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Nuvalent Gains FDA Priority Review for ALK-Positive NSCLC Candidate

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The companyâ??s NDA for neladalkib has been accepted for TKI-pretreated advanced ALK-positive non-small cell lung cancer.

Nuvalent has received U.S. FDA acceptance and Priority Review for its New Drug Application for neladalkib in tyrosine kinase inhibitor-pretreated advanced ALK-positive non-small cell lung cancer.

The FDA has assigned a Prescription Drug User Fee Act target action date of November 27, 2026. If approved, neladalkib would add a new targeted therapy option for patients whose disease has progressed after prior ALK inhibitor treatment.

This is relevant, as ALK-positive NSCLC remains a biomarker-defined cancer segment where resistance to existing kinase inhibitors can limit long-term treatment benefit. Patients may also develop brain metastases, creating a need for therapies with central nervous system activity.

Neladalkib is designed as a brain-penetrant, ALK-selective inhibitor. The company is developing it to remain active against tumors with single or compound resistance mutations, including G1202R, while avoiding inhibition of the structurally related TRK family.

The NDA is supported by data from the global ALKOVE-1 Phase 1/2 trial in patients with advanced ALK-positive NSCLC. Nuvalent said global enrolment remains ongoing for additional ALK-positive solid tumour populations, including adult and adolescent patients.

The regulatory review comes as Nuvalent builds commercial and medical affairs infrastructure for potential launches across its kinase inhibitor pipeline. The company also has zidesamtinib under FDA review for ROS1-positive NSCLC, giving it a broader position in precision oncology.