Merck Files With FDA for Expanded Approval of Pifeltro and Delstrigo

An OK would add an indication for the use of these HIV medications among those switching from stable regimens.

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The Food and Drug Administration (FDA) has accepted a supplemental new drug application from Merck for an expanded indication for the antiretroviral (ARV) Pifeltro (doravirine) and the single-tablet ARV regimen Delstrigo (doravirine/lamivudine/tenofovir disoproxil fumarate). The tablets were approved in August among those starting HIV treatment for the first time. (Pifeltro must be used in combination with other ARVs.) Merck seeks approval for the medications' use among those switching from other ARV regimens provided they have a fully suppressed viral load (below 50).

The new application is based on the results of the Phase III DRIVE-SHIFT trial, which were presented at the IDWeek 2018 conference in San Francisco. The study found that the proportion of participants who switched to Delstrigo and achieved viral suppression at the 48-week mark was comparable to the proportion who achieved viral suppression at the 24-week mark while continuing to take a baseline regimen of two nucleoside/nucleotide reverse transcriptase inhibitors (NRTIs) plus a boosted protease inhibitor, boosted Vitekta (elvitegravir) or a non-nucleoside reverse transcriptase inhibitor (NNRTI).

To read a Merck press release about the new FDA application, click here.
