Press Release

For media and investors only

Issued: 16 October 2024, London UK

ViiV Healthcare shows more than 99% effectiveness in real-world studies for *Apretude* (cabotegravir long-acting), the only approved long-acting HIV PrEP, in data presented at IDWeek 2024

- ***Studies from OPERA and Trio cohorts provide further real-world evidence supporting CAB LA for PrEP's high effectiveness and adherence in preventing HIV acquisition***
- ***Patient-reported results for CAB LA for PrEP in the PILLAR implementation study showed a reduction in stigma and anxiety – common challenges associated with daily oral PrEP***

London, [16 OCTOBER 2024] – ViiV Healthcare, the global specialist HIV company majority owned by GSK, with Pfizer and Shionogi as shareholders, today announced the presentation of new real-world evidence and implementation data showing the effectiveness, adherence, and quality-of-life improvement of *Apretude* (cabotegravir long-acting (CAB LA)) for HIV pre-exposure prophylaxis (PrEP). The data will be presented at IDWeek 2024, being held in Los Angeles, California from 16 – 19 October.

Findings from two real-world evidence studies (from OPERA and Trio Health cohorts) showed more than 99% effectiveness of CAB LA for PrEP in nearly 1,300 individuals. In the PILLAR implementation study, reductions were shown in stigma and anxiety among the 200 individuals using the long-acting injectable PrEP option.

Harmony P. Garges, M.D., MPH, Chief Medical Officer at ViiV Healthcare, said: "The findings presented at IDWeek 2024 continue to support the strong and sustained effectiveness of *Apretude* for people in real life, outside the controlled environment of a clinical trial. The results of the studies from OPERA and Trio cohorts add to the growing body of evidence generated over the last three years, showing CAB LA for PrEP is a highly effective option for HIV prevention. We believe long-acting options have the potential to be transformative in increasing uptake among a broad range of people that could benefit from PrEP and are critical to ending the HIV epidemic."

Trio Health cohort shows CAB LA for PrEP's effectiveness in the real world with zero cases of HIV acquisition during follow-up[1]

New data from the Trio Health cohort shows the real-world use of CAB LA for PrEP in preventing HIV acquisition and adherence, among 474 individuals in the U.S.. The analysis identified a diverse population of cis- and transgender male and female individuals initiating CAB LA for PrEP from electronic health records between December 2021 through January 2024.

Findings from the cohort showed that there were zero HIV diagnoses identified during follow-up among participants taking CAB LA for PrEP. Eighty-three percent persisted on CAB LA for PrEP injections at the time of analysis, and injections were also administered on time for most of the initiators. Of the 396 participants with continuation injections, 33% experienced delays with a median of one delayed injection and median delay of 12 days [IQR: 3-29]. Adherence to CAB LA for PrEP was high, with only 3% of participants experiencing a missed injection.

OPERA study highlights high adherence and effectiveness of CAB LA for PrEP[2]

Real-world findings from the OPERA study provide insights into injection timing, adherence, and effectiveness among individuals using CAB LA for PrEP in the U.S.. The OPERA study reported findings from a large, diverse U.S. cohort, which included 764 individuals using CAB LA for PrEP, 29% of whom are Black and 29% Hispanic.

CAB LA for PrEP was effective in 99.7% of individuals (762 of 764 were not diagnosed with HIV during the follow-up period). There were two cases of HIV (0.3%) observed among the CAB LA for PrEP initiators. These cases could not be directly linked to the regimen due to its discontinuation in one case and inconsistent testing in the other case.

Eighty-five percent of individuals taking CAB LA for PrEP had complete initiation of the regimen (i.e. completed their first two initiation injections 60 or less days apart from each other). Sixty-nine percent of these complete initiators received all of their continuation injections on time. While some injection delays were observed among those with complete initiation, most were short, with a median delay of three days from the target date.

PILLAR implementation study shows CAB LA for PrEP may help address key PrEP challenges of stigma and anxiety[3]

New findings from the PILLAR trial explore the experiences of more than 200 men who have sex with men (MSM) and transgender men (TGM) who initiated CAB LA for PrEP after previous experience with daily oral PrEP. PILLAR is a phase 4 implementation trial assessing the integration of CAB LA for PrEP across 17 U.S. clinics among a diverse population of MSM and TGM, 23% of whom are Black and 39% Hispanic/Latino.

