Press release

For media and investors only

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ViiV Healthcare to present phase IIIb data comparing *Dovato* with *Biktarvy* in treatment-naïve adults; alongside INSTI-powered long-acting injectable innovation at AIDS 2026

- VOGUE is the first head-to-head, randomised daily orals study comparing 2-drug regimen *Dovato* with 3-drug regimen *Biktarvy* in treatment-naïve adults living with HIV
- Real-world OPERA data continues to strengthen the evidence base for *Cabenuva*, the only complete long-acting injectable HIV treatment regimen
- Six-month results from the CLARITY study will report participant experience and acceptability of long-acting cabotegravir versus lenacapavir injections after a single dose in HIV-negative adults

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GSK plc (LSE/NYSE: GSK) announced that ViiV Healthcare, the global specialist HIV company majority owned by GSK, with Shionogi as a shareholder, today announced new clinical and real-world data highlighting its integrase strand transfer inhibitor (INSTI)-focused portfolio, including long-acting (LA) medicines and pipeline momentum, to be presented at the 26th International AIDS Conference (AIDS 2026) in Rio de Janeiro, Brazil, from 26-31 July.

VOGUE daily orals phase IIIb data will compare ViiV Healthcare's established 2-drug regimen dolutegravir/lamivudine (DTG/3TC) with 3-drug regimen bictegravir/emtricitabine/tenofovir alafenamide (BIC/FTC/TAF) in treatment-naïve adults living with HIV[1]

- Additional data from VOGUE will examine the study population demographics, including adults with high viral loads.[2]
- A pooled analysis across clinical trials will examine on-study viraemic events and outcomes for DTG/3TC compared with 3-drug regimens.[3]

Data evaluating long-acting injectable HIV treatment, including late-breaking LATA results and OPERA real-world data, will add to the evidence base for cabotegravir + rilpivirine long acting (CAB+RPV LA)

- Late-breaking week 96 results from the LATA study, led by University College London, will evaluate the efficacy, safety and acceptability of CAB+RPV LA versus daily oral tenofovir disoproxil fumarate/lamivudine/dolutegravir in virologically suppressed adolescents living with HIV across sub-Saharan Africa.[4]
- New data from OPERA will be presented, including from the US-based cohort, comparing the virologic effectiveness of injectable CAB+RPV LA versus daily oral BIC/FTC/TAF in virologically suppressed adults living with HIV.[5,6,7]
- Week 96 results from the IMPALA study, led by London School of Hygiene and Tropical Medicine, will provide new insights into the use of CAB+RPV LA in adults living with HIV with prior adherence challenges in sub-Saharan Africa, including treatment outcomes over time.[8]
- Data from Ask Us Europe, a community co-produced survey, led by an academic team in London, will explore whether people living with HIV across Europe are having meaningful and equitable conversations with healthcare providers about long-acting HIV treatment options.[9,10,11]

CAB LA for pre-exposure prophylaxis (PrEP) data, including CLARITY results comparing CAB LA with lenacapavir, will inform how long-acting injectable prevention options are used in practice

- Six-month results from the phase I CLARITY study will report participant experience and acceptability of CAB LA versus lenacapavir injections after a single dose, as well as late-breaking data on participant-reported outcomes, informing decision-making when initiating long-acting injectables for PrEP.[12,13]
- CAPTIVATE results will describe real-world use, acceptability and delivery of CAB LA for PrEP in routine US clinical practice.[14,15]
- Updated PrEPFACTS results will describe real-world use and adherence patterns for CAB LA for PrEP in the US, using healthcare administrative claims data.[16]

EXTEND 4M will evaluate a new long-acting dosing candidate for HIV prevention

- Baseline data from the phase IIb registrational EXTEND 4M trial will describe the population being evaluated in the first study evaluating a new formulation of CAB LA dosed three times a year for HIV PrEP.[17] This study builds on the established evidence for CAB LA for PrEP dosed six times a year and will assess the pharmacokinetics, safety and tolerability of the new CAB LA formulation.

