European Medicines Agency validates ViiV Healthcare's marketing authorisation application for cabotegravir long-acting injectable for HIV Prevention

PUBLISHED OCT 28, 2022
BY GSK

For media and investors only

- The marketing application is based on results from the HPTN 083 and 084 phase IIb/III studies in which the injectable 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

ViiV Healthcare, the global specialist HIV company majority owned by GSK, with Pfizer and Shionogi as shareholders, today announced that the European Medicines Agency (EMA) has validated the company's marketing authorisation application (MAA) seeking approval of cabotegravir long-acting injectable for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1. Cabotegravir long-acting for HIV prevention is administered six times per year, after initiation. 5

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

> With approximately 100,000 people in Europe newly diagnosed with HIV each year, this submission is an important step forward in offering expanded options for HIV prevention. 6 Long-acting prevention options, if used appropriately and at scale, could have the potential to transform the shape of the HIV epidemic and we look forward to continuing to work with

community groups, governments and regulatory authorities to make this option available for those who need it.

Submission to the EMA was 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 long-acting for PrEP in HIV-negative men who have sex with men, transgender women, and cisgender women who were at increased risk of HIV. The studies demonstrated that cabotegravir long-acting for PrEP was superior to daily oral emtricitabine/tenofovir disoproxil fumarate (FTC/TDF), with clinical trial participants experiencing a 69% lower rate of HIV acquisition compared to FTC/TDF tablets in HPTN 083, and a 90% lower rate of HIV acquisition compared to FTC/TDF tablets in HPTN 084. 1, 2, 3, 4

Cabotegravir long-acting for PrEP is currently approved in the US, Australia and Zimbabwe as Apretude.

About cabotegravir extended-release injectable suspension 5

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. Vocabria (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 had evidence of behaviour that would put them at high-risk for sexually acquiring HIV-1. 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 please see https://clinicaltrials.gov/ct2/show/NCT03164564.

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.

Please see full U.S. Prescribing Information for Apretude.

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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 are at risk of becoming infected with 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 www.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/company

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 2021, GSK's Q2 Results for 2022 and any impacts of the COVID-19 pandemic.

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

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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 October 2022.

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Press release distributed by Wire Association on behalf of GSK, on Oct 28, 2022. For more information subscribe and follow us.

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