FDA Approves Janssen’s Symtuza

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

Research indicates that the darunavir component (known as Prezista as an individual tablet) 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 recommend Symtuza for certain first-timers to HIV treatment, including those who may be at risk for not adhering well to the daily regimen and those for whom it is necessary to begin HIV treatment before the results from ARV drug resistance tests are available.

“Symtuza (D/C/F/TAF) is a game changer,” says Anthony Mills, MD, CEO of the Southern California Men’s Medical Group in Los Angeles. “Now we have a single-tablet formulation that will allow us to harness the strength and durability of a boosted protease regimen without compromising ease of use. Providers know and trust the regimen, and the simplicity of one pill once a day makes it a great option for patients.”

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