Key ViiV Healthcare sponsored or supported studies to be presented at AIDS 2026:

Abstract Name	Presenter	Presentation details
DTG/3TC		
In VOGUE: Primary Endpoint Results Comparing DTG/3TC 2-drug regimen to BIC/FTC/TAF 3-drug regimen in a randomized trial in adults with HIV naive to treatment	J. Ghosn	Oral presentation OAB0106LB Tuesday, 28 July 2026 10:30 – 11:30
Who's in VOGUE: a head-to-head clinical trial of dolutegravir/lamivudine (DTG/3TC) versus bictegravir/emtricitabine/tenofovir alafenamide (BIC/FTC/TAF) in adults naive to antiretroviral therapy (ART), including those with high viral loads	M. Kisare	In-person poster exhibition WEPEB094 Wednesday, 29 July 2026 12:00 – 13:00
Pooled analysis of on-study viremic events (VEs) and outcomes for dolutegravir + lamivudine (DTG+3TC) and comparator 3-drug regimens (3DRs) in clinical trials of people with HIV-1	P. Cahn	In-person poster exhibition WEPEB095 Wednesday, 29 July 2026 12:00 – 13:00
CAB + RPV LA		
Every-8-weeks injectable cabotegravir and rilpivirine versus daily oral tenofovir disoproxil fumarate/lamivudine/dolutegravir in adolescents living with HIV in sub-Saharan Africa: LATA 96-week results	M. B. Dangarembizi	Oral presentation OAX1105LB Wednesday, 29 July 2026 10:30 – 11:30am
Comparable virologic effectiveness with long-acting cabotegravir + rilpivirine vs. daily bictegravir/emtricitabine/tenofovir alafenamide in the US-based OPERA Cohort	C. Millner	In-person poster exhibition WEPEB099 Wednesday, 29 July 2026 12:00 – 13:00
Resuppression and resistance after confirme d virologic failure among women on CAB+RPV LA in the OPERA Cohort	J. Altamirano	In-person poster exhibition TUPEB129 Tuesday, 28 July 2026 12:00 – 13:00

High virologic suppression among individuals on cabotegravir + rilpivirine long-acting with viral loads ≥50 copies/mL regardless of body mass index in the OPERA Cohort	C. Millner	In-person poster exhibition TUPEB091 Tuesday, 28 July 2026 12:00 – 13:00
Efficacy and safety of long-acting cabotegravir and rilpivirine in adults with adherence or engagement challenges in sub-Saharan Africa: the IMPALA trial 96-week results	J. Kitonsa	In-person poster exhibition LB24 Tuesday 28, Wednesday 29, Thursday, 30 July 2026 12:00 – 13:00
Perspectives of people living with HIV in Europe on their clinical consultations: an equity analysis	M. Devonald	In-person poster exhibition THPEE490 Thursday, 30 July 2026 12:00 – 13:00
Interest of people living with HIV in Europe in future long-acting modalities-Ask Us Europe results	C. Orkin	In-person poster exhibition TUPEB101 Tuesday, 28 July 2026 12:00 – 13:00
Complex support needs, adherence challenges and interest in long-acting HIV treatment among trans, non-binary, and gender-diverse people living with HIV: findings from the coproduced 'Ask Us Europe' survey	M. Devonald	In-person poster exhibition WEPEB122 Tuesday, 28, Wednesday 29, Thursday, 30 July 2026 12:00 – 13:00
CAB PrEP		
Presence, Severity, Interference With Usual and Daily Life Activities and Bothersomeness of Injection Site Reactions With Cabotegravir vs Lenacapavir: Insights From Participant Reported Outcomes in the CLARITY Study.	L. Dupont-Benjamin	In-person poster exhibition WEPEC177 Wednesday 29, July 2026 12:00 – 13:00
Participant and Provider Experiences With Long-Acting Cabotegravir vs Lenacapavir Injections: Results From the CLARITY Study	N. Pilgrim	In-person poster exhibition WEPEC177 Wednesday, 29 July 2026 12:00 – 13:00
Real-world experience using cabotegravir long-acting for HIV-1 pre-exposure prophylaxis in the United States from cross-sectional surveys and retrospective chart reviews: results from the CAPTIVATE study	M. Brizzi	In-person poster exhibition TUPEC177 Tuesday, 28 July 2026 12:00 – 13:00
Operational insights for long-acting cabotegravir for HIV-1 pre-exposure prophylaxis: findings from the CAPTIVATE United States healthcare provider survey	K. Visnyei	In-person poster exhibition TUPEC200 Tuesday, 28 July 2026 12:00 – 13:00
Real-world utilization and adherence of cabotegravir long-acting for HIV pre-exposure prophylaxis in the United States: Updated results from the PrEPFACTS study using healthcare administrative claims data	A. Metzner	In-person poster exhibition TUPEC179 Tuesday, 28 July 2026 12:00 – 13:00

