Press Release

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Issued: 15 July 2024, London UK

ViiV Healthcare to announce data from largest head-to-head randomised clinical trial for 2-drug regimen *Dovato* against 3-drug regimen Biktarvy at AIDS 2024

- ***Findings from the SEIMC-GeSIDA Foundation (FSG) PASO-DOBLE study will include treatment efficacy, safety, and weight gain experienced by participants taking Dovato (dolutegravir/lamivudine) or Biktarvy (bictegravir/emtricitabine/tenofovir alafenamide)***
- ***Additional key abstracts from ViiV Healthcare's industry-leading, long-acting pipeline and portfolio include data introducing a third-generation integrase strand transfer inhibitor (INSTI) with potential for ultra long-acting applications; pregnancy data for Apretude (cabotegravir long-acting injectable) for PrEP; and real-world evidence for long-acting treatment regimen Cabenuva (cabotegravir + rilpivirine long-acting)***

London, [15 JULY 2024] – ViiV Healthcare, the global specialist HIV company majority owned by GSK, with Pfizer and Shionogi as shareholders, today announced it will be presenting the largest head-to-head, randomised clinical trial (RCT) of the 2-drug regimen *Dovato* (dolutegravir/lamivudine [DTG/3TC]) compared against the 3-drug regimen, *Biktarvy* (bictegravir/emtricitabine/tenofovir alafenamide [BIC/FTC/TAF]) at the 25th International AIDS Conference in Munich, Germany (22 – 26 July). The presentation is one of 25 abstracts evaluating the company's portfolio of marketed HIV treatment and prevention options alongside its next-generation pipeline assets.

Harmony P. Garges, M.D., Chief Medical Officer at ViiV Healthcare, said: "The exciting findings we'll be presenting at AIDS 2024 continue to underscore our position as industry leaders in the development of long-acting and 2-drug regimens and our pioneering approaches to both HIV treatment and prevention. People living with HIV continue to tell us they want more treatment options to allow for more personal choice to address needs beyond viral suppression. The breadth of the data we're announcing, including the head-to-head study between *Dovato* and *Biktarvy*, helps individuals better understand those options. We're proud to be at the forefront of innovative science, driving advancements that have and will continue to transform the future of HIV care and contribute to ending the epidemic."

Key abstracts to be presented at AIDS 2024 by ViiV Healthcare and its study partners will include:

Head-to-head study comparing ViiV Healthcare's oral 2-drug regimen against a commonly prescribed oral 3-drug regimen: The FSG-sponsored PASO-DOBLE head-to-head RCT of the 2-drug regimen *Dovato* (DTG/3TC) compared with the 3-drug regimen *Biktarvy* (BIC/FTC/TAF) will be presented as a late breaker abstract. The non-inferiority study assessed virologically suppressed adults on an established treatment regimen and who could benefit from treatment optimisation,

who were randomised to switch to treatment with DTG/3TC or BIC/FTC/TAF. Researchers will share 48-week findings on treatment efficacy and safety, as well as changes in weight experienced by participants while taking either regimen.[1]

Additional findings for DTG/3TC will include the DYAD study, presenting 48-week findings among virologically suppressed participants with no prior virologic failure who either switched to DTG/3TC or remained on BIC/FTC/TAF[2], and 96-week findings from the SOUND study, which followed virologically suppressed participants with unknown resistance history who switched from BIC/FTC/TAF to DTG/3TC.[3]

Pregnancy data from the HPTN 084 open label extension study for *Apretude*: New findings will be presented from the HPTN 084 trial that assess the impact of cabotegravir long-acting (LA) for PrEP exposure during pregnancy.[4,5] The study focuses on maternal, pregnancy, and infant safety outcomes among participants who became pregnant during the open label extension of HPTN 084 and continued with injections of cabotegravir LA for PrEP.

New pipeline data from ViiV Healthcare's third generation INSTI: Researchers will share phase I findings from the first-time-in-human study of VH184, a third-generation integrase inhibitor (INSTI), along with analysis showing potent activity *in vitro* against multiple INSTI resistant mutations.[6] This is the first data presentation of the company's next INSTI as a part of its ultra long-acting development strategy.