The six-month findings from the PILLAR trial showed that individuals taking CAB LA for PrEP reported lower rates of PrEP stigma and anxiety compared to their prior oral PrEP experience, and that the long-acting injectable was feasible, acceptable, and convenient for their life. When recounting their oral PrEP experience at the initiation of the trial, 15% of participants had worried about privacy while taking oral PrEP, 24% felt they had to hide their oral PrEP from others, and 29% expressed worry about stigma from taking oral PrEP. After initiating CAB LA for PrEP and completing surveys at month six of the trial, <1% of participants reported concerns about privacy and only 1% expressed worry about stigma while taking CAB LA for PrEP. Participants who completed interviews noted CAB

LA for PrEP reduced the stress and fear of missing a PrEP dose, while offering confidence of protection from HIV.

While 45% of participants reported injection site reactions (ISRs), 86% of participants returned to daily activities the same day and few reported being bothered by injection pain (8%). These individuals who had been initially bothered by injection pain reported that pain decreased over subsequent injections.

CAB LA for PrEP demonstrated high levels of acceptability among users, with mean acceptability scores increasing from 4.4 at baseline (SD: 0.69) to 4.6 at six months (SD: 0.61), with interviewees noting that CAB LA for PrEP was convenient for their life. This positive experience was supported by flexible clinic scheduling, transportation assistance, and the use of virtual appointments, all of which were identified as valuable facilitators of adherence.

These studies demonstrate ViiV Healthcare's commitment to generating robust real-world evidence for CAB LA for PrEP, furthering the study of its implementation, and advancing the understanding of its impact on diverse communities who can benefit from HIV prevention. Further research will continue to explore the long-term benefits of CAB LA for PrEP and optimise its use.

APRETUDE (cabotegravir) extended-release injectable suspension
Professional Indication and Important Safety Information

INDICATION
APRETUDE is indicated for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection in adults and adolescents weighing at least 35 kg who are at risk for HIV-1 acquisition. Individuals must have a negative HIV-1 test prior to initiating APRETUDE (with or without an oral lead-in with oral cabotegravir) for HIV-1 PrEP.

IMPORTANT SAFETY INFORMATION
BOXED WARNING: RISK OF DRUG RESISTANCE WITH USE OF APRETUDE FOR HIV-1 PRE-EXPOSURE PROPHYLAXIS (PrEP) IN UNDIAGNOSED HIV-1 INFECTION

Individuals must be tested for HIV-1 infection prior to initiating APRETUDE or oral cabotegravir, and with each subsequent injection of APRETUDE, using a test approved or cleared by the FDA for the diagnosis of acute or primary HIV-1 infection. Drug-resistant HIV-1 variants have been identified with use of APRETUDE by individuals with undiagnosed HIV-1 infection. Do not initiate APRETUDE for HIV-1 PrEP unless negative infection status is confirmed. Individuals who acquire HIV-1 while receiving APRETUDE for PrEP must transition to a complete HIV-1 treatment regimen.

CONTRAINDICATIONS
- Do not use APRETUDE in individuals:
  - with unknown or positive HIV-1 status
  - with previous hypersensitivity reaction to cabotegravir

- receiving carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifampin, and rifapentine

WARNINGS AND PRECAUTIONS
Comprehensive Management to Reduce the Risk of HIV-1 Infection:

- Use APRETUDE as part of a comprehensive prevention strategy, including adherence to the administration schedule and safer sex practices, including condoms, to reduce the risk of sexually transmitted infections (STIs). APRETUDE is not always effective in preventing HIV-1 acquisition. Risk for HIV-1 acquisition includes, but is not limited to, condomless sex, past or current STIs, self-identified HIV risk, having sexual partners of unknown HIV-1 viremic status, or sexual activity in a high prevalence area or network. Inform, counsel, and support individuals on the use of other prevention measures (e.g., consistent and correct condom use; knowledge of partner[s] HIV-1 status, including viral suppression status; regular testing for STIs)
- Use APRETUDE only in individuals confirmed to be HIV-1 negative. HIV-1 resistance substitutions may emerge in individuals with undiagnosed HIV-1 infection who are taking only APRETUDE, because APRETUDE alone does not constitute a complete regimen for HIV-1 treatment. Prior to initiating APRETUDE, ask seronegative individuals about recent (in past month) potential exposure events and evaluate for current or recent signs or symptoms consistent with acute HIV-1 infection (e.g., fever, fatigue, myalgia, skin rash). If recent (<1 month) exposures to HIV-1 are suspected or clinical symptoms consistent with acute HIV-1 infection are present, use a test approved or cleared by the FDA as an aid in the diagnosis of acute HIV-1 infection
- When using APRETUDE, HIV-1 testing should be repeated prior to each injection and upon diagnosis of any other STIs
- Additional HIV testing to determine HIV status is needed if an HIV-1 test indicates possible HIV-1 infection or if symptoms consistent with acute HIV-1 infection develop following an exposure event. If HIV-1 infection is confirmed, then transition the individual to a complete HIV-1 treatment
- Counsel individuals without HIV-1 to strictly adhere to the recommended dosing and testing schedule for APRETUDE

