Nuvalent Highlights Pipeline Progress, Reiterates Key Anticipated Milestones and Reports Fourth Quarter and Full Year 2023 Financial Results

Well-capitalized with operating runway anticipated into 2027

CAMBRIDGE, Mass., Feb. 27, 2024 /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, reiterated key anticipated milestones and reported fourth quarter and full year 2023 financial results.

"With our OnTarget 2026 operating plan as a clear guide, the Nuvalent team continues to prove its ability to execute on its goals as demonstrated by the recently announced initiation of the Phase 2 portion of our ALKOVE-1 study for NVL-655 and the receipt of FDA breakthrough therapy designation for NVL-520 based on preliminary data from our ARROS-1 study." **said Alexandra Balcom, Chief Financial Officer at Nuvalent**. "We now have two global registration-directed studies underway in support of our target of a first approved product in 2026 and we look forward to providing updates on both of our parallel lead programs at medical meetings later this year."

"Our ability to deliver on our program goals is interconnected with our ability to build the team and maintain a strong culture centered around our core values of Patient Impact, Empowerment, and Collaboration. In recognition of his leadership and contributions across these areas, we are proud to announce the promotion of Matthew Metivier to Senior Vice President of Human Resources," **said James Porter, Ph.D., Chief Executive Officer at Nuvalent.** "Backed by a dedicated and expert team, and a strong balance sheet, we are well positioned to continue delivering on our planned 2024 milestones across our portfolio of *precisely* targeted therapies for patients with cancer."

Recent Pipeline Progress and Anticipated Milestones

ROS1 Program

- The U.S. Food and Drug Administration (FDA) has granted breakthrough therapy designation (BTD) to NVL-520 for the treatment of patients with ROS1-positive metastatic non-small cell lung cancer (NSCLC) who have been previously treated with 2 or more ROS1 tyrosine kinase inhibitors (TKIs). NVL-520 was previously granted FDA Orphan Drug Designation for the treatment of ROS1-positive NSCLC.
- The company expects to share updated data from the ARROS-1 Phase 1/2 trial at a medical meeting in 2024. Enrollment is ongoing in the global Phase 2 portion of the study.

ALK Program

- Nuvalent recently announced the initiation of the Phase 2 portion of the ALKOVE-1 trial of NVL-655 for patients with advanced ALK-

positive NSCLC and other solid tumors, following alignment with the FDA on a recommended Phase 2 dose (RP2D) of 150 mg once daily. The Phase 2 portion of the ALKOVE-1 clinical trial is designed to 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 designed with registrational intent for TKI pre-treated patients with ALK-positive NSCLC and to enable preliminary evaluation in patients with ALK-positive NSCLC who are TKI naïve.
- The company expects to share updated data from the ALKOVE-1 trial at a medical meeting and to outline its broader front-line development strategy for its ALK program in 2024.

HER2 Program

- The company expects to initiate the Phase 1 trial for its HER2 program in 2024.

Recent Leadership Promotions

- **Promotion of Matthew Metivier to Senior Vice President of Human Resources:** Mr. Metivier brings over 20 years of experience in various human resources leadership roles, specifically within the biotechnology/pharmaceutical industry, with a focus on building companies and guiding organizations through the early development phase to commercial launch. At Nuvalent, Mr. Metivier has built and led our Human Resources capabilities and facilitated our people and culture strategy to ensure we optimize our work environment to attract, retain and develop the talent needed to achieve our mission. Prior to joining Nuvalent, he held leadership roles of increasing responsibility in human resources at Gamida Cell, Ltd, Sage Therapeutics, Inc, and Infinity Pharmaceuticals. Mr. Metivier holds an MBA from Suffolk University with a concentration in Organizational Behavior and a B.A. in Political Science and Business Studies from Providence College.

Upcoming Events

- **TD Cowen 44th Annual Health Care Conference:** Management will be participating in a fireside chat on Wednesday, March 6, 2024, at 1:30 p.m. ET in Boston, MA.
- **Leerink Global Biopharma Conference 2024:** Management will be participating in a fireside chat on Tuesday, March 12, 2024, at 8:00 a.m. ET in Miami, FL.

