Press release

For media and investors only

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ViiV Healthcare continues to deliver long-acting injectable HIV innovation with late-breaking data and real-world insights across pipeline and portfolio at CROI 2025

- Real-world and implementation data highlight effectiveness of *Cabenuva* (cabotegravir + rilpivirine LA) and *Apretude* (cabotegravir LA (CAB LA) for PrEP), the only approved long-acting injectable therapies for HIV treatment and prevention, among broad range of communities
- Late-breaking phase IIb data demonstrate the potential of an investigational new long-acting broadly neutralising antibody (bNAb)/CAB LA combination treatment
- Two proof-of-concept studies on an investigational third-generation integrase strand transfer inhibitor (INSTI) and a capsid inhibitor highlight the opportunity for further research into these assets as long-acting antiretrovirals

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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, will be presenting abstracts from its innovative HIV treatment and prevention portfolio and research pipeline at the Conference on Retroviruses and Opportunistic Infections (CROI 2025).

Kimberly Smith, M.D., MPH, Head of Research & Development at ViiV Healthcare, said: "Our long-acting injectable portfolio is being showcased at CROI 2025 with data on real-world outcomes, demonstrating the impact our industry-leading portfolio is having today. We're also sharing early data from our transformative pipeline, including results from our third-generation integrase inhibitor and partner assets. These assets have the potential to increase dosing intervals beyond what's currently available, aiming to deliver what the community of people living with HIV tells us they want and need."

Key data to be presented at CROI 2025 by ViiV Healthcare and its study partners include:

Portfolio

- **New data assessing *Apretude* (CAB LA for PrEP) in HIV prevention:** Latest data from the PILLAR implementation study, which is assessing strategies for delivering CAB LA at 17 sites in the US, will be presented; clinical assessments will include HIV incidence, HIV diagnostic testing, persistence, and safety and tolerability of CAB LA over 12 months[i]. Findings from the ImPrEP CAB Brazil implementation study will include PrEP coverage and HIV incidence among young, key populations who were given the choice of CAB LA or oral PrEP[ii].
- **Long-term real-world and clinical trial data in diverse populations on *Cabenuva* (cabotegravir + rilpivirine long-acting (CAB+RPV LA)):** New data on the utilisation and effectiveness of CAB+RPV LA in people living with HIV in the US will be presented from the Trio Health study[iii]. Long-term follow-up data from the real-world OPERA study will include CAB+RPV LA effectiveness in individuals through two years[iv], as well as clinical outcomes in women receiving CAB+RPV LA[v]. Long-term data on the efficacy, safety and tolerability of CAB+RPV LA in people living with HIV in sub-Saharan Africa will be presented from the CARES study[vi].
- **PASO-DOBLE week 48 subgroup analysis:** New data from the largest head-to-head randomised clinical trial of DTG/3TC vs BIC/FTC/TAF, looked at efficacy and clinically meaningful weight changes (>5% from baseline) across different subgroups, including but not limited to sex at birth, age groups ethnicity and prior antiretroviral therapy[vii].

Pipeline

- **Late breaking data for a new therapeutic option:** A new phase IIb study with VH3810109 (VH109), an investigational, broadly neutralising antibody (bNAb) offers efficacy and safety findings of the bNAb (subcutaneous and IV administration) in combination with CAB LA[viii].
- **New findings from our next generation of INSTIs:** A proof-of-concept clinical study with VH4524184 (VH184), an investigational third-generation integrase inhibitor with potential for long-acting dosing, assessed the drug's exposure-response relationship to HIV-1 at multiple doses and shows findings that support further development[ix].
- **Proof of concept data of a partner asset to INSTIs:** A proof-of-concept clinical trial provides insights into the antiviral effects, pharmacokinetics, safety, and tolerability of VH4011499 (VH499), a new, highly potent investigational capsid inhibitor and one of several partner asset options being evaluated for development into long-acting treatment HIV regimens[x].

