Vitekta Gets FDA Approval

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The U.S. Food and Drug Administration (FDA) has approved Gilead Sciences' integrase strand transfer inhibitor Vitekta (elvitegravir) for HIV-positive adults who have taken antiretrovirals before. The drug should be used in combination with a Norvir (ritonavir)–boosted protease inhibitor, plus one or more other antiretrovirals (ARVs). It should be taken with food.

The approval was based on results from a Phase III study in which 712 people who had previously taken other ARVs were given either Vitekta or Isentress (raltegravir), each of which was combined with a Norvir–boosted protease inhibitor to which the individual did not have drug resistance, plus one or more other ARVs. Throughout 96 weeks of treatment, outcomes were similar between the two groups. The average jump in CD4 cells after 96 weeks was 205 among those taking Vitekta and 198 among those on Isentress.

Stating that this approval "expands the repertoire of the integrase class that can be dosed once or twice daily," Antonio Urbina, MD, an HIV specialist at the Spencer Cox Center for Health in New York City, reminds clinicians that they "will need to factor in drug-drug interactions when prescribing this medication to assure adequate drug levels."

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