Press release

For media and investors only

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ViiV Healthcare announces positive new data for *Apretude* use during pregnancy at AIDS 2024

- Findings from the HPTN 084 open label extension show maternal and pregnancy outcomes with *Apretude* (cabotegravir long-acting for PrEP) exposure were comparable to those with no cabotegravir exposure
- Pharmacokinetic findings demonstrated that target concentrations of cabotegravir were maintained above those associated with protection against HIV acquisition throughout the overall pregnancy period

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 new maternal safety and pregnancy outcomes and pharmacokinetic (PK) findings from the HIV Prevention Trials Network (HPTN) 084 open label extension (OLE) evaluating cis-gender women in sub-Saharan Africa who became pregnant while using *Apretude* (cabotegravir LA for PrEP) for HIV pre-exposure prophylaxis (PrEP). The findings showed that cabotegravir LA for PrEP was generally well tolerated among pregnant women, and PK findings demonstrated that cabotegravir levels were maintained above those associated with HIV protection throughout the overall pregnancy period.[1,2] These data will be presented at the 25th International AIDS Conference being held in Munich, Germany (22 – 26 July).

Kimberly Smith, MD, MPH, Head of Research & Development at ViiV Healthcare, said: "Today's late-breaking pregnancy safety data from the HPTN 084 open label extension add to the body of evidence for *Apretude* as a prevention option for women, including those who conceive while on this long-acting regimen. Women continue to tell us they need more options for HIV prevention, which is why we have been focused on studying cabotegravir LA for PrEP in women from the very beginning. We will continue to prioritise their needs, and those of others disproportionately affected by HIV, as part of our ongoing commitment to ending the epidemic."

The original findings of HPTN 084 reported that cabotegravir LA for PrEP showed superior efficacy to daily oral emtricitabine/tenofovir disoproxil fumarate (FTC/TDF) tablets at reducing the risk of acquisition of HIV in women.[3] Participants who entered the HPTN 084 OLE (n=2472) were able to choose cabotegravir LA for PrEP or FTC/TDF tablets as PrEP, and contraceptive requirements were removed. Those with prior or current cabotegravir LA for PrEP exposure at the time of pregnancy could consent to continue injections throughout pregnancy. Maternal safety and pregnancy outcomes were assessed across the 367 confirmed pregnancies in 348 participants.

The HPTN 084 OLE findings showed that cabotegravir LA for PrEP maternal and pregnancy outcomes were consistent across cabotegravir LA for PrEP and FTC/TDF exposure groups and with the expected background rates. Pregnancy-related maternal adverse event incidence was 45.7 (95% CI 33.1-61.6), 47.1 (95% CI 20.3-92.7), and 37.5 (95% CI 13.8-81.6) per 100 person years among those using cabotegravir LA for PrEP during pregnancy, prior to pregnancy, or with no cabotegravir LA for PrEP exposure, respectively. Adverse pregnancy outcome rates were similar across groups, with 33% (70/212) using cabotegravir LA for PrEP during pregnancy, 38% (26/68) having prior cabotegravir LA for PrEP use, and 27% (12/45) never using cabotegravir LA for PrEP reporting a negative outcome. One major congenital anomaly was observed and no maternal deaths were recorded. None of the women who became pregnant acquired HIV during pregnancy.

Sinead Delany-Moretlwe, MBBCh, Ph.D., DTM&H, HPTN 084 Protocol Chair, and Research Director at Wits RHI, University of the Witwatersrand in Johannesburg, South Africa, said:
"Women of childbearing age in sub-Saharan Africa experience disproportionately higher rates of HIV incidence, making it essential that we study how HIV medicines impact their health and wellbeing during pregnancy. The findings of the HPTN 084 open label extension provide further evidence on the safety and tolerability of cabotegravir LA for PrEP in expectant mothers and their unborn infants while maintaining protective levels against HIV throughout pregnancy. These findings build upon the well-established efficacy of cabotegravir LA for PrEP and provide reassurance for its usage in this particularly vulnerable population."

