ViiV Healthcare to present first head-to-head data for long-acting HIV treatment Cabenuva against daily oral Biktarvy at CROI 2023

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For media and investors only

Other key data to be presented from ViiV Healthcare's innovative pipeline and portfolio include new HIV prevention findings for long-acting cabotegravir and predictors of response to broadly neutralising antibody N6LS

ViiV Healthcare, the global specialist HIV company majority owned by GSK, with Pfizer and Shionogi as shareholders, today announced the presentation of key abstracts from the company's diverse portfolio of industry-leading innovative HIV treatment and prevention options alongside next-generation pipeline advancements at the Conference on Retroviruses and Opportunistic Infections (CROI 2023) being held in Seattle, Washington from 19 – 22 February 2023.

Key data to be presented includes the first head-to-head study for the complete long-acting HIV treatment regimen, Cabenuva (cabotegravir, rilpivirine [CAB+RPV LA]) compared against complete daily oral Biktarvy (bictegravir/emtricitabine/tenofovir alafenamide [BIC/FTC/TAF]). Additionally, there will be new findings from the HIV Prevention Trials Network (HPTN) 083 and 084 trials of cabotegravir for PrEP.

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

> The exciting findings in HIV treatment and prevention to be presented at CROI 2023 underscore ViiV Healthcare's position as the industry leaders in 2-drug and long-acting regimens. We believe long-acting is both the present and future of HIV, and providing an option beyond daily pills is why we chose to do a

head-to-head study with a commonly prescribed, daily, oral medicine. The treatment satisfaction and preference findings for the individuals who were part of this trial demonstrate an important unmet need to address the burden of daily pills for a significant proportion of people living with HIV. We will also be presenting data showing HIV incidence and prevention efficacy of cabotegravir long-acting for PrEP among Black men having sex with men and transgender women in the US, communities not typically represented in clinical trials. ViiV Healthcare will continue to bring forward ground-breaking advances in HIV treatment and prevention and looks forward to sharing these data with the scientific and HIV communities.

Key abstracts to be presented at CROI 2023 by ViiV Healthcare and its study partners will include:

Advancing innovative long-acting HIV treatment: At CROI 2023, ViiV Healthcare will share findings from the SOLAR study, the first, head-to-head, phase IIIb study of the complete long-acting injectable regimen Cabenuva compared against complete daily oral BIC/FTC/TAF. The noninferiority study assessed virologically suppressed adults who had been taking BIC/FTC/TAF and were then randomised to switch to treatment with CAB+RPV LA or continue with BIC/FTC/TAF. Researchers will share 12-month findings on treatment satisfaction and patient preference for the two regimens along with head-to-head efficacy and safety results. 1 Additional findings from SOLAR to be presented at CROI 2023 will also include the results of an analysis observing weight and metabolic changes when switching to CAB + RPV LA or continuing on BIC/FTC/TAF. 2

New scientific data from HPTN 084 on cabotegravir long-acting for HIV prevention: New findings from the HPTN 084 trial that assess the impact of less frequent dosing of cabotegravir LA for PrEP pharmacology in women will be presented. Findings to be presented at CROI will focus on participants with delayed injections during the blinded phase of the study. 3 Additional findings on cabotegravir LA for PrEP from HPTN 084 to be presented at CROI 2023 will also include the results of an analysis observing safety, tolerability, and acceptability of the long-acting prevention medicine in a substudy that enrolled adolescent girls in sub-Saharan Africa, a population that is among the most disproportionately impacted by the HIV epidemic. 4

Advancing new mechanisms of action in HIV research: Phase IIa proof-of-concept data will be presented from the BANNER study of N6LS (VH3810109), a novel, investigational, broadly neutralising antibody (bNAb) that is being investigated in adults living with HIV at two dosing levels – a high dose and ten-fold lower dose (40 mg/kg and ~4 mg/kg (280 mg), respectively). Researchers will share how baseline viral and participant factors impact virologic response following infusion of VH3810109, and will demonstrate the utility of using a phenotypic test to determine sensitivity of pre-treatment virus to N6LS. 5

