

# Nuvalent to Present Pivotal Data from ALKOVE-1 Trial of Neladalkib in TKI Pre- treated Advanced ALK- positive NSCLC at the 2026 American Society of Clinical Oncology Annual Meeting

Company to also present  
preliminary data for zidesamtinib  
in advanced ROS1-positive solid

# tumors outside of NSCLC from the global ARROS-1 trial

CAMBRIDGE, Mass., April 21, 2026 /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 pivotal data for neladalkib, an investigational ALK-selective inhibitor, in TKI pre-treated patients with advanced ALK-positive non-small cell lung cancer (NSCLC) from the global ALKOVE-1 Phase 1/2 clinical trial, in addition to preliminary data for TKI-naïve patients, will be presented during an oral presentation at the 2026 American Society of Clinical Oncology (ASCO) Annual Meeting from May 29 – June 2, 2026, in Chicago.

Additionally, preliminary data in patients with advanced ROS1-positive solid tumors outside of NSCLC from the global ARROS-1 Phase 1/2 clinical trial of zidesamtinib, an investigational ROS1-selective inhibitor, will be presented during a poster session.

Details of the presentations are as follows:

**Title:** ALKOVE-1: Efficacy and safety of neladalkib in patients with advanced ALK+ NSCLC

**Presenting Author:** Jessica J. Lin, M.D.<sup>1</sup>

**Abstract Number:** 8503

**Oral Session Title:** Lung Cancer—Non-Small Cell Metastatic

**Presentation Date and Time:** May 29, 2026, 1:00 PM-4:00 PM CDT

**Location:** Hall D2

**Title:** Zidesamtinib efficacy and safety in patients with advanced ROS1-positive solid tumors other than NSCLC in the ARROS-1 study

**Presenting Author:** Benjamin Solomon, M.D., Ph.D.<sup>2</sup>

**Abstract Number:** 3108

**Poster Session Title:** Developmental Therapeutics—Molecularly Targeted Agents and Tumor Biology

**Session Date and Time:** May 30, 2026, 1:30 PM-4:30 PM CDT

**Location:** Hall A

**Poster Board Number:** 245

<sup>1</sup> *Mass General Brigham Cancer Institute, Boston, MA, USA,* <sup>2</sup> *Peter MacCallum Cancer Centre, Melbourne, Australia*

## About Neladalkib

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 breakthrough therapy designation from the U.S. Food and Drug Administration (FDA) 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.

## About Zidesamtinib

Zidesamtinib is an investigational, brain-penetrant, ROS1-selective inhibitor created with the aim to overcome limitations observed with currently available ROS1 inhibitors. Zidesamtinib is designed to remain active in tumors that have developed resistance to currently available ROS1 inhibitors, including tumors with treatment-emergent ROS1 mutations such as G2032R. In addition, zidesamtinib 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/ROS1 inhibitors and to drive deep, durable responses for patients across all lines of therapy.

Based on results for tyrosine kinase inhibitor (TKI) pre-treated patients with advanced ROS1-positive non-small cell lung cancer (NSCLC) enrolled in the global registrational ARROS-1 Phase 1/2 clinical trial, the U.S. Food and Drug Administration (FDA) has accepted for filing Nuvalent's NDA submission for zidesamtinib for the treatment of adult patients with locally advanced or

metastatic ROS1-positive NSCLC who received at least 1 prior ROS1 TKI. The application has been assigned a Prescription Drug User Fee Act (PDUFA) target action date of September 18, 2026. Zidesamtinib has received breakthrough therapy designation for the treatment of patients with ROS1-positive metastatic NSCLC who have been previously treated with 2 or more ROS1 TKIs and orphan drug designation for ROS1-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 programs for zidesamtinib and neladalkib; the potential benefits and effects of Nuvalent's product development candidates; the design of Nuvalent's clinical trials, including for the ARROS-1 trial its intended pivotal registration-directed design; the potential of Nuvalent's pipeline programs, including zidesamtinib and 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: unexpected concerns that may arise from additional data, analysis, or results obtained during preclinical studies and clinical 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 our zidesamtinib product candidate; 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; 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 Annual Report on Form 10-K for the fiscal year ended December 31, 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.

SOURCE Nuvalent, Inc.

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<https://investors.nuvalent.com/2026-04-21-Nuvalent-to-Present-Pivotal-Data-from-ALKOVE-1-Trial-of-Neladalkib-in-TKI-Pre-treated-Advanced-ALK-positive-NSCLC-at-the-2026-American-Society-of-Clinical-Oncology-Annual-Meeting>