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## ViiV Healthcare showcases long-acting HIV innovation and potential of ultra long-acting pipeline, including new data for first third-generation integrase inhibitor at CROI 2026

- First-in-human data for long-acting formulations of VH184, the first third-generation integrase inhibitor, and early data for capsid inhibitor VH499 to be presented, highlighting progress in ViiV's ultra long-acting pipeline
- 12-month data to be presented for investigational lotivibart (N6LS) + cabotegravir long-acting, evaluating feasibility of ultra long-acting dosing intervals
- Clinical data and real-world evidence from ViiV's innovative portfolio include insights for established INSTI-based long-acting *Cabenuva* (cabotegravir + rilpivirine LA) and 2-drug regimen *Dovato* (dolutegravir/lamivudine)

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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 data presentations from its innovative HIV treatment and prevention portfolio and integrase inhibitor (INSTI)-led pipeline at the 33rd Conference on Retroviruses and Opportunistic Infections (CROI) in Denver, Colorado from 22-25 February.

**Jean van Wyk, MBChB, MFPM, Chief Medical Officer at ViiV Healthcare, said:** "We are making major advances towards new ultra long-acting regimens that build on ViiV's legacy of integrase inhibitors, including pipeline assets such as VH184 that have the potential to extend dosing intervals to four months or longer – beyond what is available today for HIV treatment. Listening to the needs of the HIV community shapes our research and development, and the breadth of clinical and real-world data we are presenting at CROI 2026 reflects our commitment to delivering long-acting therapies that people impacted by HIV need and want."

Key data to be presented at CROI 2026 by ViiV Healthcare and study partners include:

**Advancing the next generation of ultra long-acting (ULA) HIV treatment candidates:** For VH184, the first third-generation INSTI, data from the ongoing first-in-human phase I study of injectable long-acting formulations will provide insights into its ULA potential in future regimens,<sup>1</sup> while an additional analysis evaluates its in-vitro resistance profile vs bicitegravir.<sup>2</sup>

Additionally, an interim analysis from the phase IIb EMBRACE study will report long-term data on HIV suppression and safety at 12 months with lotivibart (N6LS), an investigational broadly neutralising antibody administered every four months, in combination with monthly long-acting cabotegravir (CAB LA) for HIV treatment.<sup>3</sup> Additional presentations illustrate data that will inform dosing and ULA feasibility of the injectable HIV-1 capsid inhibitor, VH499.<sup>4,5</sup>

**Exploring longer-interval HIV prevention with cabotegravir ULA:** The phase I CAB ULA 012 study explores dose selection of cabotegravir ULA, to support administration every four months, and informs the path toward expanded prevention choices.<sup>6</sup>



**Expanding evidence across different populations for Cabenuva (cabotegravir + rilpivirine LA), the only complete long-acting injectable HIV treatment:** Late-breaking results from the phase IIIb VOLITION study will provide an update on Month 11 outcomes among ART-naïve adults who chose to switch to cabotegravir + rilpivirine (CAB+RPV) LA (branded as *Vocabria* + *Rekambys* outside the US, Canada and Australia) immediately after achieving virologic suppression on once daily *Dovato* (dolutegravir/lamivudine (DTG/3TC)).<sup>7</sup> Additionally, analyses from the real-world OPERA cohort will report virologic outcomes by body mass index categories for individuals suppressed at CAB+RPV LA initiation and four-year follow-up results for individuals initiating CAB+RPV LA with viral loads  $\geq 50$  vs  $< 50$  copies/mL.<sup>8,9</sup>

**New evidence supporting CAB LA for PrEP and understanding PrEP uptake:** An updated analysis from the phase I CLARITY study will provide detail on acceptability, visibility and size of injection-site reaction nodules following single-dose lenacapavir and cabotegravir injections, supporting informed choice.<sup>10</sup> Data from the OPERA cohort will outline *Apretude* (CAB LA for PrEP) effectiveness over three years, as well as coverage vs oral PrEP in routine care, providing important insights to guide implementation and adherence support.<sup>11,12</sup> Twelve-month real-world effectiveness and acceptance data for CAB LA for PrEP among Black women, a group disproportionately impacted by HIV, will also be presented.<sup>13</sup>

