Press release

For media and investors only

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ViiV Healthcare's long-acting *Cabenuva* (cabotegravir + rilpivirine) for HIV demonstrates superior efficacy compared to daily oral therapy for people with adherence challenges; results published in *NEJM*

- Final data from LATITUDE study show switch to long-acting injectable treatment reduced the risk of virological failure by nearly half for study participants through 48 weeks, compared to those continuing on daily oral therapy

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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 final data from the LATITUDE phase III trial, confirming its long-acting injectable treatment for HIV, *Cabenuva* (cabotegravir + rilpivirine), demonstrated superior efficacy in maintaining viral load suppression compared to daily oral therapy in individuals with a history of antiretroviral treatment (ART) adherence challenges.[1]

The 48-week data were published in the *New England Journal of Medicine*, and followed a February 2024 recommendation from an independent Data and Safety Monitoring Board to halt randomisation in the study and invite all eligible study participants to take long-acting injectable cabotegravir + rilpivirine based on interim efficacy data.[1]

Kimberly Smith, M.D., MPH, Head of Research & Development at ViiV Healthcare, said: "The LATITUDE study adds to a robust body of evidence supporting the role of long-acting injectable cabotegravir + rilpivirine as a valuable treatment option for people living with HIV. This is the first randomised study confirming this regimen is superior to daily oral therapy in this population. As such, these findings have the potential to validate a long-acting approach for this additional group of patients and could make a significant difference to people living with HIV and our goal of ending the epidemic."

LATITUDE (Long-Acting Therapy to Improve Treatment Success in Daily Life) is a phase III, randomised, open-label study which enrolled 453 participants who face challenges taking daily oral ART or who disengaged from HIV care. In the study, the median age was 40 years; 63% were Black/African American, 29% were female, 17% were Hispanic, and 14% reported either ongoing or prior injection drug use. Once enrolled, participants received adherence support including conditional economic incentives to achieve viral suppression while taking guideline-recommended daily oral ART. Researchers randomised 306 participants who were able to achieve viral suppression to either receive long-acting injectable (cabotegravir + rilpivirine) every four weeks (n=152) or continue taking daily oral ART (n=154).[1]

The primary endpoint was a comparison of regimen failure between arms, defined as a combination of virologic failures (VF) and regimen discontinuation for any reason. The cumulative risk of regimen failure through 48 weeks of treatment was reduced by nearly half in the study: 22.8% for those who were switched to long-acting injectable cabotegravir + rilpivirine vs. 41.2% for people continuing on daily oral therapy (29/152 vs. 55/154, respectively).[1]

Among participants receiving long-acting cabotegravir + rilpivirine in the trial, 29/152 (19%) experienced regimen failure, five (3%) of whom had VF and 24 (16%) had permanent treatment discontinuation as their first event. In the daily oral therapy arm, 55/154 (36%) experienced regimen failure, among whom 32 (21%) had VF as their first event and 23 (15%) had permanent treatment discontinuation.[1]

Key additional endpoints at week 48 demonstrated the superiority of cabotegravir + rilpivirine vs. daily oral therapy:[1]

Endpoint	Cumulative probability, long-acting injectable cabotegravir + rilpivirine (n=152)	Cumulative probability, daily oral therapy (n=154)	Cumulative incidence difference (98.4% CI)
VF (events)	6.8% (6)	28.2% (34)	-21.4% (-33.5%, -9.3%)
Treatment-related failure* (events)	8.9% (9)	28.1% (34)	-19.2% (-31.6%, -6.9%)
Permanent discontinuation of treatment (events)	19.8% (26)	28.2% (37)	-8.4% (-21.3%, 4.5%)

* Earliest occurrence of VF or premature treatment discontinuation due to treatment-related adverse events (AEs).

The rate of AEs was similar in both arms. The most common AE in the long-acting arm was injection site reactions (ISRs), with two participants discontinuing due to an ISR.[1] Two confirmed VF in each arm (n=4 total) had new resistance associated mutations (RAMs), including two new integrase inhibitor RAMs in both long-acting arm participants.[1]

Building on the LATITUDE study, ViiV Healthcare is conducting CROWN, a randomised study of long-acting cabotegravir + rilpivirine vs. daily oral therapy in people with adherence challenges and detectable virus.[2] Unlike LATITUDE, which included a virologic suppression phase, CROWN evaluates the regimen directly in individuals who are not yet suppressed.[1,2]

LATITUDE is sponsored and funded by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, and was conducted by ACTG, with additional support from the National Institute of Mental Health, the National Institute on Drug Abuse, the Eunice Kennedy Shriver National Institute of Child Health and Human Development, ViiV Healthcare and Johnson & Johnson.

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 ACTG

ACTG is the world's largest and longest running clinical trials network focused on HIV and other infectious diseases and the people living with them. It is funded by NIAID and collaborating NIH Institutes. Founded in 1987, ACTG conducts research to improve the management of HIV and its comorbidities; develop a cure for HIV; and innovate treatments for tuberculosis, hepatitis B, and emerging infectious diseases. It comprises thousands of dedicated researchers, staff, and community members who are pursuing research into novel treatments and cures for infectious diseases at 65 locations across four continents, with the ultimate goal of advancing science that meaningfully impacts the lives of the people we serve.

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 www.gsk.com.

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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

1. Rana A., et al. Cabotegravir plus Rilpivirine for Persons with HIV and Adherence Challenges. *N Engl J Med*. 2026.
2. Clinicaltrials.gov website. A Study to Evaluate the Effectiveness of Long-acting (LA) Cabotegravir (CAB) + Rilpivirine (RPV) LA When Given to Participants With Detectable HIV-1 (CROWN). Available at: https://clinicaltrials.gov/study/NCT06694805. Last accessed: February 2026.