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ViiV Healthcare expands on real-world data supporting use of long-acting therapies in diverse patient populations at HIV Glasgow

- ***New analyses highlight use of long-acting injectable Vocabria + Rekambys* (cabotegravir + rilpivirine LA) *in clinical trial and real-world populations, and the economic and public health impact of Apretude (cabotegravir LA for PrEP)***
- ***Findings from the DOLCE study explore the efficacy of 2-drug regimen Dovato (dolutegravir/lamivudine) compared to three-drug regimen in people with advanced HIV with CD4 count ≤ 200 cells/mm³***
- ***Additional key abstracts include findings from pipeline bNAb asset, VH3810109, as a potential approach to treating HIV***

London, [7 NOVEMBER 2024] – ViiV Healthcare, the global specialist HIV company majority owned by GSK, with Pfizer and Shionogi as shareholders, will share new data from its industry-leading HIV treatment and prevention portfolio and pipeline at HIV Glasgow 2024, being held in Glasgow, Scotland from 10 – 13 November 2024. Spanning 42 abstracts, the data showcases long-acting and two-drug regimens as care options for diverse populations in the face of a continuing HIV epidemic.

Harmony P. Garges, MD, Senior Vice President and Chief Medical Officer at ViiV Healthcare, said: "ViiV Healthcare is the first company to develop and launch long-acting options and two-drug regimens, and these therapies are transforming how physicians and providers treat and prevent HIV today. We continue evaluating how diverse populations living with or impacted by HIV respond to our therapies in the real world. Data from these studies include more than 10,000 people using *Vocabria + Rekambys,* more than 50,000 people using *Dovato* and more than 1,300 people using *Apretude*[1]. At HIV Glasgow, ViiV Healthcare is showcasing new, compelling data from our portfolio that reinforces how our medicines impact health outcomes and contribute to ending the HIV epidemic.**"**

Key data to be presented at HIV Glasgow 2024 by ViiV Healthcare and its study partners will include:

Analysis of cabotegravir + rilpivirine long-acting (CAB+RPV LA) in the real-world and across phase 3/3b studies: Findings from a large-scale post hoc analysis of the complete long-acting HIV treatment regimen CAB+RPV LA will be presented. The analysis, which pooled data from over 2,500 participants across four major phase 3/3b clinical trials (FLAIR, ATLAS, ATLAS-2M, and SOLAR), will compare virologic outcomes and isolated viraemic events between daily oral HIV treatment and CAB+RPV LA.[2] Furthermore, the real-world utilisation of CAB+RPV LA will be explored in an analysis of adherence and persistence in a Canadian patient support program. These analyses will add to the

growing body of clinical and real-world evidence for CAB+RPV LA and offer additional insights to healthcare providers on outcomes for CAB+RPV LA in diverse populations.

Data exploring the use of dolutegravir/lamivudine (DTG/3TC) in antiretroviral-naïve people living with HIV: Findings will be presented from the Fundación Huésped-sponsored DOLCE study. This is the first study to fully focus on evaluating the efficacy and safety of the 2-drug regimen DTG/3TC in people living with HIV with CD4 ≤ 200 cells/mm³.[3] Additionally, data will be shared from the phase IV D2ARLING study, which compared the efficacy and safety of DTG/3TC against a 3-drug regimen in an antiretroviral-naïve population that did not have baseline drug-resistance testing results available[4]. Many guidelines recommend baseline drug resistance testing prior to ART initiation, that may not always be readily accessible, reinforcing the need and impact of these data in an antiretroviral-naïve population.

Cost-effectiveness and usage patterns for long-acting HIV prevention: Findings from a cost-effectiveness study examining the economic and public-health impact of cabotegravir long-acting (CAB LA) for HIV pre-exposure prophylaxis (PrEP) in Canada will be presented. Researchers will compare the impact of the introduction of CAB LA for PrEP against daily oral PrEP (TDF/FTC) and no PrEP usage on cost savings and quality-adjusted life years.[5] New findings from the PROTECT survey will be shared, exploring differences in interest and intention to use long-acting PrEP among men who have sex with men, and heterosexual men and women, in 20 European countries.[6,7]

