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Global HIV prevention study to stop early after ViiV Healthcare's long-acting injectable formulation of cabotegravir dosed every two months shows higher efficacy than daily oral PrEP

- ***Interim analysis from HPTN 083 study shows investigational, long-acting injectable cabotegravir (CAB LA) administered every two months is 69% more effective than daily pills in preventing HIV acquisition***
- ***Participants who were in the daily oral emtricitabine/tenofovir disoproxil fumarate 200 mg and 300 mg (FTC/TDF) tablet arm of the study will be offered CAB LA***

London, 18 May 2020 – ViiV Healthcare, the global specialist HIV company majority owned by GSK, with Pfizer Inc. and Shionogi Limited as shareholders, today announced the interim analysis of the HIV Prevention Trials Network (HPTN) 083 study evaluating the safety and efficacy of investigational, long-acting, injectable cabotegravir for HIV prevention. In the study cabotegravir was found to be 69% more effective (95% CI 41%-84%) in preventing HIV acquisition in men who have sex with men (MSM) and transgender women who have sex with men when compared to the current standard of care, daily oral emtricitabine/tenofovir disoproxil fumarate 200 mg and 300 mg (FTC/TDF) tablets. The study achieved its primary objective of non-inferiority with the difference approaching superiority in favour of cabotegravir, pending final analysis.

The HPTN 083 study, with approximately 4,600 participants across more than 40 sites in North and South America, Asia, and Africa, is one of the first-ever clinical trials to directly compare two active prevention agents. In a planned interim review, the independent Data and Safety Monitoring Board (DSMB) found the study data clearly indicated that long-acting injectable cabotegravir was highly effective at preventing HIV in the study population. Among the 50 people in the trial who acquired HIV, 12 were randomised to the long-acting cabotegravir arm and 38 were randomised to the daily, oral

FTC/TDF arm. This translated to an HIV incidence rate of 0.38% (95% confidence interval [CI] 0.20%-0.66%) in the cabotegravir group and 1.21% (95% CI 0.86%-1.66%) in the FTC/TDF group. Adherence to oral FTC/TDF was high, based on a random subset sampling that detected tenofovir ($\geq$ 0.31 ng/ml) in 87% of all samples tested. Despite this high level of adherence to oral therapy, long-acting cabotegravir was 69% (95% CI 41%-84%) more effective than FTC/TDF in preventing HIV acquisition in the study population.

Myron S. Cohen, M.D., Co-Principal Investigator of the HPTN and the Yeargan-Bate Distinguished Professor of Medicine, Microbiology and Immunology and Epidemiology at the University of North Carolina (UNC) at Chapel Hill, said: "Each year, an estimated 1.7 million people are newly diagnosed with HIV. To lower that number, we believe more prevention options are needed in addition to currently available oral tablets for daily use. If approved, a new injectable agent, such as long-acting cabotegravir administered every two months, could play an important role in reducing HIV transmission and helping to end the HIV epidemic."

Safety was similar in the two groups. Most participants in the cabotegravir group (80%) reported pain or tenderness at the injection site, compared to only 31% of those in the FTC/TDF arm, who received placebo injections. Discontinuation due to injection site reactions or injection intolerance in the cabotegravir arm of the study was 2% and there were no discontinuations due to ISRs in the FTC/TDF arm.

Following review of these findings, the DSMB recommended the blinded, randomised portion of the study be stopped early and results released. Participants who were in the FTC/TDF arm will be offered CAB LA and participants in the CAB LA arm will continue to receive it. Participants who do not want to receive CAB LA will be offered FTC/TDF until the end of the originally planned blinded component of the study. The DSMB decision was approved by the U.S. National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), the study sponsor.

The HPTN 083 study enrolled HIV-negative men who have sex with men and transgender women who have sex with men, participants considered at risk for HIV acquisition. Two-thirds of study participants were under 30 years of age, and 12% were transgender women. Half of the participants in the United States identified as black or African American.

