Press Release

Tokyo, March 23, 2021

JT Receives Approval for Additional Indication for Iron Deficiency Anemia for Riona® and Promotion to Start in Japan

Japan Tobacco Inc. (JT) (TSE:2914) and Torii Pharmaceutical Co., Ltd. (Torii) (TSE:4551) announced today that JT received approval for an additional indication of iron deficiency anemia (IDA) (hereinafter the "New Indication") for Riona® Tablets 250mg (generic name in Japan: ferric citrate hydrate, development code: JTT-751, hereinafter "Riona®"). JT already has obtained manufacturing and marketing approval for Riona® which is being distributed by Torii as a treatment for improvement of hyperphosphatemia in patients with chronic kidney disease in Japan.

Starting today, Torii and ASKA Pharmaceutical Co., Ltd. (ASKA) (TSE:4514) jointly engage in the marketing of Riona®'s New Indication under the co-promotion agreement, dated June 1, 2020, concerning the New Indication for Riona®. Torii will mainly focus on promoting toward medical institutions with chronic kidney disease-related departments, such as nephrology and dialysis, while ASKA will mainly focus on medical institutions with obstetrics and gynecology.

JT, Torii and ASKA expect Riona® to be a new option to help patients with IDA in Japan.

Outline of approval

(The additional indication related to this approval is as underlined below.)

Product Name: Riona® Tablets 250mg Generic Name: Ferric Citrate Hydrate
Indications: Improvement of hyperphosphatemia in patients with chronic kidney disease, Iron Deficiency Anemia
Dosage and Administration:

For improvement of hyperphosphatemia in patients with chronic kidney disease;

The recommended starting dose for adult patients starts at 500 mg of ferric citrate taken orally three times daily immediately after meals. Thereafter, the dose should be adjusted as appropriate depending on the degree of symptoms and serum phosphorus concentration. The maximum daily dosage is 6,000 mg.

For patients with iron deficiency anemia;

The usual adult dosage for oral use begins at 500 mg of ferric citrate once daily immediately after meals. Thereafter, the dosage should be adjusted based on the degree of symptoms. The maximum dosage is 500 mg twice daily.

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 acquired the exclusive rights in Japan for its development and commercialization of Riona® under the agreement dated September 26, 2007 with Keryx Biopharmaceuticals, Inc., 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.

ABOUT Iron Deficiency Anemia (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 can lead to the decrease in the patient's quality of life. Treatments for IDA include the iron supplementation and the correction of underlying cause..

Contact for Japan Tobacco Inc.
Media and Investor Relations Division
Japan Tobacco Inc. Tokyo
E-mail: jt.media.relations@jt.com
Tokyo: +81-3-6636-2026

Contact for Torii Pharmaceutical Co., Ltd.
Corporate Planning Department (Public Relations)
Torii Pharmaceutical Co., Ltd
E-mail: webmaster@torii.co.jp
Tokyo: +81-3-3231-6814

Contact for ASKA Pharmaceutical Co., Ltd.
Corporate Planning Department
ASKA Pharmaceutical Co., Ltd.
E-mail: kouhou@aska-pharma.co.jp
Tokyo: +81-3-5484-8366