

# ViiV Healthcare to present new data from innovative HIV treatment and prevention portfolio at AIDS 2022

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Data to be presented include long-term and real-world data from portfolio of medicines, including long-acting and 2-drug regimens

ViiV Healthcare, the global specialist HIV company majority-owned by GSK, with Pfizer and Shionogi as shareholders, today announced the presentation of 29 abstracts from the company's diverse portfolio of licensed treatment and prevention options at the 24th International AIDS Conference (AIDS 2022) being held in Montreal, Canada from 29 July – 2 August.

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

The needs of people living with HIV continue to evolve, and the broad range of data to be presented at AIDS 2022 illustrates ViiV Healthcare's leadership and commitment to innovation in addressing these changing needs. We're excited to be presenting new data related to HIV prevention, real-world data from long-acting and 2-drug regimens, studies that are specifically aimed at understanding the impact of antiretrovirals among older patients and long-term findings for heavily treatment-experienced patients. We look forward to connecting in person at this year's meeting and sharing these data with the scientific and HIV communities.

Key abstracts to be presented at AIDS 2022 by ViiV Healthcare and its study partners will include:

- Updated efficacy and safety results from the HPTN 084 study of cabotegravir long-acting for PrEP in cisgender women 1: Findings to be presented at AIDS 2022 will report on outcomes from the 12-month

period following trial unblinding, including the rate of reduction in HIV incidence of cabotegravir, an updated efficacy reading compared to emtricitabine/tenofovir disoproxil fumarate (FTC/TDF) tablets, and pregnancy outcomes.

- An analysis of efficacy, safety, and gender affirming hormonal therapy (GAHT) interactions among transgender women in the HPTN 083 study of long-acting cabotegravir for PrEP 2: Findings to be presented at AIDS 2022 will include an evaluation of the impact of GAHT on cabotegravir in a subset of transgender women with and without GAHT. The analysis also includes a report on a comparison of participant characteristics, including history of interpersonal violence, HIV risk perception, and grade 2+ adverse events, between transgender women and the larger HPTN 083 study population.
- Week 240 results of the phase III BRIGHTE study investigating the efficacy and safety of fostemsavir in heavily treatment-experienced adults with HIV 3, which build upon earlier 96-week efficacy and safety data. Long-term results to be presented will share virologic response rates through week 240 in multi-drug resistant adults living with HIV, with mean CD4+ cell counts along with adverse events.
- Real-world outcomes from the CARLOS study evaluating switching to long-acting cabotegravir and rilpivirine for the treatment of HIV 4: Findings to be presented include an analysis of reasons for switching to long-acting therapy from the perspectives of people living with HIV and healthcare providers, and feature the most common reason for initiating cabotegravir and rilpivirine among these groups.
- Safety and effectiveness outcomes from the CARISEL study on cabotegravir and rilpivirine long-acting integration into European clinical settings 5: Findings to be presented will demonstrate that cabotegravir and rilpivirine long-acting administered every two months was well tolerated and highly effective in maintaining virologic suppression, with a low rate of virologic failure, across diverse European clinical settings and participants.
- Real-world outcomes from the TANDEM study evaluating dolutegravir-based 2-drug regimens for the treatment of HIV 6: Findings to be presented feature the most common reason for initiating dolutegravir/lamivudine (DTG/3TC) and an analysis of real-world results among treatment-naïve people living with HIV initiating a DTG/3TC regimen and people living with HIV switching to a DTG/3TC

regimen.

- 48-week results from the SALSA study analysing patient-reported outcomes in older adults after switching to a 2-drug regimen of dolutegravir/lamivudine (DTG/3TC) 7: Findings to be presented include patient-reported outcomes in virologically suppressed adults over the age of 50 living with HIV on a current antiretroviral regimen (CAR) consisting of at least three drugs on the DTG/3TC regimen including symptom distress module scores, HIV treatment satisfaction, and lifestyle/ease sub-score.

Here is a list of ViiV Healthcare sponsored and supported studies to be presented at AIDS 2022:

| Abstract title | First Author | Presentation |

| Dolutegravir | | |

| Efficacy and Safety of Switching to Dolutegravir/Lamivudine by Baseline Regimen in Virologically Suppressed Adults: 48-Week TANGO/SALSA Pooled Analysis| S. Scholten | E-poster |

| Changes in Inflammatory Biomarkers and Baseline Variables After Switching to Dolutegravir/Lamivudine (DTG/3TC) in 2 Randomized Clinical Trials of Virologically Suppressed Adults: 48-Week TANGO/SALSA Pooled Analysis| J.M. Llibre | E-poster |

| Efficacy and Safety of Switching to Dolutegravir/Lamivudine (DTG/3TC) in Treatment-Experienced, Virologically Suppressed PLHIV Aged ≥50 Years: Results from the 48-Week TANGO/SALSA Pooled Analysis| S. Walmsley | Poster Exhibition |

