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ViiV Healthcare’s Dovato gets USFDA nod to treat HIV-1

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Dovato strengthens ViiV Healthcare’s industry-leading portfolio of innovative treatment approaches for peopleliving with HIV

ViiV Healthcare, a subsidiary of GSK announced that the US Food and Drug Administration (FDA) approved Dovato, a complete, once-daily, single-tablet regimen of dolutegravir (DTG) 50 mg and lamivudine (3TC) 300 mg for the treatment of HIV-1 infection in adults with no antiretroviral (ARV) treatment history and with no known resistance to either DTG or 3TC. Dovato, a two-drug regimen (2DR), reduces exposure to the number of ARVs from the start of treatment, while still maintaining the efficacy and high barrier to resistance of a traditional DTG-based three-drug regimen.

Deborah Waterhouse, CEO, ViiV Healthcare, said: “Building on our innovative portfolio of medicines, Dovato is powered by dolutegravir, an antiretroviral included in multiple combination therapies and the most prescribed integrase inhibitor in the world, coupled with the established profile of lamivudine. With Dovato, the first complete, single-tablet, two-drug regimen for treatment-naïve adults, ViiV Healthcare is delivering what patients are requesting—a chance to treat their HIV-1 infection with as few drugs as possible, marking a significant step in HIV treatment.”

Approval based on GEMINI pivotal trials in which Dovato achieved non-inferior efficacy compared to a dolutegravir-based, traditional, three-drug regimen through 48 weeks, with no cases of resistance.