ViiV Healthcare announces US FDA approval of Triumeq PD, the first dispersible single tablet regimen containing dolutegravir, a once-daily treatment for children living with HIV

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For media and investors only

- The FDA approval of the first dispersible single tablet regimen containing dolutegravir increases age-appropriate treatment options for children living with HIV

ViiV Healthcare, the global specialist HIV company majority-owned by GlaxoSmithKline plc (GSK), with Pfizer Inc. (Pfizer) and Shionogi B.V. (Shionogi) as shareholders, has announced that the U.S. Food and Drug Administration (FDA) has approved a new drug application (NDA) for a dispersible tablet formulation of the fixed dose combination of abacavir, dolutegravir and lamivudine for the treatment of pediatric patients weighing 10kgs to

According to UNAIDS, approximately 1.7 million children globally were living with HIV in 2020, with most AIDS-related deaths among this population occurring during the first five years of life. Therefore, the availability of age-appropriate treatment options is critical in ensuring young children can access optimal care.

Deborah Waterhouse, CEO of ViiV Healthcare, said:

> We are delighted with today's FDA approval because it gives children living with HIV another age-appropriate treatment option. Developing paediatric formulations of anti-retroviral treatments is a priority for ViiV Healthcare because we want to ensure that no one living with HIV is left behind and this

> approval means that we are one step closer to closing the gap between HIV treatment options available for adults and children.

Today's FDA approval is an important step in fulfilling ViiV Healthcare's commitment to bring optimised paediatric formulations containing dolutegravir to children. In addition to today's regulatory milestones, an application to approve the new dispersible tablet of the fixed dose combination of abacavir, dolutegravir and lamivudine for the treatment of paediatric patients with human immunodeficiency virus type 1 (HIV-1) and to extend the current approved Marketing Authorisation of Triumeq tablets to include a paediatric indication for children is currently under review by the European Medicines Agency (EMA).

Chip Lyons, President and CEO of the Elizabeth Glaser Paediatric AIDS Foundation (EGPAF), said:

> Children are still disproportionality impacted by the HIV epidemic with only half of the 1.7 million children living with HIV accessing the lifesaving treatment they need and even fewer still reaching viral suppression. An obvious barrier to treatment is that for young children, tablets can be hard to swallow or unpleasant in taste and this presents a real challenge to many caregivers' ability to administer life-saving medicine. Today's approval of a child-friendly formulation of a single tablet regimen will help meet the urgent needs of this vulnerable population.

Through its paediatric voluntary licences, ViiV Healthcare enables generic versions of dolutegravir to be manufactured and sold royalty-free for the treatment of children living with HIV 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 containing dolutegravir to help the children most affected by HIV, the majority of whom reside in sub-Saharan Africa, ViiV Healthcare works with the Clinton Health Access Initiative (CHAI) and Unitaid in a public-private partnership.

Two essential steps in the HIV life cycle are replication – when the virus turns its RNA copy into DNA – and integration – the moment when viral DNA becomes part of the host cell's DNA. These

processes require two enzymes called reverse transcriptase and integrase. NRTIs and integrase inhibitors interfere with the action of the two enzymes to prevent the virus from replicating and further infecting cells.

Important Safety Information (ISI) for TRIUMEQ and TRIUMEQ PD (abacavir, dolutegravir, and lamivudine) tablets

TRIUMEQ and TRIUMEQ PD are indicated for the treatment of HIV-1 infection in adults and in pediatric patients weighing at least 10 kg.

TRIUMEQ and TRIUMEQ PD alone are not recommended in patients with resistance-associated integrase substitutions or clinically suspected INSTI resistance because the dose of dolutegravir in TRIUMEQ and TRIUMEQ PD is insufficient in these subpopulations. See full prescribing information for TIVICAY (dolutegravir).

IMPORTANT SAFETY INFORMATION

BOXED WARNING: HYPERSENSITIVITY REACTIONS AND EXACERBATIONS OF HEPATITIS B VIRUS (HBV)

Hypersensitivity Reactions:

- Serious and sometimes fatal hypersensitivity reactions, with multiple organ involvement, have occurred with abacavir, a component of TRIUMEQ and TRIUMEQ PD.

- Patients who carry the HLA-B*5701 allele are at a higher risk of experiencing a hypersensitivity reaction to abacavir, although hypersensitivity reactions have occurred in patients who do not carry the HLA-B*5701 allele

- TRIUMEQ and TRIUMEQ PD are contraindicated in patients with a prior hypersensitivity reaction to abacavir and in HLAB*5701-positive patients. All patients should be screened for the HLA-B*5701 allele prior to initiating therapy or reinitiation of therapy with TRIUMEQ or TRIUMEQ PD unless patients have a previously documented HLA-B*5701 allele assessment

- Discontinue TRIUMEQ or TRIUMEQ PD immediately if a hypersensitivity reaction is suspected, regardless of HLA-B*5701 status and even when other diagnoses are possible.