Strengthening clinical and real-world evidence for dolutegravir and 2-drug regimens: New findings for dolutegravir (DTG) will be presented at CROI, including 48-week metabolic health results from RUMBA, the first, open-label, randomised clinical trial comparing the effects of switching from a second-generation integrase inhibitor based triple antiretroviral therapy (BIC/FTC/TAF) to the 2-drug regimen Dovato (dolutegravir, lamivudine [DTG/3TC]). 6

Results from the D2EFT study, an international randomised open-label trial that compared DTG with ritonavir boosted darunavir (DRV/r) versus DTG with fixed tenofovir and lamivudine or emtricitabine (TDF/XTC) versus standard of care in adults whose first-line therapy has failed, will be presented. Data from Eswatini will also be presented, evaluating the prevalence of neural tube defects (NTDs) among women on DTG at the time of conception. 7 Previous findings from the Tsepamo study showed that NTD prevalence in infants born to women on DTG at the time of conception were not significantly different from women living with HIV or women on other antiretroviral therapy. 8

Understanding patients' experience to best meet the needs of people living with HIV: Additional findings underscoring the importance of patient preference and experience to be shared at CROI 2023 include data on the HPTN 083 study of cabotegravir LA for PrEP, evaluating participant choice of long-acting PrEP versus daily oral PrEP after study unblinding. 9 Further, results among participants from the HPTN 083 study looks at experiences among US Black men and transgender women. 10

Here is a list of ViiV Healthcare sponsored and supported studies to be presented at CROI 2023:

| Abstract Title | First Author | Presentation |

| Dolutegravir | | |

| Model informed dolutegravir dose selection in peds with 1st generation INSTI-R | H. Chandasana | Poster |

| Comparison of telomere length changes over 48 weeks in SALSA study: DTG/3TC vs CAR | M. Underwood | Poster |

| Chronic liver inflammation and use of contemporary ART among persons living with HIV | A. O. Roen | Poster |

| Dolutegravir Collaborative/Independent Studies sponsored by ViiV Healthcare | | |

| Favorable metabolic outcomes 48 weeks after switch to DTG/3TC | S. Degroote | Poster |

| D2EFT: Dolutegravir and Darunavir evaluation in adults failing first line HIV therapy | G. Matthews | Oral |

| Neural tube and other birth defects by HIV status and ART regimen in Eswatini | M. Gill | Poster |

| Cabotegravir for Treatment | | |

| SOLAR 12-month results – randomized switch trial of CAB + RPV LA vs oral B/FTC/TAF | M. N. Ramgopal | Oral |

| Weight and metabolic changes with cabotegravir + rilpivirine long-acting or bictegravir | D. H.S. Tan | Oral |

| Thigh injections of cabotegravir+rilpivirine in virally suppressed adults with HIV-1 | F. Felizarta | Poster |

| Cabotegravir for PrEP Collaborative Studies | | |

| The LEVI syndrome: characteristics of early HIV infection with cabotegravir for PrEP | S. H. Eshleman | Oral |

| Cabotegravir pharmacology in the background of delayed injections in HPTN 084 | M. A. Marzinke | Oral |

| Cabotegravir for HIV PrEP in US Black men and transgender women who have sex with men | H. Scott | Oral |

| CAB LA for HIV prevention in African cisgender female adolescents (HPTN 084-01) | S. Hosek | Oral |

| Pre-exposure prophylaxis product choice in US participants in HPTN 083 | M. E. Clement | Poster |

| Bone density changes with CAB-LA or TDF/FTC PrEP in MSM and TGW in HPTN 083 | T. T. Brown | Poster |

| Pipeline | | |

| Impact of baseline factors on virologic response to bNAb VH3810109 (N6LS) in BANNER | P. Leone | Poster |

| General | | |

| Vertical transmission in infants born to women with HIV on antiretroviral treatment | K. Anderson | Poster |

| Trends in mortality in people living with HIV in an international cohort (RESPOND) | E. Tusch | Poster |

APRETUDE (cabotegravir) extended-release injectable suspensions

APRETUDE is indicated in at-risk adults and adolescents weighing at least 35 kg for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection. 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 become infected with HIV-1 while receiving APRETUDE for PrEP must transition to a complete HIV-1 treatment regimen.

