Nuvalent Highlights Execution Across Pipeline of Novel Kinase Inhibitors and Reports Second Quarter 2022 Financial Results

Preliminary dose escalation data expected in second half of 2022 from the ARROS-1 study of NVL-520 for advanced ROS1 positive NSCLC and other solid tumors

Rapid advancement of pipeline with clinical trials ongoing for NVL-520 and NVL-655 and two additional development candidates on-track for selection in 2022

CAMBRIDGE, Mass., Aug. 10, 2022 /PRNewswire/ -- Nuvalent, Inc. (Nasdaq: NUVL), a clinical-stage biopharmaceutical company focused on creating *precisely* targeted therapies for clinically proven kinase targets in cancer, today reported pipeline progress and second quarter 2022 financial results.

"Our focus for 2022 is on execution across our pipeline of novel kinase inhibitors, and the Nuvalent team has continued to deliver. In the past quarter, we announced our plan to share preliminary dose escalation data in the second half of 2022 from the Phase 1 portion of our Phase 1/2 ARROS-1 trial for patients with advanced ROS1-positive non-small cell lung cancer (NSCLC) and other solid tumors, and dosed the first patient in our Phase 1/2 ALKOVE-1 trial for patients with advanced ALK-positive NSCLC and other solid tumors," said James Porter, Ph.D., Chief Executive Officer at Nuvalent. "Additionally, we've continued to advance our discovery pipeline and remain poised to nominate two additional development candidates by the end of this year – a testament to the strength, ingenuity, and efficiency of the Nuvalent team, our capabilities, and approach. This is an exciting time for our company, and I'm confident in our ability to deliver on our goal of *precisely* targeted therapies that can enable deep and durable responses for patients with cancer."

Recent Pipeline Achievements and Anticipated Near-Term Milestones

- **Preliminary Dose-Escalation Data from Ongoing ARROS-1 Trial Anticipated in the Second Half of 2022:** Nuvalent's Phase 1/2 ARROS-1 clinical trial evaluating NVL-520 in patients with advanced ROS1-positive NSCLC and other solid tumors, is progressing well and is continuing to enroll patients in the Phase 1 portion of the study. NVL-520 is a ROS1-selective inhibitor designed to address the clinical challenges of emergent treatment resistance, off-target CNS adverse events, and brain metastases that may limit the use of currently available ROS1 kinase inhibitors. The company plans to share preliminary data from the dose-escalation portion of the trial in the second half of 2022.
- **Dosing Initiated and Enrollment Ongoing in ALKOVE-1 Trial:** Nuvalent is actively dosing patients in the Phase 1 portion of its ALKOVE-1 trial, a Phase 1/2, multicenter, open-label, dose-escalation and expansion trial evaluating NVL-655 in patients with advanced ALK-positive NSCLC and other solid tumors. NVL-655, Nuvalent's parallel lead product candidate, is an ALK-selective inhibitor designed to address the clinical challenges of emergent treatment resistance, off-target CNS adverse events, and brain metastases that may limit the use of currently available ALK kinase inhibitors.
- **New NVL-655 Preclinical Data Presented at IASLC 2022 World Conference on Lung Cancer Annual Meeting:** A poster characterizing NVL-655 alongside other ALK inhibitors in a patient-derived model of lorlatinib-resistant ALK-positive NSCLC with the treatment-emergent G1202R/T1151M compound resistance mutation was presented at the IASLC 2022 World Conference on Lung Cancer (WCLC) Annual Meeting. The preclinical activity of NVL-655, as described in the poster presented, continues to support the potential for a best-in-class profile.
- **On-Track to Select Two Additional Development Candidates from Discovery Pipeline in 2022:** Nuvalent continues to advance its pipeline expansion efforts with multiple discovery-stage research programs. The company expects to select development candidates for its programs directed toward ALK IXDN compound resistance mutations and HER2 Exon 20 insertions in the second half of 2022.

Second Quarter 2022 Financial Results

- **Cash Position:** Cash, cash equivalents and marketable securities were $257.0 million as of June 30, 2022. Nuvalent continues to expect the existing cash and cash equivalents to be sufficient to fund its planned operations into 2024.
- **R&D Expenses:** Research and development (R&D) expenses were $13.6 million for the second quarter of 2022.
- **G&A Expenses:** General and administrative (G&A) expenses were $5.2 million for the second quarter of 2022.
- **Net Loss:** Net loss for the second quarter of 2022 was $18.5 million, or $0.38 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), along with 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 clinical development programs for NVL-520, NVL-655, ALK IXDN compound resistance mutations and HER2 Exon 20 insertions and the timing thereof; the potential clinical effect of NVL-520 and NVL-655; the design and enrollment of the ARROS-1 and ALKOVE-1 studies and the timing thereof; the potential of Nuvalent's pipeline programs, including NVL-520 and NVL-655; Nuvalent's research and development programs for the treatment of cancer; risks and uncertainties associated with drug development; and capital allocation. 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 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 HER2 Exon 20 and ALK IXDN 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, 2021, as well as any 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,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 13,558	$ 7,826	$ 26,251	$ 13,310
General and administrative	5,175	2,024	10,170	2,702
Total operating expenses	18,733	9,850	36,421	16,012
Loss from operations	(18,733)	(9,850)	(36,421)	(16,012)
Other income (expense):				
Change in fair value of preferred stock tranche rights	—	—	—	(635)
Other income, net	267	12	406	24
Total other income (expense), net	267	12	406	(611)
Net loss	$ (18,466)	$ (9,838)	$ (36,015)	$ (16,623)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.38)	$ (3.17)	$ (0.75)	$ (5.37)
Weighted average shares of common stock outstanding, basic and diluted	48,319,067	3,106,152	48,302,017	3,095,639

SELECTED BALANCE SHEET DATA
(In thousands)
(Unaudited)

	June 30, 2022	December 31, 2021
Cash, cash equivalents and marketable securities	$ 256,964	$ 288,111
Working capital	$ 248,786	$ 281,841
Total assets	$ 263,021	$ 293,824
Total liabilities	$ 10,036	$ 8,787
Total stockholders' equity	$ 252,985	$ 285,037

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