Press release

For media and investors only

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ViiV Healthcare's CLARITY study shows long-acting cabotegravir more acceptable than lenacapavir injections after a single dose, with 90% preferring cabotegravir

- Initial data from the CLARITY study are first to compare acceptability and tolerability of single-dose cabotegravir (CAB) and lenacapavir (LEN) long-acting injections, in 63 HIV-negative adults
- Sixty-nine percent of individuals found CAB injections to be 'totally or very acceptable' versus 48% for LEN injections, and 90% of participants and 86% of healthcare providers preferred CAB injections over LEN
- Findings could help inform expectations and decision-making when initiating long-acting HIV injectables

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GSK plc (LSE/NYSE: GSK) announced ViiV Healthcare, the global specialist HIV company majority owned by GSK, with Pfizer and Shionogi as shareholders, today announced data from the phase I CLARITY open-label, crossover study, showing clinically relevant differences in injection site reaction (ISR) acceptability and tolerability, with 69% of HIV-negative adults finding cabotegravir long-acting (CAB LA) injections to be "totally or very acceptable" vs 48% for lenacapavir (LEN) injections. Data presented at the 20th European AIDS Conference (EACS) in Paris, France, also showed 90% of HIV-negative adults and 86% of healthcare providers (HCPs) preferred CAB LA injections over LEN injections after a single dose, and ISR events were more frequent and visible with LEN than with CAB LA.[1]

Jean van Wyk, MBChB, MFPM, Chief Medical Officer at ViiV Healthcare, said: "We believe long-acting innovations will play a critical role in the global response to ending HIV and AIDS and understanding potential differences in acceptability and tolerability of options is an important consideration when choosing between long-acting injectables. The CLARITY study showed that after receiving a single dose of each, more individuals and healthcare professionals preferred cabotegravir over lenacapavir injections. These early findings provide valuable insights into long-acting injectable options to help empower individuals and their healthcare providers to make fully informed choices."

In the open-label crossover study, 63 HIV-negative participants were randomised to receive one medicine at Day 1, followed by the other at Day 15 - either CAB LA (a single intramuscular injection) or LEN (two subcutaneous injections). The primary endpoint was local reaction acceptability assessed seven days after each injection, and results showed clinically relevant differences in ISR acceptability. After a single dose of CAB LA and LEN, 69% (n=42/61) of individuals found CAB injections to be "totally or very acceptable" vs 48% (n=29/60) for LEN injections, which was statistically significant in a post hoc analysis (p=0.019).

Key preference data from the study:

- Ninety percent (n=54/60) of healthy HIV-negative adults and 86% (n=6/7) of HCPs preferred CAB LA and 10% (n=6/60) and 14% (n=1/7) preferred LEN, respectively.
- The four most common reasons cited by participants for why they preferred CAB LA (n=54) were less pain during injection administration (n=40/54), less pain or soreness after injection administration (n=33/54), how long the injection nodules or swelling last (n=31/54), and the size of the injection nodules or swelling (n=30/54).

- The four most common reasons cited by participants for why they preferred LEN (n=6) were less pain or soreness after injection administration (n=5/6), how long the injection nodules or swelling last (n=3/6), the size of the injection nodules or swelling (n=3/6), and fewer number of side effects (n=3/6).
- The three most common rationales for HCP preference for CAB LA (n=6) included fewer number of reported side effects (5/6), less severe side effects (4/6), and less pain during injection (4/6). One HCP preferred LEN (n=1) due to ease of injection preparation.

Key ISR data from the study:

- Single doses of CAB LA were administered as one injection and single doses of LEN as two injections per product labeling, therefore 63 participants were administered a total of 124 LEN injections and 61 CAB injections during the study. Three participants received only one of the doses, all due to non drug-related reasons.
- Following administration of both injectables, 4.4 times more ISR events were observed with LEN (n=538) than with CAB LA (n=123) and more participants experienced visible ISR events with LEN (n=221 LEN; n=36 CAB LA).
- Pain was the most commonly reported ISR for LEN in 82% (n=51/62) of participants vs 80% (n=49/61) of participants receiving CAB LA (Relative Risk [RR] 0.98 [0.82, 1.16]).
- There was a significantly higher risk of palpable and/or visible ISRs with LEN versus CAB:
    - Induration 87% (n=54) vs 18% (n=11) (RR 0.21 [0.12, 0.36])
    - Nodules 74% (n=46) vs 33% (n=20) (RR 0.44 [0.30, 0.65])
    - Erythema 57% (n=35) vs 12% (n=7) (RR 0.20 [0.10, 0.42])
    - Swelling 58% (n=35) vs 34% (n=21) (RR 0.59 [0.40, 0.89])
- No serious adverse events or discontinuations due to drug-related adverse events were reported.

These findings underscore the importance of individual choice and informed decision-making in choice of long-acting injectable HIV therapy or prevention options. Further results and additional analyses from the study will be presented at a future medical congress.

About *Apretude* (cabotegravir long-acting)
Apretude is a medicine used for preventing sexually transmitted HIV-1 infection (pre-exposure prophylaxis or PrEP) in adults and adolescents weighing at least 35 kg who are at high risk of being infected. Individuals must have a negative HIV-1 test prior to initiating *Apretude* (with or without an oral lead-in with oral cabotegravir) for HIV-1 PrEP. It should be used in combination with safer sex practices, such as using condoms. *Apretude* contains the active substance cabotegravir.

Please consult the full Summary of Product Characteristics for all the safety information: Apretude 600 mg prolonged-release suspension for injection

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 in the "Risk Factors" section in GSK's Annual Report on Form 20-F for 2024, and GSK's Q2 Results for 2025.

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References

[1] J. Boles, *et al*. Cabotegravir Injections Are More Acceptable Than Lenacapavir Injections Following a Single Dose: Results From CLARITY, a Randomized Crossover Study of Long-Acting Injectable Antiretrovirals. Presented at the European AIDS Conference (EACS 2025), 15-18 October, Paris, FR.