APRETUDE 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

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 (

- 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 HIV-1 uninfected individuals 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

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 with APRETUDE:

- 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 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 of APRETUDE:

- 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

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 WITH APRETUDE

- Refer to the full Prescribing Information for important drug interactions with APRETUDE

- Drugs that induce UGT1A1 may significantly decrease the plasma concentrations of cabotegravir

APRETUDE 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

Please see full Prescribing Information (PDF - 1,350KB).

Important Safety Information for Dovato (50mg dolutegravir/300mg lamivudine) Tablets

Dovato is indicated as a complete regimen to treat HIV-1 infection in adults with no antiretroviral (ARV) treatment history or to replace the current ARV regimen in those who are virologically suppressed (HIV-1 RNA

IMPORTANT SAFETY INFORMATION

BOXED WARNING: PATIENTS CO-INFECTED WITH HEPATITIS B VIRUS (HBV) AND HIV-1:

EMERGENCE OF LAMIVUDINE-RESISTANT HBV AND EXACERBATIONS OF HBV

All patients with HIV-1 should be tested for the presence of HBV prior to or when initiating Dovato. Emergence of lamivudine-resistant HBV variants associated with lamivudine-containing antiretroviral regimens has been reported. If Dovato is used in patients co-infected with HIV-1 and HBV, additional treatment should be considered for appropriate treatment of chronic HBV; otherwise, consider an alternative regimen.

Severe acute exacerbations of HBV have been reported in patients who are co-infected with HIV-1 and HBV and have discontinued lamivudine, a component of Dovato. Closely monitor hepatic function in these patients and, if appropriate, initiate anti-HBV treatment.

Contraindications of Dovato

- Do not use Dovato in patients with previous hypersensitivity reaction to dolutegravir or lamivudine

- Do not use Dovato in patients receiving dofetilide

Hypersensitivity Reactions:

- Hypersensitivity reactions have been reported with dolutegravir and were characterized by rash, constitutional findings, and sometimes organ dysfunction, including liver injury

- Discontinue Dovato immediately if signs or symptoms of severe skin or hypersensitivity reactions develop, as a delay in stopping treatment may result in a life-threatening reaction. Clinical status, including liver aminotransferases, should be monitored and appropriate therapy initiated

- Hepatic adverse events have been reported, including cases of hepatic toxicity (elevated serum liver biochemistries, hepatitis, and acute liver failure), in patients receiving a dolutegravir-containing regimen without pre-existing hepatic disease or other identifiable risk factors

- Patients with underlying hepatitis B or C or marked elevations in transaminases prior to treatment may be at increased risk for worsening or development of transaminase elevations with use of Dovato. In some cases, the elevations in transaminases were consistent with immune reconstitution syndrome or hepatitis B reactivation, particularly in the setting where anti-hepatitis therapy was withdrawn

- Monitoring for hepatotoxicity is recommended

- Assess the risks and benefits of Dovato and discuss with the patient to determine if an alternative treatment should be considered at the time of conception through the first trimester of pregnancy due to the risk of neural tube defects

- Pregnancy testing is recommended before initiation of Dovato. Individuals of childbearing potential should be counselled on the consistent use of effective contraception

Lactic Acidosis and Severe Hepatomegaly with Steatosis:

Fatal cases have been reported with the use of nucleoside analogues, including lamivudine. Discontinue Dovato if clinical or laboratory

findings suggestive of lactic acidosis or pronounced hepatotoxicity develop, including hepatomegaly and steatosis in the absence of marked transaminase elevations.

Adverse Reactions or Loss of Virologic Response Due to Drug Interactions with concomitant use of Dovato and other drugs may occur (see Contraindications and Drug interactions).

Immune Reconstitution Syndrome, including the occurrence of autoimmune disorders with variable time to onset, has been reported with the use of Dovato.

The most common adverse reactions (incidence ≥2%, all grades) with Dovato were headache (3%), nausea (2%), diarrhoea (2%), insomnia (2%), fatigue (2%), and anxiety (2%).

