Press release

For media and investors only

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ViiV Healthcare to present data for its next generation of ultra long-acting treatments for HIV

- Other key data to be presented from ViiV Healthcare's innovative pipeline and portfolio include the exploration of different mechanisms of action through broadly neutralising antibodies as well as real-world insights from established long-acting and 2-drug regimens

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GSK plc (LSE/NYSE: GSK) announced that ViiV Healthcare, the global specialist HIV company majority owned by GSK, with Pfizer and Shionogi as shareholders, today announced the presentation of 64 abstracts that includes highlights of the company's next-generation pipeline advancements, alongside data from its diverse portfolio of marketed HIV treatment and prevention options at the Conference on Retroviruses and Opportunistic Infections (CROI 2024) being held in Denver, Colorado, from 3 – 6 March 2024.

Kimberly Smith, M.D., MPH, Head of Research & Development at ViiV Healthcare, said: "As leaders in developing long acting injectables for the treatment of HIV, we're excited to present new data setting the stage for ViiV's next generation of medicines and demonstrating how key pipeline assets will target HIV in different ways. These findings, as well as the breadth of data we'll present on our marketed products, including new interim results from the LATITUDE study, reflect a portfolio and future-looking pipeline focused on ending the HIV epidemic. We look forward to sharing them with the scientific and HIV communities at CROI 2024."

Key abstracts to be presented at CROI 2024 by ViiV Healthcare and its study partners will include:

Data introducing our next generation of potential ultra long-acting medicines for HIV: ViiV Healthcare will share findings from a phase I study evaluating different formulations of cabotegravir and their potential for dosing every four months. The ongoing, open-label, single-dose, dose-escalation phase I study in 70 healthy adults assessed both the 200 mg/mL formulation of cabotegravir in combination with recombinant human hyaluronidase PH20 (rHuPH20), as well as a new formulation of cabotegravir (CAB-ULA) administered by itself.[1] Researchers will share safety and pharmacokinetic findings from both ultra long-acting approaches and their potential for future clinical development.

Findings advancing different mechanisms of action in HIV research: New phase IIa findings from the BANNER study of VH3810109 (N6LS), an investigational, broadly neutralising antibody (bNAb), will be presented. Researchers will share findings of the bNAb administered intravenously and the first efficacy findings of its subcutaneous administration.[2] Findings from the SPAN study of N6LS, examining the safety and tolerability of the highest subcutaneous and intravenous N6LS doses administered to date, with and without PH20, will also be presented.[3] Additionally, efficacy and safety data from a non-ViiV owned bNAb asset, VRC07-523LS, in a phase II, open-label clinical trial used in combination with long-acting CAB for maintenance antiretroviral therapy (ART) will be presented.[4]

New data of long-acting therapy vs daily oral standard of care, in traditionally non-adherent populations: Interim analysis of the LATITUDE phase III trial will be presented showing that, the injectable antiretroviral treatment for HIV, *Cabenuva* (cabotegravir and rilpivirine [CAB+RPV LA]), demonstrates superior efficacy compared to daily oral standard of care (SOC) in individuals with a history of antiretroviral adherence challenges. The NIAID/ACTG also announced a modification to the study, where further randomisation has been stopped and participants in the SOC arm are being given the option to switch to the long-acting therapy arm.[5]

Real-world evidence from across our treatment and prevention portfolios: New findings from SEARCH, a randomised study evaluating the real-world impact of the inclusion of long-acting cabotegravir for PrEP in an HIV prevention coverage package compared to the standard-of-care of oral PrEP and PEP alone in rural Uganda and Kenya, will also be presented.[6] Real-world evidence findings for the complete long-acting HIV treatment regimen *Cabenuva* will be presented from the OPERA cohort examining ART-experienced, virally suppressed adults living with HIV who switched to CAB+RPV LA or to an oral regimen.[7]

Findings for the 2-drug regimen, *Dovato* (dolutegravir, lamivudine [DTG/3TC]), will include the InfCare HIV study, which presents three-year switch data, from 3-drug regimen to *Dovato*, in a long-term real-world Swedish cohort.[8] This study adds to the body of real-world evidence to date that includes more than 40,000 people living with HIV.[9]

Here is a list of ViiV Healthcare-sponsored or supported studies to be presented at CROI 2024:

