ViiV Healthcare to present key data that provides further support for the use of 2-drug regimens, including long-term efficacy, alongside new insights into living with HIV at IDWeek 2021

PUBLISHED SEP 22, 2021
BY GSK

For media and investors only

ViiV Healthcare, the global specialist HIV company majority owned by GSK, with Pfizer Inc. and Shionogi Limited as shareholders, today announced the presentation of 13 abstracts from its diverse portfolio of innovative pipeline prevention options and licensed HIV treatments, including 2-drug and long-acting regimens, at the 2021 Infectious Disease Society of America (IDSA) IDWeek, being held virtually 29 September – 3 October.

Kimberly Smith, M.D., MPH, Head of Research & Development at ViiV Healthcare, said:

> The breadth of data we're presenting at IDWeek 2021 illustrates our commitment to understanding and addressing the variety of evolving needs and challenges faced by people living with or affected by HIV. These new data address specific questions that providers have been asking and we believe will provide increased confidence in the long-term efficacy and high barrier to resistance of our integrase inhibitor-based, 2-drug regimens. We look forward to sharing these findings with the HIV community at IDWeek.

Key abstracts to be presented by ViiV Healthcare at IDWeek 2021:

144-week findings from the TANGO study evaluate switching to the fixed-dose combination of Dovato (dolutegravir/lamivudine) compared

to the continuation of tenofovir alafenamide (TAF) -based regimens of at least three drugs in virologically suppressed people living with HIV: The three-year findings to be presented at IDWeek 2021 will include efficacy, safety and tolerability data for dolutegravir/lamivudine and build on the growing body of evidence for this 2-drug regimen.

48-week subgroup analysis of the STAT study investigating the safety and efficacy of dolutegravir/lamivudine for the treatment of HIV-1: Secondary analysis of treatment-naïve adults living with HIV was designed to build on previous 24-week feasibility, efficacy and safety outcomes of dolutegravir/lamivudine as a first-line regimen in a test-and-treat setting through 48 weeks. Findings to be presented at IDWeek 2021 will provide further insights into virologic outcomes among study participants by baseline viral load.

Pregnancy and birth outcomes following maternal dolutegravir (DTG) use: The Antiretroviral Pregnancy Registry was designed to monitor for early warning signals of ARV effects on neonatal health. Findings to be presented at IDWeek 2021 will provide additional information about pregnancy outcomes among women exposed to DTG.

Findings from the Positive Perspectives survey reported treatment outcomes and perceptions among people living with HIV following the global U=U educational campaign: The U=U campaign was designed to improve the well-being of people living with HIV and recalibrate HIV-related social norms. The findings to be presented at IDWeek 2021 examine the effects of U=U on treatment outcomes and satisfaction, mental health and sexual health among people living with HIV in North America and also provide further insight into the impact of provider relationships on quality of life.

Results analysing the impact of COVID-19 on HIV treatment and care among ongoing BRIGHTE trial participants: Rukobia (fostemsavir), in combination with other ARV therapies, was evaluated in heavily treatment-experienced adults with advanced HIV and COVID-19. Findings to be presented at IDWeek 2021 from the ongoing analysis characterise reported cases and outcomes of COVID-19 among study participants.

Real-world findings from the retrospective study examining usage patterns among people receiving tenofovir-based therapy as pre-exposure prophylaxis (PrEP) in the US: The retrospective study was designed to identify adults newly initiated on tenofovir-based therapy

as daily PrEP and monitor persistence. Findings to be presented at IDWeek 2021 will examine consistency of use on daily oral PrEP in the real-word setting in comparison to recent PrEP clinical trials.

