# Press release

For media and investors only

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# ViiV Healthcare announces new implementation study data showing zero cases of HIV with *Apretude*, the only long-acting injectable approved for HIV PrEP

- New data at CROI 2025 show zero cases of HIV acquisition reported with Apretude (cabotegravir long-acting (CAB LA) for PrEP) in varied clinical settings and populations in two implementation studies in the U.S. and Brazil
- Data for *Cabenuva* (cabotegravir + rilpivirine long-acting (CAB+RPV LA)), the only complete long-acting injectable approved for HIV treatment, show high effectiveness in two, large real-world studies

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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 new data from two implementation studies showing zero cases of HIV acquisition for *Apretude*, the only long-acting injectable approved for HIV prevention. Real-world data were also presented for *Cabenuva,* the only approved, complete long-acting injectable treatment regimen, showing its effectiveness in the three years since it has been available.

These data were presented at the Conference on Retroviruses and Opportunistic Infections (CROI 2025), in San Francisco, U.S.

**Harmony P. Garges, M.D. MPH., Chief Medical Officer at ViiV Healthcare, said:** "As the leaders in long-acting injectables for HIV, we're committed to collecting data to understand the effectiveness of these first-in-class medicines in real-world settings. Our ongoing, real-world and implementation studies for *Apretude* show effectiveness of HIV prevention of more than 99% in nearly 4,000 people; and we have real-world experience in more than 15,000 people receiving *Cabenuva* for HIV treatment showing continued high effectiveness up to two years. Our data at CROI 2025 reinforce that, across a broad range of settings and populations, our long-acting injectables provide a highly effective option for both HIV treatment and prevention, that remove the need for daily pills."

**Ricky Hsu, M.D., Department of Medicine, NYU Grossman School of Medicine and Medical Director, AHF Healthcare Center, said:** "While randomised clinical trials are the gold standard for testing the safety and efficacy of medicines, real-world evidence can provide a fuller understanding of the safety and effectiveness of a therapy over time. Since ViiV Healthcare's introduction of long-acting injectables, generating these valuable insights is more important than ever to help providers decide who could benefit from particular medicines and better understand how they address the everyday needs of people impacted by HIV."

Highlights from ViiV Healthcare and partner real-world and implementation studies for long-acting injectables *Apretude* (prevention) and *Cabenuva* (treatment):

**PILLAR 12-month clinical results: zero HIV acquisition and high persistence with CAB LA for PrEP** [1]
New 12-month findings from the PILLAR study explore effectiveness, diagnostic testing, persistence (time that an individual continued to receive injections), safety and tolerability of CAB LA in 201 participants. PILLAR is a phase IV implementation trial assessing the integration of CAB LA for PrEP across 17 clinics in the U.S. among a diverse population of men having sex with men and transgender men, 26% of whom were Black and 38% Hispanic/Latino.

No cases of HIV acquisition were observed through 12 months. Persistence on CAB LA was high, at 85% (n=171/201) at six months and 72% (n=142/196) at 12 months; excluding five participants who completed the study post-data cutoff. Five participants missed an injection and received either oral CAB or alternative PrEP.

Adverse events (AEs) related to CAB LA were uncommon, with injection site pain the most frequently reported (3%, n=6). Five percent of participants (n=11) had AEs leading to discontinuation, most commonly due to injection site pain.

This implementation study data - obtained from a diverse population - supports CAB LA as an effective PrEP option associated with high persistence.

**ImPrEP CAB Brazil implementation study data shows significantly improved PrEP coverage and protection with CAB LA[2]**
The ImPrEP CAB Brazil study (The Choice Cohort) assessed PrEP coverage and HIV incidence among 1,447 participants who were given the choice of CAB LA or oral PrEP (TDF/FTC) for HIV prevention. The Choice Cohort included PrEP-naïve, cisgender men who have sex with men, non-binary and trans people aged 18 to 30. As a comparison group, the study assessed 2,263 people of a similar demographic, initiating oral PrEP through the Brazilian public health system during the same period.

The results show that offering CAB LA injections significantly improved PrEP coverage and HIV prevention for young key populations, reinforcing the role of CAB LA in addressing adherence challenges some people face with oral PrEP.

Eighty-three percent of the 1,447 participants who were free to choose either CAB LA or oral PrEP chose CAB LA (1,200 participants) and there were zero HIV acquisitions reported over 798.4 person-years in The Choice Cohort. There were eight HIV acquisitions over 408.52 person-years reported in the comparison group (incidence rate 1.96 [95% CI 0.98-3.92] per 100 person-years).

The proportion of individuals covered by PrEP during follow-up was highest in the CAB LA group (96.2%, 221,273/ 229,951 days), followed by the oral PrEP group within The Choice Cohort (64.1%, 32,272/ 50,310 days) and lowest in the comparison group (47.4%, 191,765/ 404,781 days).

The study is sponsored by the Evandro Chagas National Institute of Infectious Diseases at the Oswaldo Cruz Foundation, Brazil, and funded by Unitaid.

**Real-world data from OPERA show high effectiveness of CAB + RPV LA in broad populations[3,4]**
The first of two OPERA analyses looked at long-term effectiveness in diverse virologically suppressed individuals on CAB+RPV LA - 42% of whom are Black and 30% Hispanic - through two years.

In this large (n=2,485) U.S. cohort of individuals who switched to CAB + RPV LA, with a median follow-up time of 11 months (IQR: 6-18), 95% maintained virological suppression (<50c/ml at last Viral Load (VL) and 1% (n=21) experienced confirmed virologic failure (CVF) after a median of seven months. Outcomes were consistent over time through 24 months and across BMI categories (<30 kg/m$^2$, ≥30 kg/m$^2$).[3]
In a second analysis among a diverse group of 381 virologically suppressed women with HIV, with a median follow-up time of 12 months (IQR:7-19), 94% maintained suppression at their last viral load and CVF was ≤1.3% (n≤5).[4]

**High rates of viral suppression observed in Trio Health cohort[5]**
The Trio Health cohort followed 928 virologically suppressed individuals initiating CAB + RPV LA in real-world settings in the U.S. The median (IQR) follow-up time after the first injection was 12 months (5-19) and 89% of injections (6176/6934) were administered without delay (<7 days after the target dosing date). Ninety-five percent of individuals on CAB+RPV LA maintained viral suppression (last VL <50 cp/mL) and 1.6% (n=15) experienced CVF.

These studies add to the real-world evidence supporting CAB+RPV LA's high effectiveness in a broad range of populations.

***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



**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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# Press release
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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 under Item 3.D "Risk factors" in GSK's Annual Report on Form 20-F for 2024.


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**References**

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