Press release

For media and investors only

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ViiV Healthcare data show 89% of treatment-naïve people with HIV choose to switch to long-acting injectable Vocabria + Rekambys from daily pills after achieving rapid viral suppression

- Multiple real-world studies show consistent high effectiveness of *Vocabria* + *Rekambys* (cabotegravir + rilpivirine LA (CAB+RPV LA)) across a broad range of populations
- Implementation science data for *Apretude* (cabotegravir long-acting (CAB LA) for PrEP) demonstrate 95% of participants were happy they switched from oral PrEP to CAB LA

GSK plc (LSE/NYSE: GSK) announced ViiV Healthcare, the global specialist HIV company majority owned by GSK, with Pfizer and Shionogi as shareholders, today shared data from the phase IIIb VOLITION study demonstrating that 89% (n=129/145) of eligible treatment-naïve people living with HIV opted to switch to long-acting injectable *Vocabria* + *Rekambys* (branded as *Cabenuva* in the US, Canada and Australia) following rapid viral suppression with daily *Dovato* (dolutegravir/lamivudine (DTG/3TC)). Additional real-world data from other studies reinforce CAB+RPV LA's effectiveness across a broad range of populations.

Jean van Wyk, MBChB, MFPM, Chief Medical Officer at ViiV Healthcare, said: "Data from the VOLITION study highlight how providing choice in HIV care empowers individuals to choose medicines that meet their evolving everyday needs. ViiV pioneered long-acting injectables for HIV, and we now have over three years of robust real-world evidence demonstrating the impact our portfolio is having today across a broad range of settings and populations. Long-acting injectables provide options that can offer high effectiveness and tolerability, improved adherence, and a preferred dosing schedule compared with daily oral pills. We believe they are a key part of HIV treatment and prevention and will play a critical role in achieving our ambition of ending HIV and AIDS."

Data summary from ViiV Healthcare and partner studies at IAS 2025:

Empowering choice: 89% of treatment-naïve people with HIV opt for CAB+RPV LA after achieving rapid viral suppression: These new data from the phase IIIb VOLITION study evaluate the experience of treatment-naïve individuals who initiated treatment with daily DTG/3TC pills and were subsequently offered the choice to switch to CAB+RPV LA after achieving viral suppression. Study results showed that participants achieved rapid viral suppression with DTG/3TC (median time to suppression: 4.14 weeks), following which they were offered to switch. At the immediate next study visit (Day of Choice), 89% (n=129/145) of eligible participants chose to switch to CAB+RPV LA, while 11% (n=16) opted to continue DTG/3TC. The most common reasons cited for choosing CAB+RPV LA were not having to worry about missing a dose each day (80%) and not having to carry medication (68%). These findings underscore the efficacy and tolerability of DTG/3TC as a rapid suppression option, and demonstrate the value of offering CAB+RPV LA as a treatment option to meet individual needs and preferences[i].

CAB+RPV LA delivers sustained effectiveness and enhanced patient experience in real-world settings: Data from multiple real-world observational studies, including the two-year BEYOND study in the US, the CARLOS study in Germany, the COMBINE-2 cohort across seven European countries, and the OPERA study, consistently reinforce the high effectiveness, favourable outcomes and patient satisfaction associated with CAB+RPV LA[ii,iii,iv,v,vi,vii].

BEYOND is a two-year prospective observational study enrolling people with HIV following the decision to switch to CAB+RPV LA across 27 US sites[ii]. Among the 308 participants, 97% maintained virologic suppression at Month 24 (at most recent viral load of <50 copies/ml), with infrequent discontinuations due to injection reactions and no new confirmed virologic failures after Month 6. Participants reported reduced stigma and improved treatment satisfaction[iii].

Similarly, the real-world CARLOS study of 351 participants in Germany, showed 77.5% virologic suppression at Month 24, with high adherence (94.2% on-time injections) and clinically meaningful improvements in treatment satisfaction[iv]. 97.7% of participants maintained virologic suppression at last known viral load at Month 24 or at discontinuation.

In Europe, the COMBINE-2 study, evaluating real-world outcomes for 956 virologically suppressed people with HIV initiating CAB+RPV LA across seven European countries, reported 99% virologic suppression at last measured viral load (median follow-up of 10.2 months), with low rates of confirmed virologic failure (0.5%) and high persistence (92% remaining on therapy)[v].