ViiV Healthcare-sponsored or supported studies to be presented at CROI 2025:

Title	Presenting author	Presentation
Cabotegravir for Pre-exposure prophylaxis (PrEP)		
PILLAR month 12 clinical results: zero HIV acquisition and high persistence with CAB LA for PrEP	T. Khan	Oral Abstract 196 12 March 2025 10:00 AM PT
Performance of HIV RNA screening in the context of long-acting injectable cabotegravir in HPTN 084	S. Delany-Moretlwe	Oral Abstract 195 12 March 2025 10:00 AM PT
ImPrEP CAB Brasil: Enhancing PrEP Coverage with CAB-LA in Young Key Populations	B. Grinsztejn	Oral Abstract 192 12 March 2025 10:00 AM PT
Estimation of prevention-effective CAB-LA concentrations among MSM/TGW in HPTN 083	B. Hanscom	Oral Abstract 193 12 March 2025 10:00 AM PT
Response to HIV Treatment After Long-Acting Cabotegravir Pre-exposure Prophylaxis in HPTN 083	R. Landovitz	Oral Abstract 197 12 March 2025 10:00 AM PT
No increased risk for hypertension with CAB-LA compared to TDF/FTC for PrEP: results from HPTN 084	S. Delany-Moretlwe	Poster 820
High incidence of curable sexually transmitted infections in HPTN 084: a tertiary analysis	H. Nuwagaba-Biribonwoha	Poster 1226
PrEP choices among sexual and gender minorities in Brazil: the ImPrEP CAB-LA study	B. Grinsztejn	Poster 1356
Depression and suicide risk among sexual and gender minorities: insights from the ImPrEP CAB Brazil	D. Richer Araujo Coelho	Poster 1302
Patterns of first choice, switching, and discontinuation of oral and injectable PrEP among adolescents from sexual and gender minorities in Brazil	L. Magno Santos de Sousa	Poster 1203
Acceptability of long-acting cabotegravir among pregnant and lactating people in South Africa	N. Wara	Poster 1357
Impact of rapid long-acting prep scale-up among MSM: closing the unmet needs and towards ending HIV	H. Wang	Poster 1297
Expanding the PrEP method market: Early insights from offering oral PrEP, PrEP ring, and injectable CAB PrEP for HIV prevention across five countries in Africa	N. Naidoo	Poster 1354
Dynamic choice HIV prevention in the context of injectable cabotegravir (CAB-LA): a model-based cost-effectiveness analysis	M. Hickey	Poster 1293

Use of DNA profiling to resolve discrepant HIV tests in the setting of injectable cabotegravir PrEP	J. Fogel	Poster 1193
Cabotegravir for Treatment		
Randomized trial of cabotegravir and rilpivirine long-acting in Africa (CARES): week 96 results	C. Kityo	Oral Abstract 202 12 March 2025 12:15 PM PT
Long-term CAB+RPV LA effectiveness in virologically suppressed individuals in the OPERA cohort	M. Sension	Poster 674
Clinical outcomes among virologically suppressed women receiving CAB+RPV LA in the OPERA cohort	J. Altamirano	Poster 676
Outcomes on cabotegravir + rilpivirine in suppressed people with HIV (PWH) in TRIO health US cohort	P. Sax	Poster 675
Decreasing oral induction duration in support of LAI ART use with hard-to-reach populations	A. Rana	Poster 692
At home CAB/RPV provides novel approach to achieve viral suppression in adherence challenged PWH	M. Dieterich	Poster 1318
Safety and pharmacokinetics of long-acting cabotegravir and rilpivirine in children between 20-40kgs	M. Archary	Poster 1046
Interim Week 48 results in South African youth living with HIV on long-acting injectable therapy: AFINAty study	L. Jennings	Poster 679
Pipeline		
Proof-of-concept trial of VH4524184 (VH-184), a third-generation integrase strand transfer inhibitor	L. Rogg	Oral Abstract 152 11 March 2025 10:13-10:21 PT
Proof-of-concept trial of oral VH4011499 (VH-499), a new HIV-1 capsid inhibitor	P.I Benn	Oral Abstract 153 11 March 2025 10:21-10:30 PT
VH3810109 (N6LS) efficacy and safety in adults who are virologically suppressed: The EMBRACE study	B. Taiwo	Oral Abstract 203 12 March 2025 12:39-12:46 PT
Pre-clinical evaluation of effector function-enhanced variants of N6 bnAb	D. Wensel	Poster 547
Fostemsavir		
Temsavir treatment improves the recognition of HIV-1 infected cells by broadly neutralizing antibodies (bnAbs)	H. Qi	Poster 507
Characteristics and treatment outcomes of people with HIV prescribed fostemsavir in the trio cohort	M. Ramgopal	Poster 699
Dolutegravir		
Dolutegravir Does Not Reduce Levonorgestrel or Medroxyprogesterone Acetate Concentrations in WLWH	R. Ryan	Oral Abstract 119 10 March 2025 12:39-12:46 PT
PK and safety of chronic dolutegravir administration in neonates exposed to HIV-1 (IMPAACT 2023)	J. Momper	Poster 1047
Baseline and emergent resistance profiles in the African paediatric CHAPAS-4 trial	A. Bamford	Poster 123
Drug interactions between dolutegravir (DTG) and escalating doses of rifampicin (RIF): DORIS study	Y. Singh	Poster 645
Switching to DTG/3TC vs. BIC/FTC/TAF and steatotic liver disease: A sub-study of PASODOBLE Trial	J. Pineda	Poster 764
Depression, sleep, and anxiety among pregnant and postpartum women using dolutegravir and efavirenz	D. Wu	Poster 986
Changes in body composition in people with HIV switching to DTG/3TC or BIC/TAF/FTC	E. Martinez	Poster 897

