Press release

For media and investors only

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GSK presents positive registrational data to potentially expand *Jideytro* (zidesamtinib) to first-line ROS1-positive non-small cell lung cancer

- 94% objective response rate at 15.2 months follow-up
- 90% of patients were progression free at 12 months, with median PFS rate still to be reached
- 70% of patients with measurable brain metastases achieved complete clearance of detectable brain tumours
- Results support potential to address key efficacy and tolerability needs in ROS1-positive NSCLC with US regulatory submission planned in 2026

GSK plc (LSE/NYSE: GSK) today announced positive results from the registrational phase I/II ARROS-1 trial evaluating *Jideytro* (zidesamtinib) in patients with advanced or metastatic ROS1-positive non-small cell lung cancer (NSCLC) who had not received previous treatment with a tyrosine kinase inhibitor (TKI-naïve). The data were presented in a Presidential Symposium session at the 2026 World Conference on Lung Cancer (WCLC) in Seoul, South Korea, and will support a planned supplemental New Drug Application to the US FDA this year to expand the indication for *Jideytro* to include first-line treatment.

In the 94 TKI-naïve patients included in the analysis, zidesamtinib achieved a clinically meaningful 94% objective response rate (ORR) (88/94; 95% CI: 87-98), including a 15% complete response rate (14/94), after a median follow-up of 15.2 months (range 1.1–30.5). Responses were durable, with 94% of patients continuing to respond to treatment at nine months and 86% at 12 months. Progression-free survival (PFS) was 90% at 12 months. Median duration of response (DOR) and median PFS had not been reached at the time of analysis. In the trial, 100% of patients with measurable brain metastases at baseline (n=10) responded to zidesamtinib (10/10, 95% CI: 69–100), and 70% achieved a complete clearance of detectable brain tumours (7/10). At 12 months, 78% of patients maintained an intracranial response, and no central nervous system progression events were observed among patients without brain metastases at baseline.[1]

Hesham Abdullah, Senior Vice President, Global Head of Oncology, R&D, GSK said, "Today's results show a combination of high response rates and a tolerability profile that helped most patients stay on treatment. They highlight the potential for a differentiated profile for zidesamtinib to become a first-line treatment for patients with ROS1-positive NSCLC – a condition where maintaining long-term disease control, managing spread to the brain and minimising treatment-related side effects remain key challenges. We look forward to sharing these data with regulators."

Low rates of treatment discontinuation were observed, consistent with previous safety reports for zidesamtinib. The most common (≥15%) treatment-related adverse events (TRAEs) were peripheral oedema, weight increase, blood creatine phosphokinase increase, dysgeusia and aspartate aminotransferase increase; most were low grade. TRAEs led to dose reductions in 11% of patients and discontinuation in 1%.[1]

Alexander Drilon, MD, ARROS-1 primary investigator and Chief of the Early Drug Development Service at Memorial Sloan Kettering Cancer Center, said: "Patients with ROS1-positive NSCLC may receive treatment for many years while continuing to work, care for their families and live their daily lives. They need treatments that provide lasting control of their disease, including in the brain, while limiting side effects and treatment disruption. The

durable responses and low rates of treatment discontinuation observed in ARROS-1 represent encouraging progress toward addressing these long-term treatment needs."

Zidesamtinib is not approved anywhere in the world for use as first-line therapy. In July 2026, the FDA approved zidesamtinib for patients with ROS1-positive NSCLC previously treated with a TKI.[2]

About ARROS-1
The global, single-arm, first-in-human phase I/II ARROS-1 study (NCT05118789) included a phase II cohort of patients with locally advanced or metastatic ROS1-positive NSCLC who were naïve to ROS1 tyrosine kinase inhibitor (TKI) therapy, with up to one prior line of chemotherapy and/or immunotherapy permitted. Of 532 patients with ROS1-positive NSCLC who received zidesamtinib 100 mg once daily across all lines of therapy, 183 were receiving their first TKI-targeted treatment. The efficacy-evaluable population (n=94) included patients with measurable disease (by blinded independent central review) who initiated treatment by 15 June 2025, to allow at least nine months of follow-up for duration of response. 27% had received prior chemotherapy, 17% of whom also had prior immunotherapy. 17% had baseline central nervous system metastases by BICR. Data cut-off was 16 April 2026.

About ROS1-positive NSCLC
ROS1 mutations occur in approximately 2% of non-small cell lung cancers, contributing to an estimated 50,000 new diagnoses worldwide each year, typically in younger patients and more often in non-smokers. The disease has a high propensity to spread to the central nervous system, with brain metastases present in up to 40% of patients at diagnosis and remaining a common site of disease progression during treatment. Despite advances in targeted therapies, unmet need remains due to challenges including central nervous system progression, acquired resistance and treatment tolerability.[3-6]

About *Jideytro*
Jideytro (zidesamtinib), part of GSK's portfolio from the recently completed acquisition of Nuvalent, Inc.[7], was designed as a ROS1 TKI 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.

Jideytro 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 TKI.

The US Prescribing Information is available here.[8]

GSK in oncology
GSK's 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.

GSK's focus in lung cancer is to develop medicines that can deliver durable responses, overcoming resistance and reducing treatment burden across small cell and non-small cell lung cancers. GSK's lung cancer portfolio is built on validated targets and modalities where we have growing expertise, including targeted small molecules and ADCs. This approach allows us to match the right therapeutic modality to the right target, tumour type and patient need – with the bold ambition to launch multiple new options in lung cancer over the next five years.

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 Q2 Results for 2026.

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References

1. Drilon A, et al. Zidesamtinib in TKI-naive patients with advanced/metastatic ROS1+ NSCLC: ARROS-1 efficacy and safety data. Presented at: 2026 World Conference on Lung Cancer (WCLC); 12-15 September 2026; Seoul, South Korea.
2. GSK press release issued 22 July 2026: Jideytro (zidesamtinib) approved in the US for previously treated ROS1-positive non-small cell lung cancer.
3. Ou SI, Zhu VW. Rearranged rules: ROS1 fusions in lung cancer. Lung Cancer. 2019;130:201-207.
4. Patil T, Smith DE, Bunn PA Jr, et al. The Incidence of Brain Metastases in Stage IV ROS1-Rearranged Non-Small Cell Lung Cancer and Rate of Central Nervous System Progression on Crizotinib. J Thorac Oncol. 2018;13(11):1717-1726.
5. Gainor JF, Tseng D, Yoda S, et al. Patterns of Metastatic Spread and Mechanisms of Resistance to Crizotinib in ROS1-Positive Non-Small-Cell Lung Cancer. JCO Precis Oncol. 2017;2017:PO.17.00063.
6. Drilon A, Somwar R, Wagner JP, et al. A Novel Crizotinib-Resistant Solvent-Front Mutation Responsive to Cabozantinib Therapy in a Patient with ROS1-Rearranged Lung Cancer. Cancer Discov. 2017;7(4):400-409.
7. GSK press release issued 15 July 2026: GSK completes acquisition of Nuvalent, Inc.
8. Jideytro (zidesamtinib) US Prescribing Information.

Memorial Sloan Kettering Cancer Center Disclosure: Dr. Drilon has financial interests related to Nuvalent, Inc.