Real-world evidence focussed on the effectiveness of CAB+RPV LA outside the labelled indication in viraemic patients: The large-scale OPERA study further explored the effectiveness of CAB+RPV LA in treatment-experienced individuals initiating therapy with detectable viral loads and long-standing HIV. Among the 3,304 participants, 11% (368 individuals) initiated with baseline viremia (≥50 copies/mL), of these, 88% achieved viral suppression to <50 copies/mL (of n=277/313 with ≥1 viral load during follow-up and VL <50 copies/mL at any point during follow-up). A separate analysis also showed that among a diverse group of 105 women initiating CAB+RPV LA with viremia, most achieved viral suppression (of 92 women with ≥1 VL at follow-up, 92% achieved VL <50 copies/mL at any point during follow-up), with confirmed virologic failure being rare[vi,vii].

Through these findings, CAB+RPV LA was shown to address challenges associated with daily oral pills, offering improved treatment satisfaction, high effectiveness and a patient-preferred treatment option that supports long-term virologic control.

Implementation studies highlight CAB LA for PrEP is highly preferred and easy to implement for key prevention groups: The PILLAR and EBONI studies highlight the high acceptability and feasibility of CAB LA for PrEP for HIV prevention in broad populations, including men who have sex with men (MSM), transgender men (TGM), and Black women (BW)[viii,ix].

PILLAR is a phase IV implementation trial assessing the integration of CAB LA for PrEP across 17 clinics in the US among a broad population of MSM and TGM (n=201)[viii]. CAB LA for PrEP was rated highly acceptable (mean 4.6/5 at Month 12) and feasible (mean 4.4/5), with 95% of participants (n=131) who switched from oral PrEP reporting being happy with the choice and 98% recommending CAB LA for PrEP (n=140). Flexible scheduling, reminders, and educational tools supported adherence, while stigma concerns were significantly lower compared to oral PrEP users.

Similarly, EBONI, an implementation study evaluating CAB LA for PrEP in Black cis and transgender women, among women's health clinics, across 72 healthcare provider respondents at 15 clinics primary care and infectious disease clinics in the US. Data found CAB LA for PrEP highly appropriate (mean 4.5/5) and feasible (mean 4.4/5) for Black women[ix]. In addition, clinic capacity to accommodate CAB LA for PrEP tripled within a year without increasing staff or time commitment. The health benefits of two monthly visits included additional opportunities to screen for STIs, screening for comorbidities or providing other health or psychological care.

These findings highlight *Apretude*'s potential to support broader PrEP implementation and improve outcomes in underserved populations who may benefit the most across varied clinical settings.

About *Apretude* (cabotegravir long-acting for PrEP)
Apretude is a medicine used for preventing sexually transmitted HIV-1 infection (pre-exposure prophylaxis or PrEP) in adults and adolescents weighing at least 35 kg who are at high risk of being infected. 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. It should be used in combination with safer sex practices, such as using condoms. *Apretude* contains the active substance cabotegravir.

Please consult the full Summary of Product Characteristics for all the safety information: Apretude 600 mg prolonged-release suspension for injection

About *Vocabria* (cabotegravir)
Vocabria injection is indicated - in combination with rilpivirine injection - for the treatment of Human Immunodeficiency Virus type 1 (HIV-1) infection in adults and adolescents (at least 12 years of age and weighing at least 35 kg) who are virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen without present or past evidence of viral resistance to, and no prior virological failure with agents of the non-nucleoside reverse transcriptase inhibitors (NNRTI) and integrase inhibitor (INI) class.

Vocabria tablets are indicated - in combination with rilpivirine tablets - for the short-term treatment of HIV-1 infection in adults and adolescents (at least 12 years of age and weighing at least 35 kg) who are virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen without present or past evidence of viral resistance to, and no prior virological failure with agents of the NNRTI and INI class for:

- oral lead-in to assess tolerability of *Vocabria* and rilpivirine prior to administration of long acting *Vocabria* injection plus long acting rilpivirine injection.
- oral therapy for adults who will miss planned dosing with *Vocabria* injection plus rilpivirine injection.

Vocabria tablets are only indicated for treatment of HIV-1 in combination with rilpivirine tablets, therefore, the prescribing information for *Edurant* (rilpivirine) tablets should also be consulted for recommended dosing.

Please consult the full Summary of Product Characteristics for all the safety information: *Vocabria* 400mg/600 mg prolonged-release suspension for injection and *Vocabria* 30 mg film-coated tablets

About *Rekambys (rilpivirine)*
Rekambys is indicated - in combination with cabotegravir injection - for the treatment of HIV-1 infection in adults and adolescents (at least 12 years of age and weighing at least 35 kg) who are virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen without present or past evidence of viral resistance to, and no prior virological failure with, agents of the NNRTI and INI class.

