Press release

For media and investors only

Issued: 29 July 2026, London UK

Cabenuva demonstrates superiority to daily oral therapy in adolescents living with HIV, as ViiV Healthcare highlights new long-acting injectable data at AIDS 2026

- Superiority data from LATA, together with OPERA findings, add to the clinical and real-world evidence base for long-acting injectable *Cabenuva*
- Six-month follow-up CLARITY data further reinforce a more favourable injection experience with long-acting cabotegravir compared with lenacapavir after a single dose; additional studies showcase high real-world adherence and a preference for *Apretude* among previous oral PrEP users
- EXTEND 4M explores a new investigational intramuscular cabotegravir formulation dosed three times a year for HIV prevention, as part of broader long-acting pipeline data

---

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 data to be presented this week at the 26th International AIDS Conference (AIDS 2026) in Rio de Janeiro, Brazil. Multiple studies span long-term outcomes, real-world use, injection experience, adherence and future long-acting options for HIV treatment and prevention.

Jean van Wyk, MBChB, MFPM, Chief Medical Officer at ViiV Healthcare, said: “The data presented at AIDS 2026 underscore the depth and breadth of evidence ViiV Healthcare has generated for long-acting injectables across HIV treatment and prevention. With OPERA, real-world evidence from nearly 6,800 adults in routine care shows *Cabenuva* maintained high and comparable virologic suppression to daily oral therapy, helping us better understand how it performs outside clinical trials and supports people over time. Together with clinical and patient-reported data, this evidence provides a trusted foundation for the next generation of innovation, shaped by people affected by HIV and designed to deliver impact at scale.”

Superiority data from LATA, together with OPERA findings, add to the clinical and real-world evidence base for cabotegravir + rilpivirine (CAB+RPV LA) in long-acting HIV treatment.

Week 96 results from the LATA trial, led by University College London, showed CAB+RPV LA dosed every two months was superior to daily oral dolutegravir/tenofovir disoproxil fumarate/lamivudine (DTG/TDF/3TC) in 476 virologically suppressed adolescents aged 12 to 19 years living with HIV in Kenya, South Africa, Uganda and Zimbabwe.[1]

- Confirmed viral rebound occurred in 0.9% (n=2/235) of adolescents receiving CAB+RPV LA versus 6.4% (n=15/241) receiving daily oral therapy.
- 94% (n=215/228) reported that long-acting injections were much easier to take than daily oral therapy.
- The findings contribute to evidence in an adolescent population, where adherence and retention in care can be challenging.

New real-world data from the US-based OPERA cohort showed CAB+RPV LA dosed every two months maintained virologic suppression comparable to daily oral bictegravir/emtricitabine/tenofovir alafenamide (BIC/FTC/TAF) in nearly 6,800 virologically suppressed adults living with HIV.[2]

- 89% (n=3,655/4,095) of individuals receiving CAB+RPV LA and 83% (n=2,239/2,699) receiving BIC/FTC/TAF had viral load <50 copies/mL, at a median follow-up of 15 months and 22 months, respectively.
- Confirmed virologic failure risk was low and comparable in both groups, occurring in 1% (n=46) of individuals receiving CAB+RPV LA and 2% (n=46) receiving BIC/FTC/TAF.

Six-month follow-up data from CLARITY reinforce a more favourable injection experience with long-acting cabotegravir (CAB LA) versus lenacapavir (LEN) after a single dose; additional studies showcase high real-world adherence and a preference for CAB LA for PrEP among previous oral PrEP users.

The phase I CLARITY study compared participant experience after a single intramuscular dose of CAB LA and a single subcutaneous dose of LEN in 63 participants without HIV-1. Building on earlier Day 22 findings published in *Advances in Therapy*, follow-up data show injection site reactions (ISRs) were less visible with CAB LA compared with LEN through six-months.[3,4]

- 70% (n=42/60) rated the CAB LA injection experience as “very acceptable” or “totally acceptable,” compared with 37% (n=22/60) for LEN LA.
- No healthcare professionals reported challenges with administration and patient management with CAB LA, whereas 3/4 had difficulty with LEN LA administration and 2/4 had difficulty managing participants on LEN LA.

Additional late-breaking participant-reported outcomes from an Injection-Site Reaction Assessment (ISRA) analysis at six months following dosing, showed CAB LA was associated with shorter lasting and less bothersome ISRs, with lower interference with daily activities.[5]

- 90% (n=54/60) of LEN participants continuing to report nodules after six-months, compared to only 20% with CAB LA (n=12).
- No severe CAB-associated ISRs were reported, while 11/54 (20%) of LEN LA-associated nodules were reported as severe.
- At Day 90, 92% of participants receiving CAB LA (n=56/61) reported they were not bothered by ISRs, compared with 58% receiving LEN LA (n=36/62).
- No participants receiving CAB LA reported being “quite a lot” or “very much bothered” by ISRs, compared with 12% (n=7/60) receiving LEN LA.
- These findings highlight the importance of ISRs in the injection experience in including patient-provider consideration that visible, persistent or bothersome ISRs may affect people’s daily lives.

