FDA OKs Odefsey, New Take on Complera

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The U.S. Food and Drug Administration (FDA) has approved the single-tablet antiretroviral regimen Odefsey (emtricitabine/rilpivirine/tenofovir alafenamide), which includes a new, safer version of tenofovir. Pronounced “oh-DEF-see,” the tablet is an updated version of Complera (rilpivirine/tenofovir disoproxil fumarate/emtricitabine) that swaps the new tenofovir alafenamide, or TAF, for the older tenofovir disoproxil fumarate, or TDF.

Research has shown that TAF is safer for the bones and kidneys than TDF and suppresses HIV just as well. TAF more efficiently enters cells, requiring a dose one tenth that of TDF, and leads to 90 percent less drug in the bloodstream, where it may cause harm.

Odefsey is approved for HIV-positive individuals ages 12 and up who have never been treated for the virus and have a viral load of 100,000 or lower. The tablet is also approved as a replacement for a stable antiretroviral (ARV) regimen among those who have never failed an HIV treatment and who have never had to swap meds because of resistance to any of the three drugs included in Odefsey.

Anthony Mills, MD, is the medical director of Southern California Men’s Medical Group in West Hollywood and conducted research on Odefsey. Pointing to the fact that the treatment is the smallest approved single-tablet HIV regimen, he remarks, “Single-tablet regimens are great but not when they are so large that they are difficult to swallow.”

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