



Issued: 6 March 2024, London UK

## **ViiV Healthcare announces interim data at CROI indicating superior efficacy of long-acting injectable HIV treatment *Cabenuva* (cabotegravir + rilpivirine) compared to daily oral therapy in individuals living with HIV who have adherence challenges**

---

London, 06 March 2024 – ViiV Healthcare, the global specialist HIV company majority owned by GSK, with Pfizer Inc. and Shionogi Limited as shareholders, today announced data from a planned interim analysis of the LATITUDE phase III trial, indicating that their long-acting injectable antiretroviral treatment (ART) for HIV, *Cabenuva* (cabotegravir + rilpivirine), demonstrated superior efficacy in maintaining viral load suppression compared to daily oral therapy in individuals with a history of ART adherence challenges.

The data were presented by the Advancing Clinical Therapeutics Globally for HIV/AIDS and Other Infections (ACTG) network at the Conference on Retroviruses and Opportunistic Infections (CROI), in Denver, Colorado.

**Kimberly Smith, MD, MPH, Head of Research & Development at ViiV Healthcare said,** “It’s estimated that one-third of people living with HIV in the United States struggle with maintaining viral suppression. The findings of the LATITUDE study show that long-acting injectable cabotegravir + rilpivirine could be important for some people in this group, giving them another option to help keep their virus under control and improve their health. Further, since we know that individuals whose virus is undetectable don’t transmit to sexual partners, this could be an important contribution to ending the HIV epidemic.”

LATITUDE is a phase III, randomised, open-label study. Participants received comprehensive and incentivised adherence support while taking guideline-recommended, three-drug regimen oral ART, including dolutegravir and bicitegravir-based regimens, to achieve viral suppression. Those who achieved viral suppression were eligible to randomise to staying on oral standard of care (SOC) regimens or switch to long-acting injectable cabotegravir + rilpivirine (LA-ART) dosed monthly.

During the randomised phase of the study, 146 participants received monthly LA-ART and 148 continued on SOC. The primary endpoint was a comparison of regimen failure, defined as a combination of virologic failures (VF) and regimen discontinuations, between arms. 24.1% of participants on LA-ART experienced regimen failure compared to 38.5% on SOC {difference -14.4 (98.75% CI -29.8%, 0.8%)}

Although the primary endpoint did not meet the strict predefined stopping criterion for the interim analysis, key secondary endpoints of virologic failure (7.2% LA-ART vs. 25.4% SOC {difference -18.2% (98.75% CI -31.1%, -5.4%)}) and treatment-related failure (9.6% LA-ART vs 26.2% SOC {difference -16.6% (98.75% CI -29.9%, -3.3%)}) favoured the LA-ART regimen. The study’s Data Safety Monitoring Board (DSMB) considered the totality of all the study endpoints together and concluded that the evidence indicated superior efficacy of long-acting ART over daily oral standard of care. The DSMB recommended that all eligible participants should be offered long-acting injectable cabotegravir + rilpivirine.

The rate of adverse events (AEs) was similar in both arms. Three participants in the LA-ART arm had serious injection site reactions (ISR) and one participant discontinued due to an ISR. Two confirmed virologic failures in each

# Stock Exchange Announcement

## For media and investors only



arm had new resistance associated mutations (RAMS), including at least two new integrase inhibitor RAMs in both LA-ART participants.

The LATITUDE (Long-Acting Therapy to Improve Treatment Success in Daily Life) study is ongoing across 31 sites in the U.S. including Puerto Rico, implemented through ACTG. The median age of study participants was 40 years old; 40 percent of participants were male, 64 percent were Black/African American, 17 percent were Hispanic, 5 percent were transgender, and 14 percent currently or previously used injection drugs. The study is sponsored and funded by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, and is being conducted by ACTG, with additional support from the National Institute of Mental Health, the National Institute on Drug Abuse, ViiV Healthcare and the Janssen Pharmaceutical Companies of Johnson & Johnson.

### **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  $\leq 100,000$  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.

Trademarks are owned by or licensed to the ViiV Healthcare group of companies.

Please consult the full Prescribing Information:

[https://gskpro.com/content/dam/global/hcpportal/en\\_US/Prescribing\\_Information/Cabenuva/pdf/CABENUVA-PI-PIL-IFU2-IFU3.PDF](https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Cabenuva/pdf/CABENUVA-PI-PIL-IFU2-IFU3.PDF)

### **About ACTG**

ACTG is the world's largest and longest running clinical trials network focused on HIV and other infectious diseases and the people living with them. It is funded by NIAID and collaborating NIH Institutes. Founded in 1987, ACTG conducts research to improve the management of HIV and its comorbidities; develop a cure for HIV; and innovate treatments for tuberculosis, hepatitis B, and emerging infectious diseases. It comprises thousands of dedicated researchers, staff, and community members who are pursuing research into novel treatments and cures for infectious diseases at hundreds of locations across four continents, with the ultimate goal of advancing science that meaningfully impacts the lives of the people we serve.

### **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.

# Stock Exchange Announcement

## For media and investors only



For more information on the company, its management, portfolio, pipeline, and commitment, please visit [viivhealthcare.com](http://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](http://gsk.com).

<b>Media enquiries:</b>	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)
<b>Investor Relations:</b>	Nick Stone	+44 (0) 7717 618834	(London)
	James Dodwell	+44 (0) 20 8047 2406	(London)
	Mick Readey	+44 (0) 7990 339653	(London)
	Josh Williams	+44 (0) 7385 415719	(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 the company's Annual Report on Form 20-F for 2023.

### Registered in England & Wales:

GSK plc	ViiV Healthcare Limited
No. 3888792	No. 06876960

### Registered Office:

GSK plc	ViiV Healthcare Limited
980 Great West Road	GSK Medicines Research Centre
Brentford, Middlesex	Gunnels Wood Road, Stevenage
United Kingdom	United Kingdom
TW8 9GS	SG1 2NY