Press release

For media and investors only

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ViiV Healthcare's investigational broadly neutralising antibody - N6LS - successfully maintains viral suppression in long-acting treatment of HIV

- Results from the phase IIb study, EMBRACE, demonstrate that N6LS, a bNAb administered every four months, effectively maintained undetectable viral load when combined with long-acting cabotegravir
- Results add to the growing body of evidence that N6LS is a potent antiviral that can function as a component of a complete antiretroviral regimen
- EMBRACE study to continue investigating a combination of N6LS dosed at six months with cabotegravir long-acting (CAB-LA)

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 the company's EMBRACE phase IIb study. The study found that N6LS (VH3810109 or VH109), given every four months in combination with monthly cabotegravir long-acting (CAB LA), successfully kept viral levels suppressed in adults living with HIV who were already stable on treatment. It was also well tolerated by participants.

These results were presented today at the Conference on Retroviruses and Opportunistic Infections (CROI 2025) in San Francisco, U.S.

Kimberly Smith, M.D., MPH, Head of Research & Development at ViiV Healthcare, said: "As leaders in long-acting injectable innovation, we are building on the positive patient and physician experience we have with *Cabenuva* and pioneering the next generation of long-acting treatment options. The EMBRACE study demonstrated that VH109, a CD4-binding broadly neutralising antibody, administered every four months with cabotegravir, achieved high efficacy and was well tolerated through six months. We're looking forward to continuing the development of VH109 as a component of our future ultra long-acting regimens."

Results from the EMBRACE study[1] at the six-month primary endpoint showed that 96% of participants receiving VH109 60 mg/kg intravenously (IV) and 88% receiving VH109 3000 mg subcutaneously (SC) with rHuPH20 maintained HIV-1 RNA levels below 50 copies/mL, compared to 96% in the standard-of-care group. VH109 was administered in both arms every four months, combined with monthly CAB-LA. Confirmed virologic failure was observed in two participants from each VH109 group.

Overall, 4% of the IV group and 6% of the SC group had HIV-1 RNA levels of 50 copies/mL or higher, compared to none in the standard-of-care group when measured at month six.

VH109 was generally well tolerated, though infusion site reactions were more frequent with SC administration, occurring in 14% compared to none with IV administration. Adverse events specific to the use of study medication were reported in 64% of the IV group and 65% of the SC group, with 16% of participants in the SC group experiencing grade 3-4 adverse events (erythema). No participants in the IV group experienced a grade 3-4 adverse event.

Based on the favourable results seen in the trial, ViiV Healthcare will be progressing a six-month IV formulation of VH109 in combination with CAB-LA for further evaluation in an EMBRACE part two trial.

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 35kg 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 U.S. 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 35kg 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.

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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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 2024.

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References

[1]Taiwo, B *et al.* VH3810109 (N6LS) Efficacy and Safety in Adults Who Are Virologically Suppressed: The EMBRACE Study. Presented at the Conference on Retroviruses and Opportunistic Infections (CROI 2025), 9-12 March, San Francisco, CA