FDA Approves New Single-Tablet HIV Regimen, Triumeq

August 25, 2014

The U.S. Food and Drug Administration (FDA) has approved Triumeq, ViiV Healthcare's single-tablet, triple-combination antiretroviral (ARV) regimen, as a first-line therapy to treat HIV. The tablet is comprised of the integrase inhibitor Tivicay (dolutegravir) plus Epzicom (abacavir and lamivudine) and is the first single-tablet regimen to receive approval that does not contain Truvada (tenofovir/emtricitabine). Consequently, Triumeq is an option for those who have impaired kidney function.

Before starting on the drug, people with HIV should receive the HLA-B*5701 genetic screen, otherwise known as the abacavir hypersensitivity reaction test, which determines if someone is likely to develop a kind of allergic reaction to the abacavir component.

The FDA approved Triumeq based on the results from various randomized controlled trials in treatment-native people with HIV, including: SINGLE, which tested the drug against Atripla (efavirenz/tenofovir/emtricitabine); SPRING-2, which put Tivicay up against Isentress (raltegravir); and FLAMINGO, in which dolutegravir bested Prezista (ritonavir-boosted darunavir).

Triumeq alone is not recommended for people with known HIV resistance to abacavir, lamivudine or any of the approved integrase inhibitors.

"Today's approval of Triumeq offers many people living with HIV in the U.S. the first single-pill regimen containing dolutegravir," Dominique Limet, MD, chief executive officer of ViiV Healthcare, said in a release. "ViiV Healthcare is committed to delivering advances in care and new treatment options to physicians and people living with HIV. We are proud to announce this important milestone, marking the second new treatment to be approved in the U.S. from our pipeline of medicines."

To read the press release, click here. For more detailed information, click here.

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http://beta.docker.poz.com/article/ViiV-Triumeq-approval-26067-7653