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JT files New Drug Application for second tenofovir alafenamide (TAF)-based anti-HIV drug in Japan

Japan Tobacco Inc. (JT) (TSE: 2914) announced today that the Company filed a New Drug Application for a fixed-dose combination for the treatment of HIV-1 infection (emtricitabine and tenofovir alafenamide 200/10 mg and 200/25 mg; F/TAF) to the Japanese Ministry of Health, Labour and Welfare on 12th August.

Under the terms of the agreement on March 2015, Torii Pharmaceutical Co., Ltd. (Torii) (TSE: 4551) holds exclusive rights to market F/TAF for the treatment of HIV infection in Japan, subsequent to JT's obtaining manufacturing and marketing approval from the country's authorities.

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 TAF to compose F/TAF.

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. TAF has been granted orphan drug designation for the treatment of HIV infection in Japan since November 2015.

In the United States and European Union (EU), F/TAF was approved in April 2016 and has been marketed by Gilead under the name of Descovy[®]. Descovy[®] 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 just launched in July 2016 in Japan, contains TAF as one of its four compounds.

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