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Merck’s PIFELTRO™ and DELSTRIGO™ get FDA permission to treat HIV-1

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Approvals based on findings from the Phase 3 DRIVE-SHIFT Trial evaluating a switch to DELSTRIGO

Merck has announced that the U.S. Food and Drug Administration (FDA) approved supplemental New Drug Applications (sNDAs) for PIFELTRO™ (in combination with other antiretroviral agents) and DELSTRIGO™ (as a complete regimen) that expand their indications to include adult patients with HIV-1 infection who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen with no history of treatment failure and no known substitutions associated with resistance to PIFELTRO or the individual components of DELSTRIGO.

PIFELTRO (doravirine, 100 mg) is a non-nucleoside reverse transcriptase inhibitor (NNRTI) to be administered in combination with other antiretroviral agents. DELSTRIGO is a once-daily fixed-dose combination tablet of doravirine (100 mg), lamivudine (3TC, 300 mg) and tenofovir disoproxil fumarate (TDF, 300 mg). DELSTRIGO contains a boxed warning regarding post-treatment acute exacerbation of hepatitis B virus (HBV) infection. DELSTRIGO and PIFELTRO do not cure HIV-1 infection or AIDS. PIFELTRO and DELSTRIGO were approved in the United States on August 30, 2018 for the treatment of HIV-1 infection in adults with no prior antiretroviral treatment history.

“Thanks to developments in HIV science, more treatment options are becoming available to address the medical needs of people living with HIV,” said Dr. Princy Kumar, Chief, Division of Infectious Diseases and Tropical Medicine at MedStar Georgetown University Hospital and Professor of Medicine and Microbiology, Georgetown University School of Medicine, Washington, D.C. “The expanded indications offer certain people with HIV-1 infection, and their doctors, the choice to switch their current antiretroviral therapy to DELSTRIGO or PIFELTRO in combination with other antiretroviral agents.”

“Today’s approvals provide doravirine treatment options for people living with HIV-1 who are virally suppressed, reflecting Merck’s continued commitment to research and development of HIV treatments,” 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 and HIV community for their collaboration that made this possible.”