Real-world evidence from long-acting treatment regimen: Findings from several real-world studies of the complete long-acting HIV treatment regimen cabotegravir + rilpivirine long-acting (CAB+RPV LA) will be presented, including the perspectives of people living with HIV 12 months after switching their treatment regimen to CAB+RPV LA from the BEYOND study;[7,8] effectiveness, participant adherence to injections, and patient reported outcomes from the German cohort of the CARLOS study[9], and utilisation and effectiveness of CAB+RPV LA among virologically suppressed, treatment-experienced individuals from the COMBINE-2 study.[10]

Here is a list of ViiV Healthcare-sponsored or supported studies to be presented at AIDS 2024:

Title	First author	Presentation number	Presentation
Dolutegravir/3TC			
Non-inferior efficacy and less weight gain when switching to DTG/3TC than when switching to BIC/FTC/TAF in virologically suppressed people with	P. Ryan	OAB3606LB	Oral Date of presentation: Friday, 26 July Session time: 12:00-13:00 CEST

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HIV (PWH): the PASO DOBLE (GeSIDA 11720) randomized clinical trial			
PAIRED - Patient reported experiences and perceived benefit of treatment with dolutegravir/lamivudine - qualitative interviews: diverse group of people with HIV-1 (PWH) reflect on life and health	J. Slim	THPEB094	Poster Date of presentation: Thursday, 25 July Time of presentation: 12:00-13:00 CEST
Real-world effectiveness and tolerability of the 2-drug regimen dolutegravir and lamivudine (DTG/3TC) in people living with HIV: a systematic literature review and meta-analysis from clinical practice	J. Fraysse	TUPEB101	Poster Date of presentation: Tuesday, 23 July Time of presentation: 12:00-13:00 CEST
Effectiveness and durability of dolutegravir/lamivudine in older people with HIV from the Veterans Aging Cohort Study (VACS)	L. Yan	WEPEB111	Poster Date of presentation: Wednesday, 24 July Time of presentation: 12:00-13:00 CEST
Switch to dolutegravir/lamivudine (DTG/3TC) in people living with HIV-1 suppressed on bictegravir/ emtricitabine/ tenofovir alafenamide (B/F/TAF): 96-week final analysis from the SOUND study	J. Slim	THPEB092	Poster Date of presentation: Thursday, 25 July Time of presentation: 12:00-13:00 CEST
Efficacy, safety and tolerability of switching to dolutegravir/lamivudine in virologically suppressed adults living with HIV on bictegravir/ emtricitabine/tenofovir alafenamide - 48-week results from the DYAD study	C. Rolle	THPEB089	Poster Date of presentation: Thursday, 25 July Time of presentation: 12:00-13:00 CEST
Dolutegravir			
Viral suppression, viral failure and safety outcomes in children and adolescents on dolutegravir (DTG) in Europe and Thailand	K. Scott	OAB3803	Oral Session date: Friday, 26 July Session time: 13:30-14:30 CEST

Changes in body mass index in children and adolescents in Europe and Thailand before and after starting dolutegravir and compared to protease inhibitors using propensity scoring analysis	S. Crichton	TUPEB086	Poster Date of presentation: Tuesday, 23 July Time of presentation: 12:00-13:00 CEST
Prenatal dolutegravir-based regimen use, and pregnancy and birth outcomes: data from the Antiretroviral Pregnancy Registry	V. Vannappagari	TUPEB128	Poster Date of presentation: Tuesday, 23 July Time of presentation: 12:00-13:00 CEST
Effectiveness and durability of dolutegravir/ rilpivirine in older people with HIV from the Veterans Aging Cohort Study (VACS)	L. Yan	THPEB090	Poster Date of presentation: Thursday, 25 July Time of presentation: 12:00-13:00 CEST
Cabotegravir for treatment			
Subcutaneous injections of cabotegravir + rilpivirine in virally suppressed adults with HIV-1: a substudy of the phase 3 FLAIR study	R. D'Amico	OAB2604	Oral Session date: Thursday, 25 July 2024 Session time: 15:00-16:00 CEST
Clinical outcomes at month 12 after initiation of cabotegravir and rilpivirine long acting (CAB+RPV LA) in an observational real-world study (BEYOND)	S. Schneider	THPEB099	Poster Date of presentation: Thursday, 25 July Time of presentation: 12:00-13:00 CEST
Perspectives of people with HIV (PWH) 12 months following a switch to cabotegravir and rilpivirine long-acting (CAB+RPV LA) in an observational real-world US study (BEYOND)	W. Valenti	TUPEB116	Poster Date of presentation: Tuesday, 23 July Time of presentation: 12:00-13:00 CEST
12-Month outcomes of cabotegravir plus rilpivirine long-acting every 2	C. Jonsson-Oldenbüttel	TBUPEB095	Poster

