Nuvalent Highlights Corporate and Pipeline Achievements and Reports Third Quarter 2023 Financial Results

Presented preliminary Phase 1 clinical data from ALKOVE-1 trial of NVL-655, initiated Phase 2 portion of ARROS-1 trial of NVL-520, and continued advancement of NVL-330 toward clinical development

Appointed industry veteran Perrin

Wilson Ph.D. as Senior Vice President of Business Development and Strategy

Net proceeds from $300 million public offering, along with cash, cash equivalents, and marketable securities as of September 30, 2023, expected to extend operating runway into 2027

CAMBRIDGE, Mass., Nov. 14, 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 third quarter 2023 financial results.

"This has been another incredible year of execution for Nuvalent. With our recent presentation at ANE, we have now delivered preliminary proof-of-concept data for both of our novel parallel lead programs in ROS1 and ALK-positive cancers, and our third development candidate, NVL-330, is advancing toward clinical development," said James Porter, Ph.D., Chief Executive Officer at Nuvalent. "This level of achievement in just over five years since first program inception is only made possible by the tireless dedication of our team to our goal of delivering potential new therapies to patients as quickly as possible."

Dr. Porter continued, "As we turn our focus towards execution on our global development plans to support potential NDA submission and continued portfolio expansion, we are committed to maintaining the high standard and sense of urgency we have established to date. We continue to grow our team in support of this next phase of development and are thrilled to welcome Dr. Perrin Wilson, who brings deep expertise in both business development and commercial strategy."

"We are encouraged by the positive reception to our progress and continued support from both new and longstanding stockholders, leading to a successful $300 million public offering," added Alexandra Balcom, Chief Financial Officer at Nuvalent. "With a strong portfolio, proven team, and meaningful cash runway extension expected into 2027, we believe we are well positioned to evaluate opportunities to further accelerate and expand the potential reach of our programs, and to deliver on our mid- and long-term goals."

Recent Pipeline Highlights and Key Anticipated Milestones

- **Reported Preliminary Phase 1 Clinical Data from ALKOVE-1 Trial that Support Best-In-Class Potential of NVL-655**

for Patients with ALK-Positive NSCLC: Nuvalent recently reported preliminary dose-escalation data from the Phase 1 portion of its ongoing ALKOVE-1 Phase 1/2 clinical trial in patients with advanced ALK-positive non-small cell lung cancer (NSCLC) at the 35th AACR-NCI-EORTC Symposium in Boston, Massachusetts. Preliminary activity was demonstrated in heavily pre-treated patients with ALK-positive NSCLC, including in subgroups of patients who had likely exhausted all available therapies including lorlatinib, had a history of brain metastases, or had single or compound ALK resistance mutations. Additionally, NVL-655 demonstrated a favorable preliminary safety profile consistent with its ALK-selective, TRK sparing design.

The ALKOVE-1 clinical trial is continuing to enroll patients in the Phase 1 portion of the trial and is focused on further characterizing the safety, pharmacokinetics, and pharmacodynamic profiles, determining the recommended Phase 2 dose (RP2D), and if applicable, the maximum tolerated dose of NVL-655. Upon RP2D selection, the trial is designed to transition directly into the Phase 2 portion, which will evaluate the safety and activity of NVL-655 in several expansion cohorts of patients defined based on the number and type of prior anti-cancer therapies they have received. The Phase 2 cohorts are intended to support potential registration in patients with ALK-positive NSCLC who are both lorlatinib-naïve and lorlatinib-treated.

In addition to the planned Phase 2 cohorts, Nuvalent intends to use these preliminary data in patients with heavily pre-treated ALK-positive NSCLC to guide discussions with physicians that will inform development strategies in TKI-naïve ALK-positive NSCLC.

- **Initiated the Phase 2 Portion of the ARROS-1 Trial of NVL-520 with Registrational Intent for Patients with Advanced ROS1-positive NSCLC:** Nuvalent announced the initiation of the Phase 2 portion of ARROS-1 trial following alignment with the US Food and Drug Administration (FDA) on a RP2D of 100 mg daily. The Phase 2 portion of the trial includes potential registrational cohorts for patients with TKI-naïve and TKI-pretreated ROS1-positive NSCLC. The company expects to share updated data from the ARROS-1 trial at a medical meeting in 2024.

- **Advancing NVL-330 through IND-enabling Studies:** Nuvalent is continuing to advance NVL-330, its novel HER2-selective inhibitor in development for the treatment of HER2 exon 20 insertion-positive cancers, through IND-enabling studies.

