ViiV Healthcare to present new long-term findings from its innovative 2-drug and long-acting HIV medicines portfolio at CROI 2022

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For media and investors only

Data reinforce ViiV Healthcare's leadership and commitment to developing ground-breaking medicines for HIV treatment and prevention

ViiV Healthcare, the global specialist HIV company majority-owned by GlaxoSmithKline plc (GSK), with Pfizer Inc. (Pfizer) and Shionogi Limited (Shionogi) as shareholders, today announced the presentation of company and investigator sponsored abstracts from its industry-leading HIV treatment and prevention portfolio of approved long-acting medicines and 2-drug regimens (2DRs) at the Conference on Retroviruses and Opportunistic Infections (CROI 2022), being held virtually 12-16 February.

Key data presentations will include:

- Data demonstrating further evidence for the long-acting regimen of Cabenuva(cabotegravir and rilpivirine) administered every two months, including ATLAS-2M 152-week efficacy and safety findings for the treatment of HIV-1 in virologically suppressed adults, which builds upon previous 96-week efficacy and safety data. An investigator-sponsored analysis of adolescent perspectives toward the long-acting regimen will also be presented.

- Data demonstrating further evidence for the 2-drug regimen Dovato (dolutegravir/lamivudine), including an analysis of long-term 144-week efficacy findings from the TANGO study, which evaluated virologic response in participants receiving dolutegravir/lamivudine versus

tenofovir alafenamide (TAF) based regimens. Two abstracts will also be presented from Week 48 findings from the SALSA study that assessed the proportion of baseline participant samples with archived resistance and metabolic health findings for the 2-drug regimen.

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

> The data to be presented at CROI includes study results of up to three years that reinforce the long-term efficacy and safety data of our long-acting medicines and 2-drug regimens. Despite the challenging environment we've faced for the last two years, ViiV Healthcare has continued to demonstrate leadership by bringing forward ground-breaking advances that offer people more options for HIV treatment and prevention. We look forward to sharing our latest findings with the HIV community at CROI 2022.

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

ATLAS-2M 152-week efficacy and safety findings for long-acting cabotegravir and rilpivirine administered every two months for the treatment of HIV-1 in virologically suppressed adults: The ATLAS-2M study was designed to assess the non-inferiority and safety of long-acting cabotegravir and rilpivirine administered every two months compared to monthly administration for the treatment of HIV-1. Findings to be presented at CROI 2022 provide long-term outcomes for cabotegravir and rilpivirine as a complete regimen for the maintenance of HIV-1 virologic suppression.

Adolescent and Parent Experiences with Long-Acting Injectables in the MOCHA study (Investigator sponsored): The ongoing More Options for Children and Adolescents Study (MOCHA) was designed to examine the use of long-acting cabotegravir and rilpivirine injections in adolescents living with HIV-1. Findings from Cohort 1 of MOCHA to be presented at CROI 2022 provide qualitative and quantitative insights into participant experiences and perceptions around acceptability of the long-acting regimen.

Low-level HIV replication for dolutegravir/lamivudine vs TAF-based regimens in the TANGO study: The TANGO study was designed to assess the antiviral efficacy and safety of switching to a 2DR

consisting of dolutegravir/lamivudine in adults living with HIV-1 who are virologically suppressed and stable on a TAF-based regimen. Findings to be presented at CROI 2022 include longer-term data analysing the proportions of participants with viral load (VL)

Post-hoc analyses evaluating archived resistance and response to dolutegravir/lamivudine, and metabolic health data, in the SALSA study: The SALSA study was set up to assess the antiviral efficacy and safety of switching to a 2DR consisting of dolutegravir/lamivudine in adults living with HIV-1 who are virologically suppressed on a current antiretroviral regimen (CAR) consisting of at least three drugs (including two nucleoside reverse transcriptase inhibitors [NRTIs] plus a third agent). Findings to be presented at CROI 2022 include data assessing the proportion of baseline participant samples with archived resistance, and virologic response through 48 weeks using the stringent VL measure