Title	First Author	Presentation Number	Presentation
Dolutegravir			
A single once-daily ABC/DTG/3TC tablet predicts safe and effective exposures in children 3 to <6kg	H. Chandasana	02770	Poster Tuesday, March 5 2:30-4:00pm MST
Population pharmacokinetics of ABC/DTG/3TC FDC to support dosing in peds with HIV-1 (IMPAACT 2019)	H. Chandasana	03110	Poster Tuesday, March 5 2:30-4:00pm MST
Dolutegravir and growth in pediatric populations with HIV-1: IMPAACT P1093 and IMPAACT 2019	M. McKenna	01783	Poster Tuesday, March 5 2:30-4:00pm MST
Switching to DTG+3TC vs 3-drug regimens in routine clinical care: long-term Swedish data	E. Sörstedt	01838	Poster Tuesday, March 5 2:30-4:00pm MST
Temporal trends of cardiovascular disease incidence in people with HIV from 2001-2021	N. Jaschinski	02263	Poster Tuesday, March 5 2:30-4:00pm MST
Increased cancer risk with low CD4 counts persists despite over 2 years of virological suppression	J. Hoy	01462	Poster Wednesday, March 6 2:30-4:00pm MST
Cabotegravir for Treatment			
Long-acting Injectable CAB/RPV is Superior to Oral ART in PWH with adherence challenges: ACTG A5359	A. Rana	03579	Oral Wednesday,

			March 6 12:51-1:00pm MST
Real-world utilization of cabotegravir + rilpivirine in the US: data from Trio Health cohort	J. J. Eron	01374	Poster Monday, March 4 2:30-4:00pm MST
Real-world effectiveness of cabotegravir + rilpivirine vs. standard of care oral regimens in the US	R. K. Hsu	01952	Poster Monday, March 4 2:30-4:00pm MST
HIV-1 RNA blips and low-level viral replication: SOLAR (CAB+RPV LA vs. BIC/FTC/TAF)	C. Latham	00138	Poster Monday, March 4 2:30-4:00pm MST
Model based comparison of cabotegravir pharmacokinetics following thigh and gluteal injections	K. Han	03157	Poster Wednesday, March 6 2:30-4:00pm MST
Cabotegravir for PrEP			
SEARCH Randomized trial of Dynamic Choice HIV Prevention including injectable cabotegravir (CAB-LA)	J. Kabami	03405	Late-Breaker Oral Tuesday, March 5 10:00-12:00pm MST
Pre-exposure prophylaxis with cabotegravir long-acting injectable in the OPERA cohort	A. Mills	01400	Poster Monday, March 4 2:30-4:00pm MST
Real-world use of cabotegravir long acting for pre-exposure prophylaxis: TRIO cohort	K. Mayer	01907	Poster Monday, March 4 2:30-4:00pm MST
Cabotegravir PopPK analysis of adults and adolescents living with HIV or at risk for HIV receiving PrEP	Y. Lin	03038	Poster Tuesday, March 5 2:30-4:00pm MST
Interest in long-acting injectable PrEP among transgender women in the United States	E. E. Cooney	00621	Poster Wednesday, March 6 2:30-4:00pm MST
Healthcare staff acceptability and feasibility of telehealth delivery of cabotegravir for PrEP	A. Liu	03080	Poster Wednesday, March 6

			2:30-4:00pm MST
Fostemsavir			
Temsavir treatment enhances bNAb recognition and subsequent clearance of HIV-1 infected cells	R. Ferris	02971	Poster Monday, March 4 2:30-4:00pm MST
Pipeline: Ultra Long-Acting Cabotegravir			
Phase I study of cabotegravir long-acting injectable formulations supports ≥4-monthly dose interval	K. Han	00251	Oral Monday, March 4 10:00-12:00pm MST
Pipeline: Broadly Neutralising Antibodies			
VH3810109 (N6LS) in antiretroviral therapy–naive adults with HIV-1: phase IIa BANNER efficacy data	P. Leone	01911	Oral Monday, March 4 10:00-12:00pm MST
Safety and efficacy of VRC07-523LS plus long-acting cabotegravir in the phase 2 ACTG A5357 Trial.	B. Taiwo	02254	Oral Monday, March 4 10:00-12:00pm MST
High-dose VH3810109 (N6LS) ± recombinant human hyaluronidase PH20: phase I SPAN study safety results	B. Win	01988	Poster Wednesday, March 6 2:30-4:00pm MST
Pipeline: Maturation Inhibitors			
Next-generation maturation inhibitor GSK3640254 showed broad spectrum potency without MI resistance	B. McAuliffe	03095	Poster Wednesday, March 6 2:30-4:00pm MST
The preclinical profile of maturation inhibitor VH3739937	J. Jeffrey	02819	Poster Wednesday, March 6 2:30-4:00pm MST
General HIV			
Resistance in young children newly diagnosed with HIV in Western Cape, South Africa	K. Anderson	01012	Poster Tuesday, March 5 2:30-4:00pm MST

***Dovato* (dolutegravir and lamivudine) tablets**

INDICATION

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 <50 copies/mL) on a stable ARV regimen with no history of treatment failure and no known resistance to any component of *Dovato*.

