Nuvalent Announces Anticipated Timing of Preliminary Phase 1 Dose-Escalation Data for NVL-655 and Reports First Quarter 2023 Financial Results

Preliminary dose-escalation data anticipated in second half of 2023 from ongoing ALKOVE-1 Phase 1/2 clinical trial of NVL-655 for patients with advanced ALK-positive NSCLC and other

solid tumors

Strong financial position with expected operating runway into the second half of 2025

CAMBRIDGE, Mass., May 11, 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 plans to share preliminary data from the dose-escalation portion of its ongoing ALKOVE-1 Phase 1/2 clinical trial for NVL-655, a novel ALK-selective inhibitor, in the second half of 2023, and reported first quarter 2023 financial results.

ALKOVE-1 is a Phase 1/2, multicenter, open-label, dose-escalation and expansion trial evaluating NVL-655 in patients with advanced ALK-positive non-small cell lung cancer (NSCLC) and other solid tumors. The Phase 1 dose-escalation portion of the study is enrolling patients with previously treated ALK-positive solid tumors and will evaluate the overall safety and tolerability of NVL-655. Additional objectives include determination of the recommended Phase 2 dose (RP2D), characterization of the pharmacokinetic profile, and evaluation of preliminary anti-tumor activity. Preclinical data, including those presented recently at the American Association for Cancer Research (AACR) Annual Meeting 2023, demonstrated that NVL-655 had broad preclinical activity across diverse ALK oncoproteins, single and compound resistance mutations, and tumor types while maintaining strong selectivity for ALK over TRKB and CNS penetrance.

"2023 is a year of focused, data-driven execution towards our goal of delivering a pipeline of novel kinase inhibitors to patients as efficiently as possible," said James Porter, Ph.D., Chief Executive Officer at Nuvalent. "We plan to report preliminary data from our ALKOVE-1 trial of NVL-655 for patients with advanced ALK-positive NSCLC and other solid tumors in the second half of the year. We continue to enroll patients in the Phase 1 portion of the ARROS-1 trial of NVL-520 for advanced ROS1-positive NSCLC and other solid tumors in support of RP2D selection, and to advance NVL-330, our novel HER2-selective inhibitor for patients with HER2 exon 20 insertion-positive cancers, through IND-enabling studies. With a solid cash position and an expert team, we are well-positioned to deliver on both our near- and long-term goals."

First Quarter 2023 Financial Results

- **Cash Position & Operating Runway:** Cash, cash equivalents and marketable securities were $450.5 million as of March 31, 2023. Nuvalent believes the existing cash, cash equivalents and marketable securities are expected to be sufficient to fund its current operating plan into the second half of 2025.
- **R&D Expenses:** Research and development (R&D) expenses were $22.1 million for the first quarter of 2023.
- **G&A Expenses:** General and administrative (G&A) expenses were $8.1 million for the first quarter of 2023.
- **Net Loss:** Net loss for the first quarter of 2023 was $25.2 million, or $0.44 per share.

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 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 period over which Nuvalent estimates its cash, cash equivalents and marketable securities will be sufficient to fund its future operating expenses and capital expenditure requirements; the expected timing of data announcements; the preclinical and clinical development programs for NVL-520, NVL-655 and NVL-330; the potential clinical effect of NVL-520 and NVL-655; the potential benefits of NVL-330; the design and enrollment of the ARROS-1 and ALKOVE-1 studies; the potential of Nuvalent's pipeline programs, including NVL-520, NVL-655 and NVL-330; 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 studies 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 ARROS-1 and ALKOVE-1 studies; 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 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.

SELECTED STATEMENTS OF OPERATIONS DATA
(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended March 31,	
	2023	**2022**
Operating expenses:		
Research and development	$ 22,125	$ 12,693
General and administrative	8,085	4,995
Total operating expenses	30,210	17,688
Loss from operations	(30,210)	(17,688)
Other income (expense):		
Interest income and other income, net	5,018	139
Total other income, net	5,018	139
Net loss	$ (25,192)	$ (17,549)

Net loss per share attributable to common stockholders, basic and diluted	$ (0.44)	$ (0.36)
Weighted average shares of common stock outstanding, basic and diluted	56,703,873	48,284,778

SELECTED BALANCE SHEET DATA
(In thousands)
(Unaudited)

	March 31, 2023	December 31, 2022
Cash, cash equivalents and marketable securities	$ 450,462	$ 472,163
Working capital	$ 439,272	$ 458,510
Total assets	$ 460,989	$ 482,459
Total liabilities	$ 17,021	$ 19,481
Total stockholders' equity	$ 443,968	$ 462,978

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