

**For media and investors only**

## **PRESS RELEASE**

### **ViiV Healthcare announces data demonstrating the feasibility of Dovato (dolutegravir/lamivudine) as a treatment option for rapid initiation after diagnosis in adults with HIV-1**

*Week 24 data from the single arm Study in Test and Treat (STAT) clinical trial demonstrates the feasibility of Dovato in a rapid Test and Treat model of care in adults with HIV-1, as well as evaluating the efficacy and safety of the regimen<sup>1</sup>*

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**London, 20 August 2020** – ViiV Healthcare, the global specialist HIV company majority owned by GSK, with Pfizer Inc. and Shionogi Limited as shareholders, today announced findings from the STAT study, a phase IIIb, multi-centre, open label, single arm, 48-week study in the United States presented at the American Conference for the Treatment of HIV (ACTHIV) 2020. The study evaluated Dovato (dolutegravir/lamivudine) for rapid initiation of treatment after diagnosis in adults with HIV-1. Dovato was found to be effective and well tolerated in this setting, indicating the feasibility of its use in Test and Treat strategies.<sup>1</sup>

The STAT study followed a rapid Test and Treat model of care increasingly seen in clinical practice, with treatment initiated within 14 days of diagnosis before baseline HBV co-infection status, renal function and resistance test results were available. All study participants were tested for HBV co-infection prior to receiving Dovato, with results available after initiation of treatment. In the study, 92% (n=102/111) of participants with available data\* at 24 weeks, achieved a viral load of <50c/mL.<sup>1</sup> This includes participants who stayed on Dovato and those who switched to alternative ART. Eight participants switched from Dovato to an alternative antiretroviral (ART) regimen; five of the eight due to HBV co-infection and one due to baseline resistance to lamivudine.<sup>1</sup> Data were available for five of these participants and showed that they all achieved a viral load of <50c/mL at 24 weeks, without developing HBV or HIV resistance-associated mutations,<sup>1</sup> indicating that rapid initiation of

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\* Observed analysis, where missing patients were not included in the analysis<sup>1</sup>

Dovato did not compromise outcomes for this subset of participants. 87% (n=97/111) of participants with available data at Week 24 and still taking Dovato\* achieved a viral load of <50c/mL.<sup>1</sup>

**Charlotte-Paige Rolle, MD, MPH, Director of Research Operations at Orlando Immunology Center and principal investigator for the STAT study, said:** “As physicians, we know the potential benefits of starting treatment as quickly as possible to reduce viral load, both to support the individual’s health as well as reduce the likelihood of HIV transmission. Data from the STAT study showed that the use of Dovato in treatment-naïve patients at the time of or soon after diagnosis, including those who were later found to have HBV co-infection or baseline resistance and underwent rapid therapy adjustment, did not adversely impact efficacy or safety outcomes.”

At the start of the study, 8% (n=10) of participants had HIV-1 RNA >1,000,000 c/mL. At week 24, 80% (n=8) of these participants had HIV-1 RNA <50 c/mL.<sup>1</sup>

**Kimberly Smith, MD, MPH, Head of Research & Development at ViiV Healthcare, said:** “The results from the STAT study reinforce the proven efficacy of Dovato and provide further evidence supporting its use in settings where rapid treatment initiation is the standard. The STAT study also shows us that this treatment can be initiated when the baseline HBV co-infection or resistance status is unknown, as appropriate therapy adjustments can be made once results become available without compromising patient safety. These findings represent an important step forward in our understanding of current treatment options that can be rapidly initiated after an HIV diagnosis and confirm the validity of this approach with Dovato.”

At 24 weeks, 11% (n=15) of participants discontinued the study, including 9% (n=12) who were lost to follow-up or withdrew consent and 2% (n=3) due to physician decision. Data were not available at week 24 for 4% (n=5) of participants.<sup>1</sup> The study found that Dovato was well tolerated, with low rates of grade 2-5 drug-related AEs (2%, n=2) and serious AEs (2%, n=2).<sup>1</sup>

#### **About Dovato (dolutegravir/lamivudine)**

Dovato is a once-daily, single-pill, 2-drug regimen (2DR) that combines the integrase strand transfer inhibitor (INI) dolutegravir (Tivicay, 50 mg) with the NRTI lamivudine (Epivir, 300 mg).<sup>2</sup>

\* Observed analysis, where missing patients were not included in the analysis<sup>1</sup>

Dovato (dolutegravir 50 mg/ lamivudine 300 mg tablets) is authorised in the EU 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 INI class, or lamivudine.<sup>2</sup> In the US, the Food and Drug Administration (FDA) approved Dovato, a complete, once-daily, single-tablet regimen of dolutegravir 50 mg and lamivudine 300 mg for the treatment of HIV-1 infection in adults with no ARV treatment history and with no known resistance to either dolutegravir or lamivudine.<sup>3</sup>

Like a dolutegravir-based three-drug regimen, Dovato uses two drugs to inhibit the viral cycle at two different sites. INIs, like dolutegravir, inhibit 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 is an NRTI that works by interfering with the conversion of viral ribonucleic acid (RNA) into deoxyribonucleic acid (DNA) which in turn stops the virus from multiplying.<sup>2</sup>

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#### **About the STAT study (NCT03945981)<sup>1</sup>**

The STAT study is a phase IIIb, multi-centre, open label, single arm, 48-week pilot study in the United States, evaluating the feasibility, efficacy and safety of using Dovato as a first line regimen in a rapid Test and Treat model of care in 131 newly diagnosed HIV-1 infected adults with treatment initiated within 14 days of diagnosis.

