

Launch of novel anti-HIV drugs, “Genvoya® Combination Tablets” and “Descovy® Combination Tablets LT and HT” in Japan



Genvoya® Combination Tablets

Descovy® Combination Tablets LT and HT

Torii launched a novel anti-HIV drug, “Genvoya® Combination Tablets” containing elvitegravir 150 mg, cobicistat 150 mg, emtricitabine 200 mg and tenofovir alafenamide 10 mg, fixed-dose combinations for the treatment of HIV-1 infection on July 8, 2016. Also, other novel anti-HIV drugs, namely “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) were launched on January 27, 2017. JT received manufacturing and marketing approval for these drugs from the Japanese Ministry of Health, Labour and Welfare.

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 (TAF) to compose “Genvoya® Combination Tablets,” antiretroviral agents that provide one tablet, once-daily treatment.

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 “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.

Marketing of “Genvoya® Combination Tablets” and “Descovy® Combination Tablets LT and HT” in Japan will constitute another contribution by Torii to the treatment of HIV.

Torii and JT Signed Exclusive License Agreement with Menlo Therapeutics for Development and Commercialization of NK-1 Receptor Antagonist in Japan

On August 10, 2016, Torii and JT signed a license agreement with Menlo Therapeutics Inc. (Menlo Therapeutics) for the exclusive rights to develop and commercialize serlopitant in Japan.

Serlopitant is a candidate compound of the first-in-class drug for the treatment of pruritus as an oral neurokinin (NK-1) receptor antagonist. It is expected to suppress pruritus involving the NK-1 signalling pathway. Serlopitant showed antipruritic effects in a phase 2 clinical trial in patients with chronic pruritus conducted by Menlo Therapeutics.

Under the terms of the agreement, it will be developed jointly by Torii and JT, and will be commercialized by Torii in Japan going forward.

Torii and JT Signed Exclusive License Agreement for Development and Commercialization of JAK Inhibitor in Japan

Torii and JT concluded an exclusive agreement for co-development and commercialization of JT's original compound, JTE-052, for topical use in dermatological indications in Japan on October 28, 2016.

JTE-052 inhibits Janus kinase (JAK), which plays important role in immunologically activating signal transduction. JTE-052 works by controlling excessive activation of immunoreaction and relieves autoimmune and allergic disease symptoms. JTE-052 is currently in phase 2 trials in atopic dermatitis patients in Japan.

Under the terms of the agreement, Torii and JT will jointly develop JTE-052 in Japan, with Torii commercializing it once the development and necessary approval procedures have been completed.

Torii and JT continue efforts to improve commercial value in JTE-052 by leveraging Torii's significant experience in the Japanese dermatology area.