**Strengthening evidence for dolutegravir-based treatment across populations:** The first efficacy meta-analysis between DTG/3TC vs DTG three drug regimens in ART-naïve people with high or very high viral load and/or low CD4 will be presented.<sup>14</sup> Several analyses from PASO DOBLE, the largest head-to-head randomised clinical trial of DTG/3TC vs bictegravir, emtricitabine and tenofovir alafenamide (BIC/FTC/TAF), will provide insights on the differential metabolic impact including steatotic liver disease and adipose tissue at 96 weeks.<sup>15,16,17</sup> Results from the SUNGURA study including safety and efficacy data in virally suppressed older people living with HIV ( $\geq 60$  years), switching to DTG/3TC from BIC/FTC/TAF will also be presented.<sup>18</sup>

**Advancing paediatric treatment with LA options and DTG-based regimens:** Week 96 and end-of-study results for adolescents (IMPAACT 2017; MOCHA), and first safety and pharmacokinetics data for children  $< 20$  kg (IMPAACT 2036; CRAYON) – from two of our registrational supported collaborative studies – illustrate CAB+RPV LA treatment strategies in younger age groups.<sup>19,20</sup> Findings from an additional study from Southern Africa will describe viral suppression in children aged  $\leq 5$  years on DTG, highlighting its role in paediatric treatment.<sup>21</sup> Results from PENTA 21 will explore non-inferiority of the simplified oral regimen DTG/3TC vs 3-drug ART in treating children.<sup>22</sup>

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

Title	Presenting author	Oral abstract session
<b>CAB+RPV LA Treatment</b>		
Long-Acting Cabotegravir + Rilpivirine in Adolescents: IMPAACT 2017 Week 96 & End of Study Results	A. Gaur	Oral Presentation Next-Generation HIV Strategies for Children and Adolescents: Breakthroughs in Pediatric HIV Prevention, Treatment, and Care 24 February 2026
<b>DTG/3TC</b>		
DTG/3TC is Non-Inferior to DTG-based 3-Drug ART in Children with HIV: D3/Penta 21 Week 96 Results	A. Turkova	Oral Presentation  Next Generation HIV Strategies for Children and Adolescents: Breakthroughs in Pediatric HIV Prevention, Treatment, and Care  24 February 2026



<b>Lotivibart (N6LS)</b>		
Maintenance of HIV Suppression at 12 Months With VH3810109 (N6LS) Q4M + CAB LA QM: The EMBRACE Study	C.P. Rolle	Oral Presentation  Extending the Reach: Long-Acting Antiviral and Novel Delivery  25 February 2026
<b>VH184</b>		
Pharmacokinetics and Evaluation of Potential Dosing Regimens for Long-Acting VH4524184	H. Back	Oral Presentation  Extending the Reach: Long-Acting Antiviral and Novel Delivery  25 February 2026
<b>VH499</b>		
Injectable HIV-1 Capsid Inhibitor VH4011499 (VH-499) Formulation Supports Ultra-Long-Acting Dosing	N. Thakkar	Oral Presentation Extending the Reach: Long-Acting Antiviral and Novel Delivery 25 February 2026

<b>Title</b>	<b>Presenting author</b>	<b>Poster abstract session</b>
<b>CAB+RPV LA Treatment</b>		
Early Switch to CAB+RPV LA in Treatment-Naive Adults With HIV-1: Month 11 Outcomes From VOLITION	B. Jones	Poster (G-04) Cabotegravir and Rilpivirine in the "Real World" 25 February 2026
Outcomes for Individuals who Initiate CAB+RPV LA in OPERA with Viral Loads $\geq 50$ vs. $< 50$ copies/mL	R. K. Hsu	Poster (G-04) Cabotegravir and Rilpivirine in the "Real World" 25 February 2026
Body Mass Index and Virologic Outcomes in Individuals on CAB+RPV LA in the OPERA Cohort	M. G. Sension	Poster (G-04) Cabotegravir and Rilpivirine in the "Real World" 25 February 2026
Safety And Pharmacokinetics of Long-Acting Cabotegravir and Rilpivirine in Young Children 10 - $< 40$ kg	M. Archary	Poster (P-04) Pharmacokinetics, Safety, and Use of ARVs, Old and New, in Infants, Children, and Adolescents 24 February 2026
<b>CAB LA for PrEP</b>		
Dose Selection of Ultra-Long-Acting Cabotegravir as HIV-1 Pre-Exposure Prophylaxis: A Phase 1 Study	E. Castronova	Poster (F-02) Going the Distance: Pharmacokinetics of Next-Generation Long-Acting Agents



