FDA Approves Evotaz (Atazanavir/Cobicistat) to Treat HIV

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The U.S. Food and Drug Administration (FDA) has approved the combination tablet Evotaz (atazanavir/cobicistat) to be used in combination with other antiretrovirals (ARVs) to treat HIV-1 in adults. Bristol-Myers Squibb (BMS) manufactures the protease inhibitor (PI) atazanavir (manufactured under the brand name Reyataz as an individual ARV). Gilead Sciences manufactures the CYP3A4 inhibitor cobicistat (brand name Tybost), which, like Norvir (ritonavir), acts as a "boosting" agent, raising the drug levels of other ARVs.

"Evotaz increases the possibility of providing HIV suppression by combining reduced pill burden with a low rate of virologic failure and zero protease inhibitor mutations," Murdo Gordon, head of worldwide markets at BMS, said in a press release.

Evotaz is the only protease inhibitor on the market that is boosted by cobicistat and backed up by Phase III data. (Prezcobix, which contains the PI darunavir boosted by cobicistat, was also just approved by the FDA, but lacks the Phase III data distinction.) The randomized, double-blind clinical trial included 692 participants, all of whom took Truvada (tenofovir/emtricitabine); 344 also took atazanavir and cobicistat (the components of Evotaz) and 348 also took atazanavir and ritonavir. After 48 weeks of treatment, 85 percent of those taking the drugs in Evotaz reached a fully suppressed viral load, compared with 87 percent in the other arm of the study. Six percent of the participants in the Evotaz arm and 4 percent of those in the atazanavir/ritonavir arm experienced virologic failure. Evotaz is the only cobicistat-boosted PI to have such a low virologic failure rate.

None of the participants developed resistance to PIs. The safety profiles in the two arms of the study were comparable. The most common side effects in the Evotaz arm and atazanavir/ritonavir were rash (a respective 5 percent and 4 percent), jaundice (5 percent, 3 percent), jaundice of the whites of the eyes (3 percent, 1 percent), nausea (2 percent for both). Seven percent of participants in both arms discontinued because of adverse side effects.

To read the press release, click here.

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