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# FDA green signal for joint GSK-Pfizer HIV drug

13 August 2013 | News | By BioSpectrum Bureau

**Singapore:** The US FDA has approved GSK and Pfizer-owned HIV dedicated firm, ViiV Healthcare's, Tivicay (dolutegravir) 50-mg tablets. Tivicay is an integrase inhibitor indicated for use in combination with other antiretroviral agents for the treatment of HIV-1 in adults and children aged 12 years and older.

"Today is a very important milestone for patients and the scientists and teams who developed Tivicay and brought it to this point of FDA approval. I am very proud that we are serving people living with HIV with a much-needed new treatment option. Today's approval shows that our singular focus on HIV can deliver important new medicines, maintaining our absolute commitment to the HIV/AIDS global response," said Dr Dominique Limet, CEO, ViiV Healthcare.

The submission included data from four pivotal phase III clinical trials that treated 2,557 adults (who received at least one dose of study medication) with HIV across the treatment spectrum; it also included data in children aged 12 years and older. Tivicay was used without a pharmacokinetic boosting agent.

"In many regimens, the differentiating component is the third agent. Tivicay provides a new opportunity for healthcare professionals to choose the right regimen for their patients, providing a focal point around which to individualise therapy," said Dr John Pottage, chief medical officer, ViiV Healthcare. "HIV treatment should not be a 'one-size fits all' paradigm."