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.

CABENUVA (cabotegravir; rilpivirine) extended-release injectable suspensions
Professional Indication and Important Safety Information

INDICATION - *CABENUVA* is indicated as a complete regimen for the treatment of HIV-1 infection in adults and adolescents 12 years of age and older and weighing at least 35 kg to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine.

IMPORTANT SAFETY INFORMATION
CONTRAINDICATIONS

- Do not use *CABENUVA* in patients with previous hypersensitivity reaction to cabotegravir or rilpivirine
- Do not use *CABENUVA* in patients receiving carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifabutin, rifampin, rifapentine, systemic dexamethasone (>1 dose), and St John's wort

WARNINGS AND PRECAUTIONS
Hypersensitivity Reactions:

- Serious or severe hypersensitivity reactions have been reported in association with other integrase inhibitors and could occur with *CABENUVA*
- Hypersensitivity reactions, including cases of drug reaction with eosinophilia and systemic symptoms (DRESS), have been reported during postmarketing experience with rilpivirine-containing regimens. While some skin reactions were accompanied by constitutional symptoms such as fever, other skin reactions were associated with organ dysfunctions, including elevations in hepatic serum biochemistries
- Discontinue *CABENUVA* immediately if signs or symptoms of hypersensitivity reactions develop. Clinical status, including liver transaminases, should be monitored and appropriate therapy initiated. Cabotegravir and rilpivirine oral lead-in may be used to help identify patients who may be at risk of a hypersensitivity reaction

Post-Injection Reactions:

- Serious post-injection reactions (reported in less than 1% of subjects) were reported within minutes after the injection of rilpivirine, including dyspnea, bronchospasm, agitation, abdominal cramping, rash/urticaria, dizziness, flushing, sweating, oral numbness, changes in blood pressure, and pain (e.g., back and chest). These events may have been associated with accidental intravenous administration and began to resolve within a few minutes after the injection
- Carefully follow the Instructions for Use when preparing and administering *CABENUVA*. The suspensions should be injected slowly via intramuscular injection and avoid accidental intravenous administration. Observe patients briefly (approximately 10 minutes) after the injection. If a post-injection reaction occurs, monitor and treat as clinically indicated

Hepatotoxicity:

- Hepatotoxicity has been reported in patients receiving cabotegravir or rilpivirine with or without known pre-existing hepatic disease or identifiable risk factors
- Patients with underlying liver disease or marked elevations in transaminases prior to treatment may be at increased risk for worsening or development of transaminase elevations
- Monitoring of liver chemistries is recommended and treatment with *CABENUVA* should be discontinued if hepatotoxicity is suspected

Depressive Disorders:

- Depressive disorders (including depressed mood, depression, major depression, mood altered, mood swings, dysphoria, negative thoughts, suicidal ideation, suicide attempt) have been reported with *CABENUVA* or the individual products
- Promptly evaluate patients with depressive symptoms
- Risk of Adverse Reactions or Loss of Virologic Response Due to Drug Interactions:
    - The concomitant use of *CABENUVA* and other drugs may result in known or potentially significant drug interactions (see Contraindications and Drug Interactions)
    - Rilpivirine doses 3 and 12 times higher than the recommended oral dosage can prolong the QTc interval

- *CABENUVA* should be used with caution in combination with drugs with a known risk of Torsade de Pointes

Long-Acting Properties and Potential Associated Risks with *CABENUVA*:

- Residual concentrations of cabotegravir and rilpivirine may remain in the systemic circulation of patients for prolonged periods (up to 12 months or longer). Select appropriate patients who agree to the required monthly or every-2-month injection dosing schedule because non-adherence could lead to loss of virologic response and development of resistance
- To minimize the potential risk of developing viral resistance, it is essential to initiate an alternative, fully suppressive antiretroviral regimen no later than 1 month after the final injection doses of *CABENUVA* when dosed monthly and no later than 2 months after the final injections of *CABENUVA* when dosed every 2 months. If virologic failure is suspected, switch the patient to an alternative regimen as soon as possible

ADVERSE REACTIONS

- The most common adverse reactions in adults (incidence ≥2%, all grades) treated with *CABENUVA* were injection site reactions, pyrexia, fatigue, headache, musculoskeletal pain, nausea, sleep disorders, dizziness, and rash
- The safety of *CABENUVA* in adolescents is expected to be similar to adults

DRUG INTERACTIONS

- Refer to the applicable full Prescribing Information for important drug interactions with *CABENUVA*, *VOCABRIA* (cabotegravir), or *EDURANT* (rilpivirine)
- Because *CABENUVA* is a complete regimen, coadministration with other antiretroviral medications for the treatment of HIV-1 infection is not recommended
- Drugs that are strong inducers of UGT1A1 or UGT1A9 are expected to decrease the plasma concentrations of cabotegravir. Drugs that induce or inhibit CYP3A may affect the plasma concentrations of rilpivirine
- *CABENUVA* should be used with caution in combination with drugs with a known risk of Torsade de Pointes

USE IN SPECIFIC POPULATIONS

- **Pregnancy**: There are insufficient human data on the use of *CABENUVA* during pregnancy to adequately assess a drug-associated risk for birth defects and miscarriage. Discuss the benefit-risk of using *CABENUVA* during pregnancy and conception and consider that cabotegravir and rilpivirine are detected in systemic circulation for up to 12 months or longer after discontinuing injections of *CABENUVA*. An Antiretroviral Pregnancy Registry has been established
- **Lactation**: Potential risks of breastfeeding include HIV-1 transmission, developing viral resistance in HIV-positive infants, and adverse reactions in a breastfed infant

For more information, please see full US Prescribing Information for *CABENUVA*:
https://gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing_Information/Cabenuva/pdf/CABENUVA-PI-PIL-IFU2-IFU3.PDF

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