# ViiV Healthcare to present new data from diverse portfolio and pipeline of 2-drug and long-acting regimens for HIV treatment and prevention at IAS 2021

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For media and investors only

Data to be presented underscore the commitment to developing innovative treatment and prevention options that address the changing needs of people living with or at risk of HIV

Note to media: ViiV Healthcare will be hosting a virtual media event, Addressing the Changing Needs of People Living with HIV, on 21 July 2021 at 8:00-9:00 EDT/13:00-14:00 BST/14:00-15:00 CET. Senior spokespeople from ViiV Healthcare, alongside leading clinical experts, will discuss new data on 2-drug regimens and long-acting medicines that will be presented at IAS. To register for the event, please click here.

ViiV Healthcare, the global specialist HIV company majority owned by GlaxoSmithKline plc (“GSK”), with Pfizer Inc. and Shionogi Limited as shareholders, today announced 12 abstracts to be presented from its diverse portfolio of innovative pipeline and licensed HIV treatment and prevention options at the International AIDS Society Conference 2021(IAS 2021), being held virtually 18-21 July.

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

> We’re excited to be presenting a broad range of data from ViiV Healthcare’s diverse portfolio and pipeline of medicines at IAS 2021. No single medicine will work for all people living with or at risk of acquiring HIV, which is precisely why we are developing innovative long-acting regimens and 2-drug

combinations that are changing the treatment paradigm. We look forward to sharing these advances, including long-term efficacy and safety findings, implementation science and preference data that articulates the perspectives of the HIV community.

Week 48 findings from the phase III SALSA study evaluating switching to the 2-drug regimen Dovato (dolutegravir/lamivudine) versus continuation on a current antiretroviral regimen (CAR) of at least 3 drugs. A press release with data from the SALSA study is now available on the media page at www.viivhealthcare.com.

Week 144 virologic and metabolic health outcomes from the TANGO study evaluating the 2-drug regimen of Dovato (dolutegravir/lamivudine) in virologically suppressed adults living with HIV-1. The phase III TANGO study was designed to compare switching to dolutegravir/lamivudine versus continuation of a ≥3-drug tenofovir alafenamide (TAF)-based regimen (TBR) in virologically suppressed adults with HIV-1. After three years of therapy, dolutegravir/lamivudine maintained non-inferior virologic efficacy compared with a TBR, with no confirmed virologic withdrawals or resistance development noted in the dolutegravir/lamivudine treatment arm. Changes in metabolic health parameters were similar between the dolutegravir/lamivudine and TBR arms, with changes in lipids generally continuing to favour the dolutegravir/lamivudine arm. Changes in weight, insulin resistance and metabolic syndrome were comparable between the treatment arms. Overall rates of AEs were comparable between groups through Week 144, with any AEs being present in 91% of participants in the dolutegravir/lamivudine arm, and 90% in the CAR arm. The most frequent AEs were nasopharyngitis, diarrhoea, back pain, upper respiratory tract infection, syphilis and arthralgia, and were reported in similar proportions across treatment groups.

Viral replication findings in the TANGO and GEMINI-1 & 2 studies for the 2-drug regimen Dovato (dolutegravir/lamivudine) and dolutegravir (DTG) plus lamivudine in virologically suppressed and treatment-naïve adults living with HIV-1, respectively.,

In the TANGO study after 96 weeks of treatment, the dolutegravir/lamivudine and TBR arms demonstrated similar proportions of participants with a viral load ‘target not detected’ (TND) (73% vs 69%, respectively), a sensitive measurement of viral load.

Across baseline viral load categories through Week 96, data for dolutegravir/lamivudine showed higher proportions of participants with TND at all study visits, at 37% versus 31% for the TBR arm. The occurrence of any elevated viral loads above 50 copies/mL was lower in the dolutegravir/lamivudine arm (6%) versus the TBR arm (10%). In addition, changes in markers of inflammation were small and comparable between treatment arms through 96 weeks of treatment.

