Press Release

For media and investors only

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LATITUDE phase III interim trial data indicates ViiV Healthcare's long-acting injectable HIV treatment Cabenuva (cabotegravir + rilpivirine) has superior efficacy compared to daily therapy in individuals living with HIV who have adherence challenges

- *Data Safety Monitoring Board (DSMB) for ACTG study recommends study be modified to stop randomisation and to give participants receiving daily oral therapy the option to transition to long-acting injectable therapy*
- *Full data set to be presented at an upcoming scientific conference*

London, 21 February 2024 – ViiV Healthcare, the global specialist HIV company majority owned by GSK, with Pfizer Inc. and Shionogi Limited as shareholders, today announced results from an interim analysis of the LATITUDE phase III trial, indicating 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 interim data indicating the superiority of long-acting therapy compared to daily oral therapy in individuals who have difficulty taking pills for HIV every day is a remarkable outcome," **said Kimberly Smith, MD, MPH, Head of R&D at ViiV Healthcare**. "There are many reasons why people may find it challenging to stay on daily oral treatment and the LATITUDE study shows cabotegravir and rilpivirine injectable treatment can help them keep their virus suppressed, which benefits their overall health. Optimising therapy for all people living with HIV, including those with adherence challenges, is critical to the effort to end the HIV epidemic."

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 Advancing Clinical Therapeutics Globally for HIV/AIDS and Other Infections (ACTG), a global NIH-funded clinical trials network focused on HIV and other infectious diseases. Participants with challenges taking daily oral ART as prescribed and evidence of viremia were screened to ensure the HIV in their blood was not resistant to the study drugs and that they met other health and safety criteria. Once enrolled, they received comprehensive and incentivised adherence support while taking guideline-recommended, three-drug regimen oral ART, including dolutegravir and bictegravir-based regimens, to achieve viral suppression. They were then randomised either to receive long-acting injectable ART (cabotegravir + rilpivirine) every four weeks or to continue taking daily oral ART.

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Last week, the DSMB held a planned interim review. They 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.

There are many factors that can influence a person's ability to take medicine every day, including access to health care or health insurance, affordability, unstable housing, stigma and fear of having their HIV status disclosed. Lack of consistent adherence is a common reason why some people living with HIV have difficulty maintaining undetectable viral loads.

LATITUDE 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 ≤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://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.

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.

Registered in England & Wales:

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