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***

London, 12 March 2025 – 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 who have 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.

These implementation study data - obtained from a diverse population - support 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 c/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.

About *Apretude*
Apretude is a medicine used for preventing sexually transmitted HIV-1 infection (pre-exposure prophylaxis or PrEP) in adults and adolescents weighing at least 35kg 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.

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 35kg 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 U.S. 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 35kg 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.

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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 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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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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[2] B Grinsztejn *et al.* ImPrEP CAB Brasil: Enhancing PrEP coverage with CAB LA in Young Key Populations. Presented at the Conference on Retroviruses and Opportunistic Infections (CROI 2025), 9-12 March, San Francisco, CA

[3] Sension M, *et al.* Long-term CAB+RPV LA Effectiveness in Virologically Suppressed Individuals in the OPERA Cohort. Presented at the Conference on Retroviruses and Opportunistic Infections (CROI 2025), 9-12 March, San Francisco, CA

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