



FOR IMMEDIATE RELEASE

Tokyo, January 17, 2014

Riona[®] Tablets 250mg for the treatment of hyperphosphatemia approved in Japan

Tokyo, January 17, 2014 --- Japan Tobacco Inc. (JT) (TSE:2914) and Torii Pharmaceutical Co., Ltd. (Torii) (TSE:4551) announced today that JT has received manufacturing and marketing approval of Riona[®] Tablets 250mg, jointly developed by JT and Torii, from the Japanese Ministry of Health, Labour and Welfare. The drug is indicated as an oral treatment for the improvement of hyperphosphatemia in patients¹ with chronic kidney disease (CKD).

Riona[®] Tablets is a novel phosphate binder containing ferric citrate hydrate as the active pharmaceutical ingredient. This new agent binds to phosphate in the gastrointestinal tract and decreases serum phosphorus concentration through inhibiting phosphate absorption into the body. Clinical efficacy in the decrease of serum phosphorus concentration was proven in Phase 3 studies, in both on dialysis and not on dialysis CKD patients with hyperphosphatemia in Japan. Furthermore, no clinically significant findings on the safety and tolerability of Riona[®] Tablets were observed in the long-term administration studies.

JT and Torii expect Riona[®] Tablets to become a new therapeutic option for hyperphosphatemia in patients with CKD, including dialysis and non-dialysis dependent CKD. Following its inclusion in the National Health Insurance (NHI) price list, Riona[®] Tablets will be sold exclusively by Torii in Japan. The drug's launch date will be announced as soon as a decision is made.

Outline of approval

Product Name: Riona[®] Tablets 250mg

Generic Name: Ferric Citrate Hydrate

Indications: Improvement of hyperphosphatemia in patients with chronic kidney disease

¹ Both dialysis and non-dialysis dependent CKD patients are included.

Dosage and Administration:

The usual adult dosage for oral use begins at 500 mg of ferric citrate three times daily immediately after meals. Thereafter, the dosage should be adjusted based on the degree of symptoms and serum phosphorus concentration. The maximum daily dosage is 6,000 mg.

About ferric citrate hydrate

JT and Torii hold the exclusive rights to develop and commercialize ferric citrate hydrate in Japan, which were licensed in September 2007 from Keryx Biopharmaceuticals, Inc. Since then, JT and Torii have jointly conducted the development of the drug, and JT submitted a New Drug Application (NDA) to the Japanese Ministry of Health, Labour and Welfare in January 2013. In the United States, Keryx filed its NDA with the U.S. Food and Drug Administration and has been assigned a Prescription Drug User Fee Act (PDUFA) goal date of June 7, 2014.

About hyperphosphatemia

Patients with CKD often suffer from hyperphosphatemia, as a result of lower phosphorous excretion from the kidney. Persisting hyperphosphatemia leads to calcareous deposition in various organs and periarticular tissues. In particular, a calcified blood vessel wall causes arterial sclerosis and increases the risk of cardiac infarct and angina. Furthermore, bone lesions can be caused by secondary hyperparathyroidism associated with the increase in secretion of parathyroid hormone, negatively affecting activities of daily living and quality of life. Therefore, it is important for hyperphosphatemia in patients with CKD, including dialysis and non-dialysis dependent CKD, to maintain the target level of serum phosphorus.

###

Japan Tobacco Inc. is a leading international tobacco product company. Its products are sold in over 120 countries and its internationally recognized cigarette brands include Winston, Camel, Mevius/Mild Seven and Benson & Hedges. With diversified operations, JT is also actively present in pharmaceuticals, beverages and processed foods. The company's revenue was ¥2.120 trillion (US\$22,543 million()) in the fiscal year ended March 31, 2013.*

**Translated at the rate of ¥94.05 per \$1, as of March 29, 2013*

Contacts for Japan Tobacco Inc.:
Ryohei Sugata, 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.:
Planning Department (Public Relations)
Torii Pharmaceutical Co., Ltd.
Tokyo: +81-3-3231-6814