Nuvalent Highlights Upcoming Data Presentations for Neladalkib and Zidesamtinib at the 2026 American Society of Clinical Oncology Annual Meeting

Presentation of pivotal data for neladalkib in TKI pre-treated patients with advanced ALK-positive NSCLC from ALKOVE-1 trial

TKI pre-treated data from ALKOVE-1 trial of neladalkib support recent NDA submission and ongoing investigation in Phase 3 ALKAZAR trial for TKI-naïve patients with advanced ALK-positive NSCLC

First presentation of encouraging preliminary data for zidesamtinib in patients with advanced ROS1-positive solid tumors other than NSCLC from ARROS-1 trial

CAMBRIDGE, Mass., May 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 highlighted 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, single-arm ALKOVE-1 Phase 1/2 clinical trial, and preliminary data in patients with advanced ROS1-positive solid tumors other than NSCLC from the global, single-arm ARROS-1 Phase 1/2 clinical trial of zidesamtinib, an investigational ROS1-selective inhibitor, to be presented at the 2026 American Society of Clinical Oncology (ASCO) Annual Meeting from May 29 – June 2, 2026, in Chicago.

"The pivotal data for neladalkib in TKI pre-treated patients with advanced ALK-positive NSCLC enabled our recent NDA submission to the FDA, and represent important progress toward our goal of offering a new treatment option for this patient

population," said **Christopher Turner, M.D., Chief Medical Officer of Nuvalent.** "Collectively, these data as well as preliminary data from the TKI-naïve cohort of our ALKOVE-1 study are supportive of further investigation of neladalkib in the global Phase 3 ALKAZAR trial of neladalkib compared to alectinib for TKI-naïve ALK-positive NSCLC, a critical step towards our ultimate goal of moving neladalkib up the treatment paradigm. We look forward to sharing these data with the medical community during an oral presentation at ASCO, and are deeply grateful to the patients, caregivers, and investigators who have made this milestone possible."

"These data build on the consistent characterization of neladalkib across preclinical and Phase 1 investigations," said **Jessica J. Lin, M.D., Program Director of Thoracic Medical Oncology at the Mass General Brigham Cancer Institute, Associate Professor of Medicine at Harvard Medical School, and presenting author**. "The data support neladalkib's potential to deliver on its design goals as an option for patients with ALK-positive NSCLC, including those whose disease progresses with brain metastases or resistance mutations, or who are unable to tolerate the currently available TKIs."

"We also continue to progress the development of zidesamtinib, our ROS1-selective inhibitor, and are pleased to share the preliminary activity observed in patients with ROS1-positive cancers other than NSCLC," said **Darlene Noci, A.L.M., Chief Development Officer of Nuvalent.** "These data highlight zidesamtinib's potential for patients with ROS1-positive solid tumors outside of NSCLC, and we believe reinforce the importance of widespread genomic testing. We continue to enroll adult and adolescent TKI-naïve and TKI pre-treated patients with advanced ROS1-positive solid tumors outside of NSCLC in the global Phase 2 portion of our ARROS-1 study, and look forward to providing additional updates in the future."

Pivotal Data for Neladalkib in TKI Pre-treated Patients with Advanced ALK-positive NSCLC from ALKOVE-1 Clinical Trial

Title: ALKOVE-1: Efficacy and safety of neladalkib in patients with advanced ALK+ NSCLC
Presenting Author: Jessica J. Lin, M.D.[1]
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

The pivotal data to be presented, initially announced in November 2025, are from TKI pre-treated patients with advanced ALK-positive NSCLC treated with neladalkib in the global, registration-directed ALKOVE-1 Phase 1/2 clinical trial. In this population, neladalkib demonstrated encouraging overall activity, including intracranial responses, the ability to address key drivers of disease progression, and a generally well-tolerated safety profile consistent with its ALK-selective, TRK-sparing design. These data served as the foundation for the company's New Drug Application (NDA) submission, announced in April 2026, to the U.S. Food and Drug Administration (FDA) for neladalkib in TKI pre-treated advanced ALK-positive NSCLC.

Preliminary Data for Zidesamtinib in Patients with Advanced ROS1-positive Solid Tumors Other than NSCLC from ARROS-1 Clinical Trial

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.[2]
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

Preliminary data are reported for 15 response-evaluable patients enrolled across 10 solid tumor types outside of NSCLC in the Phase 1 and Phase 2 portions of the ARROS-1 clinical trial as of a data cutoff date of September 22, 2025. The majority (12/15) of patients received the recommended Phase 2 dose of 100 mg once daily. Patients were refractory to standard-of-care therapies (60%, 9/15) or were previously treated with a ROS1 TKI (40%, 6/15), and 73% (11/15) of patients had received prior chemotherapy.

Among all patients with advanced ROS1-positive solid tumors treated with zidesamtinib, an objective response rate of 40% (6/15) was observed, with responses seen for ROS1 TKI-naïve patients refractory to standard-of-care therapies, and for those who had received a prior ROS1 TKI. As of the data cutoff date, four of the six responders remained on treatment with zidesamtinib. Three case studies support zidesamtinib's potential in a range of treatment settings:

- Treatment ongoing for approximately 42 months with partial response in a TKI pre-treated patient with an inflammatory myofibroblastic tumor;
- Treatment ongoing for approximately 13 months with partial response in a TKI-naïve patient with metastatic colorectal cancer previously treated with standard of care chemotherapy; and,
- Treatment ongoing for approximately 19 months with partial response in a TKI-naïve patient with cholangiocarcinoma

previously treated with standard of care chemotherapy.

Among these 15 patients, zidesamtinib was observed to be generally well-tolerated with only one dose reduction due to treatment-related adverse events (TRAEs) and no discontinuations due to TRAEs or treatment-emergent adverse events as of the data cutoff date. The preliminary overall safety profile was consistent with its ROS1-selective, TRK-sparing design, and with previously reported data.

Enrollment is ongoing in the global Phase 2 cohort of the ARROS-1 trial for adult and adolescent patients with advanced ROS1-positive solid tumors other than NSCLC.

[1] Mass General Brigham Cancer Institute, Boston, MA, USA;[2] 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) penetrance 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) penetrance 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, single-arm, 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 and FDA product approvals; the clinical development programs for neladalkib and zidesamtinib; the potential benefits and effects of Nuvalent's product development candidates; the design and enrollment of the ALKOVE-1, ARROS-1, and ALKAZAR trials, including intended pivotal registration-directed design; the potential of Nuvalent's pipeline programs, including neladalkib and zidesamtinib; the implications of data readouts and presentations; 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," "plan," "anticipate," "aim," "goal," "intend," "believe," "expect," "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 or 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 product candidates; 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 Quarterly Report on Form 10-Q for the quarter ended March 31, 2026, 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.

Investor Contact:
Chelcie Lister
Nuvalent, Inc.
clister@nuvalent.com

Media Contact:
Josie Butler
1AB
josie@labmedia.com
