RXADVANCE
2 Park Central Drive
Southborough, MA 01772

# Dovato (dolutegravir and lamivudine) Tablets
# Clinical Update

Clinical Update: FDA Approval of an Expanded Indication for Dovato (dolutegravir/lamivudine), a Complete Two-Drug Regimen for Virologically Suppressed Adults with HIV-1.
FDA approval date: August 06, 2020

Dolutegravir is an integrase strand transfer inhibitor (INSTI) for use in combination with other antiretroviral agents for the treatment of HIV-1. INSTIs block HIV replication by preventing the viral DNA from integrating into the genetic material of human immune cells (T-cells). This step is essential in the HIV replication cycle and is also responsible for establishing chronic infection. Lamivudine, commonly known as 3TC, is a nucleoside analogue used in combination with other antiretroviral agents for the treatment of HIV-1 infection.

Dolutegravir plus lamivudine (Dovato) is a complete, once-daily, single-tablet regimen to treat HIV-1 infection in adults with no antiretroviral (ARV) treatment history or to replace the current ARV regimen in those who are virologically suppressed (HIV-1 RN <50 copies/mL) on a stable ARV regimen with no known history of treatment failure and no known resistance to any component of Dovato. Lamivudine is available in branded and generic forms. Trademarks are owned by or licensed to the ViiV Healthcare group of companies.

TANGO (NCT03446573) is a phase III, randomized, open-labelled, active-controlled, multicentred study to assess the antiviral efficacy and safety of switching to a two-drug regimen consisting of DTG/3TC in HIV-infected adults who are virologically suppressed and on a stable antiretroviral regimen with no treatment failure.

Study participants were HIV-1 infected adults on a TAF-containing regimen who were virologically suppressed (HIV-1 RN <50 copies/mL) for at least 6 months, without prior virologic failure, no historical nucleoside reverse transcriptase inhibitors (NRTI) or integrase strand transfer inhibitor (INSTI) major resistance mutation, and no evidence of hepatitis B infection. Participants were randomized to switch to DTG/3TC or continue the TAF-containing regimen through Week 148. The primary endpoint was the proportion of participants with a viral load of >50 copies/mL at Week 48 (FDA Snapshot algorithm) for the Intention to Treat-Exposed (ITT-E) population.

Primarily, no participants on Dovato and one participant (<1%) on the TAF-containing regimen met confirmed virologic failure criteria, with no resistance mutations observed at failure.