The full list of ViiV Healthcare data to be presented at IDWeek 2021 is outlined below:

| Abstract title | First Author | Presentation |

| Dolutegravir | | |

| High rates of virologic suppression with DTG/3TC in newly diagnosed adults with HIV-1 infection and baseline viral load >500,000 c/mL: 48-week subgroup analysis of the STAT study| CP Rolle | Oral Presentation |

| Maternal Dolutegravir (DTG) Use, and Pregnancy and Birth Outcomes: The Antiretroviral Pregnancy Registry (APR)| V Vannappagari | Oral Presentation |

| Switching to DTG/3TC fixed-dose combination (FDC) is non-inferior to continuing a TAF-based regimen (TBR) in maintaining virologic suppression through 144 weeks (TANGO study)| O Osiyemi | E-Poster |

| Efficacy and tolerability of DTG+3TC in clinical practice: evidence from real world data | LA Evitt | E-Poster |

| The Impact of the COVID-19 Pandemic on Clinical Follow-up, Monitoring and Regimen Discontinuation for People Living with HIV in the US| G Pierone | E-Poster |

| Cabotegravir | | |

| Efficacy and safety of long-acting cabotegravir + rilpivirine in participants with HIV/HCV co-infection: ATLAS-2M 48-week results| R D'Amico | E-Poster |

| Indirect Treatment Comparison of 48-Week Efficacy and Safety of Cabotegravir + Rilpivirine Long-Acting every 8 weeks to Bictegravir/ Emtricitabine/ Tenofovir alafenamide in Suppressed HIV-1 Infected Persons| S Snedecor | E-Poster |

| Pregnancy Outcomes and Pharmacokinetics in Pregnant Women

Living with HIV Exposed to Long-Acting Cabotegravir and Rilpivirine in Clinical Trials| P Patel | E-Poster |

| North American Phase 3/3b Experience with Long-Acting Cabotegravir and Rilpivirine: Efficacy, Safety, and Virologic Outcomes| BO Taiwo | E-Poster |

| Qualitative Patient-Participant Perspectives on Implementation of Monthly Cabotegravir and Rilpivirine Long Acting (CAB+RPV LA) Injectable in the United States (CUSTOMIZE)| C Garris | E-Poster |

| Real-World Persistency of Patients Receiving Tenofovir-Based Pre-Exposure Prophylaxis for the Prevention of HIV Infection in the US| A Oglesby | E-Poster |

| Fostemsavir | | |

| Characterization of Heavily Treatment Experienced HIV-1 Infected Clinical Trial Participants infected with SARS-CoV-2 COVID 19: Fostemsavir BRIGHTE Phase 3 Clinical Trial| S Chabria | E-Poster |

| General | | |

| Effects of the “Undetectable = Untransmittable” (“U=U”) Educational Campaign on Treatment Outcomes and Perceptions among People Living with HIV in North America| F Spinelli | Oral Presentation |

Important Safety Information for Dovato (50mg dolutegravir/300mg lamivudine) Tablets

DOVATO is indicated as a complete regimen to treat HIV-1 infection in adults with no antiretroviral (ARV) treatment history or to replace the current ARV regimen in those who are virologically suppressed (HIV-1 RNA

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.

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

- Do not use DOVATO in patients receiving dofetilide

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

- 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

- 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.

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

- 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

- 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

- 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, including Boxed Warning.

Important Safety Information for Cabenuva (cabotegravir 200 mg/mL; rilpivirine 300 mg/mL) extended release injectable suspensions

Cabenuva is indicated as a complete regimen for the treatment of human immunodeficiency virus type 1 (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 with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine.

- Do not use Cabenuva in patients with previous hypersensitivity

reaction to cabotegravir or rilpivirine.

- Do not use Cabenuva in patients receiving carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifabutin, rifampin, rifapentine, systemic dexamethasone (>1 dose), and St John's wort.

Hypersensitivity Reactions:

- Hypersensitivity reactions, including cases of Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), have been reported during postmarketing experience with rilpivirine-containing regimens. While some skin reactions were accompanied by constitutional symptoms such as fever, other skin reactions were associated with organ dysfunctions, including elevations in hepatic serum biochemistries.

- Serious or severe hypersensitivity reactions have been reported in association with other integrase inhibitors and could occur with Cabenuva.

- Discontinue Cabenuva immediately if signs or symptoms of hypersensitivity reactions develop. Clinical status, including liver transaminases, should be monitored and appropriate therapy initiated. Prescribe the oral lead-in prior to administration of Cabenuva to help identify patients who may be at risk of a hypersensitivity reaction.

- Serious post-injection reactions (reported in less than 1% of subjects) were reported within minutes after the injection of rilpivirine, including dyspnea, agitation, abdominal cramping, flushing, sweating, oral numbness, and changes in blood pressure. These events may have been associated with inadvertent (partial) intravenous administration and began to resolve within a few minutes after the injection.

