Press release

For media and investors only

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ViiV Healthcare to present 23 abstracts from innovative HIV treatment and prevention portfolio at EACS 2023

- Key data to be presented include long-term and real-world data from ViiV Healthcare's portfolio of medicines, including long-acting and 2-drug regimens.

GSK plc (LSE/NYSE: GSK) announced that ViiV Healthcare, the global specialist HIV company majority owned by GSK, with Pfizer and Shionogi as shareholders, today announced the presentation of key abstracts highlighting the breadth of its approved and investigational medicines at the 19th Annual European AIDS Conference (EACS 2023) being held in Warsaw, Poland from 18-21 October 2023.

Kimberly Smith, M.D., MPH, Head of Research & Development at ViiV Healthcare said: "Living well with HIV looks different for every individual, and we believe our upcoming presentations at EACS 2023 reflect our commitment and leadership to address the evolving needs of the HIV community. Our latest data from our diverse portfolio and innovative pipeline explore real-world evidence that further evaluate the effectiveness, safety, and tolerability of 2-drug and long-acting regimens; new findings for broadly neutralizing antibodies; and long-term follow-up in heavily treatment-experienced individuals. We look forward to sharing these new insights with the scientific and HIV communities at EACS 2023."

Key data to be presented at EACS 2023 by ViiV Healthcare will include:

Strengthening clinical and real-world evidence (RWE) across our treatment portfolio: New real-world findings for the long-acting regimen of *Vocabria* (cabotegravir injection) and *Rekambys* (rilpivirine long-acting injectable suspension) (CAB+RPV LA) in clinical settings across Europe will be presented at EACS. ViiV Healthcare will share 12-month European findings from the SOLAR study, the first head-to-head, phase IIIb study of the complete long-acting injectable regimen of CAB+RPV LA compared with daily oral *Biktarvy* (bictegravir/emtricitabine/ tenofovir alafenamide [BIC/FTC/TAF]).[1]

Findings for the 2-drug regimen, *Dovato* (dolutegravir, lamivudine [DTG/3TC]), will include three-year effectiveness, safety, and tolerability outcomes among people living with HIV in a real-world German cohort and data from a large observational cohort across Europe.[2,3] Additional data to be presented will include a review of real-world experience of DTG/3TC in people living with HIV over the age of 50, as well as in treatment-naïve people with a low CD4+ cell count or high viral load at baseline.[4]

Long-term data in heavily treatment-experienced (HTE) populations: Long-term, five-year data from the phase III BRIGHTE clinical trial, which studied the use of *Rukobia* (fostemsavir) in heavily-treatment experienced populations with multi-drug resistant HIV-1, will be presented. New data will report on long-term safety and the impact of immune recovery in adults receiving fostemsavir, along with fostemsavir's impact on immune and inflammation-related biomarkers in these patients.[5,6]

Advancing new mechanisms of action in HIV research: New phase IIa, proof of concept study findings will be presented from the BANNER study of N6LS (VH3810109), a novel, investigational, broadly neutralizing antibody (bNAb). Safety and tolerability findings following a single IV infusion of subcutaneous injection will be shared.[7] N6LS is a component of the company's ultra-long-acting medicine development strategy, specifically being investigated for dosing intervals of at least every four months.

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Here is a list of ViiV Healthcare-sponsored or supported studies being presented at EACS 2023:

