Press release

For media and investors only

Issued: 8 July 2025, London UK

ViiV Healthcare presents new data demonstrating positive real-world impact of its innovative long-acting injectables for HIV at IAS 2025

- Real-world and implementation data describe effectiveness of long-acting Vocabria + Rekambys (cabotegravir + rilpivirine LA (CAB+RPV LA)) for HIV treatment and assess experiences of using Apretude (cabotegravir long-acting (CAB LA) for PrEP) in range of populations
- New phase IIIb data look at preferences among treatment-naive adults offered the choice to switch to CAB+RPV LA after attaining rapid viral suppression with Dovato (DTG/3TC) daily oral therapy
- Interim data from wave three of the Positive Perspectives study demonstrate impact of joint decision-making on HIV treatment satisfaction and health outcomes

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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 at the International AIDS Society 2025 Conference (IAS 2025) in Kigali, Rwanda. Key data will highlight the long-term effectiveness of Vocabria & Rekambys, (branded as Cabenuva in the US, Canada and Australia) the company's complete long-acting injectable regimen for treatment; evaluate patient preference for long-acting injectables compared to daily oral therapy; and measure benefits of long-acting injectables in tackling common challenges associated with taking daily pills, including stigma and adherence.

Jean van Wyk, MBChB, MFPM, Chief Medical Officer at ViiV Healthcare, said: "Our extensive real-world insights about CAB+RPV LA for HIV treatment and CAB LA for HIV prevention demonstrate how long-acting injectables are redefining the way we approach HIV care and management in broad populations. The new real-world and implementation data at IAS 2025 further reinforce their effectiveness, safety and tolerability, and underscore our commitment to delivering therapies that meet the evolving needs of people impacted by HIV, offering flexibility and choice beyond daily oral treatment."

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

- **New data assessing preference and choice to switch to CAB+RPV LA after attaining rapid viral suppression**: First data from the phase IIIb VOLITION study assessed preferences and experiences among ART-naive adults offered the option to switch to CAB+RPV LA after achieving rapid viral suppression with daily *Dovato* (dolutegravir/lamivudine (DTG/3TC))[i].
- **Growing body of real-world effectiveness data for CAB+RPV LA in broad range of populations**: New data will be presented on outcomes including effectiveness, adherence, and satisfaction with CAB+RPV LA, from several real-world studies, including COMBINE-2, and two-year data from CARLOS and BEYOND[ii,iii,iv,v]. In addition, two analyses from the OPERA cohort will focus on the effectiveness of CAB+RPV LA in real-world settings for treatment-experienced adults with viremia at therapy initiation[vi,vii].
- **New implementation data on acceptability and benefits of CAB LA for PrEP:** Data from the PILLAR and EBONI implementation studies will focus on participant experiences with CAB LA implementation among men who have sex with men and transgender men, as well as healthcare provider experiences implementing CAB LA for Black women, respectively[viii,ix].

- **New effectiveness data for DTG/3TC in different populations**: New data from VOLITION evaluate the efficacy of DTG/3TC in achieving rapid virologic suppression in a diverse treatment-naive population.[x] Data from investigator-led, ViiV Healthcare-supported studies, D2ARLING and SUNGURA will also be presented, including D2ARLING's comparison of DTG/3TC effectiveness to other regimens in the presence of transmitted resistance mutations, and an analysis from the SUNGURA study including safety and efficacy data in virally suppressed older people living with HIV switching to DTG/3TC from BIC/FTC/TAF[xi,xii].
- **Positive Perspectives wave three data highlighting the importance of community perspectives in treatment outcomes:** Interim results from wave three of the Positive Perspectives study will be presented, showing how shared decision making and treatment satisfaction are linked to treatment outcomes and self-rated health in specific sub-group analyses[xiii]. Additionally, the continued need to improve awareness, belief and confidence in U=U will be presented[xiv].

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

Title	Presenting author	Presentation
CAB+RPV LA		
Real-world effectiveness of CAB+RPV LA in individuals with HIV viremia at therapy initiation	R. Hsu	Oral Abstract OAB0104 15 July 2025 10:45 AM – 11:45 AM CAT
24-month outcomes of cabotegravir+rilpivirine long-acting every 2 months in a real-world setting: effectiveness, adherence to injections, and participant-reported outcomes from people with HIV-1 in the German CARLOS cohort	J. Scherzer	Poster Exhibition TUPEB035 15 July 2025 12:00 PM – 13:00 PM CAT
Clinical outcomes among women in the OPERA Cohort initiating CAB+RPV LA with viral loads ≥ 50 copies/mL	V. Vannappagari	Poster Exhibition WEPEB036 16 July 2025 12:00 PM – 13:00 PM CAT
Perspectives of people with HIV (PWH) 24 months following a switch to cabotegravir and rilpivirine long-acting (CAB+RPV LA) in an observational real-world US study (BEYOND)	C. Garris	Poster Exhibition THPEB036 17 July 2025 12:00 PM – 13:00 PM CAT
The power of choice: strong preference for CAB+RPV LA following rapid suppression with DTG/3TC in newly diagnosed people living with HIV	C. Gutner	E-Poster EP0170
High virologic suppression and few virologic failures with Long-Acting Cabotegravir + Rilpivirine in Treatment Experienced Virologically Suppressed Individuals from COMBINE-2 cohort in Europe	A. Pozniak	E-Poster EP0171
Clinical Outcomes at Month 24 After Initiation of Cabotegravir and Rilpivirine Long Acting (CAB+RPV LA) in an Observational Real-World Study (BEYOND)	G. Blick	E-Poster EP0178
CAB LA for PrEP		
One-Year Implementation Outcomes of Cabotegravir Long-Acting Injectable PrEP in Men who Have Sex with Men (MSM) & Transgender Men (TGM): Findings from the PILLAR Study	D. Dandachi	Poster Exhibition TUPEE116 15 July 2025 12:00 PM – 13:00 PM CAT

