FDA Approves Janssen's Symtuza for HIV Treatment

The single-tablet antiretroviral regimen includes Janssen's darunavir plus Gilead's cobicistat, emtricitabine and tenofovir alafenamide.

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The Food and Drug Administration (FDA) has approved Janssen's single-tablet regimen for the treatment of HIV in adults, Symtuza (darunavir/cobicistat/emtricitabine/tenofovir alafenamide). The tablet is approved for people who are starting antiretroviral (ARV) treatment for the first time as well as certain people who are switching from another HIV regimen and have a fully suppressed virus.

Research indicates that the darunavir component (which Janssen markets as a stand-alone tablet under the brand name Prezista) is associated with a low likelihood of HIV developing resistance to the drug as well as a high likelihood that the drug will continue to work well in combating the virus over the long term.

U.S. treatment guidelines recommended Symtuza for certain HIV treatment first-timers, including those who may be at risk for not adhering well to the daily regimen and those for whom it becomes necessary to begin HIV treatment before the results from ARV drug resistance tests are available.

Studies indicate that Gilead Sciences' tenofovir alafenamide (TAF), a component of Symtuza, is associated with improved indicators of kidney function and bone mineral density compared with the company's older version of tenofovir (tenofovir disoproxil fumarate, or TDF). However, researchers have recently argued that these comparative benefits of TAF versus TDF are limited to those who take either version of tenofovir with what is known as a boosting agent, either Tybost (cobicistat), which is included in Symtuza, or Norvir (ritonavir). When TAF and TDF are given without a boosting agent, there is no apparent major safety advantage to the newer version of tenofovir.

Gilead also manufactures the emtricitabine component of Symtuza, which as an individual tablet is known by the brand name Emtriva.

Symtuza has a boxed warning regarding the risk of post-treatment acute exacerbation of hepatitis B virus (HBV). Before beginning the HIV regimen, people should receive HBV testing as well as

kidney function screening. While on Symtuza, individuals should receive routine kidney function monitoring as is clinically appropriate.

The FDA approved Symtuza based on the results from two pivotal 48-week noninferiority Phase III studies that tested the safety and efficacy of the single-tablet regimen compared with a control regimen among those starting ARVs for the first time (in the AMBER study) and among people with full viral suppression thanks to another HIV regimen (in the EMERALD study).

In both studies, Symtuza was effective and well tolerated. Up to 95 percent of participants were virally suppressed at week 48, and those who received the TAF-inclusive Symtuza posted improved bone mineral density and kidney function test results over those who received TDF-inclusive control regimens. However, according to Janssen, the long-term significance of these improved test results are unknown. In other words, it is unclear whether TAF-inclusive regimens will actually prevent specific clinical outcomes compared with TDF-inclusive regimens, including bone fractures and diagnoses of chronic kidney disease.

To read a press release about the FDA approval, click here.

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