For media and investors only

PRESS RELEASE

ViiV Healthcare announces US FDA approval of the first-ever dispersible tablet formulation of dolutegravir, Tivicay PD, a once-daily treatment for children living with HIV

Dolutegravir is the first integrase inhibitor available as a dispersible tablet for oral suspension for children weighing at least 3kg and from four weeks of age.

The FDA approval is testament to the commitments of global stakeholders spanning regulators, industry and non-profit organisations to develop new and innovative HIV medicines for children, most of whom live in resource-poor settings.[1]

London, 12 June 2020 – ViiV Healthcare, the global specialist HIV company majority-owned by GSK, with Pfizer Inc. and Shionogi Limited as shareholders, today announced that the US Food and Drug Administration (FDA) has approved Tivicay PD (dolutegravir) tablets for oral suspension, which are used in combination with other antiretroviral agents for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in paediatric patients (treatment-naïve or -experienced but INSTI-naïve) aged at least four weeks and weighing at least 3kg, as well as an extended indication to expand the use of the already approved Tivicay (dolutegravir) 50mg film-coated tablet in paediatric HIV patients weighing 20kg and above.[2]

Paediatric HIV remains a global issue, with children disproportionately affected by the HIV epidemic. Latest statistics show there are 1.7 million children living with HIV[1], and the majority of AIDS-related deaths among children still occur during the first five years of life.[3] Major obstacles persist for children, such as continued mother-to-child transmission, the availability of HIV testing, slow initiation of treatment and poor availability of optimised paediatric formulations of antiretrovirals.[3,4]

Deborah Waterhouse, CEO of ViiV Healthcare, said: "I am delighted that our innovative approach to science has enabled us to achieve FDA approval of the first-ever dispersible tablet formulation of dolutegravir, now making it easier for young children to take this medication by dispersing the tablet in water. The development and availability of age-appropriate formulations is essential in ensuring children have access to life-saving HIV treatments from an early age and as they grow. The support

of our partners has been integral for this regulatory approval. We now need to continue our efforts to ensure this new dispersible formulation is available to children who need it around the world, in line with our mission to leave no person living with HIV behind."

Dolutegravir is the first integrase inhibitor available as a dispersible tablet for oral suspension for children as young as four weeks of age and weighing at least 3kg. Prior to this, dolutegravir was indicated in the US for children from six years of age and weighing more than 30kg.[5] This step will expand the use of dolutegravir by providing an age-appropriate formulation to a younger population and will help to close the gap between HIV treatment options available for adults and children.

Chip Lyons, President and CEO of the Elizabeth Glaser Pediatric AIDS Foundation (EGPAF), said: "Children are often forgotten in the global fight to end HIV/AIDS and face a unique set of challenges, particularly when HIV medication and treatments are often hard to swallow or tolerate. Barriers like these have resulted in only half of the 1.7 million children living with HIV accessing the lifesaving treatment they need—and even fewer still reaching viral suppression. Families affected by HIV will benefit from ViiV Healthcare's development of child-friendly formulations that aim to close the gap between treatment options available for adults and children. This tailored approach to paediatric treatment of HIV will help meet the urgent needs of this vulnerable population."

The FDA approval is based on data from the ongoing P1093[6] and ODYSSEY[7] (PENTA20) studies, which has been generated from ViiV Healthcare's collaborations with the Division of AIDS (DAIDS) at the US National Institutes of Health (NIH) and the International Maternal Pediatric Adolescent AIDS Clinical Trials Network (IMPAACT) for P1093, and the Paediatric European Network for Treatment of AIDS (Penta) and the Medical Research Council (MRC) Clinical Trials Unit at University College London for ODYSSEY.

