**FOR IMMEDIATE RELEASE**

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# JT Files for Additional Indication for Riona®, Ferric Citrate Hydrate, for Iron Deficiency Anemia in Japan

Japan Tobacco Inc. (JT) (TSE:2914) and Torii Pharmaceutical Co., Ltd. (Torii) (TSE:4551) announced that JT has today filed a supplemental New Drug Application (sNDA) for Riona® Tablets 250mg (generic name in Japan: ferric citrate hydrate, development code: JTT-751, hereinafter Riona®) for iron deficiency anemia (IDA) in adult patients in Japan.

The sNDA is based on the results from the pivotal Phase 3 clinical study in adult patients with IDA in Japan. The active controlled comparative clinical study[i] confirmed the non-inferiority of Riona® with an oral sodium ferrous citrate (control drug) in the changes in hemoglobin level from baseline after 7 weeks. In addition, Riona® showed a favorable tolerability profile on safety within the treatment period and 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 expect Riona® will serve as a new option for the treatment of IDA in adult patients.

## 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 and off dialysis in Japan. JT and Torii acquired the exclusive rights in Japan for its development and commercialization of Riona® under the agreement dated September 26, 2007 with Keryx Biopharmaceuticals, Inc., which is now a wholly owned subsidiary of Akebia Therapeutics, Inc. JT received approval for Riona® on January 17, 2014 and Torii has been promoting and distributing products Riona® 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.

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[i] https://www.jt.com/media/news/2019/pdf/20190709_E01.pdf

**ABOUT Iron Deficiency Anemia (IDA)**

IDA is the most frequent anemia, 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 can lead to a decrease in the patient's quality of life. Treatments for IDA include 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 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/.*


| Contact for Japan Tobacco Inc.: | Contact for Torii Pharmaceutical Co., Ltd.: |
|---|---|
| Dinesh Babu Thotakura, General Manager | Corporate Planning Department |
| Media and Investor Relations Division | (Public Relations) |
| Japan Tobacco Inc. Tokyo: +81-3-3582-3111 | Torii Pharmaceutical Co., Ltd. Tokyo: +81-3-3231-6814 |
| E-mail: jt.media.relations@jt.com | E-mail: webmaster@torii.co.jp |