Drug interactions for Dovato

- Consult full Prescribing Information for Dovato for more information on potentially significant drug interactions

- Dovato is a complete regimen. Coadministration with other antiretroviral medications for the treatment of HIV-1 infection is not recommended

- Drugs that induce or inhibit CYP3A or UGT1A1 may affect the plasma concentrations of dolutegravir

- Administer Dovato 2 hours before or 6 hours after taking polyvalent cation-containing antacids or laxatives, sucralfate, oral supplements containing iron or calcium, or buffered medications. Alternatively, Dovato and supplements containing calcium or iron can be taken with food

Dovato use in specific populations

- Pregnancy: The safety and efficacy of a dual regimen has not been studied in pregnancy. If a pregnancy is confirmed in the first trimester while on Dovato, the benefits and risks of continuing Dovato versus switching to another antiretroviral regimen should be discussed with the patient taking the gestational age and the critical time period of neural tube defect development into account. Data analysed from the Antiretroviral Pregnancy Registry do not indicate an increased risk of

major birth defects in women exposed to dolutegravir during pregnancy but are currently insufficient to address the risk of neural tube defects. Dovato may be used during the second and third trimester of pregnancy when the expected benefit justifies the potential risk to the foetus.

- Lactation: Breastfeeding is not recommended due to the potential for HIV-1 transmission.

- Women of childbearing potential (WOCBP): WOCBP should be counselled about the potential risk of neural tube defects with dolutegravir (a component of Dovato), including consideration of effective contraceptive measures. If a woman plans pregnancy, the benefits and the risks of continuing treatment with Dovato should be discussed with the patient. Renal Impairment: Dovato is not recommended for patients with creatinine clearance

- Hepatic Impairment: Dovato is not recommended in patients with severe hepatic impairment (Child-Pugh Score C)

Please refer to the full European Summary of Product Characteristics for Dovato for full prescribing information, including contraindications, special warnings and precautions for use. For the US, please refer to the US Prescribing Information, including Boxed Warning.

Important Safety Information for Cabenuva (cabotegravir 200mg/mL; rilpivirine 300mg/mL) extended-release injectable suspensions (marketed as Vocabria/Rekambys outside the US)

Cabenuva is indicated as a complete regimen for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults and adolescents who are 12 years of age or older and weighing at least 35 kg to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than

CONTRAINDICATIONS OF CABENUVA

- Do not use Cabenuva in patients with previous hypersensitivity reaction to cabotegravir or rilpivirine

- Do not use Cabenuva in patients receiving carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifabutin, rifampin, rifapentine, systemic dexamethasone (>1 dose), and St John’s wort

Hypersensitivity Reactions of Cabenuva:

- Hypersensitivity reactions, including cases of Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), have been reported during postmarketing experience with rilpivirine-containing regimens. While some skin reactions were accompanied by constitutional symptoms such as fever, other skin reactions were associated with organ dysfunctions, including elevations in hepatic serum biochemistries

- Serious or severe hypersensitivity reactions have been reported in association with other integrase inhibitors and could occur with Cabenuva

- Discontinue Cabenuva immediately if signs or symptoms of hypersensitivity reactions develop. Clinical status, including liver transaminases, should be monitored and appropriate therapy initiated.

- Serious post-injection reactions (reported in less than 1% of subjects) were reported within minutes after the injection of rilpivirine, including dyspnea, bronchospasm, agitation, abdominal cramping, rash/urticaria, dizziness, flushing, sweating, oral numbness, changes in blood pressure, and pain (e.g., back and chest). These events may have been associated with inadvertent (partial) intravenous administration and began to resolve within a few minutes after the injection

- Carefully follow the Instructions for Use when preparing and administering Cabenuva. The suspensions should be injected slowly via intramuscular injection and avoid accidental intravenous administration. Observe patients briefly (approximately 10 minutes) after the injection. If a post-injection reaction occurs, monitor and treat as clinically indicated

Hepatotoxicity of Cabenuva:

- Hepatotoxicity has been reported in patients receiving cabotegravir or rilpivirine with or without known pre-existing hepatic disease or identifiable risk factors

- Patients with underlying liver disease or marked elevations in transaminases prior to treatment may be at increased risk for worsening or development of transaminase elevations

- Monitoring of liver chemistries is recommended and treatment with Cabenuva should be discontinued if hepatotoxicity is suspected

Depressive Disorders with Cabenuva:

