Press release

For media and investors only

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ViiV Healthcare announces positive data demonstrating 2-drug regimen *Dovato* is as effective as 3-drug regimen *Biktarvy* for maintenance therapy of HIV-1

- Largest head-to-head randomised clinical trial between DTG/3TC and BIC/FTC/TAF, conducted by SEIMC-GeSIDA Foundation (FSG) showed DTG/3TC demonstrated non-inferior efficacy compared to BIC/FTC/TAF as a switch regimen for virologically-suppressed adults living with HIV over 48 weeks of therapy
- DTG/3TC-treated individuals had significantly less weight gain compared to those randomised to BIC/FTC/TAF

GSK plc (LSE/NYSE: GSK) announced that ViiV Healthcare, the global specialist HIV company majority owned by GSK, with Pfizer and Shionogi as shareholders, has shared 48-week findings from the PASO DOBLE (GeSIDA 11720) study, the largest head-to-head, phase IV randomised clinical trial (RCT) investigating the 2-drug regimen *Dovato* (dolutegravir/lamivudine [DTG/3TC]) compared to the 3-drug regimen *Biktarvy* (bictegravir/emtricitabine/tenofovir alafenamide fumarate [BIC/FTC/TAF]) for the treatment of HIV-1 in people who are virologically suppressed and who could benefit from treatment optimisation.

Findings showed that switching to DTG/3TC in virologically suppressed adults living with HIV demonstrated non-inferior efficacy in maintaining viral suppression compared with switching to BIC/FTC/TAF.[1] These data will be presented at the 25th International AIDS Conference (AIDS 2024), held in Munich, Germany (22-26 July).

Harmony P. Garges, M.D., MPH, Chief Medical Officer at ViiV Healthcare, said: "The results from PASO DOBLE show that *Dovato* demonstrated non-inferior efficacy compared to *Biktarvy*, and that the average weight gain for trial participants taking DTG/3TC was significantly lower than those taking BIC/FTC/FTC over the course of the year. This is a meaningful outcome, as treatment-related weight gain is an important topic for many people living with HIV. At ViiV Healthcare we're dedicated to bringing innovative HIV treatments to people living with HIV that are not only safe and effective, but also address their specific needs beyond viral suppression."

In the PASO DOBLE clinical trial, 553 people living with HIV and virally suppressed switched treatment to either DTG/3TC (n=277) or BIC/FTC/TAF (n=276). The study population included individuals who were on therapy that could be optimised, such as multiple tablet regimens, or those containing pharmacokinetic boosting agents or drugs with cumulative toxicity, such as efavirenz or tenofovir disoproxil fumarate (TDF). The study met its primary endpoint when DTG/3TC demonstrated non-inferior efficacy versus BIC/FTC/TAF based on the proportion of participants with viral RNA ≥50 copies/mL at 48 weeks using the FDA snapshot and a 4% non-inferiority margin in the exposed intention-to-treat population.

At 48 weeks, DTG/3TC was non-inferior to BIC/FTC/TAF (risk difference between DTG/3TC [2.2%] minus BIC/FTC/TAF [0.7%] of 1.4%, 95% CI -0.5 to 3.4). One participant in the BIC/FTC/TAF arm and zero in the DTG/3TC arm had protocol-defined confirmed virological failure through week 48 (HIV-1 RNA ≥50 c/mL followed by a second consecutive HIV-1 RNA assessment ≥200 c/mL).

The study found in a key secondary endpoint that weight increased significantly more in participants who switched to BIC/FTC/TAF (adjusted mean change 1.81kg, 95% CI 1.28-2.34) than in those who switched to DTG/3TC (adjusted mean change 0.89kg, 95% CI 0.37-1.41) [difference 0.92kg, 95% CI 0.17-1.66] through week 48. Equally, the proportion of participants with weight gain greater than 5% at week 48 was significantly higher at 29.9% for BIC/FTC/TAF compared to 20% for DTG/3TC (adjusted OR 1.81, 95% CI 1.19-2.76).