Through its voluntary licensing policy, ViiV Healthcare enables generic versions of dolutegravir to be manufactured and sold royalty-free in all least-developed, low-income, lower-middle-income and sub-Saharan Africa countries, as well as some upper-middle-income countries. In order to ensure licensees expedite the development and introduction of optimised paediatric formulations of dolutegravir to help the children most affected by HIV, the majority of whom reside in sub-Saharan Africa, ViiV Healthcare has worked with the Clinton Health Access Initiative (CHAI) and Unitaid since 2018 in a public-private partnership.[8] Through this partnership, two generic manufacturers who hold paediatric dolutegravir sub-licences from the Medicines Patent Pool (MPP) — Mylan Laboratories

Limited and Macleods Pharmaceuticals Limited — have been provided with the technical expertise of ViiV Healthcare and a financial incentive from Unitaid via CHAI, to accelerate the development, registration, manufacture and supply of generic dispersible formulations of dolutegravir for children. A key milestone in this collaboration was recently achieved when Mylan submitted a new drug application for a scored dolutegravir 10mg dispersible tablet for tentative approval under the FDA President's Emergency Plan for AIDS Relief (PEPFAR) scheme. The Macleods submission is imminent.

Today's FDA approval is an important step in fulfilling ViiV Healthcare's commitment to bring optimised paediatric formulations of dolutegravir to children. Additional regulatory approvals around the world are ongoing and required in order to ensure we and our partners can succeed in delivering these new HIV treatments at the speed and scale that patients need.

Tivicay PD and the extended indication of the existing Tivicay 50mg film-coated tablet are both currently under review by the European Medicines Agency (EMA).

- ENDS -

Notes to editors:

About P1093[6] and ODYSSEY[7]

- P1093 (NCT03016533): a safety, tolerability and dose finding registrational study in paediatric patients aged four weeks to 18 years being conducted by the IMPAACT network in the USA, Brazil, Thailand, South Africa, Zimbabwe, Kenya and Tanzania.
- ODYSSEY (Penta20) (NCT02259127): a randomised control efficacy trial in first and second-line treatment, in paediatric patients aged four weeks to 18 years being conducted by the PENTA network in Europe, South America, Thailand, Uganda, Zimbabwe, and South Africa. Originally designed to support World Health Organization (WHO) guideline recommendations by WHO weight bands, this study will now also provide data to support revised dosing and continue to 96 weeks. For more information, please visit the study website at: http://odysseytrial.org/

About Tivicay and Tivicay PD

Tivicay and Tivicay PD contain dolutegravir, an integrase strand transfer inhibitor for use in combination with other antiretroviral agents for the treatment of HIV. Integrase inhibitors inhibit

HIV integrase by binding to the integrase active site and blocking the strand transfer step of retroviral deoxyribonucleic acid (DNA) integration which is essential for the HIV replication cycle.

Important Safety Information (ISI) for TIVICAY (dolutegravir) tablets, for oral use and TIVICAY PD (dolutegravir) tablets for oral suspension

The following ISI is based on the highlights section of the Prescribing Information for Tivicay. These highlights do not include all the information needed to use TIVICAY safely and effectively. See full prescribing information for TIVICAY.

Indications and Usage

TIVICAY and TIVICAY PD are a human immunodeficiency virus type 1 (HIV-1) integrase strand transfer inhibitor (INSTI) indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults (treatment-naïve or -experienced) and in pediatric patients (treatment-naïve or -experienced but INSTI- naïve) aged at least 4 weeks and weighing at least 3 kg.

TIVICAY is indicated in combination with rilpivirine as a complete regimen for the treatment of HIV-1 infection in adults to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen for at least 6 months with no history of treatment failure or known substitutions associated with resistance to either antiretroviral agent.

Contraindications

- Previous hypersensitivity reaction to dolutegravir.
- Coadministration with dofetilide.

Warnings and Precautions

- Hypersensitivity reactions characterized by rash, constitutional findings, and sometimes organ dysfunction, including liver injury, have been reported. Discontinue TIVICAY or TIVICAY PD and other suspect agents 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 dolutegravir-containing regimens. Patients with underlying hepatitis B or C may be at increased risk for worsening or development of transaminase elevations. Monitoring for hepatotoxicity is recommended.

