Press release

For media and investors only

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ViiV Healthcare's 2-drug regimen *Dovato* is as effective as 3-drug regimen *Biktarvy* in first-of-its-kind head-to-head study in treatment-naïve adults living with HIV

- Positive Week 48 data from the phase IIIb VOGUE study reinforce *Dovato* as an effective treatment option with fewer medicines than *Biktarvy*, across diverse populations
- Findings build on 10 years of evidence supporting DTG/3TC as the first and only oral 2-drug regimen for treatment-naïve people living with HIV

GSK plc (LSE/NYSE: GSK) announced that ViiV Healthcare, the global specialist HIV company majority owned by GSK, with Shionogi as a shareholder, today announced data to be presented this week at the 26th International AIDS Conference (AIDS 2026) in Rio de Janeiro, Brazil, from the phase IIIb VOGUE study. Data show that *Dovato* (dolutegravir/lamivudine (DTG/3TC)) demonstrated non-inferior efficacy to *Biktarvy* (bictegravir/emtricitabine/tenofovir alafenamide (BIC/FTC/TAF)) in treatment-naïve adults living with HIV, including people with high viral loads or a low CD4+ cell count.[1] The findings also reinforced DTG/3TC's high barrier to resistance, with zero cases of treatment-emergent resistance identified across treatment arms.

Jean van Wyk, MBChB, MFPM, Chief Medical Officer at ViiV Healthcare, said: "HIV treatment is lifelong, so the number of medicines people take over decades of care can matter. As the first randomised, head-to-head study comparing DTG/3TC with BIC/FTC/TAF in treatment-naïve adults living with HIV, VOGUE adds to 10 years of real-world evidence showing that people starting treatment can successfully manage their HIV with fewer daily drugs. The data demonstrate that from day one, we can potentially reduce the number of antiretroviral drugs a person receives with DTG/3TC, without compromising on efficacy or the barrier to resistance."

The ongoing multi-country, open-label, phase IIIb VOGUE study randomised 509 treatment-naïve adults living with HIV-1 to receive either DTG/3TC (n=254) or BIC/FTC/TAF (n=255), and treatment was initiated before the availability of baseline resistance testing results. At baseline, 47% of participants had a viral load ≥100,000 copies/mL, 16% had viral load ≥500,000 copies/mL and 16% had a CD4+ cell count <200 cells/mm^3.

At Week 48, virologic suppression (HIV-1 RNA <50 copies/mL) was achieved in 89% (n=226/254) of participants receiving DTG/3TC compared with 92% (n=235/255) receiving BIC/FTC/TAF (adjusted difference: -3%, 95% confidence interval [-8%, 2%]), meeting the study's non-inferiority endpoint. Median time to viral suppression was rapid and similar in both groups (4.1 weeks). No treatment-emergent resistance was identified in either arm.

The overall safety profiles for both treatment groups were comparable, with no new safety signals observed. A similar number of participants in each group (n=7 for DTG/3TC; n=7 for BIC/FTC/TAF) stopped treatment due to not achieving or maintaining viral suppression.

About *Dovato* (dolutegravir and lamivudine)

Dovato is indicated for the treatment of 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 known or suspected resistance to the integrase inhibitor class, or lamivudine.

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 with GSK (LSE: GSK) and Shionogi as current shareholders. The company is dedicated to delivering advances in treatment and care for people living with HIV and for people who could benefit from HIV prevention. ViiV Healthcare'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 www.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 2025, and GSK's Q1 Results for 2026.

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References

[1] J. Ghosn et al. In VOGUE: DTG/3TC 2-drug regimen is non-inferior to BIC/FTC/TAF 3-drug regimen in a randomized trial in adults with HIV naive to treatment. Presented at the 26th International AIDS Conference (AIDS 2026). July 2026.