months in a real-world setting: effectiveness, adherence to injections, and patient-reported outcomes from people with HIV-1 in the German CARLOS cohort			Date of presentation: Tuesday, 23 July Time of presentation: 12:00-13:00 CEST
Increased screening for sexually transmitted infections and HIV surrogate marker testing among long-acting injectable versus daily oral antiretroviral therapy users in the OPERA® cohort	P. C. Lackey	WEPEC319	Poster Date of presentation: Wednesday, 24 July Time of presentation: 12:00-13:00 CEST
Real-world utilization and effectiveness of long-acting cabotegravir + rilpivirine in virologically suppressed treatment experienced individuals in Europe: data from COMBINE-2 cohort study	A. Pozniak	TUPEC278	Poster Date of presentation: Tuesday, 23 July Time of presentation: 12:00-13:00 CEST
Re-thinking 'community' in the implementation of long-acting injectable cabotegravir and rilpivirine: qualitative findings from the ILANA study	R. Hayes	TUPEE529	Poster Date of presentation: Tuesday, 23 July Time of presentation: 12:00-13:00 CEST
Adherence through the prism of long-acting injectable therapy: qualitative findings from the ILANA implementation study	S. Paparini	TUPED306	Poster Date of presentation: Tuesday, 23 July Time of presentation: 12:00-13:00 CEST
"Closer to a cure:" mixed-methods analysis of reasons for switching to cabotegravir + rilpivirine	S. Paparini	WEPEE551	Poster Date of presentation: Wednesday, 24 July Time of presentation: 12:00-13:00 CEST
Cabotegravir for PrEP			
"The simplest way to go:" A mixed methods analysis of why women who	A. M. Roth	OAD07	Oral Session date: Tuesday, 23 July

inject drugs selected long-acting injectable cabotegravir instead of daily oral PrEP			Session time: 17:05-17:13 CEST
Knowledge, awareness, feasibility, and acceptability of long-acting cabotegravir for HIV prevention: results from the SEARCH Dynamic Choice HIV prevention trial	E. Kakande	OAE12	Oral Session date: Wednesday, 24 July Session time: 10:41-10:49 CEST
Location preferences for accessing long-acting injectable pre-exposure prophylaxis (LA-PrEP) among men who have sex with men (MSM) in the US currently using daily-oral PrEP	J. L. Glick	WEPEC269	Poster Date of presentation: Wednesday, 24 July Time of presentation: 12:00-13:00 CEST
HIV pre-exposure prophylaxis awareness, willingness, and use among transfeminine persons with high likelihood of HIV in the United States: recent results from the Transgender Women's Internet Survey and Testing (TWIST)	D. I. Yaras	THPEC186	Poster Date of presentation: Thursday, 25 July Time of presentation: 12:00-13:00 CEST
Preference for long-acting HIV prevention methods among transgender women at greatest risk for HIV acquisition in eastern and southern United States: findings from the LITE cohort	E. E. Cooney	THPED410	Poster Date of presentation: Thursday, 25 July Time of presentation: 12:00-13:00 CEST
Influencers and decision-making factors for choosing injectable PrEP among men who have sex with men and transgender men in the United States	D. Dandachi	THPEE504	Poster Date of presentation: Thursday, 25 July Time of presentation: 12:00-13:00 CEST
Need for increased HIV testing prior to and during pre-exposure prophylaxis with cabotegravir long-acting injections in routine clinical care in the United States	R. K. Hsu	WEPEB046	Poster Date of presentation: Wednesday, 24 July

			Time of presentation: 12:00-13:00 CEST
Pre-exposure prophylaxis (PrEP) product choice of participants in HPTN 083	M. E. Clement	TUPEC184	Poster Date of presentation: Tuesday, 23 July Time of presentation: 12:00-13:00 CEST
"Everyone should have access to it": Perspectives on PrEP product choice and implementation from MSM and TGW in an injectable PrEP trial	C. Psaros	WEPEC206	Poster Date of presentation: Wednesday, 24 July Time of presentation: 12:00-13:00 CEST
Pipeline			
Phase 1 study of VH4524184 (VH-184), a new third-generation integrase strand transfer inhibitor (INSTI) with a unique resistance profile	L. Rogg	OAB26	Oral Session date: Thursday, 25 July Session time: 15:00-16:00 CEST
Preclinical assessments of a cabotegravir prodrug predicting human dosing durations of >6 months	M. Baker	WEPEA028	Poster Date of presentation: Wednesday, 24 July Time of presentation: 12:00-13:00 CEST
Pre-clinical profiles of HIV-1 capsid inhibitors VH4004280 (VH-280) and VH4011499 (VH-499)	C. Wang	WEPEA027	Poster Date of presentation: Wednesday, 24 July Time of presentation: 12:00-13:00 CEST
Clinical pharmacokinetics and safety of orally administered VH4004280 (VH-280), a novel HIV-1 capsid inhibitor, in healthy volunteers	R. Griesel	THPEB093	Poster Date of presentation: Thursday, 25 July Time of presentation: 12:00-13:00 CEST