CAPTIVATE found strong preference for CAB LA for PrEP among people with prior oral PrEP experience and positive provider experiences delivering CAB LA for PrEP in US clinical practice.[6,7] The study included 241 PrEP users and 36 healthcare providers across 18 US sites.

- Among participants with prior PrEP / oral PrEP experience, 97% (n=185/190) preferred CAB LA for PrEP, compared to daily oral PrEP (2%).
- Nearly all participants reported feeling protected from HIV (99%; n=239/241) and less worried about acquiring HIV (99%; n=238), as well as feeling more in control of their life (91%; n=219) because they use CAB LA for PrEP.
- Among healthcare providers, 89% (n=16/18) reported a positive overall opinion of administering CAB LA for PrEP in their practice. Prescribers cited benefits of regular injection visits, including assurance of adherence (89%), more frequent STI testing (72%) and opportunities to address other health needs (61%)
- These findings support CAB LA for PrEP as a preferred option for those who value control and engagement with their broader care, as well as convenience.

PrEPFACTS showed that people using CAB LA for PrEP had high adherence to their dosing schedule, in a large US real-world analysis of 2,913 people.[8]

- Overall adherence was high, with a median proportion of days covered (PDC) of 1.00 (IQR: 0.96-1.00), indicating high coverage during measured follow-up.
- 89% (n=2,588) were covered by PrEP for at least 90% of the measured period.

- Most continuation injections were given within recommended timeframes, including 85% (n= 9,798/11,476) within 67 days and 96% (n=11,009/11,476) within 90 days.
- These findings add to real-world evidence that people can maintain adherence with CAB LA for PrEP, an important factor for maintaining protection.

EXTEND 4M baseline data describe diverse enrolment in the first study of a new investigational intramuscular cabotegravir formulation dosed three times a year for HIV prevention, representative of those who could benefit from PrEP in the real-world.

Baseline data from the phase IIb EXTEND 4M registrational study include 229 participants aged 16 years and older enrolled across 27 US sites in regions with significant HIV transmission among subpopulations disproportionately affected by HIV.[9]

- Participants include 45% assigned female sex at birth, 32% Black or African American participants and 37% Hispanic/Latine participants.
- 28% of participants had previous oral PrEP use.
- The study will assess pharmacokinetics, safety and tolerability, designed to support a potential HIV prevention option that could reduce clinic visits while maintaining regular screening and care. Data is expected to be presented at a future medical congress.

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 *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.

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)
	Alison Hunt	+1 540 742 3391	(Washington DC)
Investor Relations:	Constantin Fest	+44 (0) 7831 826525	(London)
	James Dodwell	+44 (0) 20 8047 2406	(London)
	Mick Readey	+44 (0) 7990 339653	(London)
	Steph Mountifield	+44 (0) 7796 707505	(London)
	Sam Piper	+44 (0) 7824 525779	(London)
	Jeff McLaughlin	+1 215 751 7002	(Philadelphia)
	Frannie DeFranco	+1 215 751 3126	(Philadelphia)

Registered in England & Wales:
No. 3888792

Registered Office:
79 New Oxford Street
London
WC1A 1DG

References

[1] M. B. Dangarembiz, et al. Eight-weekly injectable cabotegravir and rilpivirine is superior to daily oral tenofovir disoproxil fumarate/lamivudine/dolutegravir in adolescents living with HIV in sub-Saharan Africa: LATA 96-week results. Presented at the 26th International AIDS Conference (AIDS 2026). July 2026.
[2] R. Hsu, et al. Comparable virologic effectiveness with long-acting cabotegravir + rilpivirine vs. daily bictegravir/emtricitabine/tenofovir alafenamide in the US-based OPERA Cohort. Presented at the 26th International AIDS Conference (AIDS 2026). July 2026.
[3] E. R. Elliot, et al. Long-Acting Cabotegravir Injections Are More Acceptable Than Long-Acting Lenacapavir Injections After One Dose: Results From the CLARITY Randomized Crossover Study. *Adv Ther*. 2026. https://doi.org/10.1007/s12325-026-03703-3

[4] K. L. Nelson, et al. Participant and Provider Experiences With Long-Acting Cabotegravir vs Lenacapavir Injections: Results From the CLARITY Study. Presented at the 26th International AIDS Conference (AIDS 2026). July 2026.
[5] L. Dupont-Benjamin, et al. 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. Presented at the 26th International AIDS Conference (AIDS 2026). July 2026.
[6] M. Brizzi, et al. 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. Presented at the 26th International AIDS Conference (AIDS 2026). July 2026.
[7] K. Visnyei, et al. Operational insights for long-acting cabotegravir for HIV-1 pre-exposure prophylaxis: findings from the CAPTIVATE United States healthcare provider survey. Presented at the 26th International AIDS Conference (AIDS 2026). July 2026.
[8] G. F. Herman, et al. 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. Presented at the 26th International AIDS Conference (AIDS 2026). July 2026.
[9] C. Acuipil, et al. 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. Presented at the 26th International AIDS Conference (AIDS 2026). July 2026.