- Following a hypersensitivity reaction to TRIUMEQ or TRIUMEQ PD, NEVER restart TRIUMEQ or TRIUMEQ PD or any other abacavir-containing product.

Exacerbations of Hepatitis B:

- All patients with HIV-1 should be tested for the presence of hepatitis B virus (HBV) prior to or when initiating TRIUMEQ or TRIUMEQ PD. Emergence of lamivudine-resistant HBV variants associated with lamivudine-containing antiretroviral regimens has been reported. If TRIUMEQ or TRIUMEQ PD 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 HBV and HIV-1 and have discontinued lamivudine, a component of TRIUMEQ and TRIUMEQ PD. Monitor hepatic function closely in these patients and, if appropriate, initiate anti-hepatitis B treatment.

- Do not use TRIUMEQ or TRIUMEQ PD in patients who have the HLA-B*5701 allele

- Do not use TRIUMEQ or TRIUMEQ PD in patients with previous hypersensitivity reaction to abacavir, dolutegravir, or lamivudine

- Do not use TRIUMEQ or TRIUMEQ PD in patients receiving dofetilide

- Do not use TRIUMEQ or TRIUMEQ PD in patients with moderate or severe hepatic impairment

Hypersensitivity Reactions:

- Hypersensitivity reactions have been reported with dolutegravir and were characterized by rash, constitutional findings, and sometimes organ dysfunction, including liver injury

- Clinically, it is not possible to determine whether a hypersensitivity

reaction with TRIUMEQ or TRIUMEQ PD would be caused by abacavir or dolutegravir

- Discontinue TRIUMEQ or TRIUMEQ PD immediately if signs or symptoms of 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

- 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 may be at increased risk for worsening or development of transaminase elevations with use of TRIUMEQ or TRIUMEQ PD. 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

- Drug-induced liver injury leading to liver transplant has been reported with TRIUMEQ.

- Monitoring for hepatotoxicity is recommended

Lactic Acidosis and Severe Hepatomegaly With Steatosis:

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

- Assess the risks and benefits of TRIUMEQ and discuss with the patient to determine if alternative treatments 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 use of TRIUMEQ. Adolescents and adults of childbearing potential should be counseled

on the consistent use of effective contraception

- TRIUMEQ may be considered during the second and third trimesters of pregnancy if the expected benefit justifies the potential risk to the pregnant woman and the fetus.

Adverse Reactions or Loss of Virologic Response Due to Drug Interactions with concomitant use of TRIUMEQ or TRIUMEQ PD 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 TRIUMEQ or TRIUMEQ PD.

Different Formulations Are Not Interchangeable:

TRIUMEQ and TRIUMEQ PD are not bioequivalent and are not interchangeable on a milligram-per-milligram basis. If a patient switches from one formulation to the other, the dose must be adjusted.

Myocardial Infarction (MI):

- Several observational studies have reported an association with the use of abacavir and the risk of MI; meta-analyses of randomized controlled clinical trials did not show increased risk. To date, there is no established biological mechanism to explain a potential increase in risk. In totality, the available data show inconsistency; therefore, evidence for a causal relationship between abacavir and the risk of MI is inconclusive

- The underlying risk of coronary heart disease should be considered when prescribing antiretroviral therapies, including abacavir, and action taken to minimize all modifiable risk factors (e.g., hypertension, hyperlipidemia, diabetes mellitus, smoking)

- The most common adverse reactions (incidence ≥2%, Grades 2-4) in treatment-naïve adults receiving TRIUMEQ were insomnia (3%), headache (2%), and fatigue (2%).

- Consult the full Prescribing Information for more information on potentially significant drug interactions

Use in specific populations

- Pregnancy: Assess the risks and benefits of TRIUMEQ and discuss with the patient to determine if an alternative treatment should be considered at the time of conception through the first trimester or if pregnancy is confirmed in the first trimester due to the risk of neural tube defects.

- 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

- Impaired Renal Function: TRIUMEQ and TRIUMEQ PD are not recommended for patients with creatinine clearance

- Impaired Hepatic Function: If a dose reduction of abacavir is required for patients with mild hepatic impairment, then the individual components of TRIUMEQ or TRIUMEQ PD should be used

Please see full prescribing information available at: US Prescribing Information, including Boxed Warning.

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 B.V. joined as shareholders 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 www.viivhealthcare.com.

GSK is a science-led global healthcare company. For further information please visit https://www.gsk.com/en-gb/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 in the Company's Annual Report on Form 20-F for 2021 and any impacts of the COVID-19 pandemic.

Triumeq (abacavir, dolutegravir and lamivudine) Prescribing Information. US Approval 2022.

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