FDA Approves HIV Combo Pill Prezcobix (Darunavir/Cobicistat)

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The U.S. Food and Drug Administration (FDA) has approved the combination tablet Prezcobix (darunavir/cobicistat) to treat HIV in combination with other antiretrovirals (ARVs) among both treatment-naive and treatment-experienced people who do not have resistance to darunavir. Janssen manufactures the protease inhibitor darunavir, which is marketed under the brand name Prezista as an individual ARV. Gilead Sciences manufactures the CYP3A4 inhibitor cobicistat (brand name Tybost), which, like AbbVie's Norvir (ritonavir), acts as a "boosting" agent, raising the drug levels of other ARVs.

"Additional options remain an important medical priority to meet the diverse needs of those living with and managing this disease," Karen Tashima, MD, a professor of medicine in the division of infectious diseases at Brown University, who was a lead investigator in the GS-US-216-0130 study that led to Prezcobix's approval, said in a press release. "This approval gives physicians the option of a darunavir-based fixed-dose combination tablet to treat adults living with the HIV-1 infection, which can help reduce the number of pills in their overall treatment regimen."

The FDA based its approval on data finding that using Prezcobix was equivalent to taking darunavir and cobicistat separately, and on another study that tested the safety of the combination tablet among those whose virus had no resistance mutations to darunavir.

Research showed that drug levels of darunavir were similar whether the drug was boosted with ritonavir or darunavir.

The GS-US-216-0130 study gave darunavir and cobicistat as individual tablets to 313 HIV-positive participants. After 24 weeks of treatment, the participants did not have substantially different adverse reactions to the combination when compared with people who took darunavir and ritonavir in other trials.

"Treating HIV remains an urgent healthcare need, and it's important for adults living with HIV to have regular discussions with a healthcare provider about treatment options that are right for them," Richard Nettles, MD, vice president of medical affairs at Janssen, said in the same press release.

To read the press release, click here.

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