"These study results demonstrate that long-acting injectable cabotegravir dosed every two months can successfully reduce HIV acquisition in at-risk MSM and transgender women," said **Kimberly Smith, M.D., Head of Research & Development at ViiV Healthcare.** "We are thrilled with the results not only because of the high efficacy of cabotegravir but also because we have demonstrated high efficacy in a study that adequately represents some of the populations most disproportionately impacted by HIV -- black MSM in the US, young MSM globally and transgender women," she said.

"We continue to be focused on the completion of the companion HPTN 084 study, which will give us important information about the effectiveness of cabotegravir in women. New options are needed for HIV prevention that offer an effective alternative to daily oral PrEP. If approved, this long-acting injectable has the potential to be a game-changer for HIV prevention by reducing the frequency of dosing from 365 days to six times per year."

HTPN 083 was jointly funded by the U.S. NIAID, part of the NIH, and ViiV Healthcare, and was conducted by the HPTN. Study product was provided by ViiV Healthcare and Gilead Sciences.

The DSMB also reviewed data from HPTN 084, which began a year later than HPTN 083, and recommended that it continue as planned. To date, more than 3,000 sexually active women in seven African countries have enrolled in HPTN 084, which is co-funded by NIAID, ViiV Healthcare and the Bill & Melinda Gates Foundation.

Detailed results from HPTN 083 will be presented at an upcoming scientific meeting. ViiV Healthcare plans to use the data from HPTN 083 for future regulatory submissions. Cabotegravir has not yet been approved for the treatment or prevention of HIV as a single agent by regulatory authorities anywhere in the world.

About HPTN 083 (NCT02720094)

The HPTN 083 study is a phase IIb/III double blind study 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). Each participant was to receive a maximum of three years

of blinded study medication. The study opened to enrolment in November 2016. HPTN 083 was conducted in approximately 4,600 men who have sex with men and transgender women who have sex with men at research centres in Argentina, Brazil, Peru, United States, South Africa, Thailand and Vietnam.

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

About HPTN 084 (NCT03164564)

The HPTN 084 study is a phase III double blind safety and efficacy study 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 3,200 women who are at increased risk of HIV acquisition. 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.

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

About HIV Prevention Trials Network (HPTN)

The HIV Prevention Trials Network (HPTN) is a worldwide collaborative clinical trials network that brings together investigators, ethicists, community members and other partners to develop and test the safety and efficacy of interventions designed to prevent the acquisition and transmission of HIV. The National Institutes of Health (NIH), the National Institute of Mental Health (NIMH) and the National Institute on Drug Abuse (NIDA) co-fund the HPTN. The HPTN has collaborated with more than 85 clinical research sites in 19 countries to evaluate new HIV prevention interventions and strategies in populations that bear a disproportionate burden of infection. The HPTN research agenda – more than 50 trials ongoing or completed with over 161,000 participants enrolled and evaluated – is focused primarily on the use of antiretroviral drugs (antiretroviral therapy and pre-exposure prophylaxis); and integrated strategies including interventions for substance abuse, particularly injection drug use; behavioural risk reduction interventions and structural interventions. For more information, visit hptn.org.

About ViiV Healthcare

ViiV Healthcare is a global specialist HIV company established in November 2009 by GlaxoSmithKline (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 becoming infected with HIV. Shionogi joined in October 2012. The company's aim is to take a deeper and broader interest in HIV/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 www.viivhealthcare.com.

About GSK

GSK is a science-led global healthcare company with a special purpose: to help people do more, feel better, live longer. For further information please visit www.gsk.com.

Inside information

The information contained in this announcement is inside information. If you have any queries on this, then please contact Victoria Whyte GSK Company Secretary (responsible for arranging the release of this announcement) at GSK House Brentford, Middlesex, TW8 9GS on +44 208 047 5000.

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 2019 and any impacts of the COVID-19 pandemic.

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