Press release

For media and investors only

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ViiV Healthcare presents pipeline data for two investigational HIV treatment therapies with potential for twice-yearly dosing

- VH184, the first, third-generation integrase inhibitor in development shows potential for up to twice-yearly dosing intervals
- Additional in-vitro data on VH184 demonstrate improved potency and an enhanced resistance profile versus bictegravir
- VH499 demonstrates good tolerability, supporting twice-yearly dosing intervals

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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 from its phase 1 study of long-acting formulations of VH184, the first, third-generation integrase strand transfer inhibitor (INSTI) in development for HIV.[1] Results show a single-dose injection could maintain drug levels for up to six months. In-vitro data from a separate study demonstrate improved potency and an enhanced resistance profile versus bictegravir in resistant HIV strains.[2]

Additional data from ViiV Healthcare's long-acting pipeline presented at the 33rd Conference on Retroviruses and Opportunistic Infections (CROI 2026) in Denver, Colorado, show VH499, an investigational capsid inhibitor, was generally well tolerated and support the potential for ultra long-acting (ULA) twice-yearly dosing.[3] These early-stage findings, alongside continued progress of other ULA pipeline assets, including lotivibart (N6LS), reinforce ViiV Healthcare's commitment to advancing innovative long-acting HIV therapies that reduce the need for daily treatment and expand options for people living with HIV.

Kimberly Smith, M.D., MPH, Head of Research & Development at ViiV Healthcare, said: "Our R&D efforts are built around delivering best-in-class, long-acting therapies that challenge the status quo and help make HIV treatment a smaller, less frequent part of people's lives. The data we're presenting on VH184, our third-generation INSTI, indicate a potential high barrier to resistance and twice-yearly dosing intervals. Early results for VH499, a capsid inhibitor, point to its potential for dosing every six months. These data underscore how ViiV Healthcare is working to define the future of HIV care through ultra long-acting options designed to address the needs and preferences of people living with HIV and will inform our plans to introduce the first INSTI-based, twice-yearly regimen for people with HIV."

VH184 shows potential for dosing intervals of up to twice-yearly and improved activity versus bictegravir.[1,2]
In a phase 1 study of long-acting formulations in adults without HIV, VH184 was given as a single subcutaneous (SC) or intramuscular (IM) injection in one of two formulations. Both formulations demonstrated long-acting properties, with one maintaining steady drug levels through Month 7, indicating the potential for twice-yearly dosing.

The VH184 formulations were generally well tolerated, with most side effects limited to mild grade 1 injection site reactions (ISRs) such as erythema, pain, and nodules, with fewer grade 2 and grade 3 ISRs. The safety profile of VH184 is consistent with previous studies and is similar to that of approved INSTIs.

In an in-vitro study also presented at CROI, VH184 demonstrated an improved virology profile, specifically an enhanced resistance profile compared with bictegravir, when evaluated against HIV with mutations linked to resistance to second-generation INSTIs. VH184 retained activity against a broad range of resistant virus strains, including those with multiple INSTI-associated substitutions, indicating a potential higher barrier to resistance.

Together, these results confirm VH184 as a third-generation INSTI with long-acting potential and extended coverage of viruses with INSTI resistance mutations. Phase 2b studies will further determine optimal dosing schedules and continue to assess its potential as a twice-yearly treatment for people living with HIV.

VH499 shows potential for twice-yearly dosing.[3] In an ongoing phase 1 study in adults without HIV, VH499 was given as a single IM or SC injection between 100mg and 1200mg. Both injection routes maintained stable drug levels for a prolonged period, indicating that injectable VH499 has the potential for ULA dosing intervals up to six months.

VH499 was generally well tolerated, with most common side effects being injection site reactions, most frequently injection site pain at grade 1 or 2, with the majority mild to moderate in severity and short-lived. There were no serious adverse events (AE) and no study withdrawals due to AEs.

Further studies will use these data to optimise dosing schedules for VH499. These findings build on proof-of-concept data previously presented at CROI 2025 and add to the growing body of evidence for VH184 and VH499 as potential components of future ULA treatment regimens.

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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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

[1] H. Back et al. Pharmacokinetics and Evaluation of Potential Dosing Regimens for Long-Acting VH4524184. Presented at the 33rd Conference on Retroviruses and Opportunistic Infections (CROI). February 2026.
[2] M. Underwood et al. Third-Generation INSTI VH4524184 (VH-184) Has an Enhanced Resistance Profile vs Bictegravir. Presented at the 33rd Conference on Retroviruses and Opportunistic Infections (CROI). February 2026.
[3] N. Thakkar et al. Injectable HIV-1 Capsid Inhibitor VH4011499 (VH-499) Formulation Supports Ultra-Long-Acting Dosing. Presented at the 33rd Conference on Retroviruses and Opportunistic Infections (CROI). February 2026.