Stock-exchange announcement
For media and investors only

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Jideytro (zidesamtinib) approved in the US for previously treated ROS1-positive non-small cell lung cancer

- Approval based on ARROS-1 phase I/II trial demonstrating meaningful and durable responses in patients with locally advanced or metastatic disease[1]
- Next-generation design aims to address key efficacy and tolerability challenges of treating ROS1-positive NSCLC
- GSK's first approval in lung cancer, part of a growing portfolio of targeted treatments

GSK plc (LSE/NYSE: GSK) today announced the US Food and Drug Administration (FDA) has approved *Jideytro* (zidesamtinib), a ROS1 selective inhibitor, for the treatment of adult patients with locally advanced or metastatic ROS1-positive non-small cell lung cancer (NSCLC) who received a prior ROS1 kinase inhibitor.[1] The approval comes ahead of the original target action date of 18 September 2026 and follows the FDA's Breakthrough Therapy and Orphan Drug Designations.[2]

Jideytro, part of the portfolio from the recently completed acquisition of Nuvalent, Inc.[3], was developed to address key efficacy and/or tolerability challenges of treating ROS1-postive NSCLC. Its next-generation design aims to combine high target-selectivity, broad coverage of ROS1 resistance mutations and blood-brain barrier penetration to address disease in the brain. Approximately 50,000 people worldwide are diagnosed each year with ROS1-positive NSCLC, often non-smokers in their 40s and 50s who could stay on treatment for several years.[4,5]

Tony Wood, Chief Scientific Officer, GSK, said: "The rapid progression of *Jideytro* from development to approval reflects both the strength of the underlying science and the urgent need for additional effective and tolerable treatments for ROS1-positive lung cancer. Today's approval provides an important new option for these patients and supports our strategy to acquire assets with validated targets that could meaningfully improve standards of care."

The approval of *Jideytro* is based on results from the global single-arm ARROS-1 phase I/II clinical trial in patients with advanced or metastatic ROS1-positive NSCLC previously treated with a ROS1 inhibitor. The study demonstrated meaningful and durable responses, including in patients with brain metastases and ROS1 resistance mutations. In the overall population (n=117), the objective response rate (ORR) was 44% (95% confidence interval [CI]: 34-53%). Duration of response (DOR) rates at six and 12 months were 82% and 69%, respectively.[1]

The most common (≥15%) adverse reactions in the pooled safety population (n=446) included: oedema, peripheral neuropathy, constipation, fatigue and dyspnoea.[1]

Alexander Drilon, MD, ARROS-1 trial investigator and Chief of the Early Development Service at Memorial Sloan Kettering Cancer Center, said: "Despite advances in treatment, resistance mutations, disease progression in the brain and treatment-related adverse events continue to create challenges for patients. The responses observed in ARROS-1, including in heavily pre-treated patients, represent meaningful progress for people living with this disease."

Janet Freeman-Daily, Co-Founder and President of The ROS1ders, said: "For patients, the goal is not just more time, but quality time to live life as normally as possible while on treatment. The ROS1-positive community is deeply invested in advancing care with treatments that are effective and tolerable. Today's approval gives patients and their doctors an important new option and represents meaningful progress for our community."

Jideytro is GSK's first approved medicine in lung cancer. The company is advancing additional medicines from the recent Nuvalent acquisition, including neladalkib (NVL-655) for patients with ALK-altered NSCLC, which is currently under FDA review with a target decision date of 27 November 2026, and NVL-330, an investigational treatment for HER2-altered NSCLC. GSK is also advancing risvutatug rezetecan (Ris-Rez), a B7-H3-targeted antibody-drug conjugate in late-stage development with recently reported positive phase III data[6] in relapsed small-cell lung cancer from licensor Hansoh Pharma Inc.

About *Jideytro*

Jideytro is a kinase inhibitor that is FDA approved for the treatment of adult patients with locally advanced or metastatic ROS1-positive non-small cell lung cancer (NSCLC) who received a prior ROS1 kinase inhibitor.