Weight change with DTG/3TC did not differ between men and women or based on the previous regimen of participants, whereas the proportion of trial participants experiencing greater than 5% weight gain with BIC/FTC/TAF was approximately 45% higher than those taking DTG/3TC when switching from a regimen with abacavir (30.6% BIC/FTC/TAF vs 21.1% DTG/3TC), and about 2-fold higher when switching from a regimen with TDF (40.7% BIC/FTC/TAF vs 19.5% DTG/3TC). Safety was comparable through week 48 and consistent with known safety profiles. There were few discontinuations due to adverse events in both study arms (DTG/3TC = 1, 0.4%; BIC/FTC/TAF = 2, 0.7%), with no differences between arms.[1]

Esteban Martínez, MD, PhD, Chief Executive Investigator of the PASO DOBLE study and Senior Consultant in Infectious Diseases at Hospital Clínic of Barcelona, Spain said: "The HIV treatment regimens that are commonly prescribed today are all highly effective, which makes it critical that we study the impact of these therapies beyond just viral suppression. The results from PASO DOBLE show *Dovato*, a 2-drug regimen, not just demonstrated the same efficacy as a 3-drug regimen, but also showed less weight gain compared to BIC/FTC/TAF through 48 weeks."

About PASO DOBLE
The PASO DOBLE (NCT04884139) randomised clinical trial is a phase IV, open-label, randomised multicentre clinical trial evaluating the efficacy of DTG/3TC versus BIC/FTC/TAF for the maintenance of virologic suppression in people living with HIV-1, conducted in 30 sites across Spain. Virologically suppressed people living with HIV on regimens containing ≥1 pill/day, boosters, or drugs with cumulative toxicity such as efavirenz or TDF were eligible and were randomised (1:1) to switch to either DTG/3TC or BIC/FTC/TAF. The primary endpoint was the proportion of people living with HIV with RNA ≥50 copies/mL at 48 weeks (FDA snapshot, 4% non-inferiority margin) in the intention-to-treat exposed population. Secondary outcomes measured included, among others, absolute weight gain, BMI change, and the proportion of participants with weight change greater than 5%.

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*.

Dovato is approved in the US, Europe, Japan, Australia, and other countries worldwide.

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

About SEIMC-GeSIDA Foundation (FSG)
The SEIMC-GeSIDA Foundation (FSG) was created to encourage, promote, and support scientific and technical research and development, training, and publication of findings in the field of clinical microbiology and infectious diseases and associated conditions. FSG was founded by investigators from 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 also aims to respond to the scientific concerns of the group's members. FSG 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. We also provide staff to run events such as scientific meetings and conferences (national and international) and to organize courses, lectures, talks, seminars, round-table talks, and specialized workshops. For more information on the FSG, please visit https://fundacionseimcgesida.org/en/quienes-somos/

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.

GSK enquiries:

Media:	Tim Foley	+44 (0) 20 8047 5502	(London)
	Sarah Clements	+44 (0) 20 8047 5502	(London)
	Kathleen Quinn	+1 202 603 5003	(Washington DC)
	Alison Hunt	+1 540 742 3391	(Washington DC)
Investor relations:	Nick Stone	+44 (0) 7717 618834	(London)
	James Dodwell	+44 (0) 20 8047 2406	(London)
	Mick Readey	+44 (0) 7990 339653	(London)
	Josh Williams	+44 (0) 7385 415719	(London)
	Camilla Campbell	+44 (0) 7803 050238	(London)
	Steph Mountifield	+44 (0) 7796 707505	(London)
	Jeff McLaughlin	+1 215 751 7002	(Philadelphia)
	Frannie DeFranco	+1 215 751 4855	(Philadelphia)

FSG enquiries:

Media:	Tomas Muriel	+34 605 603 382	(Spain)
	Manuela Hernández	+34 651 867 278	(Spain)

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.

Registered in England & Wales:
GSK plc
No. 3888792

ViiV Healthcare Limited
No. 06876960

Registered Office:
GSK plc
980 Great West Road
Brentford, Middlesex
United Kingdom
TW8 9GS

ViiV Healthcare Limited
GSK Medicines Research Centre
Gunnels Wood Road, Stevenage
United Kingdom
SG1 2NY

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) randomised clinical trial. Presented at the 25th International AIDS Conference. July 2024