Press Release

For media and investors only

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U.S. FDA approves ViiV Healthcare's *Tivicay* PD, helping close a critical HIV treatment gap for young children

- ***Approval makes Tivicay PD the first second-generation integrase inhibitor approved for children living with HIV weighing at least 2 kg, including eligible newborns***

London, 26 August 2026 – ViiV Healthcare, the global specialist HIV company majority owned by GSK, with Shionogi as a shareholder, today announced that the U.S. Food and Drug Administration (FDA) has approved *Tivicay* PD (dolutegravir (DTG)), for use in combination with other antiretroviral agents for the treatment of HIV-1 infection in paediatric patients (treatment-naïve or -experienced but integrase strand transfer inhibitor (INSTI)-naïve) weighing at least 2 kg.

Diana F. Clarke, Pharm.D., Assistant Professor of Paediatrics, Boston University School of Medicine and Lead Investigator of the IMPAACT 2023 study, said: "For too long, newborns living with HIV have had too few treatment options designed and studied to meet their unique needs, despite the importance of starting treatment as early as possible. With the approval of a *Tivicay* PD dosing regimen, babies born at term and weighing at least 2 kg will now have access to dolutegravir-based therapy starting at birth. This represents an important advance for the care of newborns, as early treatment with the most effective therapies results in the best possible outcomes."

Without early diagnosis and treatment, HIV can progress rapidly in infants, with around 50% of untreated infants with HIV dying by age two.[1] The urgent need for effective treatment options underscores the importance of broadening access to modern, age-appropriate HIV medicines for this vulnerable group, and this expanded indication builds on ViiV Healthcare's broader efforts to provide HIV treatment options across the paediatric treatment journey.

Jean van Wyk, MBChB, MFPM, Chief Medical Officer at ViiV Healthcare, said: "Today's approval of *Tivicay* PD expands the options available for paediatric HIV care, giving families and clinicians in the U.S. greater choice from the very beginning of life. For ViiV Healthcare, it reflects our commitment to bringing INSTI-based innovation to children and addressing persistent gaps in HIV care. This progress has been made possible through vital collaboration with the HIV community, united by a shared focus on ensuring children living with HIV are not left behind."

The FDA approval follows Priority Review for this population and is supported by data from the National Institutes of Health (NIH)-funded IMPAACT 2023 study and pharmacokinetic (PK) modelling incorporating additional paediatric data. These data showed that DTG, a second-generation INSTI with a higher barrier to resistance than previous generations, reached therapeutic drug levels in term neonates with a safety profile consistent with that established in older paediatric and adult populations.

About *Tivicay* and *Tivicay* PD

Tivicay and *Tivicay* PD contain dolutegravir, an INSTI for use in combination with other antiretroviral agents for the treatment of HIV. Integrase inhibitors inhibit HIV integrase by binding to the integrase active site and blocking the strand transfer step of retroviral deoxyribonucleic acid (DNA) integration which is essential for the HIV replication cycle.

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Please consult the full Prescribing Information **here**.

About IMPAACT
The International Maternal Pediatric Adolescent AIDS Clinical Trials (IMPAACT) Network is a global collaboration of investigators, institutions, community representatives, and other partners with a mission to improve health outcomes in infancy, childhood, adolescence, pregnancy, and postpartum among those who are impacted by or living with HIV, tuberculosis, and other related complications through the conduct of high-quality clinical trials. IMPAACT's vision and overall goal is to end the worldwide HIV epidemic among these populations. To achieve this goal, the IMPAACT Network evaluates novel and durable treatments for HIV, TB, and related diseases and conditions, strategies for antiretroviral treatment (ART)-free remission, and strategies to prevent and manage neuropsychological and mental health complications of HIV and its treatment. Overall support and funding for IMPAACT is provided by the National Institute of Allergy and Infectious Diseases (NIAID), with support and co-funding from the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) and the National Institute of Mental Health (NIMH), all components of the United States National Institutes of Health (NIH). The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH. For more information, please visit: www.impaactnetwork.org.

About the National Institutes of Health (NIH)
NIH, the nation's medical research agency, includes 27 Institutes and Centers and is a component of the U.S. Department of Health and Human Services. NIH is the primary federal agency conducting and supporting basic, clinical, and translational medical research, and is investigating the causes, treatments, and cures for both common and rare diseases. For more information about NIH and its programs, visit: www.nih.gov.

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.

ViiV Healthcare enquiries:

Media:	Kate Senter	+44 (0) 77 9670 7446	(London)
	Melinda Stubbee	+1 919 491 0831	(North Carolina)

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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:	Constantin Fest	+44 (0) 7831 826525	(London)
	Joanna Tuplin	+44 (0) 7788 351650	(London)
	James Dodwell	+44 (0) 7881 269066	(London)
	Mick Readey	+44 (0) 7990 339653	(London)
	Sam Piper	+44 (0) 7824 525779	(London)
	Dan Smith	+44 (0) 7823 523885	(London)
	Jeff McLaughlin	+1 215 751 7002	(Philadelphia)
	Frannie DeFranco	+1 215 751 3126	(Philadelphia)

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 Q2 Results for 2026.

Registered in England & Wales:

GSK plc	ViiV Healthcare Limited
No. 3888792	No. 06876960

Registered Office:

79 New Oxford Street	ViiV Healthcare Limited
London	GSK Medicines Research Centre
WC1A 1DG	Gunnels Wood Road, Stevenage
	United Kingdom
	SG1 2NY

References

[1] UNICEF and UNAIDS. The Cost of Inaction: Children and Adolescents Living with HIV in Eastern and Southern Africa. Available at: https://www.childrenandaids.org/media/6096/file/UNICEF_UNAIDS_CostofInaction_HIV_Final.pdf. Last accessed August 2026.