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**FOR IMMEDIATE RELEASE**

**Tokyo, March 25, 2013**

**JT receives manufacturing and marketing approval of a novel anti-HIV drug, “Stribild<sup>®</sup> Combination Tablets” in Japan**

**Tokyo, March 25, 2013** --- Japan Tobacco Inc. (JT) (TSE:2914) announced today that the Company has received manufacturing and marketing approval of a novel anti-HIV drug, “Stribild<sup>®</sup> Combination Tablets”, in Japan. The Company had filed a New Drug Application (NDA) for this drug with the Japanese Ministry of Health, Labour and Welfare in December 2012.

“Stribild<sup>®</sup> Combination Tablets” contains four compounds in a single tablet regimen: elvitegravir (JT’s development code: JTK-303) 150 mg; cobicistat 150 mg; emtricitabine 200 mg; and tenofovir disoproxil fumarate 300 mg.

Combination antiretroviral therapy has been a standard of care for HIV infection. Adherence is a key to increase potential for the treatment’s success with reducing the emergence of a drug-resistant virus. Accordingly, a drug which is easier and convenient to use, such as a single tablet regimen, has been desired by physicians and their patients.

“Stribild<sup>®</sup> Combination Tablets” is the first complete, once-daily, single tablet regimen to be commercialized in Japan which is used without other drugs for the treatment of HIV. The drug is expected to provide convenience and long-term adherence for patients.

The drug will be sold exclusively by Torii Pharmaceutical Co., Ltd. (Torii) in Japan, under the terms of an agreement in August 2012, following its inclusion in the National Health Insurance (NHI) price list. The drug’s launch date will be announced as soon as a decision is made.



### **Outline of approval**

Product Name: Stribild<sup>®</sup> Combination Tablets

Generic Name: elvitegravir/ cobicistat/ emtricitabine/ tenofovir disoproxil fumarate

Indications: HIV-1 Infection

Dosage and Administration:

The usual adult dosage for oral use is one tablet (containing 150 mg of elvitegravir, 150 mg of cobicistat, 200 mg of emtricitabine, and 300 mg of tenofovir disoproxil fumarate) once daily with or immediately after a meal.

### **About Stribild<sup>®</sup> Combination Tablets**

“Stribild<sup>®</sup> Combination Tablets” contains four compounds in a complete, once-daily, single tablet regimen: elvitegravir, cobicistat, emtricitabine and tenofovir disoproxil fumarate. Outside Japan, the drug has been developed and commercialized by Gilead Sciences, Inc. (Gilead). The drug has been provided to HIV patients in the United States.

Elvitegravir, a novel HIV integrase inhibitor, is JT’s original compound, and interferes with HIV replication by blocking the ability of the virus to integrate into the genetic material of human cells. The Company licensed elvitegravir to Gilead in March 2005 with exclusive rights to develop and commercialize the drug worldwide, excluding Japan.

Cobicistat is Gilead’s pharmacoenhancing or “boosting” agent that maintains blood levels of elvitegravir by inhibiting the cytochrome P450 3A (CYP3A), an enzyme that metabolizes drugs in the body.

Emtricitabine and tenofovir disoproxil fumarate, nucleoside reverse transcriptase inhibitors, have been marketed as “Emtriva<sup>®</sup> Capsules 200mg” and “Viread<sup>®</sup> Tablets 300mg” respectively in Japan. In addition, a co-formulation of these drugs has been marketed as “Truvada<sup>®</sup> Combination Tablets” in the country. These drugs have been sold exclusively by Torii.

\* Elvitegravir and cobicistat as standalone agents are investigational products and their safety and efficacy have not yet been established worldwide, including in Japan.

\* Stribild, Emtriva, Viread and Truvada are registered trademarks of Gilead Sciences, Inc.



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*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, Mild Seven and Benson & Hedges. With diversified operations, JT is also actively present in pharmaceuticals and foods. The company's revenue were ¥2.034 trillion (US\$24,745 million<sup>(\*)</sup>) in the fiscal year ended March 31, 2012.*

*\*Translated at the rate of ¥82.19 per \$1, as of March 31, 2012*

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