		24 February 2026
Injection Site Reactions More Common and Bothersome with Single Doses of Lenacapavir vs Cabotegravir	K. Brown	Poster (S-01) Who is Using Injectable PrEP, and How's That Going? 24 February 2026
Cabotegravir LA for PrEP: Progress in HIV Prevention from Three Years of OPERA Data	R. Hsu	Poster (S-01) Who is Using Injectable PrEP, and How's That Going? 24 February 2026
Comparing PrEP coverage and HIV acquisition between CAB LA and oral PrEP in the OPERA cohort	S. Barnett	Poster (S-01) Who is Using Injectable PrEP, and How's That Going? 24 February 2026
EBONI M12 Results: High Real-World Effectiveness and Acceptance of CAB LA for PrEP in Black Women	Z. Tims-Cook	Poster (U-05) Special Populations 24 February 2026
<b>DTG/3TC</b>		
Effect of DTG/3TC vs. BIC/FTC/TAF on Steatotic Liver Disease: 96-week Analysis of PASO-DOBLE Trial	J. Pineda	Themed Discussion and Poster (I-02) Extra Large Challenges in Steatotic Liver Disease 24 February 2026
CD4/CD8 T Cell Telomere Length at 96 Weeks in the PASO-DOBLE Trial Comparing BIC/FTC/TAF and DTG/3TC	A. Esteban-Cantos	Poster (L-03) Biomarkers of Aging 24 February 2026
Transcriptomic Changes in Adipose Tissue of People with HIV on BIC/FTC/TAF or DTG/3TC Treatment	P. Domingo	Poster (L-01) Weight Gain and Metabolic Disorders 23 February 2026
Efficacy and safety of switching to DTG/3TC dual therapy from B/F/TAF among older adults ≥60 years	L. A. Ombajo	Poster (G-02) TLD and HIV Treatment in LMIC: What Are We Learning? 23 February 2026
Meta-analysis of DTG/3TC vs DTG 3DRs in ART-Naive People With High Baseline Viral Loads and Low CD4+	P. Patel	Poster (G-05) Clinical Trials and Observational Studies of Antiretroviral Therapy 25 February 2026
<b>DTG</b>		
Viral Suppression with Dolutegravir-Based Regimens in Children ≤5 Years Old in Southern Africa	K. Anderson	Poster (P-05) Viral Suppression and Drug Resistance in Children and Adolescents With HIV 25 February 2026
<b>VH184</b>		



Third-Generation INSTI VH4524184 (VH-184) Has an Enhanced Resistance Profile vs Bictegravir	J. L. Jeffrey	Poster (H-01) Integrase Resistance 23 February 2026
<b>VH499</b>		
Population PK and Exposure-Response Analysis of Orally Administered VH4011499 in people living with HIV-1	N. Thakkar	Poster (F-02) Going the Distance: Pharmacokinetics of Next-Generation Long-Acting Agents 24 February 2026

#### 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. 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. It should be used in combination with safer sex practices, such as using condoms. *Apretude* contains the active substance cabotegravir.

Please consult the full Prescribing Information [here](#).

#### About *Vocabria* (cabotegravir)

*Vocabria* injection is indicated - in combination with rilpivirine injection - for the treatment of Human Immunodeficiency Virus type 1 (HIV-1) infection in adults and adolescents (at least 12 years of age and weighing at least 35 kg) who are virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen without present or past evidence of viral resistance to, and no prior virological failure with agents of the non-nucleoside reverse transcriptase inhibitors (NNRTI) and integrase inhibitor (INI) class.

