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GSK gets EU marketing nod for its HIV drug

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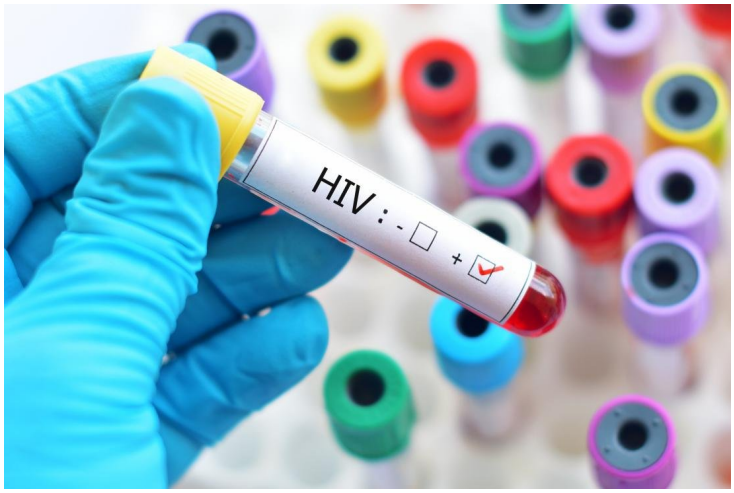
Authorisation based on GEMINI pivotal trials in which Dovato achieved non-inferior efficacy compared to a dolutegravir-based, three-drug regimen through 48 weeks, with no cases of resistance



ViiV Healthcare, the global specialist HIV company, majority owned by GlaxoSmithKline, with Pfizer Inc. and Shionogi Limited as shareholders, have announced that the European Commission has granted Marketing Authorisation for Dovato (dolutegravir/lamivudine) for the treatment of HIV-1 infection in adults and adolescents above 12 years of age weighing at least 40 kg, with no known or suspected resistance to the integrase inhibitor class, or lamivudine.

Deborah Waterhouse, CEO, ViiV Healthcare, said: “For many years, the standard of care for treatment-naïve people living with HIV in Europe has been a three-drug regimen. The data from our dolutegravir-based two-drug regimen development programme challenges this, and with the authorisation of Dovato, people living with HIV can for the first time start treatment on a once-daily, single-pill, two-drug regimen with the knowledge that efficacy is non-inferior to a three-drug regimen whilst containing fewer antiretrovirals. Dovato strengthens ViiV Healthcare’s industry-leading portfolio of innovative treatment approaches for people living with HIV.”

With around 25,000 new HIV diagnoses in Europe every year, and the fact that today HIV is considered a chronic condition which requires people living with HIV (PLHIV) to remain on antiretroviral (ARV) treatment for life, it is ever more important to provide innovative treatment options.

Marketing Authorisation for Dovato is supported by data from the landmark global GEMINI 1 and 2 studies that included more than 1,400 HIV-1 infected adults. In these studies, dolutegravir and lamivudine demonstrated non-inferior efficacy based on plasma HIV-1 RNA <50 copies per millilitre (c/mL), a standard measure of HIV control, at week 48 when compared to a three-drug regimen of dolutegravir and two nucleoside reverse transcriptase inhibitors (NRTIs), tenofovir disoproxil fumarate/emtricitabine (TDF/FTC), in treatment-naïve, HIV-1 infected adults.

The safety results for dolutegravir and lamivudine seen in GEMINI 1 and 2 were consistent with the product labelling for dolutegravir and lamivudine. Four patients (1%) in both the dolutegravir and lamivudine, and the dolutegravir and TDF/FTC, study arms experienced drug-related serious adverse events, and 15 patients (2%) in the dolutegravir and lamivudine arm

and 16 patients (2%) in the dolutegravir and TDF/FTC arm had adverse events that led to discontinuation. The most common adverse reactions included headache, diarrhoea, nausea, insomnia, and fatigue. No patient who experienced virologic failure in either treatment arm developed treatment-emergent resistance also up to week 48.