For media and investors only

Issued: 24 July 2023, London UK

ViiV Healthcare's cabotegravir for HIV prevention receives positive CHMP opinion from European Medicines Agency

- ***Cabotegravir is the first and only long-acting injectable option for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1***
- ***Positive opinion is based on results from the HPTN 083 and 084 phase IIb/III studies in which the medicine, given as few as six times per year, demonstrated superior efficacy to a daily oral PrEP option (FTC/TDF tablets) in reducing the risk of HIV acquisition[1,2,3,4]***
- ***With approximately 100,000 people in Europe newly diagnosed with HIV each year,[5] this is an important step towards expanding HIV prevention options in the region***

London, 24 July 2023 – ViiV Healthcare, the global specialist HIV company majority owned by GSK, with Pfizer and Shionogi as shareholders, welcomed a positive opinion by the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) recommending marketing authorisation for cabotegravir long-acting (LA) injectable and tablets for HIV prevention. Cabotegravir is recommended in combination with safer sex practices for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection in high-risk adults and adolescents weighing at least 35 kg.

In Europe, strong progress has been made in the delivery of HIV treatment and prevention services, seeing a continuous decline in the incidence of new HIV cases. However, with approximately 100,000 new diagnoses each year, if approved, cabotegravir LA will be the only prevention option for people at risk of HIV acquisition that is administered as few as six times per year.[5]

Kimberly Smith, M.D., MPH, Head of Research & Development at ViiV Healthcare, said: "The expansion of prevention options is critical if we are to end the HIV epidemic. Long-acting options have the potential to play an important role in reducing challenges such as inconsistent adherence to taking daily pills, and stigma associated with oral PrEP use that can be faced by people who could benefit from PrEP. At ViiV Healthcare we are at the forefront of cutting-edge science, developing innovative solutions to address the biggest unmet needs in HIV prevention. With the CHMP positive opinion, we are hopeful that people in Europe will soon be able to benefit from greater choice".

The positive opinion is supported by data from two international phase IIb/III multicentre, randomised, double-blind, active controlled studies, HPTN 083 and HPTN 084, which evaluated the safety and efficacy of cabotegravir LA for PrEP in HIV-negative men who have sex with men,

transgender women, and cisgender women who were at increased risk of acquiring HIV. The studies demonstrated that cabotegravir LA for PrEP was superior to daily oral emtricitabine/tenofovir disoproxil fumarate (FTC/TDF), with clinical trial participants given cabotegravir LA experiencing a 69% lower rate of HIV acquisition compared to FTC/TDF tablets in HPTN 083 (12 vs 39; annual incidence: 0.37% vs 1.22%; HR 0.31 [CI: 0.16, 0.58]) , and a 90% lower rate of HIV acquisition compared to FTC/TDF tablets in HPTN 084 (3 vs 36; annual incidence: 0.15% vs 1.85%; HR 0.10 [CI: 0.04, 0.27]).[1,2,3,4]

Cabotegravir LA for PrEP is currently approved for use in the US, Australia, Zimbabwe, South Africa, Malawi, Botswana, and Brazil as *Apretude*. Submission to other regulatory agencies is on-going.

About cabotegravir extended-release injectable suspension

Cabotegravir long-acting for HIV prevention is the first and only long-acting injectable PrEP option proven superior to daily oral FTC/TDF in reducing HIV acquisition.

Cabotegravir long-acting for PrEP is an integrase strand transfer inhibitor (INSTI). INSTIs, like cabotegravir extended-release injectable suspension, 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.

Cabotegravir long-acting for PrEP is provided as an injection administered six times per year by a healthcare professional and is initiated with a single 600 mg (3-ml) injection given one month apart for two consecutive months. After the second initiation injection, the recommended continuation injection dose is a single 600 mg (3-ml) injection given every two months. Cabotegravir oral tablets may be administered for approximately one month before initiating the first injection to assess the tolerability of the medicine.

About HPTN 083 (NCT02720094)[1,3]

The HPTN 083 trial is a phase IIb/III double blind non-inferiority trial designed to evaluate the safety and efficacy of long-acting injectable cabotegravir for HIV prevention administered every eight weeks compared to daily oral FTC/TDF tablets (200 mg/300 mg). The trial included the prespecified ability to test for superiority of long-acting cabotegravir over FTC/TDF.

The trial design included an oral lead-in phase to assess tolerability to cabotegravir before administering the intramuscular (IM) injection. Each participant was to receive a maximum of three years of blinded trial medication. The trial opened to enrolment in November 2016. HPTN 083 was conducted in 4,566 HIV-negative men who have sex with men and transgender women who have sex with men, who are at increased risk of HIV acquisition. The trial is being conducted at research centres in Argentina, Brazil, Peru, the United States, South Africa, Thailand, and Vietnam.

Long-acting cabotegravir 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 subjects receiving long-acting cabotegravir were injection site reactions, diarrhoea, headache, pyrexia, fatigue, sleep disorders, nausea, dizziness, flatulence, and abdominal pain.

For further information on HPTN 083 please see https://clinicaltrials.gov/ct2/show/NCT02720094.

About HPTN 084 (NCT03164564)[2,4]

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 FTC/TDF 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.

Long-acting cabotegravir 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 subjects receiving long-acting cabotegravir were injection site reactions, diarrhoea, headache, fatigue, sleep disorders, nausea, dizziness, abdominal pain, vomiting, myalgia, and rash.

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

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 https://www.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.

For media and investors only

ViiV Healthcare enquiries:

Media enquiries:	Rachel Jaikaran	+44 (0) 78 2352 3755	(London)
	Rodrigo DaCunha Acuna	+44 (0) 77 7069 3596	(London)
	Melinda Stubbee	+1 919 491 0831	(North Carolina)
Media enquiries:	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:	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 2022, GSK's Q1 Results for 2023 and any impacts of the COVID-19 pandemic.

Registered in England & Wales:

GSK plc
No. 3888792

ViiV Healthcare Limited
No. 06876960

Registered Office:

980 Great West Road
Brentford, Middlesex
TW8 9GS

References

[1] Landovitz RJ, Donnell D, Clement ME, et al. Cabotegravir for HIV Prevention in Cisgender Men and Transgender Women. *The New England Journal of Medicine* 2021;385:595-608. DOI: 10.1056/NEJMoa2101016

[2] 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;399:1779–89.

[3] Clinical Trials.gov - Safety and Efficacy Study of Injectable Cabotegravir Compared to Daily Oral Tenofovir Disoproxil Fumarate/Emtricitabine (TDF/FTC), For Pre-Exposure Prophylaxis in HIV-Uninfected Cisgender Men and Transgender Women Who Have Sex With Men. Available at https://clinicaltrials.gov/ct2/show/NCT02720094. Last accessed July 2023.

[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 2023.

[5] ECDC/World Health Organisation (2021) HIV/AIDS surveillance in Europe. Available at https://www.ecdc.europa.eu/sites/default/files/documents/2021-Annual_HIV_Report_0.pdf. Last accessed March 2023. Last accessed July 2023.