Jideytro was designed as a ROS1 selective inhibitor with broad coverage of ROS1 resistance mutations, activity against disease that has spread to the brain, durable treatment responses and a tolerable profile. Together, these features aim to help patients maintain disease control for longer while reducing the treatment challenges that can emerge over time.

The US Prescribing Information will be available here[7].

About the ARROS-1 trial

ARROS-1 (NCT05118789) is a global phase I/II trial evaluating zidesamtinib in patients with advanced ROS1-positive NSCLC and other ROS1-positive solid tumours.[8] The FDA approval is based on results from 117 patients with ROS1-positive NSCLC previously treated with a ROS1 inhibitor.[1]

Zidesamtinib continues to be studied in ARROS-1, including in first-line treatment for patients who have not previously received a ROS1 inhibitor.

About NSCLC

NSCLC is the most common form of lung cancer and is often characterised by specific genetic alterations, such as those in ALK, ROS1, or HER2. It can often metastasise (i.e., spread) to the central nervous system. It primarily affects working-age individuals. Current treatments may have efficacy and/or tolerability limitations that leave unmet need for patients.[9]

GSK in oncology

Our ambition in oncology is to help increase overall quality of life, maximise survival and change the course of disease, expanding from our current focus on blood and women's cancers into lung and gastrointestinal cancers, as well as other solid tumours. This includes accelerating priority programmes such as antibody-drug conjugates Ris-Rez targeting B7-H3 and Mo-Rez targeting B7-H4, and velzatinib, a highly selective KIT tyrosine kinase inhibitor.

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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[1] *Jideytro* US Prescribing Information.
[2] Nuvalent press release issued 19 November 2025: Nuvalent Announces FDA Acceptance of New Drug Application for Zidesamtinib for the Treatment of TKI Pre-treated Patients with Advanced ROS1-positive NSCLC. Available at: https://investors.nuvalent.com/2025-11-19-Nuvalent-Announces-FDA-Acceptance-of-New-Drug-Application-for-Zidesamtinib-for-the-Treatment-of-TKI-Pre-treated-Patients-with-Advanced-ROS1-positive-NSCLC.
[3] GSK press release issued 15 July 2026: GSK completes acquisition of Nuvalent, Inc. Available at: https://www.gsk.com/en-gb/media/press-releases/gsk-completes-acquisition-of-nuvalent-inc/.
[4] Solomon B. Validating ROS1 Rearrangements As a Therapeutic Target in Non–Small-Cell Lung Cancer. J Clin Oncol 33, 972-974(2015).
[5] Bray F, Laversanne M, Sung H, et al. Global cancer statistics 2022: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. CA Cancer J Clin. 2024; 74(3): 229-263. doi:10.3322/caac.21834
[6] GSK press release issued 10 July 2026: GSK's licensor Hansoh Pharma announces positive phase III results for Ris-Rez in China patient population. Available at: https://www.gsk.com/en-gb/media/press-releases/gsk-s-licensor-hansoh-pharma-announces-positive-phase-iii-results-for-ris-rez-in-china-patient-population/.
[7] US Prescribing Information. To be available at: https://nuvalent.com/pdfs/jideytro-full-prescribing-information.pdf.
[8] ClinicalTrials.gov. National Library of Medicine (US). Identifier NCT05118789, A Study of Zidesamtinib (NVL-520) in Patients With Advanced NSCLC and Other Solid Tumors Harboring ROS1 Rearrangement (ARROS-1) Available at: https://clinicaltrials.gov/study/NCT05118789.
[9] Duma, N., Santana-Davila, R., & Molina, J. R. (2019). Non-Small Cell Lung Cancer: Epidemiology, Screening, Diagnosis, and Treatment. Mayo Clinic proceedings, 94(8), 1623–1640. https://doi.org/10.1016/j.mayocp.2019.01.013.

Dr. Drilon has served as a consultant to and/or received expense reimbursements from Nuvalent, Inc.