Nuvalent Announces OnTarget 2026 Operating Plan Progress and Outlines Key Anticipated 2026 Milestones

FDA accepted NDA for zidesamtinib for the treatment of TKI pre-treated patients with advanced ROS1-positive NSCLC; PDUFA target action date of September 18, 2026

NDA submission for neladalkib in TKI pre-treated advanced ALK-

positive NSCLC population planned for the first half of 2026

Submission for potential indication expansion of zidesamtinib in TKI-naïve advanced ROS1-positive NSCLC population planned for the second half of 2026

Well capitalized with operating runway anticipated into 2029

Company to present at 44th Annual J.P. Morgan Healthcare Conference on Tuesday, January

13th at 9:00 a.m. PT

CAMBRIDGE, Mass., Jan. 12, 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 pipeline progress and outlined key anticipated milestones towards its first potential U.S. commercial launch under its "OnTarget 2026" operating plan.

As part of this plan, Nuvalent anticipates the following 2026 milestones:

- Commercial launch in the U.S. of zidesamtinib for the treatment of adult patients with locally advanced or metastatic ROS1-positive non-small cell lung cancer (NSCLC) who received at least 1 prior ROS1 tyrosine kinase inhibitor (TKI), pending U.S. Food and Drug Administration (FDA) review;
- Submit data to FDA for potential indication expansion of zidesamtinib in TKI-naïve patients with advanced ROS1-positive NSCLC in the second half of 2026;
- Submit a New Drug Application (NDA) for neladalkib in TKI pre-treated patients with advanced ALK-positive NSCLC in the first half of 2026;
- Progress the ongoing ALKAZAR Phase 3 randomized, controlled trial of neladalkib for TKI-naïve patients with ALK-positive NSCLC;
- Progress the ongoing HEROEX-1 Phase 1a/1b trial of NVL-330 for patients with advanced HER2-altered NSCLC; and,
- Disclose a new development candidate by year-end 2026.

"Over the past two years, the Nuvalent team has seamlessly executed against our OnTarget 2026 operating plan towards our goal of a first potential FDA approval, ending 2025 with the recent FDA acceptance of our NDA for zidesamtinib in TKI pre-treated ROS1-positive NSCLC and commercial preparedness activities well underway," **said James Porter, Ph.D., Chief Executive Officer at Nuvalent.** "If zidesamtinib is approved, a first commercial launch in 2026 would be a transformative moment for Nuvalent and the first step towards realizing our mission of becoming a sustainable company capable of not only discovering and developing, but *delivering* new medicines for patients with cancer."

"With cash runway anticipated into 2029, our strong financial position enables us to focus on the execution of a first U.S. launch while also supporting the continued advancement and expansion of both our commercial and development portfolios," **said Alexandra Balcom, Chief Financial Officer at Nuvalent.** "We have completed a pre-NDA meeting with the FDA for our ALK program and plan to move forward with an NDA submission of the data for TKI pre-treated patients with ALK-positive NSCLC from our ALKOVE-1 study of neladalkib in the first half of this year. In the second half of the year, we anticipate submitting data to support a potential indication expansion for zidesamtinib in ROS1-positive NSCLC, and growing our discovery portfolio with a new development candidate. Together, we believe the achievement of these anticipated 2026 milestones would position Nuvalent for continued, long-term growth driven by delivering meaningful impact for patients with NSCLC and beyond."

2025 Year-End Cash and Guidance

Nuvalent ended 2025 with approximately $1.4 billion in cash, cash equivalents and marketable securities (unaudited), which, based on its current operating plans, is expected to fund its operations into 2029. This amount is a preliminary, unaudited estimate only as of today, could change following completion of year-end closing procedures, and does not present all information necessary for an understanding of the company's financial position as of December 31, 2025.

Presentation at 44th Annual J.P. Morgan Healthcare Conference

Dr. Porter will present at the 44th Annual J.P. Morgan Healthcare Conference in San Francisco on Tuesday, January 13, 2026 at 9:00 a.m. PT. A live webcast will be available in the Investors section of Nuvalent's website at www.nuvalent.com, and will be archived for 30 days following the conference.

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 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 NVL-330
NVL-330 is an investigational, brain-penetrant, HER2-selective tyrosine kinase inhibitor designed to address the combined medical need of treating HER2-mutant tumors, including those with HER2 exon 20 insertion mutations, avoiding treatment related adverse events due to off-target inhibition of wild-type EGFR, and treating brain metastases.

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; Nuvalent's estimated cash runway; the expected timing of potential new product candidate announcements, clinical trial initiations, FDA submissions, product approvals and commercial launch, including the projections in our OnTarget 2026 operating plan; the clinical development programs for zidesamtinib, neladalkib and NVL-330; the potential clinical effects of Nuvalent's product development candidates; the design, timing and enrollment of Nuvalent's clinical trials, including for the ARROS-1, ALKOVE-1 and ALKAZAR trials their intended pivotal registration-directed design; the potential of Nuvalent's pipeline programs, including zidesamtinib, neladalkib and NVL-330 and expectations regarding Nuvalent's discovery pipeline; Nuvalent's potential commercialization of its product candidates, if approved; the implications of data readouts and presentations; timing and content of potential discussions with FDA; 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 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 zidesamtinib or neladalkib; risks that Nuvalent may not achieve the goals and milestones set forth in its OnTarget 2026 operating plan; 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 ARROS-1, ALKOVE-1, ALKAZAR and HEROEX-1 trials; 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 quarterly period 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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