Title	First Author	Presentation Number	Presentation
Dolutegravir			
3-year outcomes for dolutegravir (DTG) + lamivudine (3TC) in ART-naive and pre-treated people living with HIV-1 (PLHIV) in Germany: real-world data from the German URBAN cohort	S. Noe	eP.A.072	ePoster
Systematic literature review of real-world experience with the 2-drug regimen dolutegravir + lamivudine (DTG + 3TC) in people with HIV-1 (PWH) aged ≥50 years	E. Letang	eP.A.048	ePoster
Real-world effectiveness of dolutegravir + lamivudine (DTG + 3TC) in treatment-naive people with HIV-1 (PWH) and low CD4+ cell count or high viral load at baseline: a systematic literature review	E. Letang	eP.A.050	ePoster
No relevant difference in incident hypertension observed by gender, race, baseline BMI, or other key subgroups through Week 96 among people living with HIV-1 (PLWH) receiving dolutegravir (DTG)-based regimens or comparator antiretroviral therapy (cART) in pooled randomized clinical trials	P. Patel	eP.A.103	ePoster
CARAVEL: evaluation of real-world antiviral effectiveness and sustainability of the 2-drug regimen dolutegravir/lamivudine fixed dose combination (FDC) in treatment-naive adults and pre-treated adults who are virologically suppressed, in routine clinical care, in France: one-year interim analysis results	P. Philibert	eP.A.014	ePoster
Pregnancy and neonatal outcomes following prenatal exposure to dolutegravir: the DOLOMITE-EPPICC study	C. Thorne	PS5.O4	Oral in parallel session Thursday, October 19 14:50 - 14:55 GMT
Dolutegravir + lamivudine 2-drug regimen is highly effective and well-tolerated in a real-world clinical setting in Europe: data from the COMBINE-2 study	C. Mussini	eP.A.049	ePoster
Cabotegravir for Treatment			
SOLAR 12-month European results: randomized switch trial of CAB+RPV LA vs. oral BIC/FTC/TAF	I. De Los Santos Gil	eP.A.105	ePoster
Efficacy, safety, and implementation outcomes of cabotegravir + rilpivirine long-	C. J. Oldenbüttel	eP.A.101	ePoster

acting by country in the Cabotegravir And Rilpivirine Implementation Study in European Locations (CARISEL)			
Cabotegravir + rilpivirine long-acting efficacy and safety outcomes by sex at birth, age, and race: a subgroup analysis of the CARISEL study	J. Ghosn	eP.A.100	ePoster
Real-world effectiveness of cabotegravir + rilpivirine in virologically suppressed treatment experienced individuals in Europe: data from COMBINE-2 study	A. Pozniak	eP.A.039	ePoster
Cabotegravir for PrEP			
Drivers of discontinuation of oral PrEP within Europe: findings from a real-world survey of PrEP use	M. Schroeder	eP.C2.021	ePoster
Fostemsavir			
Early and durable reductions in soluble CD14 concentrations among treatment-experienced persons with HIV-1 through 96 weeks of fostemsavir treatment in a phase 2b clinical trial	E. R. Wonderlich	RA1.O4	Rapid abstract presentation Friday, October 20 12:15 - 13:15 GMT
Long-term safety and impact of immune recovery in heavily treatment-experienced adults receiving fostemsavir for up to 5 years in the BRIGHTE study	J. M. Llibre	eP.A.093	ePoster
Sustained improvements in biomarkers observed with fostemsavir in heavily treatment-experienced adults with multidrug-resistant HIV-1 from the phase 3 BRIGHTE study through Week 240	A. Castagna	eP.A.092	ePoster
Fostemsavir use in the OPERA cohort: immunologic and virologic response	R. K. Hsu	eP.A.068	ePoster
Pipeline: Maturation Inhibitor GSK3640254			
Efficacy and safety of the HIV-1 maturation inhibitor GSK3640254 + 2 NRTIs in treatment-naive adults: 24-week results from the phase IIb, dose-range finding DOMINO study	S. R. Joshi	RA2.O1	Rapid abstract presentation Friday, October 20 12:15 - 13:15 GMT
Efficacy and safety of the HIV-1 maturation inhibitor GSK3640254 + dolutegravir as a 2-drug regimen in treatment-naive adults: 24-week results from the phase IIb DYNAMIC study	S. R. Joshi	RA2.O2	Rapis abstract presentation Friday, October 20 12:15 - 13:15 GMT

