Nuvalent Announces Submission of New Drug Application to FDA for Neladalkib in TKI Pre-treated Advanced ALK-positive NSCLC

New Drug Application (NDA) based on data in TKI pre-treated patients from the global ALKOVE-1 Phase 1/2 clinical trial

CAMBRIDGE, Mass., April 7, 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 submission to the U.S. Food and Drug Administration (FDA) of the Company's NDA for neladalkib, an investigational ALK-selective inhibitor, in TKI pre-treated advanced ALK-positive NSCLC.

"The advancement of neladalkib from first clinical trial initiation to NDA submission in less than four years represents a remarkable pace in oncology drug development, underscoring the vigor and urgency our team brought to this program and our deep commitment to the ALK-positive NSCLC community," **said Darlene Noci, A.L.M., Chief Development Officer at Nuvalent**. "We would like to extend our sincere gratitude to the patients, families and investigators who have made this progress possible, and are committed to working closely with the FDA throughout the NDA review process toward our goal of

bringing neladalkib to patients as quickly as possible."

The application is based on data in 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. The company plans to share detailed results at a future medical meeting.

Neladalkib has received breakthrough therapy designation from the FDA for the treatment of patients with locally advanced or metastatic ALK-positive NSCLC who have been previously treated with 2 or more ALK tyrosine kinase inhibitors and orphan drug designation for ALK-positive NSCLC.

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 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 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 program for neladalkib; the potential benefits and effects of Nuvalent's product development candidates; the design and enrollment of the ALKOVE-1 trial; the potential of Nuvalent's pipeline programs, including neladalkib; 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 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.

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