Isentress Gets FDA Approval for Treatment Newbies

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Merck & Co. yesterday received approval by the U.S. Food and Drug Administration (FDA) to market its integrase inhibitor, Isentress (raltegravir), for people who have never taken HIV treatment. Isentress was previously approved only to treat people who have used and become resistant to other antiretroviral therapies.

The approval was based on 48 week data from the STARTMRK study comparing Isentress and Truvada (tenofovir plus emtricitabine) with Sustiva (efavirenz) and Truvada. The Isentress dose was 400 mg twice daily. In that study, 87 percent of those taking Isentress had an undetectable viral load after 48 weeks of treatment compared with 82 percent of those taking Sustiva. Isentress was therefore judged to have equivalent effectiveness to Sustiva.

Side effects from Isentress in the study were generally mild, including headache and nausea, but there were significantly fewer central nervous system side effects in people taking Isentress than in people taking Sustiva.

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