The GEMINI-1 & 2 studies are identically designed, phase III non-inferiority studies evaluating a 2-drug regimen of DTG plus lamivudine compared with a 3-drug regimen of DTG + FTC/TDF in treatment-naïve adults living with HIV. The findings continued to demonstrate the efficacy and durability of DTG plus lamivudine in treatment-naïve adults as shown by the proportion of participants with a viral load TND being similar through Week 144 in the DTG plus lamivudine and DTG + FTC/TDF arms (Intention to Treat-Exposed (ITT-E) population by Snapshot: 63% vs 65%, respectively; observed population: 77% vs 78%, respectively). Additionally, the frequency of viral load (VL) “blips” (one VL ≥50 to

Week 48 findings from the STAT study evaluating the 2-drug regimen of Dovato (dolutegravir/lamivudine) for rapid initiation of treatment after diagnosis in adults with HIV-1. The phase IIIb STAT study was designed to evaluate the feasibility, efficacy, and safety of using dolutegravir/lamivudine as a first-line regimen in a rapid Test and Treat model of care increasingly seen in clinical practice, with treatment initiated within 14 days of diagnosis before baseline hepatitis B virus (HBV) co-infection status, renal function and resistance test results were available. At Week 48, regardless of therapy, 82% (107/131) of all participants and 97% (107/110) of those with available data achieved HIV-1 RNA

Final one-year patient and healthcare team results from the implementation research study, CUSTOMIZE (Cabotegravir plus Rilpivirine in the US To Optimize and Measure Implementation and Experience). The CUSTOMIZE study was designed to identify how best to integrate the monthly injectable treatment, Cabenuva (cabotegravir/rilpivirine), into US healthcare practices. A press release with data from the CUSTOMIZE trial is available on the media page at www.viivhealthcare.com.

Week 124 findings from the FLAIR study evaluating long-acting

cabotegravir and rilpivirine administered monthly for the treatment of HIV-1. The phase III FLAIR study was designed to assess non-inferiority of the monthly regimen of Cabenuva (cabotegravir; rilpivirine) compared to daily, oral Triumeq (abacavir/dolutegravir/lamivudine). The data presented showed that the long-acting regimen maintained virologic suppression (HIV-1 RNA

Updated virology and efficacy results from HPTN 084, a study sponsored by the U.S. National Institute of Allergy and Infectious Diseases (NIAID). HPTN 084 is a randomized double-blind controlled-superiority study assessing the safety and efficacy of investigational, long-acting injectable cabotegravir for pre-exposure prophylaxis (CAB-LA) for preventing HIV in African women aged 18-45 years. Daily oral emtricitabine/tenofovir disoproxil fumarate (FTC/TDF) was an active comparator; there was no placebo control. CAB-LA and FTC/TDF tablets were both well tolerated throughout the study, with most adverse events being mild or moderate in severity and with the frequency largely balanced between both treatment arms. Injection site reactions were more frequent in the CAB-LA arm.

At the time of unblinding in November 2020, there were four infections in the CAB-LA arm detected at the site level. Following retrospective virology testing at the laboratory centre, one of four participants in the CAB-LA arm had HIV infection at enrolment prior to CAB-LA administration. Three of four infections in the CAB-LA arm occurred in women who did not receive injections or received delayed injections. There were no reports of major integrase mutations nor infections during the oral lead-in or PK tail phases. When prevalent infections were excluded, HIV incidence (95% CI) in the CAB-LA arm was 0.15 (0.03-0.45) per person year and the unadjusted hazard ratio for CAB-LA vs. FTC/TDF was 0.08 (95%CI 0.03, 0.27) yielding a 92% reduction in infections when compared to FTC/TDF, which had an unadjusted hazard ratio of (1.85 (1.3, 2.57).

Estimated investigational long-acting PrEP effectiveness in the HPTN 084 cohort using a model-based HIV incidence in the absence of PrEP. For ethical reasons, effectiveness of new HIV prevention products, such as long-acting injectable cabotegravir for pre-exposure prophylaxis (CAB-LA,) must be compared to an approved PrEP product such as FTC/TDF. A hypothetical placebo control, utilizing placebo arm data from previous trials to predict cumulative HIV incidence over one year of follow-up, suggests that CAB-LA and daily,

oral FTC/TDF have an effectiveness against HIV acquisition of 91% (95% cred. int. 76%-97%) and 15% (95% cred. int. -26%-44%), respectively when modelling efficacy data from HPTN 084 from both experimental arms. This model-based comparison provides additional assurance that CAB-LA continues to demonstrate high rates of efficacy when compared to a hypothetical placebo arm generated from previous prevention trials among women in sub-Saharan Africa (the location of the HPTN 084 patient population).