The sub-study PK analysis of the HPTN 084 OLE included 50 participants who continued to receive cabotegravir LA for PrEP prior to and during pregnancy. The study found that concentrations of cabotegravir were comparable between the pre-pregnant, pregnant and post-partum periods (median C_{trough} concentrations were 2.1 µg/mL [IQR: 1.3, 2.7], 1.9 µg/mL [IQR: 1.5, 2.2], and 2.5 µg/mL [IQR: 2.0, 3.5], respectively). Although cabotegravir LA for PrEP concentrations declined from the first trimester through to the third trimester of pregnancy (median C_{trough} concentrations during the first, second and third trimesters were 2.5 µg/mL [IQR: 2.0, 3.2], 1.8 µg/mL [IQR: 1.5, 2.2], and 1.6 µg/mL [IQR: 1.3, 2.2], respectively), 100% of C_{trough} concentrations during the first and second trimesters, and 98% of C_{trough} concentrations during the third trimester, remained above target thresholds for the medicine. These data indicate dose modifications are unlikely to be required for women who become pregnant, although additional analyses are forthcoming to supplement these findings.

Apretude (cabotegravir LA for PrEP) is approved for use in multiple countries including the US, EU, UK, Canada, Australia and South Africa. Submission to other regulatory agencies is on-going.

About HPTN 084 (NCT03164564)[3,4]
The HPTN 084 trial is a phase III double blind superiority trial designed to evaluate the safety and efficacy of the long-acting injectable cabotegravir for HIV prevention administered every eight weeks compared to daily oral TDF/FTC tablets (200 mg/300 mg) in 3,224 cisgender women who are at increased risk of HIV acquisition. The trial design included an oral lead-in phase to assess tolerability to cabotegravir before administering the IM injection. HPTN 084 opened to enrolment in November 2017 and is being conducted at research centres in Botswana, Kenya, Malawi, South Africa, Eswatini, Uganda, and Zimbabwe.

Cabotegravir long-acting was found to be superior to daily oral FTC/TDF in preventing HIV acquisition in the trial population. The most common adverse reactions (all grades) observed in at least 1% of participants receiving cabotegravir long-acting were injection site reactions, diarrhoea, headache, fatigue, sleep disorders, nausea, dizziness, abdominal pain, vomiting, myalgia, and rash.

HPTN 084 was jointly funded by the U.S. National Institutes of Health's National Institute of Allergy and Infectious Diseases (NIAID), and the National Institute of Mental Health (NIMH), the Bill & Melinda Gates Foundation and ViiV Healthcare and was conducted by the NIH-funded HPTN. Study product was provided by ViiV Healthcare and Gilead Sciences.

For further information please see https://clinicaltrials.gov/ct2/show/NCT03164564.

About *Apretude*
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. 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 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.

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 2023, and GSK's Q1 Results for 2024.

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[1] Delany-Moretlwe S, Voldal E, Saidi F, *et al.* Initial evaluation of CAB-LA Safety during pregnancy in the HPTN 084 open-label extension. Presented at the 25th International AIDS Conference. July 2024.
[2] Marzinke M, Voldal E, Hansom B, *et al.* Evaluation of Long-Acting Cabotegravir (CAB-LA) Pharmacokinetics During Pregnancy: A Sub-Study Analysis of the HPTN 084 Open Label Extension. Presented at the 25th International AIDS Conference. July 2024.
[3] Delaney-Moretlwe S, Hughes J, Bock P, *et al.* Cabotegravir for the prevention of HIV-1 in women: results from HPTN 084, a phase 3, randomised clinical trial. *The Lancet* 2022;399(10337):1779-1789. DOI: 10.1016/S0140-6736(22)00538-4.
[4] Clinical Trials.gov - Evaluating the Safety and Efficacy of Long-Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre-Exposure Prophylaxis in HIV-Uninfected Women. Available at https://clinicaltrials.gov/ct2/show/ NCT03164564. Last accessed July 2024.