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Clinical pharmacokinetics and safety of orally administered VH4011499 (VH-499), a novel HIV-1 capsid inhibitor, in healthy volunteers	N. Thakkar	WEPEB105	Poster Date of presentation: Wednesday, 24 July Time of presentation: 12:00-13:00 CEST
Above Brand			
Detailed modelling of viremia exposure does not independently predict cardiovascular disease in people with HIV	O. Elvstam	OAB34	Oral Session date: Friday, 26 July 2024 Session time: 10:30-11:30 CEST

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*.

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.

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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

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 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.

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About SEIMC-GeSIDA Foundation (FSG)

The SEIMC-GeSIDA Foundation (FSG) was founded by the Spanish Society of Clinical Microbiology and Infectious Diseases as a tool to promote high-quality investigation in the field of HIV infection and other infectious diseases. The Foundation is composed of qualified professionals with experience in the field of clinical trials and multicentre studies. Its streamlined infrastructure facilitates performance of clinical studies and responds to the needs of investigators in terms of methodology/statistical analysis and of logistics and management of trials and other multicentre studies. For more information on the SEIMC-GeSIDA Foundation (FSG), please visit https://fundacionseimcgesida.org/en/quienes-somos/

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 Q1 Results for 2024.

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References

[1] P. Ryan, et al. Non-inferior efficacy and less weight gain when switching to DTG/3TC than when switching to BIC/FTC/TAF in virologically suppressed people with HIV (PWH): the PASODOBLE (GeSIDA 11720) randomized clinical trial. Presented at the 25th International AIDS Conference. July 2024.

[2] C.P. Rolle, et al. Efficacy, safety and tolerability of switching to dolutegravir/lamivudine in virologically suppressed adults living with HIV on bictegravir/emtricitabine/tenofovir alafenamide - 48-week results from the DYAD study. Presented at the 25th International AIDS Conference. July 2024.

[3] J. Slim, et al. Switch to dolutegravir/lamivudine (DTG/3TC) in people living with HIV-1 suppressed on bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF): 96-week final analysis from the SOUND study. Presented at the 25th International AIDS Conference. July 2024.

[4] S. Delany-Moretlwe, et al. Initial evaluation of CAB-LA Safety during pregnancy in the HPTN 084 open-label extension. Presented at the 25th International AIDS Conference. July 2024.

[5] M. Marzinke, et al. Evaluation of Long-Acting Cabotegravir (CAB-LA) Pharmacokinetics During Pregnancy: A Sub-Study Analysis of the HPTN 084 Open Label Extension. Presented at the 25th International AIDS Conference. July 2024.

[6] L. Rogg, et al. Phase 1 study of VH4524184 (VH-184), a new third-generation integrase strand transfer inhibitor (INSTI) with a unique resistance profile. Presented at the 25th International AIDS Conference. July 2024.

[7] S. Schneider, et al. Clinical outcomes at Month 12 after initiation of cabotegravir and rilpivirine long acting (CAB+RPV LA) in an observational real-world study (BEYOND). Presented at the 25th International AIDS Conference. July 2024.

[8] W. Valenti, et al. Perspectives of people with HIV (PWH) 12 months following a switch to cabotegravir and rilpivirine long-acting (CAB+RPV LA) in an observational real-world US study (BEYOND). Presented at the 25th International AIDS Conference. July 2024.

[9] CJ. Oldenbüttel, et al. 12-Month outcomes of cabotegravir plus rilpivirine long-acting every 2 months in a real-world setting: effectiveness, adherence to injections, and patient-reported outcomes from people with HIV-1 in the German CARLOS cohort. Presented at the 25th International AIDS Conference. July 2024.

[10] A. Pozniak, et al. Real-world utilization and effectiveness of long-acting cabotegravir + rilpivirine in virologically suppressed treatment experienced individuals in Europe: data from COMBINE-2 cohort study. Presented at the 25th International AIDS Conference. July 2024.