



**FOR IMMEDIATE RELEASE**

Tokyo, April 5, 2016

**Novel anti-HIV drug Descovy® received US regulatory approval,  
JT's partner Gilead Sciences announced**

A New Drug Application for Descovy® (emtricitabine 200mg and tenofovir alafenamide 25mg; F/TAF) , a fixed-dose combination for the treatment of HIV-1 infection has been approved by the U.S. Food and Drug Administration (FDA). Japan Tobacco Inc. (JT) (TSE:2914) and Torii Pharmaceutical Co., Ltd. (Torii) (TSE:4551) announced that a statement has been issued to this effect by Gilead Sciences, Inc. (Gilead) on April 4, 2016, the U.S. local time.

JT holds the exclusive rights to develop and commercialize Descovy in Japan, and the Company is aiming to submit a New Drug Application for Descovy in the third quarter of FY2016, to the Japanese Ministry of Health, Labour and Welfare.

Under the terms of the agreement between JT and Torii on March 2, 2015, Torii holds exclusive rights to market Descovy in Japan, subsequent to JT's obtaining manufacturing and marketing approval from the country's authorities.

In the U.S., Descovy is indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients 12 years of age and older. No dosage adjustment of Descovy is required in patients with estimated creatinine clearance greater than or equal to 30mL per minute. Descovy is not recommended in patients with estimated creatinine clearance below 30mL per minute.

Following a positive opinion by the scientific committee of the European Medicines Agency, Descovy is now under review by the European Commission.

**About TAF**

TAF is a novel targeted prodrug of tenofovir, a nucleotide reverse transcriptase inhibitor, discovered by Gilead. It has demonstrated high antiviral efficacy similar to and at a dose less than one-tenth that of tenofovir disoproxil fumarate (TDF) in Gilead's clinical trials in combination with other antiretroviral agents.

\* TAF and TAF-based regimens are investigational products and have not been determined safe or efficacious in Japan.

\* Descovy is registered trademark of Gilead.

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*Japan Tobacco Inc. is a leading international tobacco company. Its products are sold in over 120 countries and its globally recognized brands include Winston, Camel, Mevius, LD and Natural American Spirit. With diversified operations, JT is also actively present in pharmaceuticals and processed foods. The company's revenue was ¥2.253 trillion (US\$18,679 million(\*)) in the fiscal year ended December 31, 2015.*

*\*Translated at the rate of ¥120.61 per \$1, as of December 31, 2015*

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