Isentress Gets Full FDA Approval for Experienced Patients

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The U.S. Food and Drug Administration (FDA) has granted full traditional approval to the integrase inhibitor Isentress (raltegravir) for treatment-experienced people living with HIV, according to a February 5 announcement by the agency.

Isentress works by keeping strands of viral DNA from integrating into the DNA of CD4 cells, thus stopping the cells from being able to produce new virus particles. In 2007, it received accelerated approval for HIV-positive adults who had failed other HIV treatments; that decision was based on 24 weeks of data from Phase 3 studies.

Full traditional approval was based on an FDA review of 48-week data from the same Phase 3 studies showing that Isentress worked well in combination with other antiretrovirals against drug-resistant HIV. Merck & Co., the drug's maker, is currently testing Isentress in HIV-positive people starting therapy for the first time.