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.

Contraindications

- Do not use *Dovato* in patients with previous hypersensitivity reaction to dolutegravir or lamivudine
- Do not use *Dovato* in patients receiving dofetilide

WARNINGS AND PRECAUTIONS

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

Hepatotoxicity:

- 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

Embryo Fetal Toxicity:

- 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*.

Adverse reactions

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%).

Drug interactions

- 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 <30 mL/min. Patients with a sustained creatinine clearance between 30 and 49 mL/min should be monitored for hematologic toxicities, which may require a dosage adjustment of lamivudine as an individual component
- **Hepatic Impairment:** *Dovato* is not recommended in patients with severe hepatic impairment (Child-Pugh Score C)

For more information, please see full US Prescribing Information for *Dovato:*

https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Dovato/pdf/DOVATO-PI-PIL.PDF

***Cabenuva* (cabotegravir; rilpivirine) extended-release injectable suspensions**

INDICATION

Cabenuva is indicated as a complete regimen for the treatment of HIV-1 infection in adults and adolescents 12 years of age and older and weighing at least 35 kg to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

- 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

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions:

- Serious or severe hypersensitivity reactions have been reported in association with other integrase inhibitors and could occur with *Cabenuva*
- 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
- Discontinue *Cabenuva* immediately if signs or symptoms of hypersensitivity reactions develop. Clinical status, including liver transaminases, should be monitored and appropriate therapy initiated. Cabotegravir and rilpivirine oral lead-in may be used to help identify patients who may be at risk of a hypersensitivity reaction

Post-Injection Reactions:

- 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 accidental 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:

- 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:
- Depressive disorders (including depressed mood, depression, major depression, mood altered, mood swings, dysphoria, negative thoughts, suicidal ideation, suicide 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

ADVERSE REACTIONS
- The most common adverse reactions in adults (incidence ≥2%, all grades) treated 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

DRUG INTERACTIONS
- Refer to the applicable full Prescribing Information for important drug interactions with *Cabenuva*, *Vocabria* (cabotegravir), or *Edurant* (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 UGT1A9 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:** Potential risks of breastfeeding include HIV-1 transmission, developing viral resistance in HIV-positive infants, and adverse reactions in a breastfed infant

For more information, please see full US Prescribing Information for *Cabenuva*:

https://gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing_Information/Cabenuva/pdf/CABENUVA-PI-PIL-IFU2-IFU3.PDF

***Apretude* (cabotegravir) extended-release injectable suspensions**

INDICATION

Apretude is 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.

IMPORTANT SAFETY INFORMATION

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

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* 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.

CONTRAINDICATIONS

- Do not use *Apretude* in individuals:
  - with unknown or positive HIV-1 status
  - with previous hypersensitivity reaction to cabotegravir
  - receiving carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifampin, and rifapentine

WARNINGS AND PRECAUTIONS

Comprehensive Management to Reduce the Risk of HIV-1 Infection:

- Use *Apretude* as part of a comprehensive prevention strategy, including adherence to the administration schedule and safer sex practices, including condoms, to reduce the risk of sexually transmitted infections (STIs). *Apretude* is not always effective in preventing HIV-1 acquisition. Risk for HIV-1 acquisition includes, but is not limited to, condomless sex, past or current STIs, self-identified HIV risk, having sexual partners of unknown HIV-1 viremic status, or sexual activity in a high prevalence area or network. Inform, counsel, and support individuals on the use of other prevention measures (e.g., consistent and correct condom use; knowledge of partner[s] HIV-1 status, including viral suppression status; regular testing for STIs)
- Use *Apretude* only in individuals confirmed to be HIV-1 negative. HIV-1 resistance substitutions may emerge in individuals with undiagnosed HIV-1 infection who are taking only *Apretude*, because *Apretude* alone does not constitute a complete regimen for HIV-1 treatment. Prior to initiating *Apretude*, ask seronegative individuals about recent (in past month) potential exposure events and evaluate for current or recent signs or symptoms consistent with acute HIV-1 infection (e.g., fever, fatigue, myalgia, skin rash). If recent (<1 month) exposures to HIV-1 are suspected or clinical symptoms consistent with acute HIV-1 infection are present, use a test approved or cleared by the FDA as an aid in the diagnosis of acute HIV-1 infection
- When using *Apretude*, HIV-1 testing should be repeated prior to each injection and upon diagnosis of any other STIs
- Additional HIV testing to determine HIV status is needed if an HIV-1 test indicates possible HIV-1 infection or if symptoms consistent with acute HIV-1 infection develop following an exposure event. If HIV-1 infection is confirmed, then transition the individual to a complete HIV-1 treatment