*Vocabria* tablets are indicated - in combination with rilpivirine tablets - for the short-term treatment of HIV-1 infection in adults and adolescents (at least 12 years of age and weighing at least 35 kg) who are virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen without present or past evidence of viral resistance to, and no prior virological failure with agents of the NNRTI and INI class for:

- oral lead-in to assess tolerability of *Vocabria* and rilpivirine prior to administration of long acting *Vocabria* injection plus long acting rilpivirine injection.
- oral therapy for adults who will miss planned dosing with *Vocabria* injection plus rilpivirine injection.

*Vocabria* tablets are only indicated for treatment of HIV-1 in combination with rilpivirine tablets, therefore, the prescribing information for *Edurant* (rilpivirine) tablets should also be consulted for recommended dosing.

Please consult the full Summary of Product Characteristics for all the safety information: [Vocabria 400mg/600 mg prolonged-release suspension for injection and Vocabria 30 mg film-coated tablets](#)

#### About *Rekambys* (rilpivirine)

*Rekambys* is indicated - in combination with cabotegravir injection - for the treatment of HIV-1 infection in adults and adolescents (at least 12 years of age and weighing at least 35 kg) who are virologically suppressed (HIV-1 RNA < 50 copies/mL) on a stable antiretroviral regimen without present or past evidence of viral resistance to, and no prior virological failure with, agents of the NNRTI and INI class.

*Rekambys* should always be co-administered with a cabotegravir injection. The prescribing information for cabotegravir injection should be consulted for recommended dosing. *Rekambys* may be initiated with oral lead-in or without (direct to injection).

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Please consult the full Summary of Product Characteristics for all the safety information: [Rekambys 600mg/900 mg prolonged-release suspension for injection](#)

### 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 integrase strand transfer inhibitor (INSTI) cabotegravir, developed by ViiV Healthcare, with rilpivirine, a non-nucleoside reverse transcriptase inhibitor (NNRTI) developed by Janssen Sciences Ireland Unlimited Company. 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 Human Immunodeficiency Virus type 1 (HIV-1) infection in adults and adolescents above 12 years of age weighing at least 40kg in the EU, and weighing at least 25kg in the US, with no known or suspected resistance to the integrase inhibitor class, or lamivudine.

Please consult the full Prescribing Information [here](#).

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### 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](http://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](http://www.gsk.com).

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# Press release

## For media and investors only



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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 2024, and GSK's Q4 Results for 2025.

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\*On 20 January 2026, GSK plc and Shionogi & Co., Ltd announced that they have reached agreement together with Pfizer Inc. for the economic interest in ViiV Healthcare Limited currently held by Pfizer to be replaced with an investment by Shionogi. Completion of the transaction is subject to certain regulatory clearances in relevant markets, and is expected to occur during the first quarter of 2026.

### References

<sup>1</sup> H. Back et al. Pharmacokinetics and Evaluation of Potential Dosing Regimens for Long-Acting VH4524184. Presented at the 33<sup>rd</sup> Conference on Retroviruses and Opportunistic Infections (CROI). February 2026.

<sup>2</sup> M. Underwood et al. Third-Generation INSTI VH4524184 (VH-184) Has an Enhanced Resistance Profile vs Bictegravir. Presented at the 33<sup>rd</sup> Conference on Retroviruses and Opportunistic Infections (CROI). February 2026.

<sup>3</sup> CP. Rolle et al. Maintenance of HIV Suppression at 12 Months With VH3810109 (N6LS) Q4M + CAB LA QM: The EMBRACE Study. Presented at the 33<sup>rd</sup> Conference on Retroviruses and Opportunistic Infections (CROI). February 2026.

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<sup>5</sup> N. Thakkar et al. Population PK and Exposure-Response Analysis of Orally Administered VH4011499 in people living with HIV-1. Presented at the 33<sup>rd</sup> Conference on Retroviruses and Opportunistic Infections (CROI). February 2026.

<sup>6</sup> E. Castronova et al. Dose Selection of Ultra-Long-Acting Cabotegravir as HIV-1 Pre-Exposure Prophylaxis:

A Phase 1 Study. Presented at the 33<sup>rd</sup> Conference on Retroviruses and Opportunistic Infections (CROI). February 2026.

<sup>7</sup> C. P. Rolle et al. Early Switch to CAB+RPV LA in Treatment-Naive Adults With HIV-1: Month 11 Outcomes From VOLITION. Presented at the 33<sup>rd</sup> Conference on Retroviruses and Opportunistic Infections (CROI). February 2026.