Recent Leadership Appointments

- **Strengthened Leadership Team with Appointment of Perrin Wilson, Ph.D., as Senior Vice President of Business Development & Strategy:** Dr. Wilson brings over 15 years of experience across business development and commercial functions, including leading deals from research stage to company acquisitions and integrations, championing brand strategy and product launches. Before joining Nuvalent, Dr. Wilson held positions of increasing responsibility at Forma Therapeutics/Novo Nordisk, including Head of Forma Business Development and Integration Management Office, Vice President Business Development and Senior Director Global Marketing, Sickle Cell Disease Strategy. During her time at Forma, Dr. Wilson led the Novo Nordisk acquisition and the out-licensing of Forma's oncology portfolio to three different partners, and was responsible for developing the global brand plan for Forma's lead molecule and supporting ex-US and lifecycle management strategy. Prior to Forma, Dr. Wilson spent seven years at Takeda in various business development and commercial roles leading several transactions to strengthen Takeda's oncology pipeline, including the acquisition of ARIAD, and leading the global strategy and pre-launch preparations for Takeda's myelodysplastic syndromes program. Dr. Wilson received her B.Sc. degree in biology from Lafayette College and a Ph.D. in biomedical sciences from The Rockefeller University.

Financing Highlight

- **Completed Successful Public Offering of Common Stock Raising $300 Million in Gross Proceeds:** On October 19, 2023, Nuvalent closed an underwritten public offering of 5,357,143 shares of Class A common stock at a price to the public of $56.00 per share. The gross proceeds from the offering were approximately $300 million, resulting in net proceeds of approximately $282 million after deducting underwriting discounts, commissions and other offering expenses.

Upcoming Events

- **Stifel 2023 Healthcare Conference:** Management will be participating in a fireside chat on Wednesday, November 15, 2023, at 12:00 pm ET in New York, NY.
- **Piper Sandler 35th Annual Healthcare Conference**: Management will be participating in a fireside chat on Wednesday, November 29, 2023, at 1:00 pm ET in New York, NY.

A live webcast of each fireside chat will be available in the Investors section of Nuvalent's website at www.nuvalent.com, and will be archived for 30 days following the conference.

Third Quarter 2023 Financial Results

- **Cash Position & Operating Runway:** Cash, cash equivalents and marketable securities were $413.3 million as of September 30, 2023. The company's cash, cash equivalents and marketable securities as of September 30, 2023, in

combination with the net proceeds from the public offering of approximately $282 million, are expected to extend the company's operating runway into 2027.
- **R&D Expenses:** Research and development (R&D) expenses were $29.6 million for the third quarter of 2023.
- **G&A Expenses:** General and administrative (G&A) expenses were $9.2 million for the third quarter of 2023.
- **Net Loss:** Net loss for the third quarter of 2023 was $33.6 million, or$0.59 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, a program in HER2 Exon 20 insertion-positive cancers, 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 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 trials, including for the ARROS-1 trial its intended pivotal registration-directed design; the potential of Nuvalent's pipeline programs, including NVL-520, NVL-655 and NVL-330; the implications of data readouts and presentations; timing and content of potential discussions with regulators and investigators; the design and timing of the planned Phase 2 portion of the ARROS-1 trial; 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 the ARROS-1 Phase 2 trial 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 NVL-520; 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 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 June 30, 2023, 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.

This press release contains hyperlinks to information that is not deemed to be incorporated by reference in this press release.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Operating expenses:				

Research and development	$ 29,611	$ 14,625	$ 77,658	$ 40,876
General and administrative	9,172	5,763	25,397	15,933
Total operating expenses	38,783	20,388	103,055	56,809
Loss from operations	(38,783)	(20,388)	(103,055)	(56,809)
Other income (expense):				
Interest income and other income (expense)	5,138	672	15,128	1,078
Total other income, net	5,138	672	15,128	1,078
Net loss	$ (33,645)	$ (19,716)	$ (87,927)	$ (55,731)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.59)	$ (0.41)	$ (1.55)	$ (1.15)
Weighted average shares of common stock outstanding, basic and diluted	57,091,394	48,410,514	56,888,839	48,338,580

SELECTED BALANCE SHEET DATA
(In thousands)
(Unaudited)

	September 30, 2023	December 31, 2022
Cash, cash equivalents and marketable securities	$ 413,258	$ 472,163

Working capital	$	390,670	$	458,510
Total assets	$	425,080	$	482,459
Total liabilities	$	29,103	$	19,481
Total stockholders' equity	$	395,977	$	462,978

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