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Merck receives EC approval for HIV drugs

29 November 2018 | News

The approval allows for marketing of DELSTRIGO and PIFELTRO in all 28 European Union member states.

Merck, known as MSD outside the United States and Canada, has announced that the European Commission (EC) has approved DELSTRIGO and PIFELTRO for the treatment of HIV-1 infection.

DELSTRIGO is a new once-daily fixed-dose combination tablet of doravirine (100 mg), lamivudine (3TC, 300 mg) and tenofovir disoproxil fumarate (TDF, 300 mg). It is indicated in the European Union for the treatment of adults with HIV-1 infection without past or present evidence of resistance to the non-nucleoside reverse transcriptase inhibitor (NNRTI) class of antiviral agents, lamivudine or tenofovir.

PIFELTRO (doravirine, 100 mg) is a new, once-daily NNRTI indicated (in the EU) in combination with other antiretroviral medicines for the treatment of adults with HIV-1 infection without past or present evidence of resistance to the NNRTI class.

The approval allows for marketing of DELSTRIGO and PIFELTRO in all 28 European Union member states, plus Iceland, Lichtenstein and Norway, and follows a positive opinion from the Committee for Medicinal Products for Human Use of the European Medicines Agency announced on Sept. 20, 2018.

Marketing authorization applications for DELSTRIGO and PIFELTRO are also under review in other countries, including Australia and Switzerland. The U.S. Food and Drug Administration approved DELSTRIGO and PIFELTRO on Aug. 30, 2018. Health Canada approved PIFELTRO on Oct. 12, 2018 and DELSTRIGO on Nov. 9, 2018. Availability for DELSTRIGO and PIFELTRO in the EU is anticipated to begin in the first half of 2019.