FOR IMMEDIATE RELEASE

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Top-line Results of Phase 3 Clinical Studies of JTZ-951 (enarodustat), in Anemic Patients with Chronic Kidney Disease (Comparative Study) in Japan

Japan Tobacco Inc. (JT) (TSE:2914) and Torii Pharmaceutical Co., Ltd. (TSE:4551) today announce the top-line results of two pivotal Phase 3 comparative studies in anemic patients with non-dialysis dependent chronic kidney disease (NDD-CKD) (MBA4-4 study) or hemodialysis dependent CKD (HDD-CKD) on erythropoiesis stimulating agent (ESA) therapy (MBA4-5 study) for JTZ-951 (generic name: enarodustat), an hypoxia inducible factor prolyl hydroxylase (HIF-PH) inhibitor. Enarodustat was originated by JT and has been developed by JT and Torii under the terms of an agreement for co-development and commercialization in Japan, signed on October 26, 2017.

The objectives of the studies are to evaluate the efficacy and safety of enarodustat in comparison to darbepoetin alfa (genetical recombination) (product name in Japan: Nesp®) over 24 weeks in anemic patients with NDD-CKD or HDD-CKD. The studies were designed as follows;

- MBA4-4 study: randomized, open-label, parallel-arm comparative study (intra-individual dose-adjustment design)
- MBA4-5 study: randomized, double-blind, parallel-arm comparative study (intra-individual dose-adjustment design)

The top-line results show that the differences in mean hemoglobin at week 20, 22 and 24 achieved the non-inferiority criterion and both studies met the primary endpoints. Furthermore, the favorable tolerability profile on safety of JTZ-951 was obtained during the studies.

JT and Torii will aim to submit a marketing application for JTZ-951 in Japan based on the results of this and other clinical studies.

ABOUT Enarodustat

Enarodustat is expected to inhibit HIF-PH and contributes to ensure the appearance of HIF. The candidate compound works by accelerating the production of endogenous

erythropoietin (EPO), controlling the expression of molecules responsible for iron metabolism and promoting the production of red blood cells. ESAs, the current standard of care, are injections, thus the further development of orally available enarodustat is expected to contribute to the treatment of anemic patients with CKD.

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 https://www.jt.com/.

Contact for Japan Tobacco Inc.:
Masahito Shirasu, General Manager
Media and Investor Relations Division
Japan Tobacco Inc. Tokyo: +81-3-5572-4292
E-mail: jt.media.relations@jt.com

Contact for Torii Pharmaceutical Co., Ltd.:
Corporate Planning Department
(Public Relations)
Torii Pharmaceutical Co., Ltd.
Tokyo: +81-3-3231-6814