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.

Fourth Quarter and Full Year 2023 Financial Results

- **Cash Position:** Cash, cash equivalents and marketable securities were $719.9 million as of December 31, 2023. Nuvalent believes these existing cash, cash equivalents and marketable securities to be sufficient to fund its current operating plan into 2027.
- **R&D Expenses:** Research and development (R&D) expenses were $35.6 million for the fourth quarter of 2023 and $113.2 million for the year ended December 31, 2023.
- **G&A Expenses:** General and administrative (G&A) expenses were $10.9 million for the fourth quarter of 2023 and $36.2 million for the year ended December 31, 2023.
- **Net Loss:** Net loss was $38.3 million for the fourth quarter of 2023 and $126.2 million for the year ended December 31, 2023.

About OnTarget 2026

OnTarget 2026 delineates Nuvalent's 3-year operating plan towards bringing new, potential best-in-class medicines to patients with cancer. As part of this plan announced in January 2024, Nuvalent outlined the following anticipated milestones throughout 2024, leading to the company's first potential pivotal data in 2025 and first potential approved product in 2026:

- ***2024: Execute on Global Registrational Strategies***
    - Progress the Phase 2 portion of its ARROS-1 trial of NVL-520 in patients with advanced ROS1-positive NSCLC with registrational intent;
    - Initiate the Phase 2 portion of its ALKOVE-1 trial of NVL-655 in patients with advanced ALK-positive NSCLC with registrational intent;
    - Launch the front-line development strategy for its ALK program;
    - Present interim data from its ongoing ARROS-1 and ALKOVE-1 clinical trials at medical meetings; and,
    - Initiate the Phase 1 trial for its HER2 program.
- ***2025: First Pivotal Data***
- ***2026: First Approved Product***

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 investigational candidates for ROS1-positive, ALK-positive, and HER2-positive non-small cell lung cancer, 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; Nuvalent's estimate of its cash, cash equivalents and marketable securities as of December 31, 2023; the expected timing of data announcements, clinical trial initiations and FDA product approvals, including the projections in our OnTarget 2026 operating plan; 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 their 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 and ALKOVE-1 trials; 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 our clinical trials 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 our product candidates; risks that Nuvalent may not achieve the goals and milestones set forth in its OnTarget 2026 operating plan; the occurrence of adverse safety events; risks that the FDA may not approve our potential products on the timelines we expect, or at all; 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 September 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.

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

	Three Months Ended December 31,		Year Ended December 31,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 35,585	$ 22,855	$ 113,243	$ 63,731
General and administrative	10,852	6,444	36,249	22,377
Total operating expenses	46,437	29,299	149,492	86,108
Loss from operations	(46,437)	(29,299)	(149,492)	(86,108)
Other income (expense):				
Interest income and other income (expense), net	8,145	3,176	23,273	4,254
Total other income (expense), net	8,145	3,176	23,273	4,254
Net loss	$ (38,292)	$ (26,123)	$ (126,219)	$ (81,854)
Net loss per share				

attributable to common stockholders, basic and diluted	$ (0.62)	$ (0.49)	$ (2.17)	$ (1.65)
Weighted average shares of common stock outstanding, basic and diluted	62,183,325	53,616,336	58,223,339	49,668,864

SELECTED BALANCE SHEET DATA
(In thousands)
(Unaudited)

	December 31,	
	2023	**2022**
Cash, cash equivalents and marketable securities	$ 719,905	$ 472,163
Working capital	$ 694,665	$ 458,510
Total assets	$ 732,384	$ 482,459
Total liabilities	$ 31,823	$ 19,481
Total stockholders' equity	$ 700,561	$ 462,978

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https://investors.nuvalent.com/2024-02-27-Nuvalent-Highlights-Pipeline-Progress,-Reiterates-Key-Anticipated-Milestones-and-Reports-Fourth-Quarter-and-Full-Year-2023-Financial-Results