Potential Risk of Resistance with APRETUDE:

- There is a potential risk of developing resistance to APRETUDE if an individual acquires HIV-1 either before, while taking, or following discontinuation of APRETUDE. To minimize this risk, it is essential to clinically reassess individuals for risk of HIV-1 acquisition and to test before each injection to confirm HIV-1–negative status. Individuals who are confirmed to have HIV-1 infection must transition to a complete HIV-1 treatment. If individuals at continuing risk of HIV-1 acquisition discontinue APRETUDE, alternative forms of PrEP should be considered and initiated within 2 months of the final injection of APRETUDE

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Long-Acting Properties and Potential Associated Risks with APRETUDE:

- Residual concentrations of cabotegravir may remain in the systemic circulation of individuals for prolonged periods (up to 12 months or longer). Take the prolonged-release characteristics of cabotegravir into consideration and carefully select individuals who agree to the required every-2-month injection dosing schedule because non-adherence or missed doses could lead to HIV-1 acquisition and development of resistance

Hypersensitivity Reactions:

- Serious or severe hypersensitivity reactions have been reported in association with other integrase inhibitors and could occur with APRETUDE
- Discontinue APRETUDE immediately if signs or symptoms of hypersensitivity reactions develop. Clinical status, including liver transaminases, should be monitored and appropriate therapy initiated

Hepatotoxicity:

- Hepatotoxicity has been reported in a limited number of individuals receiving cabotegravir with or without known pre-existing hepatic disease or identifiable risk factors
- Clinical and laboratory monitoring should be considered and APRETUDE should be discontinued if hepatotoxicity is suspected and individuals managed as clinically indicated

Depressive Disorders:

- Depressive disorders (including depression, depressed mood, major depression, persistent depressive disorder, suicidal ideation or attempt) have been reported with APRETUDE
- Promptly evaluate patients with depressive symptoms

Risk of Reduced Drug Concentration of APRETUDE Due to Drug Interactions:

- The concomitant use of APRETUDE and other drugs may result in reduced drug concentration of APRETUDE
- Refer to the full Prescribing Information for steps to prevent or manage these possible and known significant drug interactions, including dosing recommendations. Consider the potential for drug interactions prior to and during use of, and after discontinuation of APRETUDE; review concomitant medications during use of APRETUDE

ADVERSE REACTIONS

The most common adverse reactions (incidence ≥1%, all grades) with APRETUDE were injection site reactions, diarrhea, headache, pyrexia, fatigue, sleep disorders, nausea, dizziness, flatulence, abdominal pain, vomiting, myalgia, rash, decreased appetite, somnolence, back pain, and upper respiratory tract infection.

DRUG INTERACTIONS

- Refer to the full Prescribing Information for important drug interactions with APRETUDE
- Drugs that induce UGT1A1 may significantly decrease the plasma concentrations of cabotegravir

USE IN SPECIFIC POPULATIONS

- **Lactation:** Assess the benefit-risk of using APRETUDE to the infant while breastfeeding due to the potential for adverse reactions and residual concentrations in the systemic circulation for up to 12 months or longer after discontinuation
- **Pediatrics:** Not recommended in individuals weighing less than 35 kg

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 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.

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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 GSK’s Annual Report on Form 20-F for 2023, and GSK’s Q2 Results for 2024.

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References

1. M Ramgopal, *et al.* Real-world use of cabotegravir long-acting for pre-exposure prophylaxis: Data from Trio Health cohort. Presented at the Infectious Disease society of America (IDSA) IDWeek™ 2024, 16-19 October, Los Angeles, CA.
2. R Hsu, *et al.* Cabotegravir Long-Acting for Pre-Exposure Prophylaxis (PrEP): Real World Data on On-Time Dosing, HIV Testing and HIV Acquisition from the OPERA Cohort. Presented at the Infectious Disease society of America (IDSA) IDWeek™ 2024. October 2024.
3. H. Holder, *et al.* Patient Experiences at Month 6 after Initiation of Cabotegravir Long-Acting (CAB LA) for PrEP in the First Male Gender Concordant Implementation Science Trial (PILLAR) in the US. Presented at the Infectious Disease society of America (IDSA) IDWeek™ 2024. October 2024.

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