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ViiV Healthcare premieres early data showing antiviral activity against integrase resistance from its investigational, third-generation integrase inhibitor

- Data, along with results from a phase I study, are the first public presentation of VH4524184, which is part of the company's long-term strategy to deliver ultra long-acting HIV medicines

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 shared positive in vitro findings showing that an investigational integrase strand transfer inhibitor (INSTI), VH4524184 (VH184), retained its antiviral activity and could be effective in countering second-generation INSTI resistance. Additional analysis presented of a phase I study showed pharmacokinetic (PK) and safety data supported further development of VH184.¹ The findings are being presented at the 25th International AIDS Conference (AIDS 2024) being held in Munich, Germany, from 22 – 26 July 2024.

Kimberly Smith, M.D., MPH, Head of Research & Development at ViiV Healthcare, said: "ViiV Healthcare's ambition is to end the HIV epidemic, in large part, by delivering a new generation of long-acting medicines for people seeking options to treat or prevent HIV. VH184, the first third-generation integrase inhibitor, with the potential for long-acting dosing and coverage of INSTI resistant viruses, builds upon our legacy of developing novel agents that address unmet needs."

The presentation at AIDS 2024 is a combination of two separate analyses. The first evaluated VH184, in vitro, against more than 20 clinically derived HIV-1 viruses with mutations known to be associated with resistance to INSTIs. These viruses were identified from two phase III clinical trials of second-generation integrase inhibitors in treatment-experienced people living with HIV. Results from this analysis suggest VH184 has a resistance profile distinct from prior generations of INSTIs, showing that it was able to retain antiviral activity against clinically relevant mutations.

The second analysis comes from a double-blind, randomised, placebo-controlled phase I study that evaluated the PK and safety of an oral version of VH184 in 84 participants without HIV. The study showed VH184 achieved drug levels in the blood that could potentially exhibit sufficient antiviral activity against the clinically derived INSTI mutations seen in vitro. Administration of VH184 was also well tolerated with no adverse events (AEs) leading to participant discontinuation. AEs were generally mild (n=44 in 29 participants), few were considered to be related to VH184 (n=6 in 5 participants, all of which were mild) and none were serious.

ViiV Healthcare is also conducting a phase I study evaluating long-acting injectable formulations of VH184 in participants without HIV. Additionally, a phase IIa proof-of-concept study is underway to define the efficacy, safety, and tolerability of VH184 in people living with HIV who are naïve to antiretroviral 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 are at risk of acquiring HIV. 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.

Press release

For media and investors only



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](https://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 under Item 3.D "Risk factors" in GSK's Annual Report on Form 20-F for 2023, and GSK's Q1 Results for 2024.

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References

¹ L. Rogg, et al. Phase 1 study of VH4524184 (VH-184), a new third-generation integrase strand transfer inhibitor (INSTI) with a unique resistance profile. Presented at the 25th International AIDS Conference. July 2024.