



**FOR IMMEDIATE RELEASE**

Tokyo, September 25, 2020

**JT Receives Manufacturing and Marketing Approval of  
ENAROY<sup>®</sup> Tablets 2 mg·4 mg  
for the Treatment of Anemia Associated with Chronic Kidney Disease in Japan**

Japan Tobacco Inc. (JT) (TSE:2914) and Torii Pharmaceutical Co., Ltd. (Torii) (TSE:4551) announced that JT has today received manufacturing and marketing approval for ENAROY<sup>®</sup> Tablet 2 mg and 4 mg (generic name: enarodustat) (hereinafter “ENAROY<sup>®</sup>”), a hypoxia inducible factor prolyl hydroxylase (HIF-PH) inhibitor, for an indication of anemia associated with chronic kidney disease (CKD) in Japan.

ENAROY<sup>®</sup> is an orally-active HIF-PH inhibitor that promotes erythropoiesis by accelerating the endogenous production of erythropoietin (EPO) and controlling the expression of molecules responsible for iron metabolism. The Phase 3 clinical studies confirmed the efficacy and safety of ENAROY<sup>®</sup> in anemic patients with CKD not on dialysis, on peritoneal dialysis and on hemodialysis.

JT and Torii expect ENAROY<sup>®</sup> to be a new option for the treatment of anemia associated with CKD in Japan. Under the terms of the October 2017 agreement between JT and Torii, the drug will exclusively be sold by Torii in Japan, following its inclusion in the National Health Insurance (NHI) price list. The drugs’ launch date will be announced as soon as a decision is made.

**Outline of approval**

Product Name: ENAROY<sup>®</sup> Tablet 2 mg·4 mg

Generic Name: Enarodustat

Indications: Anemia associated with CKD

Dosage and Administration:

For patients with CKD not on dialysis and on peritoneal dialysis;

The recommended starting dose for adult patients is 2 mg taken orally once daily before a meal or at bedtime. Thereafter, the dose should be adjusted as appropriate depending on the patient’s condition. The maximum dose is 8 mg per dose.

For patients with CKD on hemodialysis;

The recommended starting dose for adult patients is 4 mg taken orally once

daily before a meal or at bedtime. Thereafter, the dose should be adjusted as appropriate depending on the patient's condition. The maximum dose is 8 mg per dose.

### **ABOUT Anemia Associated with CKD**

Anemia is one of the complications in CKD patients. The major cause of anemia in patients with CKD is considered to be a decreased ability to produce EPO in the kidney associated with renal dysfunction. Insufficient oxygen supply due to decreased erythrocyte counts associated with anemia decreases the energy production in organs and induces reduction in mobility and activities in daily life, which leads to a poor quality of life.

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*Japan Tobacco Inc. is a leading international tobacco company with operations in more than 130 countries. With approximately 62,000 employees, it manufactures and sells some of the world's best-known brands including Winston, Camel, MEVIUS and LD. The JT Group is committed to investing in Reduced-Risk Products (RRP) and currently markets its tobacco vapor products under its Ploom brand, and various e-cigarette products under its Logic brand. The Group is also present in the pharmaceutical and processed food businesses. For more information, visit <https://www.jt.com/> .*

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