Press release

For media and investors only

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ViiV Healthcare showcases leadership in long-acting injectables innovation at CROI 2025 with data on third-generation integrase inhibitor (INSTI) and highly potent capsid inhibitor against HIV-1

- Results illustrate ViiV Healthcare's pipeline is generating multiple options for the development of new ultra long-acting HIV regimens
- VH4524184 (VH184), a potent, investigational third-generation integrase inhibitor (INSTI), demonstrates strong antiviral activity and positive safety results across multiple dose levels in people with HIV-1, supporting further development as a long-acting injectable antiretroviral
- VH4011499 (VH499), a promising, highly potent investigational capsid inhibitor, shows positive antiviral activity and good safety findings for treatment of HIV-1, supporting further development as a long-acting antiretroviral

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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 findings from two phase IIa proof-of-concept studies of investigational antiretroviral therapies VH4524184 (VH184) and VH4011499 (VH499). These findings, presented at the Conference on Retroviruses and Opportunistic Infections (CROI 2025) in San Francisco, U.S., support the continued development of these two compounds as distinct options for a new generation of long-acting injectables for HIV, with the potential for extended dosing intervals.

Kimberly Smith, M.D., MPH, Head of Research & Development at ViiV Healthcare said: "It's clear long-acting injectable medicines deliver on unmet patient need and will play a critical role in achieving our ambition of ending HIV and AIDS. Our pipeline with INSTIs at the core showcases our continued leadership in long-acting injectable innovation. Data shows that the potency and tolerability of our third-generation INSTI and our capsid inhibitor will make them a major part in the development of our next generation of long-acting injectable therapies."

VH184 demonstrated high antiviral potency[1]

This study aimed to explore the antiviral activity and safety of three doses of VH184 (10mg, 50mg and 300mg taken once every three days) by assessing the maximum change in plasma HIV-1 RNA levels during a 10-day monotherapy period in 22 adults who had not previously received antiretroviral therapy. People who participated in the study had HIV-1 RNA levels of at least 3000 copies/mL.

VH184, a third-generation INSTI, demonstrated potency at all doses leading to a marked drop in the HIV-1 viral load. After 10 days of monotherapy, the average decreases were -1.17, -2.15, and -2.31 log10 copies/mL for the 10mg, 50mg, and 300mg doses, respectively. The maximum viral load decline (-2.69 log10) was observed in the 300mg dose. Additionally, no drug resistance mutations were observed at the end of the study. All side effects were mild to moderate, and no serious side effects or participant discontinuations occurred.

Long-acting formulations of VH184 in adults without HIV are being evaluated in an ongoing phase 1 study NCT06310551. The findings of this trial support further development of VH184 as a potential long-acting injectable antiretroviral.

Higher VH499 dose correlated with greater decline in viral load[2]
This study evaluated the compound's antiviral effect, safety, and tolerability by assessing the maximum change in plasma HIV-1 RNA levels from baseline through day 11 in 23 adults who had not previously received antiretroviral therapy. People who participated in the study also had HIV-1 RNA levels of at least 3000 copies/mL.

The trial of VH499, an investigational capsid inhibitor, showed that all oral doses (25mg, 100mg, and 250mg) led to a decrease in HIV-1 viral load ranging from -2.2 log 10 copies/mL in the 250mg arm, to -1.8 log10 copies/mL in the 25mg and 100mg arms. VH499 was well tolerated with all adverse events being mild to moderate in severity. There were no adverse events leading to withdrawal and no serious adverse events were reported. On day 11, one individual on the 25mg dose developed a single mutation associated with reduced susceptibility to capsid inhibitors.

In a previous phase I clinical trial of adults without HIV-1, VH499 was well- tolerated, and showed no induction or inhibition of CYP3A4.[3] Long-acting formulations of VH499 in adults without HIV are being evaluated in ongoing phase 1 studies NCT06012136; NCT06724640.

These findings, in combination with the potent antiviral activity in this phase IIa study, support further development of VH499 as a potential long-acting antiretroviral for HIV treatment.

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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[3] Thakkar *et al.* AIDS 2024; Munich, Germany. Poster WEPEB105.