- Depressive disorders (including depressed mood, depression, major depression, mood altered, mood swings, dysphoria, negative thoughts, suicidal ideation or attempt) have been reported with Cabenuva or the individual products

- Promptly evaluate patients with depressive symptoms

Risk of Adverse Reactions or Loss of Virologic Response Due to Drug Interactions:

- The concomitant use of Cabenuva and other drugs may result in known or potentially significant drug interactions (see Contraindications and Drug Interactions)

- Rilpivirine doses 3 and 12 times higher than the recommended oral dosage can prolong the QTc interval

- Cabenuva should be used with caution in combination with drugs with a known risk of Torsade de Pointes

Long-Acting Properties and Potential Associated Risks with Cabenuva:

- Residual concentrations of cabotegravir and rilpivirine may remain in the systemic circulation of patients for prolonged periods (up to 12 months or longer). Select appropriate patients who agree to the required monthly or every-2-month injection dosing schedule because non-adherence could lead to loss of virologic response and development of resistance

- To minimize the potential risk of developing viral resistance, it is essential to initiate an alternative, fully suppressive antiretroviral regimen no later than 1 month after the final injection doses of Cabenuva when dosed monthly and no later than 2 months after the final injections of Cabenuva when dosed every 2 months. If virologic failure is suspected, switch the patient to an alternative regimen as soon as possible

- The most common adverse reactions (incidence ≥2%, all grades)

with Cabenuva were injection site reactions, pyrexia, fatigue, headache, musculoskeletal pain, nausea, sleep disorders, dizziness, and rash

- The safety of Cabenuva in adolescents is expected to be similar to adults

DRUG INTERACTIONS WITH CABENUVA

- Refer to the applicable full Prescribing Information for important drug interactions with Cabenuva, VOCABRIA, or EDURANT

- Because Cabenuva is a complete regimen, coadministration with other antiretroviral medications for the treatment of HIV-1 infection is not recommended

- Drugs that are strong inducers of UGT1A1 or 1A9 are expected to decrease the plasma concentrations of cabotegravir. Drugs that induce or inhibit CYP3A may affect the plasma concentrations of rilpivirine

- Cabenuva should be used with caution in combination with drugs with a known risk of Torsade de Pointes

CABENUVA USE IN SPECIFIC POPULATIONS

- Pregnancy: There are insufficient human data on the use of Cabenuva during pregnancy to adequately assess a drug-associated risk for birth defects and miscarriage. Discuss the benefit-risk of using Cabenuva during pregnancy and conception and consider that cabotegravir and rilpivirine are detected in systemic circulation for up to 12 months or longer after discontinuing injections of Cabenuva. An Antiretroviral Pregnancy Registry has been established

- Lactation: The CDC recommends that HIV 1–infected mothers in the United States not breastfeed their infants to avoid risking postnatal transmission of HIV-1 infection. Breastfeeding is also not recommended due to the potential for developing viral resistance in HIV-positive infants, adverse reactions in a breastfed infant, and detectable cabotegravir and rilpivirine concentrations in systemic circulation for up to 12 months or longer after discontinuing injections of Cabenuva

For more information please see US Prescribing Information for Cabenuva.

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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 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 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 Q4 Results for 2022 and any impacts of the COVID-19 pandemic.

M. N. Ramgopal et. al. SOLAR 12-month results – randomized switch trial of CAB + RPV LA vs oral B/FTC/TAF. Presented at Conference on Retroviruses and Opportunistic Infections (CROI) February 2023.

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G. Matthews et. al. D2EFT: Dolutegravir and Darunavir evaluation in adults failing first line HIV therapy. Presented at Conference on Retroviruses and Opportunistic Infections (CROI) February 2023.

R. Zash et. al. Update on neural tube defects with antiretroviral exposure in the Tsepamo Study, Botswana. Presented at AIDS 2022.

M. E. Clement et. al. Pre-exposure prophylaxis product choice in US participants in HPTN 083. Presented at Conference on Retroviruses and Opportunistic Infections (CROI) February 2023.

H. Scott et. al. Cabotegravir for HIV PrEP in US Black men and transgender women who have sex with men. Presented at Conference on Retroviruses and Opportunistic Infections (CROI) February 2023.

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cabenuva-against-daily-oral-biktarvy-at-croi-2023-1779

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