| Low Level of Virologic Failure and Resistance in ART-Experienced, Integrase Inhibitor-Naïve Participants Receiving Dolutegravir (DTG) and Nucleoside Reverse Transcriptase Inhibitors (NRTIs) Combined Regimens: 10-Year Follow-up in the SAILING Study| R. Wang | E-poster |

| Switching to Dolutegravir/Lamivudine Two-drug Regimen: Durability and Virologic Outcomes in Routine U.S. Clinical Care| G. Pierone | E-poster |

| A Multicentre Observational Study to Determine the Safety and

- Effectiveness of Dolutegravir (DTG) Use During Pregnancy: Data from DOLOMITE-NEAT ID Network Study| J.D. Kowalska | E-poster |
- | Treatment Experience of Single-tablet Dolutegravir/Lamivudine in the United States: Results from the ‘Real-world Outcomes With Dolutegravir-based Two-drug-regimens for the Treatment of HIV-1’ (TANDEM Study)| S. Schneider | E-poster |
- | Improvements in Patient-Reported Outcomes in Older Adults Aged  $\geq 50$  Years With HIV-1 After Switching to a 2-Drug Regimen of Fixed-Dose Combination DTG/3TC: 48-Week Results from the SALSA Study| P.N. Kumar | E-poster |
- | Cabotegravir for treatment | | |
- | Long-acting Cabotegravir + Rilpivirine Injection Site Reactions: Pooled Week 96 Results | N. Chamay | E-poster |
- | Long-acting Cabotegravir + Rilpivirine in Older Adults: Pooled Phase 3 Week 96 Results | E.R. Elliot | E-poster |
- | “Give it a Shot”: Best Practices from HCPS for Administering Long-acting CAB+RPV | P. Teichner | E-poster |
- | A Study Evaluating the Safety, Tolerability and Pharmacokinetics of a High-Concentration (CAB 400mg/mL) Cabotegravir Long-Acting Injectable Formulation Following Subcutaneous and Intramuscular Administration in Healthy Adult Participants| P. Benn | Poster Exhibition |
- | Initiating Long-Acting cabotegravir and rilpivirine in a Real-World Setting – Clinical Characteristics and Switch Reasons from PLHIV and Health Care Provider Perspective in the German CARLOS Cohort| C. Wyen | E-poster |
- | Week 96 Weight and Lipid Changes from Baseline Among Participants Receiving cabotegravir and rilpivirine Long-Acting or Comparator Therapy in the ATLAS-2M and FLAIR Studies| P. Patel | E-poster |
- | Pharmacokinetics (PK) and Tolerability of Cabotegravir (CAB) and Rilpivirine (RPV) Long-Acting (LA) Intramuscular (IM) Injections to the Vastus Lateralis (Lateral Thigh) Muscles of Healthy Adult Participants|

K. Han | E-poster |

| Factors Associated with Healthcare Providers' Preference for Forgoing an Oral lead-in Phase when Initiating Long-acting Injectable ART in the SOLAR Clinical Trial| T.S. Karver | E-poster |

| Safety and Effectiveness Outcomes From the CARISEL Study: Phase 3b Hybrid-3 Implementation Study Integrating Cabotegravir + Rilpivirine Long-Acting Into European Clinical Settings| C. Jonsson-Oldenbuttel | E-poster |

| Cabotegravir long-acting for prevention | | |

| Willingness And Preferences For Long-Acting Injectable PrEP Among US Men Who Have Sex With Men | S.W. Beckham | E-poster |

| Audience Segmentation of Preferences for Long-Acting Injectable PrEP Among US MSM: A Latent Class Analysis| S.W. Beckham | E-poster |

| Supporting achievement of the State of Georgia's 25% HIV Incidence Reduction Target Among MSM: A Mathematical Model To Evaluate The Potential Impact Of Long-Acting Preexposure Prophylaxis In Atlanta| R. Blissett | E-poster |

| Cabotegravir for prevention collaborative studies | | |

| Transgender Women (TGW) in HPTN 083: An Evaluation of Safety, Efficacy, and Gender Affirming Hormonal Therapy (GAHT) Interactions with Long-acting Cabotegravir (CAB-LA)| B. Grinsztejn | E-poster |

| Long-acting Cabotegravir: Updated Efficacy And Safety Results From HPTN 084 | S. Delany-Moretlwe | Co-Chair's Choice Oral Presentation |

| Selection of Cabotegravir Dosing Regimens for HIV Treatment and Pre-exposure Prophylaxis (PrEP) in Adolescents by Leveraging Adult Data| K. Han | Poster Exhibition |

| Acceptability of Injectable Versus Daily Oral Pills for HIV Prevention: Lesson from HPTN 084 | E. Tolley | E-poster |