Advancing novel mechanisms of action in HIV research: New findings from the BANNER study of VH3810109 (N6LS), an investigational, broadly neutralising antibody (bNAb), will be presented. Previously presented phase IIa proof-of-concept findings from the BANNER study suggested VH109 was well-tolerated and efficacious in people living with HIV.[8] Researchers will share new findings exploring the correlation between baseline phenotypic sensitivity to N6LS and virologic response after treatment with N6LS.[9] Additional research evaluating N6LS will focus on administration and dose responsiveness, adding to the growing body of evidence supporting the bNAb as a potential new approach to treating HIV.[10]

ViiV Healthcare-sponsored or supported studies to be presented at HIV Glasgow 2024:

Title	First Author	Presentation
Cabotegravir + rilpivirine long-acting		
Similar virologic outcomes and frequency of isolated viraemic events (blips, low-level viraemia and suspected virologic failure) between oral and long-acting antiretroviral therapy: a pooled analysis of phase 3/3b cabotegravir + rilpivirine long-acting studies	J. Thornhill	Poster Presentation

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Real-world utilization of cabotegravir/rilpivirine: an observational analysis of adherence and persistence using a patient support program in Canada, preliminary results	C. LaForty	Poster Presentation
Feasibility and satisfaction of interventions measures (FIM and HIVTISQ) of implementation long-acting (LA) CAB+RPV administration out of HIV units: the IMADART study	A. Cabello	Poster Presentation
Cabotegravir and rilpivirine concentrations and HIV-1 RNA suppression in male and female genital fluids and rectal tissue in people with HIV on antiretroviral therapy with long-acting intramuscular cabotegravir plus rilpivirine	A. Fernández	Oral Presentation
Use of long-acting cabotegravir and rilpivirine in a real-life setting: 12-month results of virological outcome, adherence, safety, durability, in the ANRS CO3 AquiVIH-NA cohort-France	M. Hessamfar	Poster Presentation
Results at month 7 of CABO-CHANCE study: real-world-evidence (RWE) on the use of intramuscular cabotegravir plus rilpivirine long-acting (CAB+RPV LA) dosed every 2 months in viral suppressed people with HIV (PWH)	C. H. Tenorio	Poster Presentation
Re-suppression regimens and outcomes after virological failure in randomised controlled trials and real-world evidence studies evaluating cabotegravir and rilpivirine (CAB+RPV)	A. Elias	Poster Presentation
Virological failure rate and emergent resistance in real-world studies evaluating long-acting cabotegravir and rilpivirine in people with baseline viral suppression	M. Smuk	Poster Presentation
Cabotegravir long-acting for PrEP		
PrEP-associated stigma in Europe: findings from a real-world survey	M. Schroeder	Poster Presentation
Cost-effectiveness and public-health impact of cabotegravir long-acting injectable for HIV pre-exposure prophylaxis in Canada	A. Adelakun	Poster Presentation
Prevalence of HIV drug resistance in people newly diagnosed with HIV who have used pre-exposure prophylaxis in Europe; the PrEPaRe study	V. Cambiano	Poster Presentation
Differences in oral PrEP use patterns and intention to use long-acting regimens among MSM between formal and informal PrEP	H. Wang	Oral Presentation