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Pipeline: VH3810109 (N6LS)			
Safety and tolerability of VH3810109 (N6LS) among antiretroviral therapy–naive adults living with HIV-1: results from the monotherapy phase of the phase IIa BANNER study	P. Leone	PS8.O5	Oral parallel session Friday, October 20 10:45 - 11:45 GMT
Pharmacokinetics/ Pharmacodynamics and virological activity of VH3810109 (N6LS) in antiretroviral-naive viremic adults from the phase IIa BANNER study	A. Y. Edwards	eP.A.099	ePoster
General HIV			
Drivers of satisfaction and health-related quality of life of people living with HIV within Europe: findings from a real-world survey of people living with HIV	P. O'Brien	MtE3.O1	Oral meet-the-expert Thursday, October 19 07:30 - 08:30 GMT
Patients' fears and expectations related to HIV infection and its treatment in Poland: a Positive Perspective 2 (PP2) substudy	M. Moskwa	eP.C3.010	ePoster
Modifiable risk factors and their population attributable fractions for TB in people with HIV across Europe	C. Kraef	OS2.O5	Oral presentation Friday, October 20 10:45 - 11:45 GMT

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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: ema.europa.eu/en/medicines/human/EPAR/dovato

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: https://www.ema.europa.eu/en/medicines/human/EPAR/vocabria

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: https://www.ema.europa.eu/en/medicines/human/EPAR/rekambys

About *Rukobia*

Rukobia, in combination with other antiretrovirals, is indicated for the treatment of adults with multidrug resistant HIV-1 infection for whom it is otherwise not possible to construct a suppressive anti-viral regimen. Recommended dose is 600mg fostemsavir twice daily.

Please consult the full Summary of Product Characteristics for all the safety information: https://www.ema.europa.eu/en/medicines/human/EPAR/rukobia

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: https://www.ema.europa.eu/en/medicines/human/EPAR/apretude

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 the company's Annual Report on Form 20-F for 2022, and Q2 Results for 2023 and any impacts of the COVID-19 pandemic.

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References

[1] De Los Santos Gil I, *et al.* SOLAR 12-month European results: randomized switch trial of CAB+RPV LA vs. oral BIC/FTC/TAF. Presented at European AIDS Society Conference (EACS). October 2023.
[2] Noe S, *et al.* 3-year outcomes for dolutegravir (DTG) + lamivudine (3TC) in ART-naive and pre-treated people living with HIV-1 (PLHIV) in Germany: real-world data from the German URBAN cohort. Presented at European AIDS Society Conference (EACS). October 2023.
[3] Mussini C, *et al.* Dolutegravir + lamivudine 2-drug regimen is highly effective and well-tolerated in a real-world clinical setting in Europe: data from the COMBINE-2 Study. Presented at European AIDS Society Conference (EACS). October 2023.
[4] Letang E, *et al.* Systematic literature review of real-world experience with the 2-drug regimen dolutegravir + lamivudine (DTG + 3TC) in people with HIV-1 (PWH) aged ≥50 years. Presented at European AIDS Society Conference (EACS). October 2023.
[5] Libre J, *et al.* Long-term safety and impact of immune recovery in heavily treatment-experienced adults receiving fostemsavir for up to 5 years in the BRIGHTE study. Presented at European AIDS Society Conference (EACS). October 2023.
[6] Castagna A, *et al*. Sustained improvements in biomarkers observed with fostemsavir in heavily treatment-experienced adults with multidrug-resistant HIV-1 from the phase 3 BRIGHTE study through Week 240. Presented at European AIDS Society Conference (EACS). October 2023.
[7] Leone P, *et al.* VH3810109 (N6LS) Was Safe and Well Tolerated Among Antiretroviral Therapy-Naïve Adults Living with HIV-1: Results from the Phase IIa BANNER Study. Presented at European AIDS Society Conference (EACS). October 2023.