

Nuvalent to Present Preliminary Data from ALKOVE-1 Phase 1/2 Clinical Trial of NVL-655 at 35th AACR-NCI-EORTC Symposium

Company plans to host a conference call on October 13, 2023

CAMBRIDGE, Mass., Sept. 18, 2023 [/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 it will present preliminary dose-escalation data from its ongoing ALKOVE-1 Phase 1/2 clinical trial of NVL-655 at the 35th AACR-NCI-EORTC (ANE) Symposium taking place October 11-15, 2023, in Boston, Massachusetts.

The presentation marks the first disclosure of data characterizing the safety and clinical activity of NVL-655 from the Phase 1 dose-escalation portion of the ongoing ALKOVE-1 Phase 1/2 clinical trial evaluating NVL-655 in patients with advanced ALK-positive non-small cell lung cancer (NSCLC) and other solid tumors. NVL-655 has been designed with the aim to address challenges that limit clinical use of existing ALK tyrosine kinase inhibitors (TKIs), including treatment emergent resistance mutations, lack of brain penetrance, and off-target CNS adverse events. The ALKOVE-1 clinical trial is continuing to enroll patients in the Phase 1 portion of the trial.

Nuvalent plans to host a conference call and webcast on October 13, 2023. Details for the conference call will

be provided at a future date and available on the Nuvalent website at www.nuvalent.com.

Details for the presentation are as follows:

Title: Safety and preliminary activity of the selective ALK inhibitor NVL-655 in patients with ALK fusion-positive solid tumors

Abstract Number: 35177

Poster Number: B154

Session: Poster Session B

Session Date and Time: Friday, October 13, 12:30 pm-4:00 pm

Presenting Author: Jessica J Lin, Massachusetts General Hospital (MGH), Boston, MA

About NVL-655

NVL-655 is a novel brain-penetrant ALK-selective inhibitor created to overcome limitations observed with currently available ALK inhibitors. NVL-655 is designed to remain active in tumors that have developed resistance to first-, second-, and third-generation ALK inhibitors, including tumors with the solvent front G1202R mutation or compound mutations G1202R / L1196M ("GRLM"), G1202R / G1269A ("GRGA"), or G1202R/L1198F ("GRLF"). NVL-655 has been optimized for CNS penetrance to improve treatment options for patients with brain metastases. NVL-655 has been observed in preclinical studies to selectively inhibit wild-type ALK and its resistance variants over the structurally related tropomyosin receptor kinase (TRK) family to potentially avoid TRK-related CNS adverse events seen with dual TRK/ALK inhibitors and drive more durable responses for patients. NVL-655 is currently being investigated in the ALKOVE-1 clinical trial ([NCT05384626](https://clinicaltrials.gov/ct2/show/study/NCT05384626)), a first-in-human Phase 1/2 clinical trial for patients with advanced ALK-positive non-small cell lung cancer (NSCLC) and other solid tumors.

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 parallel lead programs in ROS1-positive and ALK-positive non-small cell lung cancer (NSCLC), a program in HER2 Exon 20 Insertion positive cancers, and multiple discovery-stage research programs. We routinely post information that may be important to investors on our website at www.nuvalent.com. Follow us on Twitter ([@nuvalent](https://twitter.com/nuvalent)) and [LinkedIn](https://www.linkedin.com/company/nuvalent).

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 preclinical and clinical development programs for NVL-655; the potential clinical effect of NVL-655; the design and enrollment of the ALKOVE-1 clinical trial; the potential of NVL-655; 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," "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 the ALKOVE-1 clinical trial 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, including ALKOVE-1; the occurrence of adverse safety events; 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 ALKOVE-1 clinical trial; 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 the Company's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2023, 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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