Nuvalent Highlights Pipeline and Business Progress and Reports Fourth Quarter and Full Year 2022 Financial Results

Significant progress made across pipeline of novel kinase inhibitors with parallel-lead programs in ongoing Phase 1 clinical trials and a third program advancing toward clinical development

Strengthened leadership team with key internal promotions

Strong financial position with $472 million in cash, cash equivalents and marketable securities to support operating runway into the second half of 2025

CAMBRIDGE, Mass., March 16, 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 and business progress and fourth quarter and full year 2022 financial results.

"2022 was a remarkable year of progress for Nuvalent. The first half of the year marked our transition to a clinical-stage company with the initiation of dosing in clinical trials for both of our parallel-lead programs, ROS1-selective inhibitor, NVL-520, and ALK-selective inhibitor, NVL-655. The team continued to execute through the second half of the year with our first clinical data presentation demonstrating preliminary clinical proof-of-concept data for NVL-520, as well as the nomination of our third novel development candidate, NVL-330, for HER2 exon 20-positive cancers," said James Porter, Ph.D., Chief Executive Officer at Nuvalent. "Going into 2023, we remain committed to following the data and opportunities to carry this positive progress forward. Enrollment continues in the Phase 1 portions of our ARROS-1 and ALKOVE-1

clinical trials, and we continue to progress NVL-330 towards IND as well as pursue further expansion of our discovery pipeline."

Dr. Porter continued, "To have discovered and advanced a pipeline of novel candidates to this point in just a few years from company creation is a testament to our team's expertise, ability to execute, and commitment to bringing new therapies to patients as quickly as possible. In recognition of their embodiment of these qualities and outstanding contributions to date, we are pleased to promote Dr. Henry Pelish to Senior Vice President, Drug Discovery, and Dr.John Soglia to Senior Vice President, Translational Development. I'm incredibly excited about the future of Nuvalent and believe that with a promising portfolio, dedicated and expert team, and a solid cash position, we are well-positioned to continue advancing towards our goal of delivering *precisely* targeted therapies for patients with cancer."

Key Achievements
To date, Nuvalent has achieved a number of milestones across its pipeline of novel kinase inhibitors and its research efforts, including:

NVL-520:

- Presented preliminary Phase 1 data supportive of the potential best-in-class profile of NVL-520 as a brain-penetrant, ROS1-selective inhibitor from the ongoing Phase 1/2 ARROS-1 study for patients with advanced ROS1-positive NSCLC and other solid tumors;
- Presented preclinical data supporting the potential for broad clinical utility of NVL-520 across an expanded set of ROS1 fusion partners, resistance mutations, and tumor types beyond NSCLC; and,
- Published the organization's first manuscript in *Cancer Discovery* describing the design and characterization of NVL-520 and detailing Nuvalent's approach to rationally targeting ROS1.

NVL-655:

- Initiated clinical development with parallel-lead candidate, NVL-655, a brain penetrant, ALK-selective inhibitor, in the Phase 1 portion of its ongoing ALKOVE-1 Phase 1/2 study for patients with advanced ALK-positive NSCLC and other solid tumors; and,
- Presented preclinical data in multiple patient derived models that continued to support the potential best-in-class preclinical profile of NVL-655.

Earlier-stage Pipeline:

- Declared a third development candidate, NVL-330, a novel HER2-selective inhibitor for patients with HER2 exon 20 insertion-positive cancers; and,
- Continued to advance pipeline expansion efforts with multiple discovery-stage research programs.

In addition, Nuvalent raised $264.5 million in an upsized public offering and strengthened its leadership with key internal promotions and appointments to its Board of Directors.

Recent Leadership Promotions

- **Henry Pelish, Ph.D., Promoted to Senior Vice President, DrugDiscovery:** Dr. Pelish contributed to the creation of Nuvalent and joined the company as Biology lead in 2018, bringing over 15 years of experience in cancer biology, chemical biology and organic synthesis. At Nuvalent, Dr. Pelish leads discovery efforts and oversaw the discovery and early-stage development of NVL-520, NVL-655 and NVL-330. Prior to joining Nuvalent, Dr. Pelish was a group leader in the laboratory of Professor Matthew Shair at Harvard University. In that role, he led a team that discovered a new target, mechanism of action and therapeutic opportunity for treatment of acute myeloid leukemia, culminating in a licensing deal and research agreement between Harvard and Merck in 2016. Dr. Pelish earned his Ph.D. in chemistry from Harvard University.
- **John Soglia, Ph.D., Promoted to Senior Vice President, Translational Development:**Dr. Soglia joined Nuvalent inJanuary 2020 and has since led the strategy and execution of translational development activities of the company's lead programs, including ADME, nonclinical safety and clinical pharmacology. Prior to Nuvalent, Dr. Soglia was at Decibel Therapeutics where, in addition to leading the DMPK, clinical pharmacology and regulated bioanalytical functions, he was the early Product Development Scientific Lead on the DB-020 program. Previously, he served as head of DMPK at Infinity Pharmaceuticals and was also the eganelisib (IPI-549) product development team leader, successfully leading the cross-functional team to IND submission and into early clinical development. Prior to Infinity Pharmaceuticals, he held various positions of increasing responsibility at GlaxoSmithKline and Pfizer. Dr. Soglia earned his Ph.D. in chemistry from Northeastern University.

Fourth Quarter and Full Year 2022 Financial Results

- **Cash Position:** Cash, cash equivalents and marketable securities were $472.2 million as of December 31, 2022. 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 $22.9 million for the fourth quarter of 2022 and$63.7 million for the year ended December 31, 2022, compared to $13.2 million for the fourth quarter of 2021 and $35.6 million for the year ended December 31, 2021.
- **G&A Expenses:** General and administrative (G&A) expenses were $6.4 million for the fourth quarter of 2022 and$22.4 million for the year ended December 31, 2022, compared to $4.2 million for the fourth quarter of 2021 and $10.3 million for the year ended December 31, 2021.
- **Net Loss:** Net loss was $26.1 million for the fourth quarter of 2022 and$81.9 million for the year ended December 31, 2022, compared to $17.3 million for the fourth quarter of 2021 and $46.3 million for the year ended December 31, 2021.

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 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 Quarterly Report on Form 10-Q for the quarterly period ended September 30, 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 December 31,		Year Ended December 31,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 22,855	$ 13,194	$ 63,731	$ 35,559
General and administrative	6,444	4,184	22,377	10,258
Total operating expenses	29,299	17,378	86,108	45,817
Loss from operations	(29,299)	(17,378)	(86,108)	(45,817)
Other income (expense):				
Change in fair value of preferred stock tranche rights	—	—	—	(635)
Interest income and other income, net	3,176	89	4,254	114
Total other income (expense), net	3,176	89	4,254	(521)
Net loss	$ (26,123)	$ (17,289)	$ (81,854)	$ (46,338)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.49)	$ (0.36)	$ (1.65)	$ (2.13)
Weighted average shares of common stock outstanding, basic and diluted	53,616,336	48,268,256	49,668,864	21,783,754

SELECTED BALANCE SHEET DATA
(In thousands)
(Unaudited)

	December 31,	
	2022	2021
Cash, cash equivalents and marketable securities	$ 472,163	$ 288,111
Working capital	$ 458,510	$ 281,841
Total assets	$ 482,459	$ 293,824
Total liabilities	$ 19,481	$ 8,787
Total stockholders' equity	$ 462,978	$ 285,037

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