Nuvalent Highlights Pipeline Progress and Reports Second Quarter 2023 Financial Results

Continued execution across pipeline with clinical trials ongoing for NVL-520 and NVL-655, and advancement of NVL-330 toward clinical development

Preliminary dose-escalation data anticipated from ongoing ALKOVE-1 study of NVL-655 for patients with advanced ALK-positive NSCLC and other solid tumors at a medical meeting in the fourth quarter of 2023

$431.2 million in cash, cash equivalents and marketable securities expected to support operating runway into the second half of 2025

CAMBRIDGE, Mass., Aug. 10, 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 highlighted pipeline progress and reported second quarter 2023 financial results.

"As we enter the second half of 2023, we are well positioned to continue advancing our pipeline of novel kinase inhibitors," said James Porter, Ph.D., Chief Executive Officer at Nuvalent. "The focused efforts of our team in the first half of 2023 have laid the foundation for a number of meaningful development milestones, including the planned reporting of preliminary Phase 1 data at a medical meeting in the fourth quarter of the year from the dose-escalation portion of our ALKOVE-1 Phase 1/2 trial of NVL-655. Additionally, progress continues towards the selection of a recommended Phase 2 dose and transition to Phase 2 in our ARROS-1 Phase 1/2 trial

of NVL-520, and the submission of a new IND application for NVL-330 for the treatment of patients with HER2 exon 20 insertion-positive cancers. I'm incredibly proud of what this team has accomplished to date and look forward to providing further updates later on this year."

Pipeline Highlights and Key Anticipated Milestones

- **Preliminary Data from ALKOVE-1 Phase 1/2 Trial of NVL-655 Anticipated at a Medical Meeting in the Fourth Quarter of 2023:** NVL-655 is a brain-penetrant ALK-selective inhibitor designed with the aim to address the clinical challenges of emergent treatment resistance, central nervous system (CNS)-related adverse events, and brain metastases that may limit the use of first-, second-, and third-generation ALK inhibitors. Our ALKOVE-1 clinical trial is a first-in-human Phase 1/2, multicenter, open-label, dose-escalation and expansion study evaluating NVL-655 as an oral monotherapy in patients with advanced ALK-positive 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. The company anticipates reporting preliminary dose-escalation data from this trial at a medical meeting in the fourth quarter of 2023.
- **ARROS-1 Phase 1/2 Trial of NVL-520 Progressing Toward Selection of RP2D:** NVL-520 is a novel ROS1-selective inhibitor designed with the aim to address the clinical challenges of emergent treatment resistance, CNS-related adverse events, and brain metastases that may limit the use of currently available ROS1 inhibitors. Our ARROS-1 clinical trial is a first-in-human Phase 1/2, multicenter, open-label, dose-escalation and expansion study evaluating NVL-520 as an oral monotherapy in patients with advanced ROS1-positive NSCLC and other solid tumors. Enrollment of patients with previously treated ROS1-positive solid tumors is ongoing in the Phase 1 portion of ARROS-1 and the company is advancing toward the selection of an RP2D.
- **NVL-330 Continuing to Advance through IND-enabling Studies:** NVL-330, is a brain-penetrant HER2-selective inhibitor designed with the aim to address the combined medical need of treating tumors driven by HER2 mutations occurring through deletions, insertions, or duplications (collectively, known as HER2 Exon 20 Insertions, or HER2ex20), treating brain metastases, and avoiding treatment-limiting adverse events including due to off-target inhibition of wild-type EGFR. NVL-330 is advancing through IND-enabling studies.

Second Quarter 2023 Financial Results

- **Cash Position & Operating Runway:** Cash, cash equivalents and marketable securities were $431.2 million as of June 30, 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 $25.9 million for the second quarter of 2023.
- **G&A Expenses:** General and administrative (G&A) expenses were $8.1 million for the second quarter of 2023.
- **Net Loss:** Net loss for the second quarter of 2023 was $29.1 million, or $0.51 per share.

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 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 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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 25,922	$ 13,558	$ 48,047	$ 26,251
General and administrative	8,140	5,175	16,225	10,170
Total operating expenses	34,062	18,733	64,272	36,421
Loss from operations	(34,062)	(18,733)	(64,272)	(36,421)
Other income (expense):				
Interest income and other income (expense), net	4,972	267	9,990	406
Total other income, net	4,972	267	9,990	406
Net loss	$ (29,090)	$ (18,466)	$ (54,282)	$ (36,015)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.51)	$ (0.38)	$ (0.96)	$ (0.75)

Weighted average shares of common stock outstanding, basic and diluted	56,866,991	48,319,067	56,785,883	48,302,017

SELECTED BALANCE SHEET DATA
(In thousands)
(Unaudited)

	June 30, 2023	December 31, 2022
Cash, cash equivalents and marketable securities	$ 431,239	$ 472,163
Working capital	$ 416,197	$ 458,510
Total assets	$ 441,948	$ 482,459
Total liabilities	$ 20,795	$ 19,481
Total stockholders' equity	$ 421,153	$ 462,978

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