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ViiV Healthcare announces U.S. FDA approval of Dovato (dolutegravir/lamivudine) for adolescents living with HIV

- Dovato is now the first and only oral, two-drug, single-tablet regimen available for people aged 12 and older living with HIV, a population in need of additional treatment options

GSK plc (LSE/NYSE: GSK) announced that ViiV Healthcare, the global specialist HIV company majority owned by GSK, with Pfizer and Shionogi as shareholders, today announced the U.S. Food and Drug Administration (FDA) approved *Dovato* (dolutegravir/lamivudine) for the treatment of HIV-1 infection in adolescents 12 years of age and older and weighing at least 25 kg with no antiretroviral (ARV) treatment history or to replace the current ARV regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies/mL) on a stable ARV regimen with no history of treatment failure and no known substitutions associated with resistance to the individual components of *Dovato*.¹

In the U.S., 20 percent of new HIV diagnoses in 2020 were among young people aged 13-24.² This expanded indication marks the first time an oral, two-drug, single-tablet regimen is available for adolescents between 12- and 18-years old living with HIV and underscores ViiV Healthcare's ongoing commitment to bringing more therapeutic options to young people.

Lynn Baxter, Head of North America at ViiV Healthcare, said: "This expanded indication for *Dovato* brings an oral, two-drug, single-tablet regimen to adolescents living with HIV, providing a complete HIV therapy with fewer ARV medicines – an important consideration for young people who will require lifelong treatment. As a leader in HIV, ViiV Healthcare is proud of our focused efforts to improve and expand care for children and adolescents and we remain committed to addressing the existing treatment gaps in these communities."

The approval is supported by data from the DANCE study which evaluated *Dovato* in treatment-naïve adolescents as well as evidence from well-controlled trials in adults living with HIV, GEMINI-1 and GEMINI-2 (treatment-naïve adults) and TANGO (treatment-experienced adults).¹ Results from the DANCE study, which included adolescents between 12- and 18-years old weighing at least 25 kg with HIV-1 RNA 1000 to \leq 500,000 c/mL, showed that 26/30 participants achieved and maintained viral suppression at Week 48.¹ The safety and efficacy data in adolescents from the DANCE study were comparable to those observed in adults.¹ Exposures for components of *Dovato* were higher but were not clinically significant.¹

About *Dovato* (dolutegravir/lamivudine)^{1,3}

Dovato is a once-daily, oral, two-drug, single-tablet regimen that combines the integrase strand transfer inhibitor (INSTI) dolutegravir (50 mg) with the nucleoside reverse transcriptase inhibitor (NRTI) lamivudine (300 mg).

Dovato contains two medicines to inhibit the viral life cycle at two different sites. INSTIs, like dolutegravir inhibit HIV integrase by binding to the integrase active site and blocking the strand transfer step of retroviral DNA integration which is essential for the HIV replication cycle. The principal mode of action of lamivudine, an NRTI, is inhibition of reverse transcriptase via DNA chain termination.

Dovato is approved in the U.S., Europe, Japan, Australia and other countries worldwide.



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About the DANCE Study

DANCE ([NCT03682848](#)) is an ongoing phase 3b, single-arm, multicenter, open-label study evaluating once-daily, fixed-dose combination of Dovato (50 mg/300 mg) as initial ARV therapy for adolescents aged ≥ 12 to < 18 years and weighing ≥ 25 kg, with HIV-1 RNA 1000 to $\leq 500,000$ c/mL. The primary endpoint assessed proportions achieving HIV-1 RNA < 50 c/mL at Week 48. A total of 32 participants were enrolled across nine centers from Thailand, Kenya, and South Africa.¹

DOVATO (dolutegravir and lamivudine) tablets

INDICATION

DOVATO is indicated as a complete regimen for the treatment of HIV-1 infection in adults and adolescents 12 years of age and older and weighing at least 25 kg with no antiretroviral treatment history or to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies/mL) on a stable antiretroviral regimen with no history of treatment failure and no known substitutions associated with resistance to the individual components of DOVATO.

IMPORTANT SAFETY INFORMATION

BOXED WARNING: PATIENTS CO-INFECTED WITH HEPATITIS B VIRUS (HBV) AND HIV-1: EMERGENCE OF LAMIVUDINE-RESISTANT HBV AND EXACERBATIONS OF HBV

All patients with HIV-1 should be tested for the presence of HBV prior to or when initiating DOVATO. Emergence of lamivudine-resistant HBV variants associated with lamivudine-containing antiretroviral regimens has been reported. If DOVATO is used in patients co-infected with HIV-1 and HBV, additional treatment should be considered for appropriate treatment of chronic HBV; otherwise, consider an alternative regimen.

Severe acute exacerbations of HBV have been reported in patients who are co-infected with HIV-1 and HBV and have discontinued lamivudine, a component of DOVATO. Closely monitor hepatic function in these patients and, if appropriate, initiate anti-HBV treatment.

