Nuvalent Announces Key Program and Business Updates, Strengthening Foundation for Global Leadership in ROS1- and ALK-positive NSCLC

New Drug Application for neladalkib in TKI pre-treated advanced ALK-positive NSCLC accepted for filing with Priority Review by the FDA with PDUFA target action date of November 27, 2026

Veteran biopharmaceutical executive, Georg Pirmin Meyer, M.D., joins as Chief International Officer to lead Nuvalent's global expansion strategy

CAMBRIDGE, Mass., May 27, 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 the acceptance of its New Drug Application (NDA) for neladalkib for filing by the U.S. Food and Drug Administration (FDA). The FDA has granted the application Priority Review and assigned a Prescription Drug User Fee Act (PDUFA) target action date of November 27, 2026. The company further announced that Georg Pirmin Meyer, M.D., has joined the company as Chief International Officer.

"With today's announcement, New Drug Applications for both zidesamtinib and neladalkib in TKI pre-treated populations are now under review with the FDA, and TKI-naïve expansion strategies are underway," **said James Porter, Ph.D., Chief Executive Officer of Nuvalent.** "Our U.S. commercial and medical affairs teams are in place and focused on establishing the strong foundational systems and infrastructure required to effectively deliver on multiple synergistic launches in biomarker-driven NSCLC."

Dr. Porter continued, "Nuvalent's commitment to patients is global, and we are thrilled to welcome Georg Pirmin as we develop an international strategy with the goal of delivering new medicines beyond the U.S. His proven track record of establishing global operations and strategic partnerships that maximize patient access will be instrumental in realizing the full potential for Patient Impact with our parallel-lead programs."

"Nuvalent presents a unique near-term opportunity to advance multiple potential best-in-class product candidates for patients with cancer, backed by robust clinical experience demonstrating clear global medical need and enthusiasm," **said Dr. Meyer**. "I am excited to join at this pivotal moment and to partner with the team to realize our shared vision of global leadership in ROS1- and ALK-positive NSCLC."

Neladalkib NDA Accepted for Filing with Priority Review

The U.S. FDA has accepted for filing Nuvalent's NDA for neladalkib, an investigational ALK-selective inhibitor, in tyrosine kinase inhibitor (TKI) pre-treated advanced ALK-positive non-small cell lung cancer (NSCLC). The application has been granted Priority Review and assigned a PDUFA target action date of November 27, 2026.

The submission is based on data in TKI pre-treated patients with advanced ALK-positive NSCLCtreated with neladalkib in the global, registration-directed ALKOVE-1 Phase 1/2 clinical trial. These data, along with preliminary data for TKI-naïve patients, will be shared during an oral presentation at the 2026 American Society of Clinical Oncology (ASCO) Annual Meeting from May 29 – June 2, 2026, in Chicago.

Georg Pirmin Meyer, M.D. Joins as Chief International Officer

In this newly created role, Dr. Meyer will be responsible for spearheading Nuvalent's international expansion strategy and establishing the company's presence in key markets outside the U.S.

Dr. Meyer brings extensive expertise in global commercial strategy, market access, product launches, and business development across major international markets. Most recently, he served as Senior Vice President and General Manager, International at Blueprint Medicines, where he held full P&L accountability for international operations. In this role, Dr. Meyer led

the European market preparation and successful launches of Ayvakit® (avapritinib) across three indications, while building and scaling a cross-functional team spanning nine European countries. Prior to Blueprint Medicines, Dr. Meyer served as General Manager, Germany at Vertex Pharmaceuticals, where he held full P&L responsibility for the German market, scaled commercial operations for four marketed orphan disease products, and drove uncompromising market access strategies including HTA submissions and complex price negotiations. Earlier in his career, he held progressive global commercial operational roles at Amgen and Sanofi, establishing a strong foundation in biopharmaceutical commercialization. Dr. Meyer received his M.D. from the University of Freiburg, Germany and the University of Innsbruck, Austria.

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.

Based on data in tyrosine kinase inhibitor (TKI) pre-treated patients with advanced ALK-positive non-small cell lung cancer (NSCLC) enrolled in the global registrational ALKOVE-1 Phase 1/2 clinical trial, the U.S. Food and Drug Administration (FDA) has accepted for filing Nuvalent's NDA submission for neladalkib in TKI pre-treated advanced ALK-positive NSCLC. The application has been granted Priority Review and assigned a Prescription Drug User Fee Act (PDUFA) target action date of November 27, 2026. 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 the ALKOVE-1 Phase 1/2 Clinical Trial
The ALKOVE-1 trial (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 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 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 and other development and regulatory 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 and ALKOVE-1 trials their 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; the success of our preparatory activities and strategy in connection with a potential commercial launch of one or more of our product candidates; 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.

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