid reabsorption and lowers blood uric acid levels, by selectively inhibiting the urate transporter (URAT1) related to reabsorption of uric acid in the kidney. In Japan, FUJI YAKUHIN obtained manufacturing and marketing approval for dotinurad in January 2020 and launched it in May 2020.

Under this agreement, Eisai will proceed with the development and commercialization of dotinurad in the said five countries, and aim to contribute to patients with unmet medical needs in Southeast Asia. FUJI YAKUHIN anticipates maximizing the value of dotinurad in Asia by leveraging Eisai’s business base.

Through the development and commercialization of dotinurad, Eisai and FUJI YAKUHIN will provide new treatment options for hyperuricemia and gout in the said five countries in addition to China, and contribute to improving the quality of life of patients in Asia.

| |
|---|
| Media Inquiries |
| Eisai Co., Ltd. Public Relations Department TEL: +81-(0)3-3817-5120 |

<Notes to editors>

1. About Eisai Co., Ltd.

Eisai is a leading global research and development-based pharmaceutical company headquartered in Japan, with approximately 10,000 employees worldwide. Eisai defines our corporate mission as “giving first thought to patients and their families and to increasing the benefits health care provides,” which we call our *human health care (hhc)* philosophy. We strive to realize our *hhc* philosophy by delivering innovative products in therapeutic areas with high unmet medical needs, including Oncology and Neurology.

In the spirit of *hhc*, Eisai takes that commitment even further by applying our scientific expertise, clinical capabilities and patient insights to discover and develop innovative solutions that help address society’s toughest unmet needs, including neglected tropical diseases and the Sustainable Development Goals.

For further information on Eisai Co., Ltd., please visit <https://www.eisai.com> and connect with us on Twitter [@Eisai_SDGs](https://twitter.com/Eisai_SDGs).

2. About FUJI YAKUHIN CO., LTD.

FUJI YAKUHIN was founded in 1930 as a distributor of placement drugs, and is now a diversified pharmaceutical company that operates drugstores and dispensing pharmacies, pharmaceutical manufacturing, pharmaceutical research and development, and prescription drug sales in addition to its placement drug sales business.

The Group applies its 1,360 drugstores centering on SEIMS, in addition to a comprehensive nationwide network of placement drug as well as pharmaceutical research and development and manufacturing capabilities, and aims to realize a society in which everyone can lead an abundant life by supporting people in every aspect of their lives and continuing to deliver wellness to them daily.

In the prescription drug research and development business, the Group created two drugs with different mechanisms of action for the treatment of gout and hyperuricemia, topiroxostat (product name: TOPILORIC® Tablets) and dotinurad (product name: URECE® Tablets). With regard to dotinurad, we are working on licensing activities with the aim of contributing to patients around the world who require treatment for gout and hyperuricemia.

For further information on FUJI YAKUHIN CO., LTD., please visit <https://www.fujiyakuin.co.jp/> (Japanese only)

3. About dotinurad

Dotinurad is a therapeutic medicine for gout and hyperuricemia discovered by FUJI YAKUHIN. Dotinurad selectively inhibits URAT1, one of the uric acid transporters, thus preventing reabsorption of uric acid by the kidneys and promoting uric acid excretion in the urine. In addition, it has a small effect on other transporters affecting uric acid secretion, so it reduces serum uric acid levels at lower doses. Dotinurad is expected to have a low risk of side effects and drug interaction. In Japan, FUJI YAKUHIN obtained manufacturing and marketing approval for dotinurad in January 2020 and launched it in May 2020.

¹ Saeid Safiri et al., Prevalence, Incidence, and Years Lived With Disability Due to Gout and Its Attributable Risk Factors for 195 Countries and Territories 1990–2017: A Systematic Analysis of the Global Burden of Disease Study 2017, *American College of Rheumatology*, 2020 Nov; 72: 1916–1927.