FDA Approves New HIV Drug: Edurant (Rilpivirine)

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The U.S. Food and Drug Administration (FDA) has approved a new HIV-fighting non-nucleoside reverse transcriptase inhibitor (NNRTI) called Edurant (rilpivirine). The drug was approved for use as part of a complete treatment regimen for people who haven't taken antiretroviral (ARV) drugs before.

"Patients may respond differently to various HIV drugs or experience varied side effects. FDA's approval of Edurant provides an additional treatment option for patients who are starting HIV therapy," said Edward Cox, MD, MPH, director of the Office of Antimicrobial Products in the FDA's Center for Drug Evaluation and Research.

In a study comparing Edurant to another NNRTI—Sustiva (efavirenz)—researchers found that the two drugs were quite similar, with both resulting in undetectable HIV levels after 48 weeks for about 80 percent of those who took the drugs. The FDA noted in its approval announcement, however, that people with high viral loads were more likely to fail Edurant than those taking Sustiva. Also, when people failed treatment, those taking Edurant were more likely to develop resistance to the drugs in their regimen than those taking Sustiva.

Though the most common side effects were similar to those experienced with Sustiva—depression, difficulty sleeping, headaches and rash—people taking Edurant generally had fewer side effects than those on Sustiva.

Edurant's maker, Tibotec Therapeutics—a division of Centocor Ortho Biotech Inc.—is also partnering with Gilead Sciences to develop a single pill combining Edurant with Gilead's Truvada (tenofovir plus emtricitabine). Approval of that combination pill is expected within the year.

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