provision pathways in 20 European countries: a latent class analysis		
Preparing for long-acting PrEP delivery: provider preferences for the provision of long-acting PrEP differ between MSM and heterosexual individuals in Europe	H. M. L. Zimmerman	Poster Presentation
Intention to use long-acting PrEP among heterosexual women and men in 20 European countries – results from the PROTECT survey	K. Jonas	Poster Presentation
Dolutegravir		
Two-year long-term data on the efficacy and tolerability of dolutegravir-based regimens from the prospective multi-centre TESLA cohort study in ART-naive and pre-treated people living with HIV in Russia	A. Basova	Poster Presentation
The analysis of metabolic parameters in people living with HIV using dolutegravir-based regimens in routine clinical practice in Russia	A. Basova	Poster Presentation
Outcomes following prenatal exposure to DTG-containing antiretroviral therapy regimens: data from the DOLOMITE-EPPICC study	R. Sconza	Poster Presentation
Incident hypertension with antiretroviral therapy: real-world evidence from the OPERA cohort	P. Lackey	Poster Presentation
A multicentre observational study to determine the safety and effectiveness of dolutegravir (DTG) use during pregnancy: data from DOLOMITE-NEAT ID Network study	J. D. Kowalska	Poster Presentation
Mortality using raltegravir versus other integrase inhibitors in people with HIV in Europe and Australia	E. Tusch	Poster Presentation
Mental health in PWH: Patient-reported outcomes in the DUALIS study	E. Wolf	Poster Presentation
Evaluating the cardiovascular risk and the achievement of target levels in low-density lipoprotein cholesterol in PLWH: Insights from the DUALIS study	F. Voit	Poster Presentation
Dolutegravir-based antiretroviral therapy does not reduce plasma levonorgestrel or medroxyprogesterone acetate concentrations among contraceptive users living with HIV compared with HIV-negative controls	R. Ryan	Poster Presentation
Efficacy and safety of dolutegravir (DTG)-based antiretroviral treatment (ART) in patients with HIV and solid organ transplantation (SOT): A single-arm clinical trial (DTG-SOT)	J. Miro	Poster Presentation

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Dolutegravir/lamivudine		
PAIRED - PAtIent Reported Experiences and perceiveD benefit of treatment with dolutegravir/lamivudine (DTG/3TC): a sub-analysis of people with HIV (PWH) switching from bictegravir/emtricitabine/ tenofovir alafenamide (BIC/FTC/TAF) in the United States (US)	J. Slim	Poster Presentation
Treatment-emergent integrase strand transfer inhibitor (INSTI) resistance-associated mutations among people living with HIV-1 treated with dolutegravir (DTG) + lamivudine (3TC) with pre-existing M184V/I from real-world and interventional studies	D. Fox	Poster Presentation
An EYEWITNESS to successful diversity in antiretroviral switch studies	C. V. Dam	Poster Presentation
CARAVEL: evaluation of real-world effectiveness and sustainability of the 2-drug regimen dolutegravir/lamivudine fixed-dose combination in treatment-naive adults and pre-treated adults who are virologically suppressed, in routine clinical care, in France. Two-year interim analysis results	P. Philibert	Poster Presentation
Real world experience of DTG+3TC regimen: results from the French Dat'AIDS cohort (2015-2022)	C. Allavena	Poster Presentation
Changes in patient-reported neuropsychological outcomes in virologically suppressed persons with HIV switching to DTG/3TC or BIC/FTC/TAF: a substudy of the PASO-DOBLE randomized clinical trial	L. Garcia-Fraile	Poster Presentation
Comparable efficacy and safety of dolutegravir / lamivudine to a three drug regimen amongst ARV naive people living with HIV with CD4 <200/mm^3: the DOLCE study	M. I. Figueroa	Oral Presentation
RUMBA's week 144 results confirm reassuring metabolic outcomes in both DTG/3TC and B/FTC/TAF	S. Degroote	Poster Presentation
Efficacy of dolutegravir plus lamivudine in treatment-naïve people living with HIV without baseline drug-resistance testing available: 48-week results from the randomised D2ARLING study	E. Cordova	Poster Presentation
Long-term efficacy and safety of Dolutegravir/Lamivudine in virologically suppressed persons with resistance to	M. De Lagarde	Poster Presentation

