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JT files Application for Additional Pediatric Dosage and Administration for Genvoya® Combination Tablets, an anti-HIV drug

Japan Tobacco Inc. (JT) (TSE:2914) announced today that the Company has filed a supplemental New Drug Application (sNDA) for an additional dosage and administration for Genvoya® Combination Tablets (Elvitegravir 150 mg/Cobicistat 150 mg/Emtricitabine 200 mg/Tenofovir Alafenamide 10 mg Combination Tablets) (hereinafter "Genvoya®"), an anti-HIV drug, for the treatment of pediatric HIV-1 infection.

Genvoya® was discovered by Gilead Sciences Inc. (hereinafter "Gilead"). In 2015, Gilead received an approval of Genvoya® in the U.S, and JT received approval in Japan in 2016. The approved dosage and administration of Genvoya® was one tablet taken orally once daily in adults and pediatric patients 12 years of age and older with body weight 35kg. Subsequently, the results of the Phase II/III clinical study conducted by Gilead confirmed the efficacy and safety of Genvoya® in HIV-1 infected pediatric patients aged 6 to under 12 years and weighing 25 kg or more. In 2016, Gilead received the approval for an additional dosage and administration for HIV-1 infected pediatric patients weighing 25 kg or more in U.S.

Based on the approval in U.S., JT filed sNDA to add the dosage and administration for pediatric HIV-1 infection weighing 25 kg or more in Japan. JT expects Genvoya® will serve as a new option for the treatment of pediatric HIV-1 infection and significantly improve the quality of life of the patients.

As announced on November 29, 2018 and December 14, 2018, JT will transfer the manufacturing and marketing approval of Genvoya® in Japan to Gilead Sciences K.K., the Japanese subsidiary of Gilead, scheduled to be completed in 2019. Torii will be responsible for the distribution of Genvoya® in Japan and Gilead K.K. will be responsible for providing information relating to Genvoya® to all medical institutions in Japan before the completion of the transfer.

Outline of application

Product Name: Genvoya® Combination Tablets
Generic Name: elvitegravir/ cobicistat/ emtricitabine/ tenofovir alafenamide

Indications: HIV-1 Infection

Dosage and Administration:

The usual dosage in adults and pediatric patients with body weight at least 25 kg is one tablet (containing 150 mg of elvitegravir, 150 mg of cobicistat, 200 mg of emtricitabine, and 10 mg of tenofovir alafenamide) taken orally once daily after a meal.

About: GENVOYA® Combination Tablets

"Genvoya® Combination Tablets" contain four compounds in a complete, once-daily, single tablet regimen: elvitegravir, cobicistat, emtricitabine and tenofovir alafenamide. In the United States and the European Union (EU), the drug was approved in November 2015 and has been marketed by Gilead under the name of Genvoya®.

* 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. Pursuant to the termination agreement announced on November 29, 2018 and December 14, 2018, Japan has been added to Gilead's license territory, while JT retains certain rights until the completion of transfer of the marketing approvals.

* Genvoya is registered trademarks of Gilead.

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Japan Tobacco Inc. is a leading international tobacco company with operations in more than 130 countries. With close to 60,000 employees, it manufactures and sells some of the world's best-known brands including Winston, Camel, MEVIUS and LD. The JT Group is committed to investing in Reduced-Risk Products (RRP) and currently markets Ploom TECH, its tobacco vapor product, and various e-cigarette products under the Logic brand. The Group is also present in the pharmaceutical and processed food businesses. For more information, visit https://www.jt.com/.

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