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JT receives manufacturing and marketing approval of novel anti-HIV drugs, “Descovy[®] Combination Tablets LT and HT” in Japan

Japan Tobacco Inc. (JT) (TSE: 2914) announced today that the Company has received manufacturing and marketing approval of 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 antiretroviral agent(s). The Company filed a New Drug Application (NDA) for those drugs with the Japanese Ministry of Health, Labour and Welfare on 12th August.

Tenofovir disoproxil fumarate (TDF), one of two ingredients of Truvada[®] Combination Tablets which has been marketed by Torii Pharmaceutical Co., Ltd. (Torii) (TSE:4551) 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.

Under the terms of the agreement on March 2015 between JT and Torii, the drugs will be sold exclusively by Torii in Japan, following its inclusion in the National Health Insurance (NHI) price list. The drugs’ launch date will be announced as soon as a decision is made.

Outline of approval

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.

About: Descovy[®] Combination Tablets

“Descovy[®] 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.