



**FOR IMMEDIATE RELEASE**

February 25, 2020

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 China**

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 China.

Based on this agreement, Eisai will acquire exclusive development and marketing rights for dotinurad in China from FUJI YAKUHIN. FUJI YAKUHIN will retain responsibility for manufacturing the formulation of dotinurad, and supply to Eisai. Eisai will be responsible for a New Drug Application for dotinurad in China and pay FUJI YAKUHIN upfront payment, development milestone and sales milestone.

Hyperuricemia is the second most common metabolic disease after diabetes mellitus in China. In addition, 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 China, the number of patients with hyperuricemia is approximately 190 million and the number of patients with gout is approximately 16 million.<sup>1</sup> 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 China.

Dotinurad is a new therapeutic agent 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.

Under this agreement, Eisai will proceed with the development of dotinurad in China. Following commercialization, Eisai will aim to contribute to patients with hyperuricemia that is unmet medical needs by utilizing the knowledge and networks that Eisai has cultivated through its China business. FUJI YAKUHIN anticipates maximizing the value of dotinurad in China by leveraging Eisai's business base as the first step in the global expansion of dotinurad. Through the development and commercialization of dotinurad, Eisai and FUJI YAKUHIN will provide new treatment options for hyperuricemia and gout in China and contribute to improving the quality of life of patients.

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

## <Notes to editors>

### 1. About Eisai Co., Ltd.

Eisai Co., Ltd. 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. With approximately 10,000 employees working across our global network of R&D facilities, manufacturing sites and marketing subsidiaries, we strive to realize our *hhc* philosophy by delivering innovative products to address unmet medical needs, with a particular focus in our strategic areas of Neurology and Oncology.

As a global pharmaceutical company, our mission extends to patients around the world through working with key stakeholders to improve access to medicines in developing and emerging countries.

For further information on Eisai Co., Ltd., please visit <https://www.eisai.com>.

### 2. About FUJI YAKUHIN CO., LTD.

FUJI YAKUHIN CO., LTD. is a complex pharmaceutical company with an integrated manufacturing and sales system consisting of ethical drug sales, placement drug sales, drugstore business, and the pharmaceutical manufacturing business that supports them. Regarding ethical drugs, FUJI YAKUHIN has created two drugs with different mechanisms of action, topiroxostat and dotinurad, for gout and hyperuricemia.

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

### 3. About dotinurad

Dotinurad is a treatment for gout and hyperuricemia created by FUJI YAKUHIN CO., LTD. Dotinurad selectively inhibits URAT1 and has a small effect on other transporters, 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, on January 23, 2020, FUJI YAKUHIN CO., LTD. obtained manufacturing and marketing approval for dotinurad.

###

#### References:

<sup>1</sup> For the estimated data regarding the number of patients with hyperuricemia as well as the number of patients with gout:

- Data of morbidity prevalence rate - Rui Liu et al., Prevalence of Hyperuricemia and Gout in Mainland China from 2000 to 2014: A Systematic Review and Meta-Analysis, BioMed Research International, Volume 2015, Article ID 762820
- Estimated data calculated from United Nations World Population Estimates - World Population Prospects, URL : <http://www.un.org/en/development/desa/population/>