JT and Torii sign agreement to market two new tenofovir alafenamide (TAF)-based anti-HIV drugs in Japan

Japan Tobacco Inc. (JT) (TSE: 2914) and Torii Pharmaceutical Co., Ltd. (Torii) (TSE: 4551) announced today that they have signed an agreement to market two new tenofovir alafenamide (TAF)-based anti-HIV drugs, for which JT holds the exclusive rights to develop and commercialize in Japan. Under the terms of the agreement, Torii holds exclusive rights to market the drugs in Japan, subsequent to JT’s obtaining manufacturing and marketing approval from the country’s authorities.

TAF is a novel prodrug of tenofovir, a nucleotide reverse transcriptase inhibitor (NRTI) discovered by Gilead Sciences, Inc. (Gilead). Previously, only a prodrug of tenofovir, tenofovir disoproxil fumarate (TDF) has been available in the market as an active ingredient of Viread®, Truvada® and Stribild®. TAF has demonstrated high antiviral efficacy at a dose 10 times lower than TDF. It is also expected that influence on kidneys and bones can be reduced with TAF compared to TDF.

JT is currently preparing to file its New Drug Application (NDA) in Japan for an investigational once-daily single tablet regimen (E/C/F/TAF) containing elvitegravir 150mg, cobicistat 150mg, emtricitabine 200mg and TAF 10mg, one of the two TAF-based drugs pertaining to the agreement. E/C/F/TAF is an antiretroviral which can treat HIV infection with once-daily administration. TDF 300mg, one of four ingredients of Stribild® Combination Tablets which has been marketed by Torii in Japan from 2013, is replaced with TAF 10mg to compose E/C/F/TAF. In Gilead’s two Phase 3 studies, E/C/F/TAF showed high efficacy and good tolerability comparable to Stribild®, a comparator of the studies. Significantly better renal and bone laboratory parameters were also observed when compared with Stribild®. Gilead has submitted an NDA to the U.S. Food and Drug Administration (FDA) and a Marketing Authorisation Application (MAA) to the European Medicines Agency (EMA) for E/C/F/TAF.

The other TAF-based drug comprises emtricitabine and TAF (F/TAF). TDF, one of two active ingredients of Truvada®, is replaced with TAF to compose F/TAF. Gilead is conducting a Phase 3 study for F/TAF and plans to submit regulatory applications in the U.S. and EU in 2Q of 2015. JT plans to submit its NDA in Japan for F/TAF upon Gilead’s obtaining approval outside Japan.
Currently in the JT Group, Torii has been marketing anti-HIV drugs in Japan including Stribild® Combination Tablets, Truvada® Combination Tablets, Emtriva® Capsules 200mg, Viread® Tablets 300mg and Viracept® Tablets 250mg. Marketing of E/C/F/TAF and F/TAF in Japan, following approval, would constitute another contribution by JT Group to the treatment of HIV.

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

* Viread, Truvada, Stribild and Emtriva are trademarks of Gilead Sciences, Inc.

About the Status of New Drug Applications for E/C/F/TAF Overseas
Gilead has filed its NDA for E/C/F/TAF with FDA and MAA with EMA. In the United States, it has been assigned a Prescription Drug User Fee Act (PDUFA) goal date of November 5, 2015. The NDA for E/C/F/TAF is supported by 48-week data from two pivotal Phase 3 studies (Studies 104 and 111) evaluating E/C/F/TAF compared to Stribild® among treatment-naïve patients. The NDA is also supported by data from additional Phase 3 studies evaluating E/C/F/TAF among virologically suppressed patients who switched to E/C/F/TAF and among patients with renal impairment.

For Gilead’s press release on the detail of Phase 3 results dated February 26, 2015, visit http://www.gilead.com/.

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Japan Tobacco Inc. is a leading international tobacco company. Its products are sold in over 120 countries and its internationally recognized brands include Winston, Camel, Mevius and LD. With diversified operations, JT is also actively present in pharmaceuticals and processed foods. The company’s revenue was ¥2.154 trillion (US$17,867 million(*)) in the fiscal year ended December 31, 2014(**).

*Translated at the rate of ¥120.55 per $1, as of December 31, 2014
**Due to a change in the accounting period from March 31 to December 31, the fiscal year 2014 covered nine months for Japanese domestic businesses and 12 months for the consolidated subsidiaries which operate the Group’s international tobacco business. On a comparable full calendar year basis, revenue was ¥2.433 trillion (US$20,186 million(*)).

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