In addition to these studies assessing ViiV Healthcare's long-acting and 2-drug HIV treatment regimens, the HIV Prevention Trials Network (HPTN) will present new data from four abstracts related to cabotegravir long-acting for PrEP from the HPTN 083 and 084 studies. Data from the HPTN studies, which were among the most diverse and comprehensive HIV prevention trial programs to date, will include updated efficacy, safety and case studies for cabotegravir long-acting for PrEP from HPTN 083; an evaluation of safety and pharmacokinetics in pregnant women from HPTN 084; findings on the early detection of HIV infection and the impact on integrase strand transfer inhibitor (INSTI) resistance risk when taking cabotegravir long-acting for PrEP; and a counterfactual estimation of the efficacy of cabotegravir long-acting for PrEP against placebo using external trial data.

The full list of ViiV Healthcare data and investigator sponsored studies to be presented at CROI 2022 is outlined below:

| Abstract Title | First Author | Presentation |

| Dolutegravir | | |

| Low-level HIV viral replication for DTG/3TC vs TAF-based regimen in the TANGO through Week 144 | R. Wang | Poster |

| Archived resistance and response to

| Week 48 metabolic health after switch to DTG/3TC vs CAR by baseline regimen (SALSA) | D. Hagins | Poster |

| Birth outcomes following prenatal exposure to dolutegravir: the Dolomite-EPPICC study | C. Thorne | Poster |

| Cabotegravir/rilpivirine LA for treatment | | |

| Long-acting cabotegravir + rilpivirine every 2 months: ATLAS-2M week 152 weeks | E. T. Overton | Poster |

| Adolescent and parent experiences with long-acting injectables in the MOCHA study | E. D. Lowenthal | Poster (Investigator sponsored) |

| Safety and PK of long-acting cabotegravir and rilpivirine in adolescents | C. B. Moore | Poster (Investigator sponsored) |

| Effect of L74I Polymorphism on fitness of HIV-1 subtype A6 resistant to cabotegravir | Z. Hu | Poster (Investigator sponsored) |

| Cabotegravir LA for PrEP | | |

| Updated efficacy, safety, and case studies in HPTN 083: CAB-LA vs. TDF/FTC for PrEP | R. Landovitz | Oral Presentation (Investigator sponsored) |

| CAB-LA PrEP: Early Detection of HIV infection may reduce INSTI resistance risk | S. Eshleman | Oral Presentation (Investigator sponsored) |

| Evaluation of CAB-LA safety and PK in pregnant women in the blinded phase of HPTN 084 | S. Delany-Moretlwe | Poster (Investigator sponsored) |

| Counterfactual estimation of CAB-LA efficacy against placebo using external trial data | D. Donnell | Oral Presentation (Investigator sponsored) |

| General | | |

| Trends in cancer incidence in different modern art-eras among people living with HIV | L. Greenberg | 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 ≥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)

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; rilpivirine) 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, 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 ≥2%, all grades) with Cabenuva were injection site reactions, pyrexia, fatigue, headache, musculoskeletal pain, nausea, sleep disorders, dizziness, and rash.

- The most common injection site reactions (grades 1-3, ≥1%) were pain/discomfort, nodules, induration, swelling, erythema, pruritus, bruising/discoloration, warmth, and hematoma

- 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

Please see full Prescribing Information.

Important Safety Information for Apretude (cabotegravir 200 mg/mL extended-release injectable suspension)

Apretude is an HIV-1 integrase strand transfer inhibitor (INSTI) indicated in at-risk adults and adolescents weighing at least 35 kg for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection. Individuals must have a negative HIV-1 test prior to initiating Apretude (with or without an oral lead-in with oral cabotegravir) for HIV-1 PrEP. Apretude is administered as a single 600-mg (3-mL) intramuscular (IM) injection of cabotegravir in the muscle of the buttock by a health care professional once every 2 months.