- Counsel HIV-1 uninfected individuals to strictly adhere to the recommended dosing and testing schedule for *Apretude*

Potential Risk of Resistance with *Apretude*:
- There is a potential risk of developing resistance to *Apretude* if an individual acquires HIV-1 either before, while taking, or following discontinuation of *Apretude*. To minimize this risk, it is essential to clinically reassess individuals for risk of HIV-1 acquisition and to test before each injection to confirm HIV-1–negative status. Individuals who are confirmed to have HIV-1 infection must transition to a complete HIV-1 treatment. If individuals at continuing risk of HIV-1 acquisition discontinue APRETUDE, alternative forms of PrEP should be considered and initiated within 2 months of the final injection of *Apretude*

Long-Acting Properties and Potential Associated Risks with *Apretude*:
- Residual concentrations of cabotegravir may remain in the systemic circulation of individuals for prolonged periods (up to 12 months or longer). Take the prolonged-release characteristics of cabotegravir into consideration and carefully select individuals who agree to the required every-2-month injection dosing schedule because non-adherence or missed doses could lead to HIV-1 acquisition and development of resistance

Hypersensitivity Reactions:
- Serious or severe hypersensitivity reactions have been reported in association with other integrase inhibitors and could occur with *Apretude*
- Discontinue *Apretude* immediately if signs or symptoms of hypersensitivity reactions develop. Clinical status, including liver transaminases, should be monitored and appropriate therapy initiated

Hepatotoxicity:
- Hepatotoxicity has been reported in a limited number of individuals receiving cabotegravir with or without known pre-existing hepatic disease or identifiable risk factors
- Clinical and laboratory monitoring should be considered and *Apretude* should be discontinued if hepatotoxicity is suspected and individuals managed as clinically indicated

Depressive Disorders:
- Depressive disorders (including depression, depressed mood, major depression, persistent depressive disorder, suicidal ideation or attempt) have been reported with *Apretude*
- Promptly evaluate patients with depressive symptoms

Risk of Reduced Drug Concentration of APRETUDE Due to Drug Interactions:
- The concomitant use of *Apretude* and other drugs may result in reduced drug concentration of *Apretude*
- Refer to the full Prescribing Information for steps to prevent or manage these possible and known significant drug interactions, including dosing recommendations. Consider the potential for drug interactions prior to and during use of, and after discontinuation of *Apretude*; review concomitant medications during use of *Apretude*

ADVERSE REACTIONS

The most common adverse reactions (incidence ≥1%, all grades) with *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.

DRUG INTERACTIONS

- Refer to the full Prescribing Information for important drug interactions with *Apretude*
- Drugs that induce UGT1A1 may significantly decrease the 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

For more information, please see full US Prescribing Information for *Apretude*:

https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Apretude/pdf/APRETUDE-PI-PIL-IFU.PDF

***Rukobia* (fostemsavir) extended-release tablets**

INDICATION

Rukobia, in combination with other antiretrovirals (ARVs), is indicated to treat HIV-1 infection in heavily treatment-experienced adults with multidrug-resistant HIV-1 infection failing their current ARV regimen due to resistance, intolerance, or safety considerations.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

- 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)*.

WARNINGS AND PRECAUTIONS

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).

Adverse reactions

- 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.

Drug interactions
- 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 full US Prescribing Information for *Rukobia*:

https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Rukobia/pdf/RUKOBIA-PI-PIL.PDF

About ViiV Healthcare

ViiV Healthcare is a global specialist HIV company established in November 2009 by GSK (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 acquiring HIV. Shionogi became a ViiV shareholder 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 viivhealthcare.com.

About GSK

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.

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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 under Item 3.D "Risk factors" in the company's Annual Report on Form 20-F for 2022, and Q4 Results for 2023.

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