



Issued: 7 October 2024, London UK

ViiV Healthcare to triple annual supply of long-acting HIV PrEP for low- and middle-income countries

- At least two million doses of long-acting cabotegravir for PrEP to be made available in 2025-2026 to meet growing demand where HIV burden and unmet need are greatest
- Strong progress made with generic manufacturers through Medicines Patent Pool (MPP) voluntary licensing agreement
- Despite availability of PrEP, an estimated 1.3 million people acquired HIV in 2023, highlighting urgent need to scale up access to innovative new options¹

London, [7 OCTOBER 2024] – GSK plc (LSE/NYSE: GSK) announced that ViiV Healthcare, the global specialist HIV company majority owned by GSK, with Pfizer and Shionogi as shareholders, has today shared the company's commitment to make at least two million doses of long-acting cabotegravir for HIV pre-exposure prophylaxis (CAB LA for PrEP) available for procurement for low- and middle-income countries (L&MICs) during 2025-2026. The new commitment will triple the company's available supply versus 2024, to accelerate access and meet growing demand where the HIV burden and unmet need are greatest. The announcement was made at the [HIV R4P 2024 conference](#), being held in Lima, Peru from 6-10 October.

Deborah Waterhouse, Chief Executive Officer at ViiV Healthcare and President, Global Health at GSK, said: "Today's announcement marks another important milestone in our efforts to accelerate access to the only long-acting PrEP available now -- CAB LA -- where it's needed most. We know long-acting PrEP provides a crucial option to suit the needs and circumstances of populations disproportionately affected by HIV, including young women and girls in Sub-Saharan Africa. We are committed to working at pace with our partners and the community -- globally, regionally, and locally -- to continue enabling sustainable access to CAB LA for PrEP as a key part of our mission to help end the HIV epidemic."

ViiV's strategy for CAB LA for PrEP in L&MICs is to maximise rapid access and uptake for populations with highest unmet needs, in a sustainable way, centred on partnership and integration into existing healthcare services and HIV prevention programmes.

The roll-out of CAB LA for PrEP -- the first long-acting injectable PrEP option -- is progressing at record pace in Sub-Saharan Africa (SSA) and lower income countries. Following the first approval of CAB LA for PrEP by the U.S. FDA in December 2021, under the brand name *Apretude*, regulatory submissions have been prioritised in countries where the HIV burden is greatest; half of the approvals to date are in SSA and 79% are in L&MICs.

ViiV-manufactured CAB LA for PrEP is available at a not-for-profit price for roll-out in low-income and SSA countries via partners including the United States President's Emergency Plan For AIDS Relief (PEPFAR) and The Global Fund. The first of these rollouts was in Zambia in February 2024, just two years after the U.S.; since then, initiations have started in Malawi, Zimbabwe, Eswatini and Ukraine. By the end of 2024, ViiV will have supplied CAB LA for PrEP to key partners for roll-out to a total of 14 countries (13 countries in Sub-Saharan Africa and Ukraine).

Expanding capacity and improving affordability in resource-limited settings is critical to ensuring sustainable access to innovative medicines. In addition to providing CAB LA for PrEP at a non-profit price, ViiV announced the signing of a licensing agreement with the Medicines Patent Pool in July 2022, to enable the development of generic formulations. ViiV is actively engaged with the generic manufacturers, providing technology transfer and expertise, to expedite this process and the availability of generic CAB LA for PrEP.

Apretude (cabotegravir LA for PrEP) has received marketing authorisation from 24 regulatory agencies, covering 53 countries. For more information on approvals and submissions around the world, click [here](#).

Press release

For media and investors only



About *Apretude* (cabotegravir LA for PrEP)

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](#). Trademarks are owned by or licensed to the ViiV Healthcare group of companies.

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.

GSK enquiries:

Media:	Tim Foley	+44 (0) 20 8047 5502	(London)
	Sarah Clements	+44 (0) 20 8047 5502	(London)
	Kathleen Quinn	+1 202 603 5003	(Washington DC)
	Lyndsay Meyer	+1 202 302 4595	(Washington DC)
	Alison Hunt	+1 540 742 3391	(Washington DC)
Investor Relations:	James Dodwell	+44 (0) 20 8047 2406	(London)
	Mick Readey	+44 (0) 7990 339653	(London)
	Camilla Campbell	+44 (0) 7803 050238	(London)
	Steph Mountifield	+44 (0) 7796 707505	(London)
	Jeff McLaughlin	+1 215 751 7002	(Philadelphia)
	Frannie DeFranco	+1 215 751 4855	(Philadelphia)

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 Q2 Results for 2024.

Registered in England & Wales:

GSK plc
No. 3888792

ViiV Healthcare Limited
No. 06876960

Registered Office:

79 New Oxford Street
London
WC1A 1DG

ViiV Healthcare Limited
GSK Medicines Research Centre
Gunnels Wood Road, Stevenage
United Kingdom
SG1 2NY

¹ UNAIDS 2024 Global AIDS Update: The Urgency of Now. Available at https://www.unaids.org/sites/default/files/media_asset/2024-unaids-global-aids-update_en.pdf. Last accessed October 2024.