| Fostemsavir | | |

| Efficacy and Safety of Fostemsavir Plus Optimized Background Therapy in Heavily Treatment-Experienced Adults With HIV-1: Week 240 Results of the Phase 3 BRIGHT Study| J. Aberg | E-poster |

| General | | |

| Bridging the Gap Between Patient Perceptions and Delivered Care Among People Living with HIV in the Asian Region| S. Park | E-Poster |

| General partner studies | | |

| Implementation of Telemedicine for HIV Care in Public Health System of Buenos Aires, Argentina: A Qualitative Study Based on Surveys Among Health Workers to Assess Acceptability of This Strategy| M. Bullo | E-Poster |

| Do ART and Chemsex Drugs Get Along? Potential Drug-Drug Interactions in a Cohort of HIV-Positive Chemsex Users| L. de la Mora | E-Poster |

| U=U Awareness Promotes Engagement in HIV Care Among HIV Negative Men Who Have Sex With Men in Mississippi and Alabama| T. McKay | Poster Exhibition |

| Differences in Burden of Internalized HIV Stigma (IHS) by Race/Ethnicity Among People With HIV (PWH) Living in the US| L. N. Drumright | E-Poster |

| Does Travel Time Matter?: Transportation Vulnerability and Access to HIV Care Among People Living with HIV in South Carolina| P. Hung | Poster Exhibition |

| Implementation of a Ridesharing Intervention to Address Transportation Vulnerability for People Living with HIV in the Southern United States: Qualitative Findings on Acceptability and Feasibility| S. E. Harrison | 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 counselled on the consistent use of effective contraception

#### Lactic Acidosis and Severe Hepatomegaly with Steatosis:

Fatal cases have been reported with the use of nucleoside analogues, 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  $\geq 2\%$ , all grades) with Dovato were headache (3%), nausea (2%), diarrhoea (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)

For more information, please see US prescribing information.

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

(marketed as Vocabria/Rekambys outside the US)

Cabenuva is indicated as a complete regimen for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults and adolescents who are 12 years of age or older and weighing at least 35 kg to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than

- 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.

- Serious post-injection reactions (reported in less than 1% of subjects) were reported within minutes after the injection of rilpivirine, including dyspnea, bronchospasm, agitation, abdominal cramping, rash/urticaria, dizziness, flushing, sweating, oral numbness, changes in blood pressure, and pain (e.g., back and chest). 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. The suspensions should be injected slowly via intramuscular injection and 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 or every-2-month injection dosing schedule because

non-adherence 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 when dosed monthly and no later than 2 months after the final injections of Cabenuva when dosed every 2 months. If virologic failure is suspected, switch the patient to an alternative regimen as soon as possible
- The most common adverse reactions (incidence  $\geq 2\%$ , all grades) with Cabenuva were injection site reactions, pyrexia, fatigue, headache, musculoskeletal pain, nausea, sleep disorders, dizziness, and rash
- The safety of CABENUVA in adolescents is expected to be similar to adults
- Refer to the applicable full Prescribing Information for important drug interactions with Cabenuva, VOCABRIA, or EDURANT
- 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

For more information please see US Prescribing Information.

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  $\geq 5\%$  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.

For more information please see US Prescribing Information.

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 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](http://www.viivhealthcare.com).

GSK is a global biopharma company with a purpose to unite science, technology, and talent to get ahead of disease together. Find out more at [gsk.com/company](http://gsk.com/company)

#### 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, GSK's Q1 Results for 2022 and any impacts of the COVID-19 pandemic.

1 S. Delany-Moretlwe et. al. Long acting cabotegravir: updated efficacy and safety results from HPTN 084. Presented at AIDS 2022.

2 B. Grinsztejn et. al. Transgender Women (TGW) in HPTN 083: An Evaluation of Safety, Efficacy, and Gender Affirming Hormonal Therapy (GAHT) Interactions with Long-acting Cabotegravir (CAB-LA). Presented at AIDS 2022.

3 J. Aberg. B. Shepard et. al. Efficacy and Safety of Fostemsavir Plus Optimized Background Therapy in Heavily Treatment-Experienced Adults With HIV-1: Week 240 Results of the Phase 3 BRIGHT Study. Presented at AIDS 2022.

4 C. Wyen et. al. Initiating Long-Acting cabotegravir and rilpivirine in a Real-World Setting – Clinical Characteristics and Switch Reasons from PLHIV and Health Care Provider Perspective in the German

CARLOS Cohort. Presented at AIDS 2022.

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6 S. Schneider et. al. Treatment Experience of Single-tablet Dolutegravir/Lamivudine in the United States: Results from the 'Real-world Outcomes With Dolutegravir-based Two-drug-regimens for the Treatment of HIV-1' (TANDEM Study). Presented at AIDS 2022.

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*Press release distributed by Wire Association on behalf of GSK, on Jul 25, 2022. For more information subscribe and [follow](#) us.*

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## GSK

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