Press Release
For media and investors only

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ViiV Healthcare aims to close treatment gaps for children living with HIV with paediatric *Dovato* marketing applications to the EMA and FDA

- ***Dovato (dolutegravir/lamivudine (DTG/3TC)) applications seek to introduce a new dispersible tablet formulation for younger children, and to extend use into lower weight bands***
- ***Only 55% of children living with HIV receive life-saving antiretroviral therapy versus 78% of adults; and children continue to have fewer modern, age-appropriate treatment options***

London, 11 May 2026 – ViiV Healthcare, the global specialist HIV company majority owned by GSK, with Shionogi as a shareholder, today announced that the European Medicines Agency (EMA) has validated the company's marketing application seeking approval to extend the use of *Dovato* (dolutegravir/lamivudine (DTG/3TC)) to younger age groups. A New Drug Application was also submitted to the U.S. Food and Drug Administration (FDA) as part of ViiV Healthcare's commitment to help address longstanding gaps in HIV treatment options for children living with HIV.

An estimated 620,000 of the 1.4 million children living with HIV were not receiving antiretroviral therapy (ART) in 2024.[1] Paediatric treatment options remain limited, and younger children lack child-friendly formulations, underscoring the need for age-appropriate options.[2]

The applications include a new dispersible tablet formulation for children aged ≥3 months and weighing ≥6 kg to <25kg and an extension of the film-coated tablet indication to paediatric patients weighing at least 20 kg. If approved, this 2-drug regimen could help reduce cumulative drug exposure for children who face decades of continuous ART.

Jean van Wyk, MBChB, MFPM, Chief Medical Officer at ViiV Healthcare, said: "Addressing the needs of children living with HIV has long been a priority for ViiV Healthcare, and follows our commitments to the Rome Action Plan for this highly vulnerable group. We are dedicated to bringing innovation to children, building on our belief that INSTI-based regimens are central to advancing age-appropriate treatment options from the earliest stages of life. The EMA and FDA applications reflect our leadership in paediatric HIV, desire to offer a treatment portfolio for the entire lifespan, and our determination to leave no person living with HIV behind."

Data supporting these applications are from ViiV Healthcare's paediatric DTG/3TC development programme, including paediatric/adult bridging data and pharmacokinetic (PK) data from the D3/Penta-21 study, sponsored by the PENTA Foundation with support from ViiV Healthcare. Together, these data highlight the need for simplified regimens that could help reduce lifetime cumulative drug exposure for children.

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About *Dovato*
Dovato is indicated for the treatment of Human Immunodeficiency Virus type 1 (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 Prescribing Information **here**.

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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 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.

Registered in England & Wales:

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References

[1] 2025 Global AIDS Update (UNAIDS). AIDS, Crisis and the Power to Transform. Available at: https://www.unaids.org/sites/default/files/2025-07/2025-global-aids-update-JC3153_en.pdf Last accessed: May 2026.

[2] World Health Organization (WHO). HIV treatment and care in children and adolescents. Available at: https://www.who.int/teams/global-hiv-hepatitis-and-stis-programmes/hiv/treatment/treatment-and-care-in-children-and-adolescents Last accessed: May 2026.