FDA approves second drug to prevent HIV infection

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January 2020—The FDA approved Descovy (emtricitabine 200 mg and tenofovir alafenamide 25 mg) in at-risk adults and adolescents weighing at least 35 kg (approximately 77 lbs.) for HIV-1 pre-exposure prophylaxis to reduce the risk of HIV-1 infection from sex, excluding those who have receptive vaginal sex. (Descovy is not indicated in individuals at risk of HIV-1 infection from receptive vaginal sex, the company reports, because the effectiveness in this population has not been evaluated.)

The safety and efficacy of Descovy for PrEP were evaluated in a randomized, double-blind multinational trial in 5,387 HIV-negative men and transgender women who have sex with men and were at risk of HIV-1 infection. The trial compared once daily Descovy with Truvada (emtricitabine, tenofovir disoproxil fumarate, 200 mg/300 mg), a daily fixed-dose combination of two drugs approved in 2012 to prevent the sexual acquisition of HIV; participants were followed for 48 to 96 weeks. The primary endpoint was the rate of HIV-1 infection in each group. The trial showed that Descovy was similar to Truvada in reducing the risk of acquiring HIV-1 infection.

The FDA granted the approval of Descovy to Gilead Sciences.

Gilead Sciences, 650-574-3000