



FOR IMMEDIATE RELEASE

Tokyo, December 21, 2016

Launch of novel anti-HIV drugs, "Descovy® Combination Tablets LT and HT" in Japan

Japan Tobacco Inc. (JT) (TSE: 2914) and Torii Pharmaceutical Co., Ltd. (Torii) (TSE:4551), JT's pharmaceutical subsidiary, announced today that Torii will launch novel anti-HIV drugs, "Descovy® Combination Tablets LT" containing emtricitabine and tenofovir alafenamide 200/10 mg and "Descovy® Combination Tablets HT" containing emtricitabine and tenofovir alafenamide 200/25 mg, fixed-dose combinations for the treatment of HIV-1 infection in combination with other anitiretroviral agent(s) on January 27, 2017. JT received manufacturing and marketing approval for those drugs from the Japanese Ministry of Health, Labour and Welfare on December 9, 2016.

Tenofovir disoproxil fumarate (TDF), one of two ingredients of Truvada[®] Combination Tablets which has been marketed by Torii in Japan since 2005, is replaced with tenofovir alafenamide (TAF) to compose "Descovy® Combination Tablets LT and HT".

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

Marketing of "Descovy[®] Combination Tablets LT and HT" in Japan will constitute another contribution by JT Group to the treatment of HIV. Torii has been marketing anti-HIV drugs in Japan including "Genvoya[®] Combination Tablets", "Stribild[®] Combination Tablets", "Truvada[®] Combination Tablets", "Emtriva[®] Capsules 200 mg", "Viread[®] Tablets 300 mg" and "Viracept[®] Tablets 250 mg".

The effects on business performance of this launch are to be included in both the Group's consolidated and Torii's forecasts for the fiscal year ending December 2017, to be announced on February 6 and February 2, 2017, respectively.

About Descovy® Combination Tablets

Product Name : Descovy® Combination Tablets LT and HT

Generic Name : emtricitabine/tenofovir alafenamide

Indications : HIV-1 Infection

Dosage and Administration:

For adults and adolescents aged 12 years and older with body weight at least 35 kg, Descovy[®] should usually be taken orally according to the following dosage and administration. Descovy[®] should be coadministered with other anti-HIV drugs.

- 1. When ritonavir or cobicistat is coadministered, one tablet of Descovy[®] Combination Tablets LT (containing 200 mg of emtricitabine and 10 mg of tenofovir alafenamide) should be administered orally once daily.
- 2. When ritonavir or cobicistat is not coadministered, one tablet of Descovy[®] Combination Tablets HT (containing 200 mg of emtricitabine and 25 mg of tenofovir alafenamide) should be administered orally once daily.

Packages : Descovy® Combination Tablets LT : (Bottle) 30 tablets

Descovy® Combination Tablets HT: (Bottle) 30 tablets

NHI Drug Price : Descovy® Combination Tablets LT : ¥ 2,748.20 per tablet

Descovy® Combination Tablets HT: ¥ 3,934.30 per tablet

Approval Date : December 9, 2016

NHI Pricing Date : December 21, 2016

Launch Date : January 27, 2017

Manufacturer and Distributor: Japan Tobacco Inc.
Distributor: Torii Pharmaceutical Co., Ltd.

 $\hbox{``Descovy}^{\hbox{\'e}} \ \hbox{Combination Tablets'' contains two compounds: emtricitabine and tenofovir alafenamide.}$

In the United States and European Union (EU), the drug was approved in April 2016 and has been marketed by Gilead under the name of Descovy[®]. Descovy[®], when used in combination with certain other antiretroviral agent(s), is included in the recommended initial regimens for antiretroviral-naïve patients 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.

^{*} Genvoya[®] Combination Tablets, Torii launched in July 2016 in Japan, contains TAF as one of its four compounds.

^{*} Descovy, Truvada, and Genvoya are registered trademarks of Gilead.