Effectiveness and inflammatory markers after 144 weeks of switch to DTG/3TC in a randomized trial	E. Blomme	Poster 663
Switch to DTG/3TC vs BIC/FTC/TAF (PASO-DOBLE study): Efficacy and Weight Changes by Predefined Subgroups	J. Tiraboschi	Poster 661
Impact of art simplification with dolutegravir and lamivudine on the HIV reservoir	Fombellida-Lopez	Poster 664
Risk of obesity, cardiometabolic disease and MACE after switch to an integrase inhibitor in REPRIEVE	E. Kileel	Poster 838
Risk of incident hypertension with common antiretroviral agent combinations in the OPERA cohort	G. Pierone Jr	Poster 823
General HIV		
Brain volume normalization after 96 weeks of ART started during acute HIV infection	R. Paul	Oral Abstract 167 12 March 2025 10:00 AM PT
People with HIV exhibit structural brain changes following infection with SARS-Cov-2	J. Bolzenius	Oral Abstract 174 12 March 2025 10:00 AM PT
Frailty is associated with higher MACE incidence but does not appear to modify pitavastatin effects	K. Erlandson	Oral Abstract 179 12 March 2025 10:00 AM PT
Plaque, inflammation, subclinical myocardial injury and MACE in the REPRIEVE mechanistic substudy	S. Grinspoon	Oral Abstract 178 12 March 2025 10:00 AM PT
Cancer incidence in women with HIV in Europe and Australia: a combined D:A:D and RESPOND cohort analysis	W. M. Han	Poster 803
Statin effect heterogeneity on plaque volume & composition in the REPRIEVE mechanistic substudy	B. Foldyna	Poster 850
No evidence of a detrimental effect of pitavastatin on neurocognitive function among people with HIV	K. Erlandson	Poster 624
Prognostic factors of physical function decline in the PREPARE study	G. Ditzenberger	Poster 881
Time-updated win ratio aligns with primary REPRIEVE findings and suggests early pitavastatin benefit	E. Smith	Poster 853
Determinants of steatotic liver disease among people with HIV in Europe and Australia	C. Riebensahm	Poster 762
Hospitalization incidence among young children living with HIV in the Western Cape, South Africa	K. Anderson	Poster 1051
People with HIV at high cardiovascular risk were undertreated with statins	S. Esser	Poster 851
Increasing methamphetamine use and group sex observed in MSM with acute HIV infection in Bangkok	P. Chan	Poster 1144
Heart failure risk and events in people with HIV in the REPRIEVE trial	M. Watanabe	Poster 818
Cognitive trajectories 1 year before and after COVID-19 in an AHI cohort	F. Ocampo	Poster 926
Immune and virologic trajectories 1.5 years before and after COVID-19 in an early-treated HIV cohort	F. Ocampo	Poster 931
ART exposure and accelerated aging in PLHIV: insights from proteomic and methylation clocks	N. Vadaq	Poster 866
CCR5 Expression Is Critical for the Maintenance of HIV Control and Reservoir Size	J. dos Santos	Poster 563
Genetic regulation of immune responses to CMV in spontaneous HIV controllers	S. Ruijten	Poster 499