<sup>8</sup> R. Hsu et al. Outcomes for Individuals who Initiate CAB+RPV LA in OPERA with Viral Loads  $\geq 50$  vs.  $< 50$  copies/mL. Presented at the 33<sup>rd</sup> Conference on Retroviruses and Opportunistic Infections (CROI). February 2026.

<sup>9</sup> M. G. Sension et al. Body Mass Index and Virologic Outcomes in Individuals on CAB+RPV LA in the OPERA Cohort. Presented at the 33<sup>rd</sup> Conference on Retroviruses and Opportunistic Infections (CROI). February 2026.

<sup>10</sup> K. Brown et al. Injection Site Reactions More Common and Bothersome with Single Doses of Lenacapavir vs Cabotegravir. Presented at the 33<sup>rd</sup> Conference on Retroviruses and Opportunistic Infections (CROI). February 2026.

<sup>11</sup> R. Hsu et al. Cabotegravir LA for PrEP: Progress in HIV Prevention from Three Years of OPERA Data. Presented at the 33<sup>rd</sup> Conference on Retroviruses and Opportunistic Infections (CROI). February 2026.

<sup>12</sup> S. Barnett et al. Comparing PrEP coverage and HIV acquisition between CAB LA and oral PrEP in the OPERA cohort. Presented at the 33<sup>rd</sup> Conference on Retroviruses and Opportunistic Infections (CROI). February 2026.

<sup>13</sup> Z. Tims-Cook et al. EBONI M12 Results: High Real-World Effectiveness and Acceptance of CAB LA for PrEP in Black Women. Presented at the 33<sup>rd</sup> Conference on Retroviruses and Opportunistic Infections (CROI). February 2026.

<sup>14</sup> P. Patel et al. Meta-analysis of DTG/3TC vs DTG 3DRs in ART-Naive People With High Baseline Viral Loads and Low CD4+. Presented at the 33<sup>rd</sup> Conference on Retroviruses and Opportunistic Infections (CROI). February 2026.



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- <sup>15</sup> A. Esteban-Cantos et al. CD4/CD8 T Cell Telomere Length at 96 Weeks in the PASO-DOBLE Trial Comparing BIC/FTC/TAF and DTG/3TC. Presented at the 33<sup>rd</sup> Conference on Retroviruses and Opportunistic Infections (CROI). February 2026.
- <sup>16</sup> J. Pineda. Effect of DTG/3TC vs. BIC/FTC/TAF on Steatotic Liver Disease: 96-week Analysis of PASO-DOBLE Trial. Presented at the 33<sup>rd</sup> Conference on Retroviruses and Opportunistic Infections (CROI). February 2026.
- <sup>17</sup> P. Domingo. Transcriptomic Changes in Adipose Tissue of People with HIV on BIC/FTC/TAF or DTG/3TC Treatment. Presented at the 33<sup>rd</sup> Conference on Retroviruses and Opportunistic Infections (CROI). February 2026.
- <sup>18</sup> L. A. Ombajo et al. Efficacy and safety of switching to DTG/3TC dual therapy from B/F/TAF among older adults  $\geq 60$  years. Presented at the 33<sup>rd</sup> Conference on Retroviruses and Opportunistic Infections (CROI). February 2026.
- <sup>19</sup> A. Gaur et al. Long-Acting Cabotegravir+Rilpivirine in Adolescents: IMPAACT 2017 Week 96 & End of Study Results. Presented at the 33<sup>rd</sup> Conference on Retroviruses and Opportunistic Infections (CROI). February 2026.
- <sup>20</sup> M. Archary et al. Safety And Pharmacokinetics of Long-Acting Cabotegravir and Rilpivirine in Young Children 10 - <40kg. Presented at the 33<sup>rd</sup> Conference on Retroviruses and Opportunistic Infections (CROI). February 2026.
- <sup>21</sup> K. Anderson et al. Viral Suppression with Dolutegravir-Based Regimens in Children  $\leq 5$  Years Old in Southern Africa. Presented at the 33<sup>rd</sup> Conference on Retroviruses and Opportunistic Infections (CROI). February 2026.
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