

# Nuvalent Announces Timing of Topline Pivotal Data for TKI Pre-treated Patients with Advanced ALK-positive NSCLC from ALKOVE-1 Clinical Trial of Neladalkib

## Company to host webcast and conference call on November 17, 2025 at 8:00am ET

CAMBRIDGE, Mass., Nov. 14, 2025 /PRNewswire/ -- [Nuvalent, Inc.](#) (Nasdaq: NUVL), a clinical-stage biopharmaceutical company focused on creating *precisely* targeted therapies for clinically proven kinase targets in cancer, today announced that the company will host a webcast and conference call on Monday, November 17, 2025 at 8:00 a.m. ET, to discuss topline pivotal data for neladalkib, an investigational ALK-selective inhibitor, in TKI pre-treated patients with advanced ALK-positive non-small cell lung cancer from the global ALKOVE-1 Phase 1/2 clinical trial.

### **Webcast and Conference Call Information**

To access the call, please dial +1 (800) 836-8184 (domestic) or +1 (646) 357-8785 (international) at least 10 minutes prior to

the start time and ask to be joined to the Nuvalent call.

Accompanying slides and a live video webcast will be available in the Investors section of the Nuvalent website at <https://investors.nuvalent.com/events>. A replay and accompanying slides will be archived on the Nuvalent website for 30 days.

### **About Neladalkib and the ALKOVE-1 Phase 1/2 Clinical Trial**

Neladalkib is an investigational brain-penetrant ALK-selective inhibitor created with the aim to overcome limitations observed with currently available ALK inhibitors. Neladalkib is designed to remain active in tumors that have developed resistance to first-, second-, and third-generation ALK inhibitors, including tumors with single or compound treatment-emergent ALK mutations such as G1202R. In addition, neladalkib is designed for central nervous system (CNS) penetration to improve treatment options for patients with brain metastases, and to avoid inhibition of the structurally related tropomyosin receptor kinase (TRK) family. Together, these characteristics have the potential to avoid TRK-related CNS adverse events seen with dual TRK/ALK inhibitors and to drive deep, durable responses for patients across all lines of therapy. Neladalkib has received U.S. Food and Drug Administration (FDA) breakthrough therapy designation for the treatment of patients with locally advanced or metastatic ALK-positive non-small cell lung cancer (NSCLC) who have been previously treated with 2 or more ALK tyrosine kinase inhibitors and orphan drug designation for ALK-positive NSCLC.

The ALKOVE-1 trial ([NCT05384626](https://clinicaltrials.gov/ct2/show/study/NCT05384626)) is a first-in-human Phase 1/2 clinical trial for patients with advanced ALK-positive NSCLC and other solid tumors. The completed Phase 1 portion enrolled ALK-positive NSCLC patients who previously received at least one ALK TKI, or patients with other ALK-positive solid tumors who had been previously treated or for whom no satisfactory standard of care exists. The Phase 1 portion of the trial was designed to evaluate the overall safety and tolerability of neladalkib, with additional objectives including determination of the recommended Phase 2 dose (RP2D), characterization of the pharmacokinetic profile, and evaluation of preliminary anti-tumor activity. The global, single arm, open label Phase 2 portion is designed with registrational intent for TKI pre-treated patients with advanced ALK-positive NSCLC. Global enrollment in ALKOVE-1 remains ongoing for adult and adolescent patients with ALK-positive solid tumors outside of NSCLC, and adolescent patients with ALK-positive NSCLC.

### **About Nuvalent**

Nuvalent, Inc. (Nasdaq: NUVL) is a clinical-stage biopharmaceutical company focused on creating *precisely* targeted therapies for patients with cancer, designed to overcome the limitations of existing therapies for clinically proven kinase targets. Leveraging deep expertise in chemistry and structure-based drug design, we develop innovative small molecules that have the potential to overcome resistance, minimize adverse events, address brain metastases, and drive more durable responses. Nuvalent is advancing a robust pipeline with investigational candidates for ROS1-positive, ALK-positive, and HER2-altered non-small cell lung cancer, and multiple discovery-stage research programs.

### **Forward-Looking Statements**

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, implied and express statements regarding Nuvalent's strategy, business plans, and focus; the expected timing of data announcements; the clinical development program for neladalkib; the design and enrollment of Nuvalent's clinical trials, including for ALKOVE-1 its intended pivotal registration-directed design; the potential of Nuvalent's pipeline programs, including neladalkib; Nuvalent's research and development programs for the treatment of cancer; and risks and uncertainties associated with drug development. The words "may," "might," "will," "could," "would," "should," "expect," "plan," "anticipate," "aim," "goal," "intend," "believe," "estimate," "seek," "predict," "future," "project," "potential," "continue," "target" or the negative of these terms and similar words or expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Drug development and commercialization involve a high degree of risk, and only a small number of research and development programs result in commercialization of a product. You should not place undue reliance on these statements or the scientific data presented.

Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties, and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation: risks that Nuvalent may not fully enroll its clinical trials or that enrollment will take longer than expected; unexpected concerns that may arise from additional data, analysis, or results obtained during preclinical studies and clinical trials; the risk that preliminary results of clinical trials may not be predictive of future results from the same or other trials; the risk that results of earlier clinical trials may not be predictive of the results of later-stage clinical trials; the risk that data from our clinical trials may not be sufficient to support registration and that Nuvalent may be required to conduct one or more additional studies or trials prior to seeking registration of neladalkib; the occurrence of adverse safety events; risks that the FDA may not approve our potential products on the timelines we expect, or at all; risks of unexpected costs, delays, or other unexpected hurdles; risks that Nuvalent may not be able to nominate drug candidates from its discovery programs; the direct or indirect impact of public health emergencies or global geopolitical circumstances on the timing and anticipated timing and results of Nuvalent's clinical trials, strategy, and future operations, including the ALKOVE-1 trial; the timing and outcome of Nuvalent's planned interactions with regulatory authorities; and risks related to obtaining, maintaining, and protecting Nuvalent's intellectual property. These and other risks and uncertainties are described in greater detail in the section entitled "Risk Factors" in Nuvalent's Quarterly Report on Form 10-Q for the quarter ended September 30, 2025, as well as any prior and subsequent filings with the Securities and

Exchange Commission. In addition, any forward-looking statements represent Nuvalent's views only as of today and should not be relied upon as representing its views as of any subsequent date. Nuvalent explicitly disclaims any obligation to update any forward-looking statements.

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