

## Merck bags USFDA approval for 2 new HIV drugs

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Merck recently bagged the U.S. Food and Drug Administration (FDA) approval for two new HIV-1 medicines: DELSTRIGO, a once-daily fixed-dose combination tablet of doravirine (100 mg), lamivudine (3TC, 300 mg) and tenofovir disoproxil fumarate (TDF, 300 mg); and PIFELTRO (doravirine, 100 mg), a new non-nucleoside reverse transcriptase inhibitor (NNRTI) to be administered in combination with other antiretroviral medicines.

Both DELSTRIGO and PIFELTRO are indicated for the treatment of HIV-1 infection in adult patients with no prior antiretroviral treatment experience, and are administered orally once daily with or without food. DELSTRIGO contains a boxed warning regarding post-treatment acute exacerbation of hepatitis B (HBV) infection. DELSTRIGO and PIFELTRO do not cure HIV-1 infection or AIDS. DELSTRIGO and PIFELTRO are contraindicated when co-administered with drugs that are strong cytochrome P450 (CYP)3A enzyme inducers as significant decreases in doravirine plasma concentrations may occur, which may decrease the effectiveness of DELSTRIGO and PIFELTRO.

“As part of Merck’s 30-year commitment to the care of people with HIV, we are pleased to now bring forward these two new antiretroviral treatment options, DELSTRIGO and PIFELTRO, which we believe offer a compelling clinical profile for clinicians and people living with HIV,” said Dr. George Hanna, vice president and therapeutic area head of infectious diseases, Global Clinical Development, Merck Research Laboratories. “We are thankful to the researchers as well as those living with HIV and their communities for the collaboration that made today’s approval possible.”

Since the beginning of the epidemic, more than 70 million people have been infected with the HIV virus and about 35 million people have died of HIV. Globally, 36.9 million [31.1–43.9 million] people were living with HIV at the end of 2017. An estimated 0.8% [0.6-0.9%] of adults aged 15–49 years worldwide are living with HIV, although the burden of the epidemic continues to vary considerably between countries and regions. The WHO African region remains most severely affected, with nearly 1 in every 25 adults (4.1%) living with HIV and accounting for nearly two-thirds of the people living with HIV worldwide