Delayed HIV-1 rebound correlates with enhanced CD8 T Cell activation in human trials	R. Thomas	Poster 484
Rapid clearance of the inducible HIV-1 reservoir after initiation of antiretroviral therapy	M. Puertas	Poster 571
Virulent HIV-1B: clinical challenges and proteomic insights	K. Mehta	Poster 358
Distinct metabolic perturbations link liver steatosis and incident CVD in lean but not obese PLHIV	N. Vadaq	Poster 760
Mitochondrial gene variants in VARS2 influence HIV reservoir and T cells in European HIV controllers	V. Rios Vazquez	Poster 487
Multiomics Clustering Reveals Distinct HIV Reservoir Profiles in the 2000HIV Cohort	V. Rios Vazquez	Poster 565
Heterogeneity of PD-1 Expression in PLHIV and Its Relationship With Host and Viral-Related Factors	A. Navas	Poster 462
Residual HIV Viremia Associates With Reservoir Size, but Not With Immune Activation or Inflammation	T. Otten	Poster 355
Neuronal injury in a subset of individuals during acute HIV infection and after immediate treatment	P. Chan	Poster 615
Early HIV-1 genetic diversity includes CTL and drug resistance mutations	J. Coffin	Poster 346
RV550: the effects of IL-15 super-agonist N-803 with ART in acute infection on T and NK cells	H. Takata	Poster 444
RV550: Safety and virological outcomes in blood and lymph nodes of N-803 with ART in acute infection	C. Sacdalan	Poster 512
Sex-based differences and genetic regulation of cytokine responses in people living with HIV	S. Ruijten	Poster 371
Females with HIV favor interferon responses over inflammation upon TLR7 activation	A. Huber	Poster 470
Translational bNAbs		
Maximizing benefits to participants in analytic treatment interruption studies with bnAb infusions	Y. Li	Poster 508
Sensitivity of HIV-1 CRF01_AE Envelopes to Broadly Neutralizing Antibodies VRC07-523 and PGDM1400	G. Smith	Poster 421

***APRETUDE* (cabotegravir) extended-release injectable suspension**
Professional Indication and Important Safety Information
INDICATION
APRETUDE is indicated for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection in adults and adolescents weighing at least 35 kg who are at risk for HIV-1 acquisition. 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 acquire 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 individuals without HIV-1 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

CABENUVA (cabotegravir; rilpivirine) extended-release injectable suspensions
Professional Indication and Important Safety Information

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

***DOVATO* (dolutegravir and lamivudine) tablets**
Professional Indication and Important Safety Information

INDICATION
DOVATO 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 25 kg with no antiretroviral treatment history or to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies/mL) on a stable antiretroviral regimen with no history of treatment failure and no known substitutions associated with resistance to the individual components 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.

CONTRADICTIONS

- 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

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 could benefit from HIV prevention. 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.

GSK enquiries:

Media:	Tim Foley	+44 (0) 20 8047 5502	(London)
	Sarah Clements	+44 (0) 20 8047 5502	(London)
	Kathleen Quinn	+1 202 603 5003	(Washington DC)
	Lyndsay Meyer	+1 202 302 4595	(Washington DC)
	Alison Hunt	+1 540 742 3391	(Washington DC)
Investor Relations:	Annabel Brownrigg-Gleeson	+44 (0) 7717 618834	(London)
	James Dodwell	+44 (0) 20 8047 2406	(London)
	Mick Readey	+44 (0) 7990 339653	(London)
	Camilla Campbell	+44 (0) 7803 050238	(London)
	Steph Mountifield	+44 (0) 7796 707505	(London)
	Jeff McLaughlin	+1 215 751 7002	(Philadelphia)
	Frannie DeFranco	+1 215 751 4855	(Philadelphia)

Registered Office:
79 New Oxford Street
London
WC1A 1DG

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