Understanding participant experiences and preferences in an injectable PrEP trial: HPTN 083, sponsored by the U.S. National Institute of Allergy and Infectious Diseases (NIAID), is a randomised, double-blind international clinical trial of investigational long-acting injectable cabotegravir (CAB-LA) versus daily oral FTC/TDF for HIV prevention among cisgender men and transgender women who have sex with men (MSM/TGW). Previous results demonstrated a 66% reduction in HIV incidence in participants randomised to CAB-LA versus FTC/TDF. The CAB-LA injection and FTC/TDF tablets were both well tolerated throughout the study, with most adverse events being mild or moderate in nature and balanced between both treatment arms.

Participants' experiences prior to unblinding in May 2020 provided initial insights into preferences and best practices for implementing injectable PrEP. Seventy-two participants enrolled in HPTN 083 were sampled for individual qualitative interviews. MSM/TGW viewed site/clinic flexibility and an open and affirming clinic environment as key facilitators to injection adherence. To support injection adherence over time, interventions that target structural barriers and flexible means of injection delivery may be most effective.

Survey findings on interest in a long-acting injectable option for HIV prevention and preferences for implementation among US men having sex with men (MSM). Findings from the annual American Men's Internet Survey of more than 10,000 men included questions about the willingness to use a long-acting, injectable (LAI) medicine for pre-exposure prophylaxis (PrEP) and perceived facilitators of and barriers to its uptake. Among men having sex with men (MSM), a group potentially at higher risk of acquiring HIV, 72% said they were somewhat or very likely to use LAI-PrEP. Facilitators of uptake included every 2-month dosing, but a preference was expressed for even longer dosing intervals and emphasis on optimizing adherence,

persistence, and reducing clinical burden. Barriers to uptake included out of pocket costs (52%) and a product with perceived severe side effects (30%).

ViiV Healthcare will be part of an IAS-led symposium about the latest advances in HIV cure, presenting a summary of the work being done as part of its collaboration with the University of North Carolina at Chapel Hill, including an update on approaches that induce latent HIV and reduce the viral load.

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

| Abstract title | First Author | Presentation |

| Dolutegravir/lamivudine | | |

| Switching to the 2-drug regimen of dolutegravir/lamivudine (DTG/3TC) fixed-dose combination (FDC) is non-inferior to continuing a 3-drug regimen through 48 weeks in a randomized clinical trial (SALSA)| Llibre J | Oral Presentation |

| Feasibility, Efficacy, and Safety of Dolutegravir/Lamivudine (DTG/3TC) as a First-line Regimen in a Test-and-Treat Setting for Newly Diagnosed People Living with HIV (PLWH): 48-Week Results of the STAT Study| Rolle CP | E-Poster |

| Metabolic health outcomes at week 144 in the TANGO Study, comparing a switch to DTG/3TC versus maintenance of TAF-based regimens| Van Wyk J | E-Poster |

| Comparison of Viral Replication for the 2-Drug Regimen (2DR) of Dolutegravir/Lamivudine (DTG/3TC) versus a 3/4-Drug Tenofovir Alafenamide-based regimen (TBR) in the TANGO Study through Week 96| Wang R | On-Demand Oral Abstract Presentation |

| DTG+3TC in GEMINI-1&-2: HIV-1 replication at

| Cabotegravir/rilpivirine LA for treatment | | |

| CAB+RPV LA implementation outcomes and acceptability of monthly clinic visits improved during COVID-19 pandemic across US healthcare clinics (CUSTOMIZE: Hybrid III Implementation-Effectiveness Study)| Czarnogorski M | E-Poster |

| Clinical outcomes during CUSTOMIZE: a hybrid III implementation-effectiveness study focused on implementation of cabotegravir plus rilpivirine (CAB+RPV) LA in US healthcare settings| Sinclair G | E-Poster |

| CUSTOMIZE: Overall results from a hybrid III implementation-effectiveness study examining implementation of cabotegravir and rilpivirine long-acting injectable (CAB+RPV LA) or HIV treatment in US healthcare settings; final patient and provider data| Czarnogorski M | On-Demand Oral Abstract Presentation |

| Week 124 results of the randomized, open-label, phase 3 FLAIR study evaluating long-acting cabotegravir + rilpivirine for treatment in adults with HIV-1 infection (ITT-E population)| Orkin C | On-Demand Oral Abstract Presentation |

