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FDA approves new labeling for Merck's HIV drug

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Singapore: Merck has received US FDA nod for new labeling for Isentress (raltegravir) film-coated tablets, Merck's integrase inhibitor for the treatment of HIV-1 infection in adult patients as part of combination HIV therapy.

The updated prescribing information now includes 240-week results from the Startmrk study, which is the longest double-blind phase III non-inferiority study evaluating an integrase inhibitor in treatment-naÃ¯ve adult patients with HIV-1 infection.

The results show that the regimen containing Isentress in combination therapy demonstrated long-term viral suppression and a greater immunologic response than the efavirenz-containing regimen, as well as a proven, long-term safety and tolerability profile through 240 weeks in previously untreated (treatment-naÃ¯ve) adult HIV-1 infected patients.

Isentress is an integrase inhibitor indicated in combination with other antiretroviral (ARV) agents for the treatment of HIV-1 infection in adults. This indication is based on analyses of plasma HIV-1 RNA levels in three double-blind controlled studies of Isentress.

Two of these studies were conducted in clinically advanced, three-class ARV [non-nucleoside reverse transcriptase inhibitor (NNRTI), nucleoside reverse transcriptase inhibitor (NRTI), protease inhibitor (PI)] treatment-experienced adult patients through 96 weeks and one was conducted in treatment-naÃ¯ve adults through 240 weeks.