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

Japan Tobacco Inc. (JT) (TSE: 2914) announced today that the Company has filed a New Drug Application for an anti-HIV single tablet regimen (E/C/F/TAF) containing elvitegravir, cobicistat, emtricitabine and tenofovir alafenamide to the Japanese Ministry of Health, Labour and Welfare.

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

E/C/F/TAF is a complete single tablet regimen which can treat HIV infection with once-daily administration. Tenofovir disoproxil fumarate (TDF), one of four ingredients of Stribild[®] Combination Tablets which has been marketed by Torii in Japan since 2013, is replaced with tenofovir alafenamide fumarate (TAF) to compose E/C/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 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 Europe, E/C/F/TAF 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 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.

* TAF and TAF-based regimens are investigational products and have not been determined safe or efficacious in Japan.

* Stribild and Genvoya are registered trademarks of Gilead.