Nuvalent to Present ALKOVE-1 Trial in Progress Poster for NVL-655 at the European Lung Cancer Congress (ELCC 2023)

CAMBRIDGE, Mass., March 23, 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 poster presentation for the ongoing Phase 1/2 ALKOVE-1 study of its ALK-selective inhibitor, NVL-655. The poster will be presented at the European Lung Cancer Congress (ELCC 2023), taking place in Copenhagen, Denmark, and virtually, March 29 – April 1, 2023.

The "Trial in Progress" poster includes background and study design considerations for the ALKOVE-1 Phase 1/2 study (NCT05384626) evaluating the safety and preliminary activity of NVL-655 in patients with solid tumors harboring oncogenic ALK alterations, including those with acquired ALK resistance mutations and CNS metastases. The first-in-human, multicenter, open-label, dose-escalation and expansion study is currently evaluating NVL-655 as an oral monotherapy in the Phase 1 portion.

The poster will be archived on the Nuvalent website atwww.nuvalent.com following the presentation.

Details for the poster presentation are as follows:

Title: NVL-655, a Selective Anaplastic Lymphoma Kinase (ALK) Inhibitor, in Patients with Advanced ALK-Positive Solid Tumors: The Phase 1/2 ALKOVE-1 Study
Authors: Melissa Johnson[1], Sai-Hong Ignatius Ou[2], Enriqueta Felip[3], Christina Baik[4], Benjamin Besse[5], Julien Mazieres[6], D. Ross Camidge[7], Shirish Gadgeel[8], Alexander Drilon[9], Yasir Elamin[10], Geoffrey Liu[11], Joshua E. Reuss[12], Tina Kehrig[13], Henry E. Pelish[13], Viola Zhu[13], Jessica J. Lin[14]
Presentation Number: 81TiP
Abstract Category: Advanced NSCLC
Session Date and Time: Friday, March 31, 2023 from 12:00 – 12:45pm CEST
Location: Bella Center Copenhagen, Exhibition and Poster Area

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[6]Institut Universitaire du Cancer, Toulouse, France, [7]University of Colorado Cancer Center - Anschutz Medical Campus, Aurora, CO, United States of America, [8]Henry Ford Cancer Institute, Detroit, MI, United States of America, [9]Memorial Sloan Kettering Cancer Center and Weill Cornell Medical Center, New York, NY, United States of America, [10]MD Anderson Cancer Center, Houston, TX, United States of America, [11]Princess Margaret Cancer Center, Toronto, Ontario, Canada, [12]Georgetown University, Washington, DC, United States of America, [13]Nuvalent, Inc., Cambridge, MA, United States of America, [14]Massachusetts General Hospital, Boston, MA, United States of America

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), 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) and LinkedIn.

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 Annual Report on Form 10-K for the fiscal year ended December 31, 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.

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