Health Care Provider Experiences After 12 Months of Implementing Cabotegravir Long-Acting Injectable PrEP (CAB LA) for Black Women: Results from the EBONI Study	Z. Tims-Cook	Poster Exhibition THPEE096 17 July 2025 12:00 PM – 13:00 PM CAT
DTG/3TC		
Rapid virologic suppression with DTG/3TC facilitates early switch to CAB+RPV LA for treatment-naive people living with HIV: suppression phase outcomes from the phase 3b VOLITION study	B. Jones	Poster Exhibition WEPEB033 16 July 2025 12:00 PM – 13:00 PM CAT
Efficacy of dolutegravir plus lamivudine in treatment-naïve people with HIV with baseline transmitted drug-resistance mutations: a subanalysis of the D2ARLING study	E. Cordova	E-Poster EP0172
Positive Perspectives		
Treatment Satisfaction was Linked to Improved Adherence, and Mental, Physical, Sexual and Overall Health Among People Living with HIV in the Positive Perspectives 3 Study	R. Patel	Poster Exhibition WEPED080 16 July 2025 12:00 PM – 13:00 PM CAT
Data from the Positive Perspectives 3 Study Highlights the Continued Need for Expansion of Awareness, Belief and Confidence in Undetectable Equals Untransmittable (U=U)	N. Nwokolo	E-Poster EP0597
Joint Patient-Provider Decision Making was Associated with Improvements in Quality of Life and Treatment Satisfaction for People Living with HIV in the Positive Perspectives 3 study	R. Patel	E-Poster EP0608

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 *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).

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 as a complete regimen to treat 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 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*.

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

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.

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References

[i] E. Cordova, *et al*. Rapid virologic suppression with DTG/3TC facilitates early switch to CAB+RPV LA for treatment-naive people living with HIV: suppression phase outcomes from the Phase 3b VOLITION study. Presented at the International AIDS Society Conference (IAS 2025), 13-17 July, Kigali, RW.

[ii] A. Pozniak, *et al*. High virologic suppression and few virologic failures with Long-Acting Cabotegravir + Rilpivirine in Treatment Experienced Virologically Suppressed Individuals from COMBINE-2 cohort in Europe. Presented at the International AIDS Society Conference (IAS 2025), 13-17 July, Kigali, RW.

[iii] C. Wyen, *et al*. 24-month outcomes of cabotegravir+rilpivirine long-acting every 2 months in a real-world setting: effectiveness, adherence to injections, and participant-reported outcomes from people with HIV-1 in the German CARLOS cohort. Presented at the International AIDS Society Conference (IAS 2025), 13-17 July, Kigali, RW.

[iv] F. Felizarta, *et al*. Perspectives of people living with HIV (PWH) 24 months following a switch to cabotegravir and rilpivirine long-acting (CAB+RPV LA) in an observational real-world US study (BEYOND). Presented at the International AIDS Society Conference (IAS 2025), 13-17 July, Kigali, RW.

[v] G. Blick, *et al*. Clinical outcomes at month 24 after initiation of cabotegravir and rilpivirine long acting (CAB+RPV LA) in an observational real-world study (BEYOND). Presented at the International AIDS Society Conference (IAS 2025), 13-17 July, Kigali, RW.

[vi] R. Hsu, *et al*. Real-world effectiveness of CAB+RPV LA in individuals with HIV viremia at therapy initiation. Presented at the International AIDS Society Conference (IAS 2025), 13-17 July, Kigali, RW.

[vii] J. Altamirano, *et al*. Clinical outcomes among women in the OPERA cohort initiating CAB+RPV LA with viral loads ≥ 50 copies/mL. Presented at the International AIDS Society Conference (IAS 2025), 13-17 July, Kigali, RW.

[viii] D. Dandachi, *et al*. One-year implementation outcomes of cabotegravir long-acting injectable PrEP in men who have sex with men (MSM) & transgender men (TGM): findings from the PILLAR study. Presented at the International AIDS Society Conference (IAS 2025), 13-17 July, Kigali, RW.
[ix] Z. Tims-Cook, *et al*. Health care provider experiences after 12 months of implementing cabotegravir long-acting injectable PrEP (CAB LA) for Black women: EBONI study results. Presented at the International AIDS Society Conference (IAS 2025), 13-17 July, Kigali, RW.

[x] B. Jones, *et al*. Rapid virologic suppression with DTG/3TC facilitates early switch to CAB+RPV LA for treatment-naive people living with HIV: suppression phase outcomes from the phase 3b VOLITION study. Presented at the International AIDS Society Conference (IAS 2025), 13-17 July, Kigali, RW.

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[xii] L.A. Ombajo, *et al*. Efficacy and safety of switching to dolutegravir/lamivudine dual therapy from bictegravir/emtricitabine/tenofovir alafenamide among virally suppressed older adults ≥60 years: week 24 results from the Sungura study. Presented at the International AIDS Society Conference (IAS 2025), 13-17 July, Kigali, RW.

[xiii] R. Patel, *et al*. Treatment satisfaction was linked to improved adherence, and mental, physical, sexual and overall health among people living with HIV in the Positive Perspectives 3 study. Presented at the International AIDS Society Conference (IAS 2025), 13-17 July, Kigali, RW.

[xiv] R. Patel, *et al*. Data from the Positive Perspectives 3 Study highlights the continued need for expansion of awareness, belief and confidence in undetectable equals untransmittable (U=U). Presented at the International AIDS Society Conference (IAS 2025), 13-17 July, Kigali, RW.