WARNING: RISK OF DRUG RESISTANCE WITH USE OF APRETUDE FOR HIV-1 PRE-EXPOSURE PROPHYLAXIS (PrEP) IN UNDIAGNOSED HIV-1 INFECTION

See full prescribing information for complete boxed warning.

Individuals must be tested for HIV-1 infection prior to initiating

Apretude or oral cabotegravir, and with each subsequent injection of Apretude, using a test approved or cleared by the FDA for the diagnosis of acute or primary HIV-1 infection. Drug-resistant HIV-1 variants have been identified with use of Apretude for HIV-1 PrEP by individuals with undiagnosed HIV-1 infection. Do not initiate Apretude for HIV-1 PrEP unless negative infection status is confirmed. Individuals who become infected with HIV-1 while receiving Apretude for PrEP must transition to a complete HIV-1 treatment regimen.

- Unknown or positive HIV-1 status.

- Previous hypersensitivity reaction to cabotegravir.

- Coadministration with drugs where significant decrease in cabotegravir plasma concentrations may occur.

- Use Apretude for HIV-1 PrEP to reduce the risk of HIV-1 infection as part of comprehensive management to reduce the risk of HIV-1 acquisition.

- Potential risk of developing resistance to Apretude if an individual acquires HIV-1 either before or while taking Apretude or following discontinuation of Apretude. Reassess risk of HIV-1 acquisition and test before each injection to confirm HIV-1 negative status.

- Residual concentrations of cabotegravir may remain in the systemic circulation of individuals up to 12 months or longer.

- Hypersensitivity reactions have been reported in association with other integrase inhibitors. Discontinue Apretude immediately if signs or symptoms of hypersensitivity reactions develop.

- Hepatotoxicity has been reported in patients receiving cabotegravir. Clinical and laboratory monitoring should be considered. Discontinue Apretude if hepatotoxicity is suspected.

- Depressive disorders have been reported with Apretude. Prompt evaluation is recommended for depressive symptoms.

The most common adverse reactions (all grades) observed in at least 1% of subjects receiving Apretude were injection site reactions, diarrhea, headache, pyrexia, fatigue, sleep disorders, nausea, dizziness, flatulence, abdominal pain, vomiting, myalgia, rash,

decreased appetite, somnolence, back pain, and upper respiratory tract infection.

To report SUSPECTED ADVERSE REACTIONS, contact ViiV Healthcare at 1-877-844-8872 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

- Refer to the full prescribing information for important drug interactions with Apretude.

- Drugs that induce uridine diphosphate glucuronosyltransferase (UGT1A1) may significantly decrease plasma concentrations of cabotegravir.

USE IN SPECIFIC POPULATIONS

- Lactation: Assess the benefit-risk of using Apretude to the infant while breastfeeding due to the potential for adverse reactions and residual concentrations in the systemic circulation for up to 12 months or longer after discontinuation.

- Pediatrics: Not recommended in individuals weighing less than 35 kg.

Please see full Prescribing Information.

ViiV Healthcare is a global specialist HIV company established in November 2009 by GlaxoSmithKline (LSE/NYSE: 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.

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 Q3 Results and any impacts of the COVID-19 pandemic.

Approved as Vocabria and Rekambys by the European Medicines Agency

Overton E, Richmond G, Rizzardini G, et al., Long-acting cabotegravir + rilpivirine every 2 months: ATLAS-2M Week 152 results. Presented at Conference on Retroviruses and Opportunistic Infections (CROI) February 2022.

Lowenthal E, Chapman J, Calabrese K, et al., Adolescent and parent experiences with long-acting injectables in the MOCHA study. Presented at Conference on Retroviruses and Opportunistic Infections (CROI) February 2022.

Wang R, George N, Ait-Khaled M, et al., Low-level HIV replication for DTG/3TC vs TAF-Based Regimen in TANGO through Week 144

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https://wireassociation.eu/newsroom/gsk/releases/en/viiv-healthcare-to-present-new-long-term-findings-from-its-innovative-2-drug-and-long-acting-hiv-medicines-portfolio-at-croi-2022-1874

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