Press release

For media and investors only

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ViiV Healthcare to present data for its next generation of ultra long-acting treatments for HIV

- Other key data to be presented from ViiV Healthcare's innovative pipeline and portfolio include the exploration of different mechanisms of action through broadly neutralising antibodies as well as real-world insights from established long-acting and 2-drug regimens

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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 the presentation of 64 abstracts that includes highlights of the company's next-generation pipeline advancements, alongside data from its diverse portfolio of marketed HIV treatment and prevention options at the Conference on Retroviruses and Opportunistic Infections (CROI 2024) being held in Denver, Colorado, from 3 – 6 March 2024.

Kimberly Smith, M.D., MPH, Head of Research & Development at ViiV Healthcare, said: "As leaders in developing long acting injectables for the treatment of HIV, we're excited to present new data setting the stage for ViiV's next generation of medicines and demonstrating how key pipeline assets will target HIV in different ways. These findings, as well as the breadth of data we'll present on our marketed products, including new interim results from the LATITUDE study, reflect a portfolio and future-looking pipeline focused on ending the HIV epidemic. We look forward to sharing them with the scientific and HIV communities at CROI 2024."

Key abstracts to be presented at CROI 2024 by ViiV Healthcare and its study partners will include:

Data introducing our next generation of potential ultra long-acting medicines for HIV: ViiV Healthcare will share findings from a phase I study evaluating different formulations of cabotegravir and their potential for dosing every four months. The ongoing, open-label, single-dose, dose-escalation phase I study in 70 healthy adults assessed both the 200 mg/mL formulation of cabotegravir in combination with recombinant human hyaluronidase PH20 (rHuPH20), as well as a new formulation of cabotegravir (CAB-ULA) administered by itself.[1] Researchers will share safety and pharmacokinetic findings from both ultra long-acting approaches and their potential for future clinical development.

Findings advancing different mechanisms of action in HIV research: New phase IIa findings from the BANNER study of VH3810109 (N6LS), an investigational, broadly neutralising antibody (bNAb), will be presented. Researchers will share findings of the bNAb administered intravenously and the first efficacy findings of its subcutaneous administration.[2] Findings from the SPAN study of N6LS, examining the safety and tolerability of the highest subcutaneous and intravenous N6LS doses administered to date, with and without PH20, will also be presented.[3] Additionally, efficacy and safety data from a non-ViiV owned bNAb asset, VRC07-523LS, in a phase II, open-label clinical trial used in combination with long-acting CAB for maintenance antiretroviral therapy (ART) will be presented.[4]

New data of long-acting therapy vs daily oral standard of care, in traditionally non-adherent populations: Interim analysis of the LATITUDE phase III trial will be presented showing that, the injectable antiretroviral treatment for HIV, *Cabenuva* (cabotegravir and rilpivirine [CAB+RPV LA]), demonstrates superior efficacy compared to daily oral standard of care (SOC) in individuals with a history of antiretroviral adherence challenges. The NIAID/ACTG also announced a modification to the study, where further randomisation has been stopped and participants in the SOC arm are being given the option to switch to the long-acting therapy arm.[5]

Real-world evidence from across our treatment and prevention portfolios: New findings from SEARCH, a randomised study evaluating the real-world impact of the inclusion of long-acting cabotegravir for PrEP in an HIV prevention coverage package compared to the standard-of-care of oral PrEP and PEP alone in rural Uganda and Kenya, will also be presented.[6] Real-world evidence findings for the complete long-acting HIV treatment regimen *Cabenuva* will be presented from the OPERA cohort examining ART-experienced, virally suppressed adults living with HIV who switched to CAB+RPV LA or to an oral regimen.[7]

Findings for the 2-drug regimen, *Dovato* (dolutegravir, lamivudine [DTG/3TC]), will include the InfCare HIV study, which presents three-year switch data, from 3-drug regimen to *Dovato*, in a long-term real-world Swedish cohort.[8] This study adds to the body of real-world evidence to date that includes more than 40,000 people living with HIV.[9]

Here is a list of ViiV Healthcare-sponsored or supported studies to be presented at CROI 2024:

Title	First Author	Presentation Number	Presentation
Dolutegravir			
A single once-daily ABC/DTG/3TC tablet predicts safe and effective exposures in children 3 to <6kg	H. Chandasana	02770	Poster Tuesday, March 5 2:30-4:00pm MST
Population pharmacokinetics of ABC/DTG/3TC FDC to support dosing in peds with HIV-1 (IMPAACT 2019)	H. Chandasana	03110	Poster Tuesday, March 5 2:30-4:00pm MST
Dolutegravir and growth in pediatric populations with HIV-1: IMPAACT P1093 and IMPAACT 2019	M. McKenna	01783	Poster Tuesday, March 5 2:30-4:00pm MST
Switching to DTG+3TC vs 3-drug regimens in routine clinical care: long-term Swedish data	E. Sörstedt	01838	Poster Tuesday, March 5 2:30-4:00pm MST
Temporal trends of cardiovascular disease incidence in people with HIV from 2001-2021	N. Jaschinski	02263	Poster Tuesday, March 5 2:30-4:00pm MST
Increased cancer risk with low CD4 counts persists despite over 2 years of virological suppression	J. Hoy	01462	Poster Wednesday, March 6 2:30-4:00pm MST
Cabotegravir for Treatment			

Long-acting Injectable CAB/RPV is Superior to Oral ART in PWH with adherence challenges: ACTG A5359	A. Rana	03579	Oral Wednesday, March 6 12:51-1:00pm MST
Real-world utilization of cabotegravir + rilpivirine in the US: data from Trio Health cohort	J. J. Eron	01374	Poster Monday, March 4 2:30-4:00pm MST
Real-world effectiveness of cabotegravir + rilpivirine vs. standard of care oral regimens in the US	R. K. Hsu	01952	Poster Monday, March 4 2:30-4:00pm MST
HIV-1 RNA blips and low-level viral replication: SOLAR (CAB+RPV LA vs. BIC/FTC/TAF)	C. Latham	00138	Poster Monday, March 4 2:30-4:00pm MST
Model based comparison of cabotegravir pharmacokinetics following thigh and gluteal injections	K. Han	03157	Poster Wednesday, March 6 2:30-4:00pm MST
Cabotegravir for PrEP			
SEARCH Randomized trial of Dynamic Choice HIV Prevention including injectable cabotegravir (CAB-LA)	J. Kabami	03405	Late-Breaker Oral Tuesday, March 5 10:00-12:00pm MST
Pre-exposure prophylaxis with cabotegravir long-acting injectable in the OPERA cohort	A. Mills	01400	Poster Monday, March 4 2:30-4:00pm MST
Real-world use of cabotegravir long acting for pre-exposure prophylaxis: TRIO cohort	K. Mayer	01907	Poster Monday, March 4 2:30-4:00pm MST
Cabotegravir PopPK analysis of adults and adolescents living with HIV or at risk for HIV receiving PrEP	Y. Lin	03038	Poster Tuesday, March 5 2:30-4:00pm MST
Interest in long-acting injectable PrEP among transgender women in the United States	E. E. Cooney	00621	Poster Wednesday, March 6 2:30-4:00pm MST

Healthcare staff acceptability and feasibility of telehealth delivery of cabotegravir for PrEP	A. Liu	03080	Poster Wednesday, March 6 2:30-4:00pm MST
Fostemsavir			
Temsavir treatment enhances bNAb recognition and subsequent clearance of HIV-1 infected cells	R. Ferris	02971	Poster Monday, March 4 2:30-4:00pm MST
Pipeline: Ultra Long-Acting Cabotegravir			
Phase I study of cabotegravir long-acting injectable formulations supports ≥4-monthly dose interval	K. Han	00251	Oral Monday, March 4 10:00-12:00pm MST
Pipeline: Broadly Neutralising Antibodies			
VH3810109 (N6LS) in antiretroviral therapy–naive adults with HIV-1: phase IIa BANNER efficacy data	P. Leone	01911	Oral Monday, March 4 10:00-12:00pm MST
Safety and efficacy of VRC07-523LS plus long-acting cabotegravir in the phase 2 ACTG A5357 Trial.	B. Taiwo	02254	Oral Monday, March 4 10:00-12:00pm MST
High-dose VH3810109 (N6LS) ± recombinant human hyaluronidase PH20: phase I SPAN study safety results	B. Win	01988	Poster Wednesday, March 6 2:30-4:00pm MST
Pipeline: Maturation Inhibitors			
Next-generation maturation inhibitor GSK3640254 showed broad spectrum potency without MI resistance	B. McAuliffe	03095	Poster Wednesday, March 6 2:30-4:00pm MST
The preclinical profile of maturation inhibitor VH3739937	J. Jeffrey	02819	Poster Wednesday, March 6 2:30-4:00pm MST
General HIV			
Resistance in young children newly diagnosed with HIV in Western Cape, South Africa	K. Anderson	01012	Poster Tuesday, March 5 2:30-4:00pm MST

