European Commission authorises ViiV Healthcare's Apretude (cabotegravir long-acting and tablets) for HIV prevention

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For media and investors only

- Given as few as six times per year, cabotegravir has demonstrated superior efficacy to a daily oral PrEP option (FTC/TDF tablets) in reducing the risk of HIV acquisition in clinical trials.1,2,3,4

- With approximately 100,000 people newly diagnosed with HIV each year in Europe,5 expanding HIV prevention options is crucial in reducing HIV transmission.

GSK plc (LSE/NYSE: GSK) announced that ViiV Healthcare, the global specialist HIV company majority owned by GSK, with Pfizer and Shionogi as shareholders, today announced that the European Commission has authorised Apretude (cabotegravir long-acting (LA) injectable and tablets) for HIV prevention. Cabotegravir is indicated 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 (at least 12 years of age), weighing at least 35 kg.

Cabotegravir LA injectable and tablets for PrEP is the first and only HIV prevention option approved in the European Union (EU) that reduces the number of doses needed for effective HIV prevention from 365 daily pills to as few as six injections per year. Cabotegravir LA injectable and tablets for PrEP has demonstrated superior efficacy to daily oral emtricitabine/tenofovir disoproxil fumarate (FTC/TDF) in reducing the risk of HIV acquisition in clinical trials, giving people in the EU more options for PrEP.1,2,3,4

Deborah Waterhouse, CEO at ViiV Healthcare, said:

> This authorisation marks a pivotal milestone for people across the EU who could benefit from an innovative, long-acting HIV prevention option that may better suit their personal preferences. Long-acting PrEP, alongside other HIV prevention strategies, plays an important role in helping to address some of the challenges that people may have with oral PrEP options

This approval 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 (MSM), transgender women and cisgender women who were at increased risk of sexually acquired HIV. The studies demonstrated that cabotegravir LA for PrEP was superior to daily oral FTC/TDF tablets, with clinical trial participants given cabotegravir LA for PrEP 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 approved for use in the US, Australia, South Africa, as well as a number of other countries, 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 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.

The Apretude EMA Reference Information, including a full list of adverse events and the complete important safety information in the EU, will shortly be available on the European Medicines Agency website.

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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 could benefit from HIV prevention options. 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.

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.

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 Q2 Results for 2023 and any impacts of the COVID-19 pandemic.

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