FDA grants Priority Review to ViiV Healthcare's New Drug Application for cabotegravir long-acting for prevention of HIV

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For media and investors only

Final FDA decision anticipated by 23 January 2022; if approved, cabotegravir would be the first long-acting therapy for HIV PrEP

London, 28 September 2021 – ViiV Healthcare, the global specialist HIV company majority owned by GlaxoSmithKline plc (GSK), with Pfizer Inc. and Shionogi as shareholders, today announced that the U.S. Food and Drug Administration (FDA) has accepted and granted Priority Review for a New Drug Application (NDA) for investigational, injectable cabotegravir long-acting for pre-exposure prophylaxis, or PrEP. The Priority Review designation of cabotegravir long-acting for PrEP builds upon its prior identification as a Breakthrough Therapy by the FDA.

If approved, cabotegravir would be the first, long-acting therapy for the prevention of HIV for individuals at risk of sexually acquired HIV-1 infection, who have a negative HIV-1 test prior to initiation. The FDA has set a target approval date of 24 January 2022.

The NDA was based on the results from two phase IIb/III studies, HPTN 083 and HPTN 084, which evaluated the safety and efficacy of cabotegravir long-acting for PrEP in men who have sex with men, transgender women, and cisgender women. The blinded, randomised portions of both studies were stopped early by independent Data Safety Monitoring Boards after cabotegravir was shown to be superior to daily oral emtricitabine/tenofovir disoproxil fumarate (FTC/TDF) tablets in preventing the acquisition of HIV.

Kimberly Smith, M.D., MPH, Head of Research & Development at ViiV Healthcare, said:

> The FDA's Priority Review designation of cabotegravir long-acting for PrEP underscores the importance of this medicine, supported by the results of the HPTN studies, which demonstrated cabotegravir's superior efficacy over daily oral FTC/TDF tablets. In the United States, fewer than 25% of those who could benefit from PrEP are currently taking it, which points to the need for additional HIV prevention options. We believe new options like investigational cabotegravir long-acting for PrEP will help play a significant role in our collective efforts to end the HIV epidemic.

ViiV Healthcare will initiate submissions of cabotegravir long-acting for PrEP to other regulatory authorities by the end of 2021. Cabotegravir long-acting for PrEP has not been approved or licensed anywhere in the world for use in HIV prevention.

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). The trial design included an oral lead-in phase to assess tolerability to cabotegravir before administering the intramuscular injection. HPTN 083 was conducted in 4,566 men who have sex with men and transgender women who have sex with men. The study opened to enrolment in November 2016 at research centres in Argentina, Brazil, Peru, 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 study population. The most common adverse reactions (all grades) observed in at least 1% of subjects receiving long-acting cabotegravir were injection site reactions, diarrhea, 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)

The HPTN 084 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) in 3,223 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 intramuscular 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 study population. The most common adverse reactions (all grades) observed in at least 1% of subjects receiving long-acting cabotegravir were injection site reactions, diarrhea, headache, fatigue, sleep disorders, nausea, dizziness, abdominal pain, vomiting, myalgia, and rash. For further information please see https://clinicaltrials.gov/ct2/show/NCT03164564.

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 as a shareholder in October 2012. The company's aims are 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.

GSK is a science-led global healthcare company. For further information please visit www.gsk.com/about-us.

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 in the Company's Annual Report on Form 20-F for 2020, GSK's Q1 Results and any impacts of the COVID-19 pandemic.

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Centers for Disease Control and Prevention. Prevent new HIV transmissions by using proven interventions, including pre-exposure prophylaxis (PrEP) and syringe services programs (SSPs). Accessed September 7, 2021. https://www.cdc.gov/endhiv/prevent.html

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