**FOR IMMEDIATE RELEASE**

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# JT receives manufacturing and marketing approval of a novel anti-HIV drug, "Genvoya® Combination Tablets" in Japan

Japan Tobacco Inc. (JT) (TSE: 2914) announced today that the Company has received manufacturing and marketing approval of a novel anti-HIV drug, "Genvoya® Combination Tablets", containing elvitegravir 150 mg, cobicistat 150 mg, emtricitabine 200 mg and tenofovir alafenamide (TAF) 10 mg in Japan. The Company filed a New Drug Application (NDA) for this drug with the Japanese Ministry of Health, Labour and Welfare in March 2016.

"Genvoya® Combination Tablets" is a complete single tablet regimen which can treat HIV-1 infection with once-daily administration. Tenofovir disoproxil fumarate (TDF), one of four ingredients of Stribild® Combination Tablets which has been marketed by Torii Pharmaceutical Co., Ltd. (Torii) (TSE: 4551) in Japan since 2013, is replaced with TAF to compose "Genvoya® Combination Tablets".

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

Under the terms of the agreement on March 2015 between JT and Torii, the drug will be sold exclusively by Torii in Japan, 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: Genvoya® Combination Tablets
Generic Name: elvitegravir/ cobicistat/ emtricitabine/ tenofovir alafenamide
Indications: HIV-1 Infection
Dosage and Administration:

The usual dosage in adults and pediatric patients 12 years of age and older with body weight at least 35 kg is one tablet (containing 150 mg of elvitegravir, 150 mg of cobicistat, 200 mg of emtricitabine, and 10 mg of tenofovir alafenamide) taken orally once daily after a meal.

**About: GENVOYA® Combination Tablets**

"Genvoya® Combination Tablets" contains four compounds in a complete, once-daily, single tablet regimen: elvitegravir, cobicistat, emtricitabine and tenofovir alafenamide.

In the United States and the European Union (EU), the drug was approved in November 2015 and has been marketed by Gilead under the name of Genvoya®. Genvoya® is classified as one of the recommended initial regimens for antiretroviral-naïve individuals 12 years or older with estimated creatinine clearance (a renal laboratory parameter which is related to renal function), greater than or equal to 30 mL/min in "Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents" issued by U.S. Department of Health and Human Services.

* Elvitegravir was discovered by JT. The Company licensed elvitegravir to Gilead in 2005 with exclusive rights to develop and commercialize in all countries of the world, excluding Japan, where JT retains the rights.