PrEP modality preference and socio-structural HIV vulnerability among transgender women and transfeminine persons in the United States: A latent class analysis	J. L. Glick	In-person poster exhibition TUPED349 Tuesday, 28 July 2026 12:00 – 13:00
Socio-structural HIV vulnerability and PrEP willingness among transgender women and transfeminine persons in the United States: A latent class analysis	J. L. Glick	In-person poster exhibition THPED316 Thursday, 30 July 2026 12:00 – 13:00
No HIV acquisitions among women on cabotegravir long-acting injectable PrEP despite mostly short injection delays in the US OPERA Cohort	L. Armas-Kolostroubis	Oral presentation OAC2805 Thursday, 30 July 2026 15:27 – 15:35
Evolving PrEP use in the long-acting injectable era: Findings from a cohort of transgender women in the United States and Puerto Rico, 2023–2025	C. Pontes	In-person poster exhibition TUPEC210 Tuesday, 28 July 2026 12:00 – 13:00
DTG		
Cross-network, multicentre cohort study assessing real-world pregnancy and birth outcomes following prenatal dolutegravir exposure in Europe	R. Sconza	In-person poster exhibition TUPEB119 Tuesday, 28 July 2026 12:00 – 13:00
Risk of fracture with contemporary antiretrovirals within the RESPOND Consortium	B. Neesgaard	In-person poster exhibition TUPEB076 Tuesday, 28 July 2026 12:00 – 13:00
Association between integrase inhibitors (INSTIs) and tenofovir alafenamide (TAF) and moderate chronic kidney disease (CKD) and in the RESPOND HIV cohort collaboration	L. Greenberg	E-poster EP056 Monday, 27 July 2026 14:00
Dolutegravir Markedly Improves 6- and 12-Month Viral Suppression in Children ≤5 Years, South Africa	K. Anderson	In-person poster exhibition WEPEB121 Wednesday, 29 July 2026 12:00 – 13:00
Pipeline		
Baseline demographics in the phase 2b registrational EXTEND 4M trial: evaluating a novel every-4-month cabotegravir formulation in a population who could benefit from PrEP	A. Rinehart	In-person poster exhibition WEPEB096 Wednesday, 29 July 2026 12:00 – 13:00
Participants experiences switching from subcutaneous to intravenous lotivibart (LVB, N6LS, VH3810109) and cabotegravir long-acting injections for HIV-1 treatment in EMBRACE study	C. Gutner	In-person poster exhibition WEPEB097 Wednesday, 29 July 2026 12:00 – 13:00
Above Brand		

Stigma-Related Challenges for People Living with HIV and Gaps in Patient Advocacy Group Responses: Perspectives from HIV Organizational Personnel	A. Appiah	In-person poster exhibition THPED312 Thursday, 30 July 2026 12:00 – 13:00

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

The complete regimen combines the INSTI cabotegravir, developed by ViiV Healthcare, with rilpivirine, a non-nucleoside reverse transcriptase inhibitor (NNRTI) developed by Johnson & Johnson. Rilpivirine tablets are approved in the US and when used with cabotegravir is indicated for short-term treatment of HIV-1 infection in adults and adolescents 12 years and older and weighing at least 35 kg who are virologically suppressed (HIV-1 RNA less than 50 copies/mL) on a stable regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine.

INSTIs inhibit HIV replication by preventing the viral DNA from integrating into the genetic material of human immune cells (T-cells). This step is essential in the HIV replication cycle and is also responsible for establishing chronic disease. Rilpivirine is an NNRTI that works by interfering with an enzyme called reverse transcriptase, which stops the virus from multiplying.

Please consult the full Prescribing Information here.

About *Dovato* (dolutegravir and lamivudine)
Dovato is indicated for the treatment of HIV-1 infection in adults and adolescents above 12 years of age weighing at least 40 kg in the EU, and weighing at least 25 kg in the US, with no known or suspected resistance to the integrase inhibitor class, or lamivudine.

Please consult the full Summary of Product Characteristics for all the safety information: *Dovato* 50 mg/300 mg film-coated tablets.

About *Apretude* (cabotegravir long acting)
Apretude is a medicine used for preventing sexually transmitted HIV-1 infection (pre-exposure prophylaxis or PrEP) in adults and adolescents weighing at least 35 kg who are at high risk of being infected. It should be used in combination with safer sex practices, such as using condoms. *Apretude* contains the active substance cabotegravir.

Please consult the full Summary of Product Characteristics for all the safety information: *Apretude* 600 mg prolonged-release suspension for injection

About ViiV Healthcare
ViiV Healthcare is a global specialist HIV company established in November 2009 with GSK (LSE: GSK) and Shionogi as current shareholders. The company is dedicated to delivering advances in treatment and care for people living with HIV and for people who could benefit from HIV prevention. ViiV Healthcare'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 www.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 in the "Risk Factors" section in GSK's Annual Report on Form 20-F for 2025, and GSK's Q1 Results for 2026.

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