| Cabotegravir LA for PrEP | | |

| High interest long-acting injectable HIV pre-exposure prophylaxis among nationwide sample of men who have sex with men in the US: AMIS 2019| Sanchez T | E-Poster |

| Preferences for Implementing Long-Acting Injectable Pre-Exposure Prophylaxis among Cisgender Men Who have Sex with Men in the US| Beckham SW | Oral Presentation |

| Variation in preferences for long-acting injectable PrEP among US men who have sex with men: A latent class analysis| Beckham SW | On-Demand Oral Abstract Presentation |

| Fostemsavir | | |

| Antiretroviral agents used in optimized background therapy with fostemsavir in heavily treatment-experienced adults with HIV-1: exploratory analyses of the phase 3 BRIGHTE study| Ackerman P | E-Poster |

| Long-term (96 week) safety of fostemsavir (FTR) in heavily-treatment experienced (HTE) adults infected with multi-drug resistance (MDR) HIV-1 (BRIGHTE phase 3 study)| Shepherd B | E-Poster |

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 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

- 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

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 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.

Llibre J, Alves C, Cheng CY, et al. Switching to the 2-drug regimen of dolutegravir/lamivudine (DTG/3TC) fixed-dose combination (FDC) is non-inferior to continuing a 3-drug regimen through 24 weeks in a randomised clinical trial (SALSA). Presented at the International AIDS Society Conference on HIV Science (IAS 2021).

van Wyk J, Ait-Khaled M, Santos J, et al. Metabolic health outcomes at week 144 in the TANGO Study, comparing a switch to DTG/3TC versus maintenance of TAF-based regimens. Presented at the International AIDS Society Conference on HIV Science (IAS 2021).

Clinicaltrials.gov. Switch study to evaluate dolutegravir plus lamivudine in virologically suppressed human immunodeficiency virus type 1 positive adults (TANGO). Available at: https://clinicaltrials.gov/ct2/show/NCT03446573. Accessed July 2021.

Wang R, Wright J, George N, et al. Comparison of viral replication for the 2-drug regimen (2DR) of dolutegravir/lamivudine (DTG/3TC) versus a 3/4-drug tenofovir alafenamide–based regimen (TBR) in the TANGO study through week 96. Presented at the International AIDS Society Conference on HIV Science (IAS 2021).

Underwood M, Urabityte R, Wang R, et al. DTG+3TC in GEMINI-1&-2: HIV-1 replication at

Rolle CP, Berhe M, Singh T, et al. Feasibility, efficacy, and safety of dolutegravir/lamivudine (DTG/3TC) as a first-line regimen in a test-and-treat setting for newly diagnosed people living with HIV (PLWH): 48-week results of the STAT study. Presented at the International AIDS Society Conference on HIV Science (IAS 2021).

Czarnogorski M, Garris C, D'Amico R, et al. CUSTOMIZE: overall results from a hybrid III implementation-effectiveness study examining implementation of cabotegravir and rilpivirine long-acting injectable for HIV treatment in US healthcare settings; final patient and provider data. Presented at the International AIDS Society Conference on HIV Science (IAS 2021).

Orkin C, D'Amico R, Morell EB, et al. Week 124 results of the randomised, open-label, phase 3 flair study evaluating long-acting cabotegravir + rilpivirine for treatment in adults with HIV-1 infection (ITT-E population). Presented at the International AIDS Society Conference on HIV Science (IAS 2021).

Beckham SW, Sanchez T, Zlotorzynska M, et al. Preferences for Implementing Long-Acting Injectable Pre-Exposure Prophylaxis among Cisgender Men Who have Sex with Men in the US. Presented at the International AIDS Society Conference on HIV Science (IAS 2021).

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 and any impacts of the COVID-19 pandemic.

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**Newsroom:** https://wireassociation.eu/newsroom/gsk
**Website:** https://www.gsk.com/
**Primary Email:** corporate.media@gsk.com

## Social Media

Facebook - https://www.facebook.com/GSK
Twitter - http://twitter.com/GSK
Youtube - http://www.youtube.com/GSK
Linkedin - http://www.linkedin.com/company/glaxosmithkline
Instagram - https://www.instagram.com/gsk/

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