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Lamivudine: Week 96 results of VOLVER clinical trial - GESIDA 11820		
Fostemsavir		
CD4 T-cell, CD4/CD8 ratio improvement and a general reduction in inflammatory biomarkers with low-level viremia (LLV) up to Week 192 with fostemsavir (FTR)-based regimens in individuals with multidrug-resistant (MDR) HIV-1	V. Spagnuolo	Encore Poster Presentation
Similar efficacy, safety and CD4 T-cell increase up to Week 96 observed with fostemsavir (FTR)-based regimens in the BRIGHTE study and dolutegravir (DTG)-based regimens in the VIKING-3 study in individuals with multidrug-resistant (MDR) HIV-1	A. Castagna	Encore Poster Presentation
Pipeline		
Correlation of baseline phenotypic sensitivity with virologic response to VH3810109 (N6LS) in BANNER	M. Gartland	Poster Presentation
VH3810109 (N6LS) administration dose-responsively enhances anti-HIV antibody-dependent cellular cytotoxicity (ADCC) and antibody-dependent cellular phagocytosis (ADCP) activity in ex vivo models	M. Keegan	Encore Poster Presentation
Additional Studies		
Mortality and clinical outcomes after common cancers in people	A. Timiryasova	Poster Presentation
The association between anticholinergic medication use and cognitive function in older people with HIV in the Pharmacokinetic and clinical Observations in PeoPle over fifty (POPPY) Study	S. Deb	Poster Presentation
Comparison of 4 frailty scores to predict adverse health outcomes and mortality in people living with HIV aged 70 years and more (ANRS EP66 SEPTAVIH study)	C. Allavena	Poster Presentation
The prevalence and factors associated with polypharmacy in participants with HIV in the Pharmacokinetic and clinical Observations in PeoPle over fiftY (POPPY) study over a 3-5 year period	L. Sukumaran	Poster Presentation

About *Dovato*

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 <50 copies/mL) on a stable ARV regimen with no history of treatment failure and no known resistance to any component of *Dovato*.

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

About *Vocabria*

Vocabria (cabotegravir) injection is indicated - in combination with rilpivirine injection - for the treatment of Human Immunodeficiency Virus type 1 (HIV-1) infection in adults 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 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* 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*

Rekambys is indicated - in combination with cabotegravir injection - for the treatment of HIV-1 infection in adults 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

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About *Apretude*

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. 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 Fundación Huésped

Fundación Huésped is an Argentine organisation with a regional reach that has been working in public health since 1989, aiming to ensure the right to health and the control of diseases are guaranteed. Our comprehensive approach includes the development of research, practical solutions, and communications related to public health policies in our country and the region. Our mission is to conduct scientific research and implement preventive actions and rights-promotion initiatives to ensure access to healthcare and reduce the impact of diseases, with a focus on HIV/AIDS, viral hepatitis, vaccine-preventable diseases, and other transmissible diseases, as well as sexual and reproductive health.

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 Q3 Results for 2024.

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References:

[1] Data on file

[2] J. Thornhill, *et al.* Similar virologic outcomes and frequency of isolated viraemic events (blips, low-level viraemia and suspected virologic failure) between oral and long-acting antiretroviral therapy: a pooled analysis of phase 3/3b cabotegravir + rilpivirine long-acting studies. Presented at HIV Glasgow 2024, 10 – 13 November, Glasgow, Scotland.

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[4] E. Cordova, *et al.* Efficacy of dolutegravir plus lamivudine in treatment-naïve people living with HIV without baseline drug-resistance testing available: 48-week results from the randomised D2ARLING study. Presented at HIV Glasgow 2024, 10 – 13 November, Glasgow, Scotland.

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[6] H. Wang, *et al.* Differences in oral PrEP use patterns and intention to use long-acting regimens among MSM between formal and informal PrEP provision pathways in 20 European countries: a latent class analysis. Presented at HIV Glasgow 2024, 10 – 13 November, Glasgow, Scotland.
[7] K. Jonas, et al. Intention to use long-acting PrEP among heterosexual women and men in 20 European countries – results from the PROTECT survey. Presented at HIV Glasgow 2024, 10 – 13 November, Glasgow, Scotland.
[8] P. Leone, *et. al*. VH3810109 (N6LS) Reduces Viremia Across a Range of Doses in ART-Naive Adults Living with HIV: Proof of Concept Achieved in the Phase IIa BANNER (207959, NCT04871113) Study. Presented at HIV Glasgow 2022.
[9] M. Gartland, *et al*. Correlation of baseline phenotypic sensitivity with virologic response to VH3810109 (N6LS) in BANNER. Presented at HIV Glasgow 2024, 10 – 13 November, Glasgow, Scotland.
[10] M. Keegan, *et al*. VH3810109 (N6LS) administration dose-responsively enhances anti-HIV antibody-dependent cellular cytotoxicity (ADCC) and antibody-dependent cellular phagocytosis (ADCP) activity in ex vivo models. Presented at HIV Glasgow 2024, 10 – 13 November, Glasgow, Scotland.