

# Nuvalent to Present New Preclinical Data on ALK-Selective Inhibitor NVL-655 at AACR Annual Meeting 2023

CAMBRIDGE, Mass., March 14, 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 an upcoming preclinical data poster presentation supporting the ongoing clinical development of its ALK-selective inhibitor, NVL-655. The data, resulting from a collaboration with the Yonsei University College of Medicine, will be presented at the American Association for Cancer Research (AACR) Annual Meeting 2023, taking place April 14-19 in Orlando, Florida.

The poster describes the preclinical intracranial antitumor activity of NVL-655 in a brain-implanted xenograft model derived from a patient with lung cancer harboring the alectinib-resistant EML4-ALK v3 G1202R mutation. The poster additionally expands the characterization of NVL-655 alongside other ALK inhibitors. NVL-655 has previously demonstrated intracranial efficacy in a cell line-derived xenograft model as well as broad preclinical activity across diverse ALK resistance mutations and tumor types while maintaining high selectivity for ALK over TRKB. NVL-655 is currently being investigated in the ALKOVE-1 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.

The poster will be archived on the Nuvalent website at [www.nuvalent.com](http://www.nuvalent.com) following the presentation.

## **Details for the poster presentation are as follows:**

**Title:** [Preclinical intracranial activity of NVL-655 in an alectinib-resistant patient-derived model harboring EML4-ALK fusion with G1202R mutation](#)

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**Presenter:** Anupong Tangpeerachaikul, Ph.D.

**Permanent Abstract:** 4022

**Session Category:** Experimental and Molecular Therapeutics

**Session Title:** Tyrosine Kinase and Phosphatase Inhibitors 1

**Session Date and Time:** Tuesday April 18, 2023 from 9:00 a.m. – 12:30 p.m. ET

**Location:** Orange County Convention Center, Poster Section 20

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## 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 study ([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](https://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 preclinical and clinical development programs for NVL-655; the potential clinical effect of NVL-655; the design and enrollment of the ALKOVE-1 study; the potential of Nuvalent's pipeline programs, including 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 study 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 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 COVID-19 or other global geopolitical circumstances on the timing and anticipated timing and results of Nuvalent's clinical trials, strategy, and future operations, including the ALKOVE-1 study; the timing and outcome of Nuvalent's planned interactions with regulatory authorities; and obtaining, maintaining, and protecting its 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 September 30, 2022, 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.

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<https://investors.nuvalent.com/2023-03-14-Nuvalent-to-Present-New-Preclinical-Data-on-ALK-Selective-Inhibitor-NVL-655-at-AACR-Annual-Meeting-2023>