Rekambys should always be co-administered with a cabotegravir injection. The prescribing information for cabotegravir injection should be consulted for recommended dosing. *Rekambys* may be initiated with oral lead-in or without (direct to injection).

Please consult the full Summary of Product Characteristics for all the safety information: *Rekambys* 600mg/900 mg prolonged-release suspension for injection

About *Cabenuva (cabotegravir + rilpivirine)*
Cabenuva is indicated as a complete regimen for the treatment of HIV-1 infection in adults and adolescents 12 years and older and weighing at least 35 kg to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA <50 c/ml) on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine.

The complete regimen combines the integrase strand transfer inhibitor (INSTI) cabotegravir, developed by ViiV Healthcare, with rilpivirine, a non-nucleoside reverse transcriptase inhibitor (NNRTI) developed by Janssen Sciences Ireland Unlimited Company. Rilpivirine tablets are approved in the US and when used with cabotegravir is indicated for short-term treatment of HIV-1 infection in adults and adolescents 12 years and older and weighing at least 35 kg who are virologically suppressed (HIV-1 RNA less than 50 copies/mL) on a stable regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine.

INSTIs 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. Rilpivirine is an NNRTI that works by interfering with an enzyme called reverse transcriptase, which stops the virus from multiplying.

Please consult the full Prescribing Information here

About *Dovato* (dolutegravir and lamivudine)
Dovato is indicated as a complete regimen to treat HIV-1 infection in adults and adolescents above 12 years of age weighing at least 40 kg in the EU, and weighing at least 25 kg in the US, with no antiretroviral (ARV) treatment history or to replace the current ARV regimen in those who are virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable ARV regimen with no history of treatment failure and no known resistance to any component of *Dovato*.

Please consult the full Summary of Product Characteristics for all the safety information: *Dovato* 50 mg/300 mg film-coated tablets.

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 could benefit from HIV prevention. 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 in the "Risk Factors" section in GSK's Annual Report on Form 20-F for 2024, and GSK's Q1 Results for 2025.

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References

[i] F. Felizarta, *et al*. The power of choice: strong preference for CAB+RPV LA following rapid suppression with DTG/3TC in treatment naive people living with HIV. Presented at the International AIDS Society Conference (IAS 2025), 13-17 July, Kigali, RW.
[ii] F. Felizarta, *et al*. Perspectives of people living with HIV (PWH) 24 months following a switch to cabotegravir and rilpivirine long-acting (CAB+RPV LA) in an observational real-world US study (BEYOND). Presented at the International AIDS Society Conference (IAS 2025), 13-17 July, Kigali, RW.
[iii] G. Blick, *et al*. Clinical outcomes at month 24 after initiation of cabotegravir and rilpivirine long acting (CAB+RPV LA) in an observational real-world study (BEYOND). Presented at the International AIDS Society Conference (IAS 2025), 13-17 July, Kigali, RW.
[iv] C. Wyen, *et al*. 24-month outcomes of cabotegravir+rilpivirine long-acting every 2 months in a real-world setting: effectiveness, adherence to injections, and participant-reported outcomes from people with HIV-1 in the German CARLOS cohort. Presented at the International AIDS Society Conference (IAS 2025), 13-17 July, Kigali, RW.
[v] A. Pozniak, *et al*. High virologic suppression and few virologic failures with Long-Acting Cabotegravir + Rilpivirine in Treatment Experienced Virologically Suppressed Individuals from COMBINE-2 cohort in Europe. Presented at the International AIDS Society Conference (IAS 2025), 13-17 July, Kigali, RW.
[vi] R. Hsu, *et al*. Real-world effectiveness of CAB+RPV LA in individuals with HIV viremia at therapy initiation. Presented at the International AIDS Society Conference (IAS 2025), 13-17 July, Kigali, RW.
[vii] J. Altamirano, *et al*. Clinical outcomes among women in the OPERA cohort initiating CAB+RPV LA with viral loads ⩾ 50 copies/mL. Presented at the International AIDS Society Conference (IAS 2025), 13-17 July, Kigali, RW.
[viii] D. Dandachi, *et al*. One-year implementation outcomes of cabotegravir long-acting injectable PrEP in men who have sex with men (MSM) & transgender men (TGM): findings from the PILLAR study. Presented at the International AIDS Society Conference (IAS 2025), 13-17 July, Kigali, RW.
[ix] Z. Tims-Cook, *et al*. Health care provider experiences after 12 months of implementing cabotegravir long-acting injectable PrEP (CAB LA) for Black women: EBONI study results. Presented at the International AIDS Society Conference (IAS 2025), 13-17 July, Kigali, RW.