Nuvalent to Present Updated Data for ROS1-Selective Inhibitor, Zidesamtinib, and ALK-Selective Inhibitor, NVL-655, at the ESMO Congress 2024

CAMBRIDGE, Mass., July 16, 2024 /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 that updated data from the ARROS-1 Phase 1/2 clinical trial of zidesamtinib and ALKOVE-1 Phase 1/2 clinical trial of NVL-655, will be presented during two oral presentations at the European Society for Medical Oncology (ESMO) Congress 2024 taking place September 13-17, 2024, in Barcelona, Spain.

Details for the presentations are as follows:

Title: Phase 1/2 ALKOVE-1 study of NVL-655 in ALK-positive (ALK+) solid tumors
Presentation Number: 1253O
Session Category: Proffered paper session
Session Title: NSCLC metastatic
Presentation Date and Time: Saturday September 14, 2024, 9:40 –9:50 CEST
Location: Barcelona Auditorium – Hall 2
Presenter: Alexander Drilon, M.D. (Memorial Sloan Kettering Cancer Center,New York, USA)

Title: Phase 1/2 ARROS-1 study of zidesamtinib (NVL-520) in ROS1 fusion-positive solid tumors
Presentation Number: 1256MO
Session Category: Mini oral session
Session Title: NSCLC metastatic
Presentation Date and Time: Saturday September 14, 2024, 10:30 –10:35 CEST
Location: Santander Auditorium – Hall 5
Presenter: Benjamin Besse, M.D., Ph.D. (Institut Gustav Roussy, Villejuif,France)

Additionally, the company will present new preclinical data further characterizing the intracranial activity of zidesamtinib during a

poster session. The title is:

Title: Profiling of Zidesamtinib and Other ROS1 Inhibitors in an Intracranial CD74-ROS1 G2032R Preclinical Model
Abstract Number: 4811
Presenter: Anupong Tangpeerachaikul (Nuvalent, Inc., Cambridge, Massachusetts, United States)

About zidesamtinib
Zidesamtinib is a novel 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. Zidesamtinib has received breakthrough therapy designation for the treatment of patients with ROS1-positive metastatic non-small cell lung cancer (NSCLC) who have been previously treated with 2 or more ROS1 tyrosine kinase inhibitors and orphan drug designation for ROS1-positive NSCLC. Zidesamtinib is currently being investigated in the ARROS-1 trial (NCT05118789), a first-in-human Phase 1/2 clinical trial for patients with advanced ROS1-positive NSCLC and other solid tumors.

About NVL-655
NVL-655 is a novel brain-penetrant ALK-selective inhibitor created with the aim 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 single or compound treatment-emergent ALK mutations such as G1202R. In addition, NVL-655 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. NVL-655 has received orphan drug designation for ALK-positive non-small cell lung cancer (NSCLC) and is currently being investigated in the ALKOVE-1 clinical trial (NCT05384626), a first-in-human Phase 1/2 clinical trial for patients with advanced ALK-positive 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 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; the potential benefits and effects of Nuvalent's product development candidates; the potential of Nuvalent's pipeline programs, including zidesamtinib and NVL-655; 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," "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 ARROS-1 or ALKOVE-1 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; 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 and ALKOVE-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 March 31, 2024, 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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