FOR IMMEDIATE RELEASE

Tokyo, November 29, 2019

JT Files New Drug Application of Enarodustat (JTZ-951), for the Treatment of Anemia Associated with CKD in Japan

Japan Tobacco Inc. (JT) (TSE:2914) and Torii Pharmaceutical Co., Ltd. (Torii) (TSE:4551) announced that JT has filed today a New Drug Application for JTZ-951 (generic name: enarodustat), a hypoxia inducible factor prolyl hydroxylase (HIF-PH) inhibitor, for anemia associated with chronic kidney disease (CKD).

Enarodustat was originated by JT and has been developed in Japan by JT and Torii under the terms of an agreement for co-development and marketing in Japan, signed on October 26, 2017. Under this agreement, JT grants Torii the exclusive rights to market enarodustat in Japan, subsequent to JT’s obtaining manufacturing and marketing approval.

Enarodustat 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 efficacy in anemic patients with non-dialysis dependent CKD and dialysis dependent CKD. Furthermore, the favorable tolerability profile on safety of enarodustat was obtained during the studies.

JT and Torii expect enarodustat to be a new therapeutic option for anemia associated with CKD in Japan.

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 over 63,000 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 the Ploom brand and various e-cigarette products under the Logic brand. The Group is also present in the pharmaceutical and processed food businesses. For more information, visit
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