- Embryo-fetal toxicity may occur when used at the time of conception and in early pregnancy. An alternative treatment to dolutegravir should be considered at the time of conception through the first trimester of pregnancy due to the risk of neural tube defects. Counsel adolescents and adults of childbearing potential to use effective contraception.
- Immune reconstitution syndrome has been reported in patients treated with combination antiretroviral therapy.
- TIVICAY tablets and TIVICAY PD tablets for oral suspension are not interchangeable.

Adverse Reactions

- The most common adverse reactions of moderate to severe intensity and incidence at least 2% (in those receiving TIVICAY in any one adult trial) are insomnia, fatigue, and headache.

Drug Interactions

- Refer to the full prescribing information for important drug interactions with TIVICAY or TIVICAY PD.
- Drugs that are metabolic inducers may decrease the plasma concentrations of dolutegravir.
- TIVICAY or TIVICAY PD should be taken 2 hours before or 6 hours after taking cation-containing antacids or laxatives, sucralfate, oral supplements containing iron or calcium, or buffered medications. When taken with food, TIVICAY and supplements containing calcium or iron can be taken at the same time.

Use in Specific Populations

- Pregnancy: An alternative treatment to dolutegravir 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 adolescents and adults of childbearing potential.

Please see full US prescribing information available at:

https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing_Information/Tivicay/pdf/TIVICAY-PI-PIL.PDF#page=1

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 aim is 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.

About ViiV Healthcare's Patient Assistance Programme

ViiV Healthcare is committed to providing assistance to eligible people living with HIV in the US who need our medicines. ViiV Healthcare's centralised service, ViiV Connect, provides comprehensive information on access and coverage to help patients living in the US get their prescribed ViiV Healthcare medicines whether they are insured, underinsured or uninsured. ViiV Connect provides one-on-one support from dedicated access coordinators, as well as having an integrated website, one site with many resources, including a portal. For more information on ViiV Connect, visit www.viivconnect.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.

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 any impacts of the COVID-19 pandemic.

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References

[1] UNAIDS. Global HIV & AIDS statistics – 2019 fact sheet. Available at: https://www.unaids.org/en/resources/fact-sheet Last accessed: June 2020.

[2] Tivicay (dolutegravir) US Prescribing Information. Updated in June 2020.

[3.] UNAIDS. Get on the fast-track. The life-cycle approach to HIV. Available at: https://www.unaids.org/sites/default/files/media_asset/Get-on-the-Fast-Track_en.pdf Last accessed: June 2020

[4.] UNAIDS. Children and HIV – 2016 fact sheet. Available at: https://www.unaids.org/sites/default/files/media_asset/FactSheet_Children_en.pdf Last accessed: June 2020

[5.] ViiV Healthcare. Tivicay. Available at: https://viivhealthcare.com/en-gb/our-medicines/tivicay/ Last accessed: June 2020

[6] Clinicaltrials.gov. (2019). PH3b, DTG Study in HIV-1 Subjects Completing IMPAACT Study P1093. Available at: https://clinicaltrials.gov/ct2/show/NCT03016533 Last accessed: June 2020.

[7] Clinicaltrials.gov. (2019). A Randomised Trial of Dolutegravir (DTG)-Based Antiretroviral Therapy vs. Standard of Care (SOC) in Children With HIV Infection Starting First-line or Switching to Second-line. Available at: https://clinicaltrials.gov/ct2/show/NCT02259127?term=PENTA20&draw=2&rank=1 Last accessed: June 2020.

[8] Unitaid statement. New partnership to help fast-track affordable HIV medicine for children living with HIV. Available at: https://unitaid.org/news-blog/new-partnership-to-help-fast-track-affordable-hiv-medicine-for-children-living-with-hiv/#en. Last accessed: June 2020.