Press release

For media and investors only

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ViiV Healthcare reports positive 12-month data showing investigational bNAb lotivibart (N6LS) maintains high levels of viral suppression in long-acting HIV treatment regimen

- 94% of adults on stable therapy maintained viral suppression with intravenous lotivibart dosed every four months in combination with long-acting cabotegravir
- These phase IIb results reinforce lotivibart's ultra long-acting potential, with the trial progressing to evaluate a twice-yearly intravenous dosing interval

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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 positive 12-month interim efficacy and tolerability data from the phase IIb EMBRACE study.[1] In adults living with HIV on stable therapy, a regimen of lotivibart (N6LS), a broadly neutralising antibody, administered every four months combined with monthly intramuscular (IM) long-acting cabotegravir (CAB LA), maintained viral suppression in 94% of participants receiving lotivibart intravenously (IV) and 82% subcutaneously (SC), compared with 88% in the standard of care group.

These favourable data reinforce lotivibart's ultra long-acting potential (dosing every four months or longer) and support the progression of the study, which will evaluate a twice-yearly IV dosing interval for lotivibart.

Results were presented today at the 33rd Conference on Retroviruses and Opportunistic Infections (CROI 2026) in Denver, Colorado.

Kimberly Smith, M.D., MPH, Head of Research & Development at ViiV Healthcare, said: "These positive 12-month data from EMBRACE strengthen the evidence that lotivibart has the potential to be a part of an ultra long-acting HIV treatment regimen and support our efforts to evaluate lotivibart in a twice-yearly dosing interval. These results build on our legacy of developing innovative long-acting options for HIV treatment that offer greater choice for people living with HIV."

At the 12-month interim analysis, lotivibart combined with CAB LA maintained viral suppression in a high proportion of adults living with HIV on stable therapy, with confirmed virologic failure observed in two participants (4%; n=2/50) from the IV group and three participants (6%; n=3/49) in the SC group, compared to one (4%; n=1/26) receiving a daily oral standard of care.

Lotivibart was generally well tolerated, with participants in both groups reporting high acceptability through month 12. Mean perception of injection (PIN) scores for "bother of ISRs," "physical impact," "sleep" and "acceptability" remained "very acceptable" to "totally acceptable" throughout the study in both groups. Adverse events related to lotivibart were less common in the IV group (24%; n=12/50) compared with the SC group (53%; n=26/49). Higher grade (grade 3-4) infusion-site reactions were reported in 16% (n=8/49) of participants in the SC group, while none were reported in the IV group.

These findings build on the six-month EMBRACE data presented at CROI 2025, which first showed that lotivibart, administered every four months in combination with monthly CAB LA, effectively maintained an undetectable viral load in adults living with HIV on stable therapy.

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] CP. Rolle et al. Maintenance of HIV Suppression at 12 Months With VH3810109 (N6LS) Q4M + CAB LA QM: The EMBRACE Study. Presented at the 33rd Conference on Retroviruses and Opportunistic Infections (CROI). February 2026.