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Eisai Co., Ltd.

## **“URECE®” (DOTINURAD) APPROVED IN CHINA FOR GOUT PATIENTS WITH HYPERURICEMIA**

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, “Eisai”) announced today that it has received approval for “URECE®” (brand name in China: “优乐思®”, generic name: dotinurad) from the National Medical Products Administration in China as a treatment for gout patients with hyperuricemia.

This approval is based on the results of a multicenter, active-controlled, double-blind, parallel-group, randomized, Phase 3 study conducted by Eisai in China.<sup>1</sup> In this study, 451 gout patients were randomized into either the dotinurad group or febusostat group in a 1:1 ratio. The results of this study showed that the proportion of subjects with serum uric acid levels of 6.0 mg/dL or less at 24 weeks, which was the primary endpoint, was 73.6% [95% confidence interval (CI): 67.8, 79.5] in the dotinurad group and 38.1% [95% CI: 31.6, 44.5] in the febusostat group, confirming the statistical superiority of dotinurad 4 mg over febusostat 40 mg (difference of proportion 35.87% [95% CI: 27.36, 44.37,  $p < 0.001$ ]).

The most common adverse events were gouty arthritis, COVID-19, and liver function abnormality in the dotinurad group, and gouty arthritis, COVID-19, and increased alanine aminotransferase (ALT) in the febusostat group. No new safety concerns with dotinurad were observed.

“URECE” is a new therapeutic medicine for gout and hyperuricemia discovered by FUJI YAKUHIN. It 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. Eisai concluded a license agreement with FUJI YAKUHIN for China and five ASEAN member states: Indonesia, Malaysia, Myanmar, the Philippines, and Thailand, granting exclusive development and distribution rights in these countries. URECE was approved in Thailand for gout and hyperuricemia in September, 2024. In Japan, FUJI YAKUHIN obtained manufacturing and marketing approval for URECE in January 2020 and launched it in May 2020.

It is estimated that there are currently about 16 million patients with gout in China.<sup>2</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.

Eisai is committed to providing “URECE” to more patients with gout in China, including through its inclusion in the National Reimbursement Drug List (NRDL), and will contribute to improving the quality of life (QOL) of patients.

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**<Notes to editors>**

**1. “优乐思®” Product Outline**

Chinese Trade name: “优乐思” (URECE)

Chinese generic name: 多替诺雷片 (Dotinurad Tablets)

Indication for use: It is indicated for gout patients with hyperuricemia.

Dosage and administration: For oral use, the usual adult initial dosage is 1 mg of dotinurad once daily. The dose level should then be gradually increased as needed by checking blood uric acid levels. The usual maintenance dosage is 2 mg once daily and may be adjusted according to the patient’s condition, but up to 4 mg once daily.

**2. About “URECE®” (Dotinurad)**

URECE is a therapeutic medicine for gout and hyperuricemia discovered by FUJI YAKUHIN. URECE 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, URECE has a small effect on other transporters affecting uric acid secretion, so it reduces serum uric acid levels at lower doses. URECE is expected to have a low risk of side effects and drug interactions.

In Japan, FUJI YAKUHIN obtained manufacturing and marketing approval for URECE in January 2020 and launched it in May 2020.

**3. About the Phase 3 Clinical Trial (Study FYU-981-J086-301)<sup>1</sup>**

This was a multicenter, active-controlled, double-blind, parallel-group, randomized, Phase 3 study conducted to confirm the superiority of dotinurad 4mg over febuxostat 40mg as the primary evaluation, assess safety, and confirm the non-inferiority of dotinurad 2mg to febuxostat 40mg as the secondary evaluation in Chinese patients with gout.

Patients with gout and serum uric acid (SUA) levels exceeding 7.0 mg/dL were randomly assigned to either the dotinurad group or the febuxostat group in a 1:1 ratio, investigational product treatment for 24 weeks (the dotinurad group received 1mg/day for 4 weeks, 2mg/day for 8 weeks, and 4mg/day for 12 weeks, while the febuxostat group received 20mg/day for 4 weeks and 40mg/day for 20 weeks). The primary endpoint was the proportion of patients with SUA  $\leq$ 6.0mg/dL at 24 weeks, and the secondary endpoint was the proportion of patients with SUA  $\leq$ 6.0mg/dL at 12 weeks.

Of the total 451 patients, 225 were assigned to the dotinurad group and 226 to the febuxostat group. Of these, 441 patients (220 in the dotinurad group and 221 in the febuxostat group) were included in the Full Analysis Set (FAS).

For the primary endpoint, the proportion of patients with SUA  $\leq$ 6.0mg/dL at 24 weeks was 73.6% [95% confidence interval (CI): 67.8, 79.5] in the dotinurad group and 38.1% [95% CI: 31.6, 44.5] in the febuxostat group, confirming the statistical superiority of dotinurad 4mg over febuxostat 40mg (difference of proportion 35.87% [95% CI: 27.36, 44.37,  $p < 0.001$ ]).

For the secondary endpoint, the proportion of patients with SUA  $\leq$ 6.0mg/dL at 12 weeks was 55.5% in the dotinurad group and 50.5% in the febuxostat group, confirming the statistical non-inferiority of dotinurad 2mg to febuxostat 40mg (difference of proportion 5.24% [95% CI: -3.69, 14.17]).

The most common adverse events were gouty arthritis, COVID-19, and liver function abnormality in the dotinurad group, and gouty arthritis, COVID-19, and increased alanine aminotransferase (ALT) in the febuxostat group. No new safety concerns with dotinurad were observed.

1. Sun J, Wang Y, Zhang X, et al. POS0255 A RANDOMIZED, MULTICENTER, DOUBLE-BLIND, PHASE 3 STUDY COMPARING EFFICACY OF DOTINURAD AND FEBUXOSTAT FOR THE TREATMENT OF GOUT IN CHINESE SUBJECTS. *Annals of the Rheumatic Diseases* 2024;83:407-408.
2. For the estimated data regarding 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 : <https://population.un.org/wpp/>