About *Dovato*
Dovato is indicated as a complete regimen to treat HIV-1 infection in adults with no antiretroviral (ARV) treatment history or to replace the current ARV regimen in those who are virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable ARV regimen with no history of treatment failure and no known resistance to any component of *Dovato*.

Please consult the full Prescribing Information:
https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Dovato/pdf/DOVATO-PI-PIL.PDF

About *Cabenuva* (cabotegravir + rilpivirine)
Cabenuva is indicated as a complete regimen for the treatment of HIV-1 infection in adults 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 US as a 25mg tablet taken once a day to treat HIV-1 in combination with other antiretroviral agents in antiretroviral treatment-naïve patients 12 years of age and older and weighing at least 35kg with a viral load ≤100,000 HIV RNA c/ml.

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:
https://gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing_Information/Cabenuva/pdf/CABENUVA-PI-PIL-IFU2-IFU3.PDF

About *Rukobia*
Rukobia, in combination with other antiretrovirals, is indicated for the treatment of adults with multidrug resistant HIV-1 infection for whom it is otherwise not possible to construct a suppressive anti-viral regimen. Recommended dose is 600mg fostemsavir twice daily.

Please consult the full Prescribing Information:
https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Rukobia/pdf/RUKOBIA-PI-PIL.PDF

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 Prescribing Information:
https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Apretude/pdf/APRETUDE-PI-PIL-IFU.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 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 the company's Annual Report on Form 20-F for 2022, and Q4 Results for 2023.

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References

[1] Han, et al. Phase I Study of Cabotegravir Long-Acting Injectable Formulations Supports ≥4-Monthly Dose Interval. Presented at 31st Conference on Retroviruses and Opportunistic Infections (CROI). March 2024.
[2] Leone, et al. VH3810109 (N6LS) in Antiretroviral Therapy–Naive Adults With HIV-1: Phase IIa BANNER Efficacy Data. Presented at 31st Conference on Retroviruses and Opportunistic Infections (CROI). March 2024.
[3] Win, et al. High-Dose VH3810109 (N6LS) ± Recombinant Human Hyaluronidase PH20: Phase I SPAN Study Safety Results. Presented at 31st Conference on Retroviruses and Opportunistic Infections (CROI). March 2024.
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[5] Rana, et al. Long-acting Injectable CAB/RPV is Superior to Oral ART in PWH with adherence challenges: ACTG A5359. Presented at 31st Conference on Retroviruses and Opportunistic Infections (CROI). March 2024.
[6] Kamya, et al. SEARCH Randomized trial of Dynamic Choice HIV Prevention including injectable cabotegravir (CAB-LA). Presented at 31st Conference on Retroviruses and Opportunistic Infections (CROI). March 2024.
[7] Hsu, et al. Real-World Effectiveness of Cabotegravir + Rilpivirine vs. Standard of Care Oral Regimens in the US. Presented at 31st Conference on Retroviruses and Opportunistic Infections (CROI). March 2024.
[8] Sörstedt, et al. Switching to DTG+3TC vs 3-drug regimens in routine clinical care: long-term Swedish data. Presented at 31st Conference on Retroviruses and Opportunistic Infections (CROI). March 2024.
[9] Data on File