- Carefully follow the Instructions for Use when preparing and administering Cabenuva to avoid accidental intravenous administration. Observe patients briefly (approximately 10 minutes) after the injection. If a post-injection reaction occurs, monitor and treat as clinically indicated.

- Hepatotoxicity has been reported in patients receiving cabotegravir or rilpivirine with or without known pre-existing hepatic disease or identifiable risk factors.

- Patients with underlying liver disease or marked elevations in transaminases prior to treatment may be at increased risk for worsening or development of transaminase elevations.

- Monitoring of liver chemistries is recommended and treatment with Cabenuva should be discontinued if hepatotoxicity is suspected.

- Depressive disorders (including depressed mood, depression, major depression, mood altered, mood swings, dysphoria, negative thoughts, suicidal ideation or attempt) have been reported with Cabenuva or the individual products.

- Promptly evaluate patients with depressive symptoms.

Risk of Adverse Reactions or Loss of Virologic Response Due to Drug Interactions:

- The concomitant use of Cabenuva and other drugs may result in known or potentially significant drug interactions (see Contraindications and Drug Interactions).

- Rilpivirine doses 3 and 12 times higher than the recommended oral dosage can prolong the QTc interval. Cabenuva should be used with caution in combination with drugs with a known risk of Torsade de Pointes.

Long-Acting Properties and Potential Associated Risks with Cabenuva:

- Residual concentrations of cabotegravir and rilpivirine may remain in the systemic circulation of patients for prolonged periods (up to 12 months or longer). Select appropriate patients who agree to the required monthly injection dosing schedule because non-adherence to monthly injections or missed doses could lead to loss of virologic response and development of resistance.

- To minimize the potential risk of developing viral resistance, it is essential to initiate an alternative, fully suppressive antiretroviral regimen no later than 1 month after the final injection doses of Cabenuva. If virologic failure is suspected, switch the patient to an alternative regimen as soon as possible.

- The most common adverse reactions (incidence ≥2%, all grades)

with Cabenuva were injection site reactions, pyrexia, fatigue, headache, musculoskeletal pain, nausea, sleep disorders, dizziness, and rash.

- Refer to the applicable full Prescribing Information for important drug interactions with Cabenuva, Vocabria, or rilpivirine.

- Because Cabenuva is a complete regimen, coadministration with other antiretroviral medications for the treatment of HIV-1 infection is not recommended.

- Drugs that are strong inducers of UGT1A1 or 1A9 are expected to decrease the plasma concentrations of cabotegravir. Drugs that induce or inhibit CYP3A may affect the plasma concentrations of rilpivirine.

- Cabenuva should be used with caution in combination with drugs with a known risk of Torsade de Pointes.

USE IN SPECIFIC POPULATIONS

- Pregnancy: There are insufficient human data on the use of Cabenuva during pregnancy to adequately assess a drug-associated risk for birth defects and miscarriage. Discuss the benefit-risk of using Cabenuva during pregnancy and conception and consider that cabotegravir and rilpivirine are detected in systemic circulation for up to 12 months or longer after discontinuing injections of Cabenuva. An Antiretroviral Pregnancy Registry has been established.

- Lactation: The CDC recommends that HIV 1–infected mothers in the United States not breastfeed their infants to avoid risking postnatal transmission of HIV-1 infection. Breastfeeding is also not recommended due to the potential for developing viral resistance in HIV-positive infants, adverse reactions in a breastfed infant, and detectable cabotegravir and rilpivirine concentrations in systemic circulation for up to 12 months or longer after discontinuing injections of Cabenuva.

Please see full Prescribing Information for Cabenuva.

Important Safety Information for Rukobia (fostemsavir), 600 mg extended-release tablets

- RUKOBIA, a human immunodeficiency virus type 1 (HIV-1) gp120-directed attachment inhibitor, in combination with other antiretroviral(s), is indicated for the treatment of HIV-1 infection in heavily treatment-experienced adults with multidrug-resistant HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations.

- Do not use in patients with previous hypersensitivity to fostemsavir or any of the components of RUKOBIA.

- Do not use RUKOBIA in patients receiving strong cytochrome P450 (CYP)3A inducers, including but not limited to enzalutamide, carbamazepine, phenytoin, rifampin, mitotane, and St John's wort (Hypericum perforatum).