Contraindications

- Do not use DOVATO in patients with previous hypersensitivity reaction to dolutegravir or lamivudine
- Do not use DOVATO in patients receiving dofetilide

Warnings and precautions

Hypersensitivity Reactions:

- Hypersensitivity reactions have been reported with dolutegravir and were characterized by rash, constitutional findings, and sometimes organ dysfunction, including liver injury
- Discontinue DOVATO immediately if signs or symptoms of severe skin or hypersensitivity reactions develop, as a delay in stopping treatment may result in a life-threatening reaction. Clinical status, including liver aminotransferases, should be monitored and appropriate therapy initiated

Hepatotoxicity:



- Hepatic adverse events have been reported, including cases of hepatic toxicity (elevated serum liver biochemistries, hepatitis, and acute liver failure), in patients receiving a dolutegravir-containing regimen without pre-existing hepatic disease or other identifiable risk factors
- Patients with underlying hepatitis B or C or marked elevations in transaminases prior to treatment may be at increased risk for worsening or development of transaminase elevations with use of DOVATO. In some cases, the elevations in transaminases were consistent with immune reconstitution syndrome or hepatitis B reactivation, particularly in the setting where anti-hepatitis therapy was withdrawn
- Monitoring for hepatotoxicity is recommended

Embryo Fetal Toxicity:

- Assess the risks and benefits of DOVATO and discuss with the patient to determine if an alternative treatment should be considered at the time of conception through the first trimester of pregnancy due to the risk of neural tube defects
- Pregnancy testing is recommended before initiation of DOVATO. Individuals of childbearing potential should be counseled on the consistent use of effective contraception

Lactic Acidosis and Severe Hepatomegaly With Steatosis:

Fatal cases have been reported with the use of nucleoside analogs, including lamivudine. Discontinue DOVATO if clinical or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity develop, including hepatomegaly and steatosis in the absence of marked transaminase elevations.

Adverse Reactions or Loss of Virologic Response Due to Drug Interactions with concomitant use of DOVATO and other drugs may occur (see Contraindications and Drug interactions).

Immune Reconstitution Syndrome, including the occurrence of autoimmune disorders with variable time to onset, has been reported with the use of DOVATO.

Adverse reactions

The most common adverse reactions (incidence $\geq 2\%$, all grades) with DOVATO were headache (3%), nausea (2%), diarrhea (2%), insomnia (2%), fatigue (2%), and anxiety (2%).

Drug interactions

- Consult full Prescribing Information for DOVATO for more information on potentially significant drug interactions
- DOVATO is a complete regimen. Coadministration with other antiretroviral medications for the treatment of HIV-1 infection is not recommended
- Drugs that induce or inhibit CYP3A or UGT1A1 may affect the plasma concentrations of dolutegravir
- Administer DOVATO 2 hours before or 6 hours after taking polyvalent cation-containing antacids or laxatives, sucralfate, oral supplements containing iron or calcium, or buffered medications. Alternatively, DOVATO and supplements containing calcium or iron can be taken with food

Use in specific populations

- **Pregnancy:** There are insufficient human data on the use of DOVATO during pregnancy to definitively assess a drug-associated risk for birth defects and miscarriage. An Antiretroviral Pregnancy Registry has been established. Advise individuals of childbearing potential of the potential risk of neural tube defects. Assess the risks and benefits of DOVATO and discuss with the patient to determine if an alternative treatment should be considered at the time of conception through the first trimester of pregnancy or if pregnancy is confirmed in the first trimester
- **Lactation:** Breastfeeding is not recommended due to the potential for HIV-1 transmission, developing viral resistance in HIV-positive infants, and adverse reactions in a breastfed infant

Press release

For media and investors only



- **Females and Males of Reproductive Potential:** Pregnancy testing is recommended before initiation of DOVATO. Counsel individuals of childbearing potential taking DOVATO on the consistent use of effective contraception
- **Renal Impairment:** DOVATO is not recommended for patients with creatinine clearance <30 mL/min. Patients with a sustained creatinine clearance between 30 and 49 mL/min should be monitored for hematologic toxicities, which may require a dosage adjustment of lamivudine as an individual component
- **Hepatic Impairment:** DOVATO is not recommended in patients with severe hepatic impairment (Child-Pugh Score C)

About ViiV Healthcare

ViiV Healthcare is a global specialist HIV company established in November 2009 by GSK (LSE: GSK) and Pfizer (NYSE: PFE) dedicated to delivering advances in treatment and care for people living with HIV and for people who are at risk of acquiring HIV. Shionogi became a ViiV shareholder in October 2012. The company's aims are to take a deeper and broader interest in HIV and AIDS than any company has done before and take a new approach to deliver effective and innovative medicines for HIV treatment and prevention, as well as support communities affected by HIV.

For more information on the company, its management, portfolio, pipeline, and commitment, please visit viivhealthcare.com.

About GSK

GSK is a global biopharma company with a purpose to unite science, technology, and talent to get ahead of disease together. Find out more at gsk.com.

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Cautionary statement regarding forward-looking statements

GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Such factors include, but are not limited to, those described under Item 3.D "Risk factors" in the company's Annual Report on Form 20-F for 2023.

Registered in England & Wales:

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References

¹ Dovato US Prescribing Information. Available at: https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Dovato/pdf/DOVATO-PI-PIL.PDF. Accessed April 2024.

² "HIV Information and Youth." Centers for Disease Control and Prevention. https://www.cdc.gov/healthyouth/youth_hiv/hiv-information-and-youth.htm. Accessed April 2024.

³ Dovato EU Summary of Product Characteristics. February 2024. Available at: <https://www.medicines.org.uk/emc/product/10446/smpc>. Accessed April 2024.