



**FOR IMMEDIATE RELEASE**

Tokyo, June 29, 2016

## **Launch of a novel anti-HIV drug “Genvoya<sup>®</sup> Combination Tablets” in Japan**

Japan Tobacco Inc. (JT) (TSE: 2914) and Torii Pharmaceutical Co., Ltd. (Torii) (TSE:4551), JT’s pharmaceutical subsidiary, announced today that Torii would launch a novel anti-HIV drug, “Genvoya<sup>®</sup> Combination Tablets” containing elvitegravir 150mg, cobicistat 150mg, emtricitabine 200mg and tenofovir alafenamide (TAF) 10mg in Japan on July 8, 2016. JT received manufacturing and marketing approval for this drug from the Japanese Ministry of Health, Labour and Welfare on June 17, 2016.

“Genvoya<sup>®</sup> 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<sup>®</sup> Combination Tablets which has been marketed by Torii in Japan since 2013, is replaced with TAF to compose “Genvoya<sup>®</sup> 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.

Marketing of “Genvoya<sup>®</sup> Combination Tablets” in Japan would constitute another contribution by JT Group to the treatment of HIV. Torii has been marketing anti-HIV drugs in Japan including “Stribild<sup>®</sup> Combination Tablets”, “Truvada<sup>®</sup> Combination Tablets”, “Emtriva<sup>®</sup> Capsules 200mg”, “Viread<sup>®</sup> Tablets 300mg” and “Viracept<sup>®</sup> Tablets 250mg”.

The effects on business performance of this launch are included in the Group’s consolidated forecast for the fiscal year ending December 31, 2016, announced on February 5, and are also included in Torii’s forecast for the fiscal year ending December 31, 2016, announced on February 3, 2016.

### About Genvoya® Combination Tablets

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.

Packages: Genvoya® Combination Tablets: (Bottle) 30 tablets

NHI Drug Price: ¥ 6,942.10 per tablet

Approval Date: June 17, 2016

NHI Pricing Date: June 29, 2016

Launch Date: July 8, 2016

Manufacturer and Distributor: Japan Tobacco Inc.

Distributor: Torii Pharmaceutical Co., Ltd.

“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 individual 12 years or older patients 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.

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