The primary analysis was the proportion of all participants who have plasma HIV-1 RNA <50 c/mL regardless of ART regimen. Missing viral load data at week 24, for any reason, is considered failure, with failure representing  $\geq 50$  c/mL (ITT-E missing=failure). A secondary analysis was the proportion of all participants with available data at Week 24 who achieved plasma HIV-1 RNA <50 c/mL, regardless of ART regimen (observed analysis), including those who switched to an alternative ART for any reason, such as baseline HBV co-infection or resistance.

#### **Important Safety Information for Dovato**

The following ISI is based on the Highlights section of the Prescribing Information for Dovato. Please consult the full Prescribing Information for all the labeled safety information for Dovato.

**WARNING: PATIENTS CO-INFECTED WITH HEPATITIS B VIRUS (HBV) AND HUMAN IMMUNODEFICIENCY VIRUS (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

**DOSAGE AND ADMINISTRATION**

- Prior to or when initiating Dovato, test patients for HBV infection.
- Pregnancy Testing: Perform pregnancy testing before initiation of Dovato in individuals of childbearing potential.
- One tablet taken orally once daily with or without food.
- The dolutegravir dose (50 mg) in Dovato is insufficient when coadministered with carbamazepine or rifampin. If Dovato is coadministered with carbamazepine or rifampin, take one tablet of Dovato once daily, followed by an additional dolutegravir 50-mg tablet, approximately 12 hours from the dose of Dovato

**CONTRAINDICATIONS**

- Prior hypersensitivity reaction to dolutegravir or lamivudine.
- Coadministration with dofetilide.

**WARNINGS AND PRECAUTIONS**

- Hypersensitivity reactions characterized by rash, constitutional findings, and sometimes organ dysfunction, including liver injury, have been reported with dolutegravir. Discontinue Dovato immediately if signs or symptoms of hypersensitivity reactions develop, as a delay in stopping treatment may result in a life-threatening reaction.
- Hepatotoxicity has been reported in patients receiving a dolutegravir-containing regimen. Patients with underlying hepatitis B or C may be at increased risk for worsening or development of transaminase elevations with Dovato. Monitoring for hepatotoxicity is recommended.
- Embryo-fetal toxicity may occur when used at the time of conception and in early pregnancy. Avoid use of Dovato at the time of conception through the first trimester of pregnancy due to the risk of neural tube defects. Advise individuals of childbearing potential to use effective contraception.
- Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogues.
- Immune reconstitution syndrome has been reported in patients treated with combination antiretroviral therapy.

**ADVERSE REACTIONS**

The most common adverse reactions (all grades) observed in  $\geq 2\%$  (in those receiving Dovato) were headache, nausea, diarrhea, insomnia, fatigue, and anxiety.

## DRUG INTERACTIONS

- Dovato is a complete regimen for the treatment of HIV-1 infection; therefore, coadministration with other antiretroviral drugs for the treatment of HIV-1 infection is not recommended.
- Refer to the full prescribing information for important drug interactions with Dovato

## USE IN SPECIFIC POPULATIONS

- Pregnancy: An alternative treatment to Dovato should be considered at the time of conception through the first trimester due to the risk of neural tube defects.
- Lactation: Breastfeeding is not recommended due to the potential for HIV-1 transmission.
- Females and males of reproductive potential: Pregnancy testing and contraception are recommended in individuals of childbearing potential.
- Renal Impairment: Dovato is not recommended in patients with creatinine clearance less than 50 mL/min.
- Hepatic Impairment: Dovato is not recommended in patients with severe hepatic impairment (Child-Pugh Score C).

Please refer to the full European Summary of Product Characteristics for [Dovato for full prescribing information](#), including contraindications, special warnings and precautions for use. For the US, please refer to the [US Prescribing Information](#).

## About ViiV Healthcare

ViiV Healthcare is a global specialist HIV company established in November 2009 by GlaxoSmithKline (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 becoming infected with HIV. Shionogi joined in October 2012. The company's aims are to take a deeper and broader interest in HIV/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 [www.viivhealthcare.com](http://www.viivhealthcare.com).

## About GSK

GSK is a science-led global healthcare company with a special purpose: to help people do more, feel better, live longer. For further information please visit [www.gsk.com/about-us](http://www.gsk.com/about-us).

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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 2019 and as set out in GSK's "Principle risks and uncertainties" section of the Q2 Results and any impacts of the COVID-19 pandemic.

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**References**

<sup>1</sup> Rolle CP, Berhe M, Singh T, et al. Feasibility, Efficacy, and Safety of Using Dolutegravir/Lamivudine (DTG/3TC) as a First-Line Regimen in a Test-and-Treat Setting for Newly Diagnosed People Living with HIV (PLWH): the STAT Study. Presented at the American Conference for the Treatment of HIV (ACTHIV) 2020.

<sup>2</sup> Dovato EU Summary of Product Characteristics. July 2019. Available at: <https://www.medicines.org.uk/emc/product/10446/smpc>. Accessed July 2020.

<sup>3</sup> Dovato US Prescribing Information. [https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing\\_Information/Dovato/pdf/DOVATO-PI-PIL.PDF](https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing_Information/Dovato/pdf/DOVATO-PI-PIL.PDF). Accessed July 2020.