



FOR IMMEDIATE RELEASE

Tokyo, November 18, 2020

Listing on the Japanese National Health Insurance Drug Price List and Launch of ENAROY[®] 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 ENAROY[®] Tablets 2 mg and 4 mg (generic name: enarodustat) (hereinafter "ENAROY[®]"), a hypoxia inducible factor prolyl hydroxylase (HIF-PH) inhibitor, have been listed on the Japanese National Health Insurance (NHI) drug price list as of today. On September 25, 2020, JT received manufacturing and marketing approval of ENAROY[®] in Japan for an indication of anemia associated with chronic kidney disease (CKD). Torii plans to launch ENAROY[®] in Japan on December 8, 2020.

ENAROY[®] 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[®] in anemic patients with CKD, including non-dialysis patients and those receiving peritoneal dialysis or hemodialysis.

JT and Torii expect ENAROY[®] to be a new option for the treatment of anemia associated with CKD in Japan.

ENAROY[®] Tablets 2 mg · 4 mg

Product Name:	ENAROY [®] Tablets 2 mg · 4 mg
Generic Name:	Enarodustat
Indications:	Anemia associated with CKD
Package:	ENAROY [®] Tablets 2 mg :
	140 tablets (14 tablets (PPT) × 10)
	ENAROY [®] Tablets 4 mg :
	140 tablets (14 tablets (PPT) × 10)
Dosage and	For non-dialysis CKD patients and peritoneal dialysis
Administration:	patients;
	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 hemodialysis patients;
	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.
NHI Drug Price:	ENAROY [®] Tablets 2 mg : ¥ 275.90 per tablet
	ENAROY [®] Tablets 4 mg : ¥ 486.10 per tablet
Approval Date:	September 25, 2020
NHI Pricing Date:	November 18, 2020
Launch Date:	December 8, 2020
Manufacturing and	Japan Tobacco Inc.
Distributor:	
Distributor:	Torii Pharmaceutical Co., Ltd.

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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