FOR IMMEDIATE RELEASE

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Top-line Results of Phase 3 Clinical Study of Riona®, (ferric citrate hydrate), in Adult Patients with Iron Deficiency Anemia (Comparative Study) in Japan

Japan Tobacco Inc. (JT) (TSE: 2914) and Torii Pharmaceutical Co., Ltd. (Torii) (TSE: 4551) today announce the top-line results of the pivotal Phase 3 comparative study in adult patients with iron deficiency anemia (IDA) in Japan for Riona® Tablets 250mg (generic name in Japan: ferric citrate hydrate, development code: JTT-751, hereinafter Riona®).

This study used a double blind, randomized and parallel-group design to evaluate the efficacy and safety of oral Riona® in comparison to oral sodium ferrous citrate (product name in Japan: Ferromia®, hereinafter control drug) over 7 weeks in adult patients with IDA.

The top-line results show that the study met the primary endpoint by establishing non-inferiority of Riona® compared with a control drug in the changes in hemoglobin level from baseline at week 7. Riona® showed a favorable tolerability profile on safety within the treatment period. Regarding the safety endpoint, the incidence rates of nausea / vomiting (adverse events) were 13.0% / 3.2% (Riona®) and 32.7% / 15.2% (control drug), respectively.

JT and Torii will aim to file for an additional indication of improving IDA for Riona® in Japan based on this and other clinical studies.

ABOUT Riona® Tablets 250mg

“Riona® Tablets 250mg” is approved and marketed for the treatment of hyperphosphatemia in adult patients with chronic kidney disease (CKD) both on dialysis and not on dialysis in Japan. JT and Torii hold the exclusive rights in Japan for development and commercialization in September 26, 2007 from Keryx Biopharmaceuticals, Inc., which is now a wholly owned subsidiary of Akebia Therapeutics, Inc. JT received approval for Riona® in January 17, 2014 and Torii has been promoting and distributing products since May 12, 2014.

In the United States, Ferric citrate is approved and marketed by Akebia Therapeutics,

Inc. under the trade name Auryxia® for the control of serum phosphorus levels in adult patients with CKD on dialysis and for the treatment of IDA in adult patients with CKD not on dialysis.

ABOUT IDA

IDA is the most frequent anemia, which is caused by decreasing hemoglobin production due to iron deficiency. IDA involves symptoms of anemia with palpitations and shortness of breath, as well as pica, fatigability, etc., which leads to the decrease in the patient's quality of life. The treatment for IDA is the iron supplementation and the correction of the underlying cause.

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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/.

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