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

- QTc Prolongation with Higher than Recommended Dosages: RUKOBIA at 2,400 mg twice daily has been shown to significantly prolong the QTc interval of the electrocardiogram. Use RUKOBIA with caution in patients with a history of QTc interval prolongation or in patients with relevant pre-existing cardiac disease or who are taking drugs with a known risk of Torsade de Pointes. Elderly patients may be more susceptible to drug-induced QT interval prolongation.

Elevations in Hepatic Transaminases in Patients with Hepatitis B or C Virus Co-infection:

- Monitoring of liver chemistries is recommended in patients with hepatitis B and/or C co-infection.

- Diligence should be applied in initiating or maintaining effective hepatitis B therapy when starting RUKOBIA in patients co-infected with hepatitis B.

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

- The most common adverse reaction (all grades, randomized cohort) observed in ≥5% of subjects was nausea (10%).

- 81% of adverse reactions reported with RUKOBIA were mild or moderate in severity.

- See the full Prescribing Information for RUKOBIA for a complete list of significant drug interactions.

- Temsavir may increase plasma concentrations of grazoprevir and voxilaprevir. Use an alternative hepatitis C virus regimen if possible.

- Use the lowest possible starting dose for statins and monitor for statin-associated adverse events.

- Patients receiving RUKOBIA should not take doses of estrogen-based therapies, including oral contraceptives, that contain more than 30 mcg/day of ethinyl estradiol. Caution is advised particularly in patients with additional risk factors for thromboembolic events.

Use in specific populations

- Pregnancy: There are insufficient human data on the use of RUKOBIA during pregnancy to definitively assess a drug-associated risk for birth defects and miscarriage. An Antiretroviral Pregnancy Registry has been established.

- Lactation: Breastfeeding is not recommended due to the potential for HIV-1 transmission, developing viral resistance, and adverse reactions in a breastfed infant.

Please see full Prescribing Information for Rukobia

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 as a shareholder 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.

GSK is a science-led global healthcare company. 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 in the Company's Annual Report on Form 20-F for 2020, GSK's Q1 Results and any impacts of the COVID-19 pandemic.

Osiyemi O, Ajana F, Bisshop F, et al. Switching to DTG/3TC Fixed-Dose Combination (FDC) Is Non-inferior to Continuing a TAF-Based Regimen (TBR) in Maintaining Virologic Suppression through 144 Weeks (TANGO Study). Presented at IDWeek 2021.

Rolle CP, Berhe M, Singh T, et al. High Rates of Virologic Suppression with DTG/3TC in Newly Diagnosed Adults with HIV-1 Infection and Baseline Viral Load >500,000 c/mL: 48-Week Subgroup Analysis of the STAT Study. Presented at IDWeek 2021.

Vannappagari V, Albano JD, Ragone L, et al. Maternal Dolutegravir (DTG) Use, and Pregnancy and Birth Outcomes: The Antiretroviral Pregnancy Registry (APR). Presented at IDWeek 2021.

Spinelli F, Richman, B, del los Rios P, et al. Effects of the "Undetectable = Untransmittable" ("U=U") Educational Campaign on Treatment Outcomes and Perceptions among People Living with HIV in North American Countries. Presented at IDWeek 2021.

Chabria S, De Wit S, Pierce A, et al. Characterization of Heavily Treatment Experienced HIV-1 Infected Clinical Trial Participants infected with SARS-CoV-2 COVID 19: Fostemsavir BRIGHTE Phase 3 Clinical Trial. Presented at IDWeek 2021.

Ogelsby A, Germain G, Laliberté F, et al. Real-World Persistency of Patients Receiving Tenofovir-Based Pre-Exposure Prophylaxis for the Prevention of HIV Infection in the US. Presented at IDWeek 2021.

Press release distributed by Wire Association on behalf of GSK, on Sep 22, 2021. For more information subscribe and follow us.

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https://wireassociation.eu/newsroom/gsk/releases/en/viiv-healthcare-to-present-key-data-that-provides-further-support-for-the-use-of-2-drug-regimens-including-long-term-efficacy-alongside-new-insights-into-living-with-hiv-at-idweek-2021-1912

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