Nuvalent Reports Pipeline and Business Progress and Fourth Quarter and Full Year 2021 Financial Results

NVL-655 IND cleared by FDA, supporting planned initiation of ALKOVE-1 Phase 1/2 clinical trial in patients with ALK-positive NSCLC and other solid tumors in second quarter of 2022

Enrollment ongoing in

ARROS-1 trial of NVL-520 for advanced ROS1-positive NSCLC and other solid tumors

Discovery pipeline continues to advance toward two development candidate nominations in 2022

CAMBRIDGE, Mass., March 29, 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 and business progress and fourth quarter and full year 2021 financial results.

As part of today's update, Nuvalent is announcing that its Investigational New Drug (IND) application for NVL-655 for the treatment of ALK-positive NSCLC and other solid tumors was cleared by the U.S. Food and Drug Administration (FDA). NVL-655 is a novel 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 currently available ALK inhibitors. Nuvalent plans to initiate the ALKOVE-1 Phase 1/2 study of NVL-655 for patients with advanced ALK-positive non-small cell lung cancer (NSCLC) and other solid tumors in the second quarter of 2022.

"The Nuvalent team has continued to demonstrate the ability to discover novel molecules with preclinical profiles suggesting best-in-class potential and to progress them efficiently into clinical development. With the clearance of our IND for NVL-655, Nuvalent is on track to have two parallel lead compounds in clinical trials by mid-year," said James Porter, Ph.D., Chief Executive Officer at Nuvalent. "We believe we are well positioned with two clinical-stage, novel product candidates in areas of significant medical need, and sustainable internal discovery efforts with the goal of delivering multiple additional product candidates. I am incredibly proud of all that this team has accomplished and their continued dedication to advancing new potential therapeutic options for patients in need."

Recent Pipeline Highlights

- **Enrollment Ongoing in ARROS-1 Trial of NVL-520 for Patients with Advanced ROS1-positive NSCLC**: Nuvalent is actively enrolling patients in the Phase 1 portion of its ARROS-1 clinical trial, a Phase 1/2 study evaluating NVL-520 in patients with advanced ROS1-positive NSCLC and other solid tumors. NVL-520, Nuvalent's lead product candidate, is a novel ROS1-selective inhibitor designed with the aim to

address the clinical challenges of emergent treatment resistance, CNS adverse events, and brain metastases that may limit the use of currently available ROS1 kinase inhibitors.
- **Discovery Pipeline Advancing toward Selection of Next Development Candidates:** Nuvalent continues to advance its early pipeline efforts with multiple discovery-stage research programs. The company expects to nominate product candidates in 2022 for its discovery programs directed toward ALK IXDN compound resistance mutations and HER2 exon 20 insertions.

Recent Business Highlights

- **Strengthened Board of Directors with Appointment of Emily Drabant Conley, Ph.D.:** In February 2022, Nuvalent appointed Emily Drabant Conley, Ph.D., Chief Executive Officer of Federation Bio, to its Board of Directors. Dr. Conley's work has contributed to industry-shaping advances in genomics that empower patients and clinicians with actionable health data. Prior to Federation Bio, she spent over a decade at 23andMe where, as Vice President of Business Development, she was instrumental in powering the company's growth from 30 employees into a household name.

Fourth Quarter and Full Year 2021 Financial Results

- **Cash Position:** Cash, cash equivalents and marketable securities were $288.1 million as of December 31, 2021. Nuvalent expects that its existing cash, cash equivalents and marketable securities will be sufficient to fund its planned operations into 2024.
- **R&D Expenses:** Research and development (R&D) expenses were $13.2 million for the quarter ended December 31, 2021, and $35.6 million for the year ended December 31, 2021.
- **G&A Expenses:** General and administrative (G&A) expenses were $4.2 million for the quarter ended December 31, 2021, and $10.3 million for the year ended December 31, 2021.
- **Net Loss:** Net loss was $17.3 million for the quarter ended December 31, 2021, and $46.3 million for the year ended December 31, 2021.

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

	Three Months Ended December 31,		Year Ended December 31,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	$ 13,194	$ 4,699	$ 35,559	$ 15,403
General and administrative	4,184	515	10,258	1,502
Total operating expenses	17,378	5,214	45,817	16,905
Loss from operations	(17,378)	(5,214)	(45,817)	(16,905)
Other income (expense):				
Change in fair value of preferred stock tranche				

rights	—	(1,363)	(635)	2,384
Other income (expense), net	89	(3)	114	(35)
Total other income (expense), net	89	(1,366)	(521)	2,349
Net loss	$ (17,289)	$ (6,580)	$ (46,338)	$ (14,556)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.36)	$ (2.14)	$ (2.13)	$ (5.08)
Weighted average shares of common stock outstanding, basic and diluted	48,268,256	3,070,672	21,783,754	2,867,221

SELECTED BALANCE SHEET DATA
(In thousands)
(Unaudited)

	December 31,	
	2021	**2020**
Cash, cash equivalents and marketable securities	$ 288,111	$ 10,332
Working capital	$ 281,841	$ 6,266
Total assets	$ 293,824	$ 10,646
Total liabilities	$ 8,787	$ 6,615
Total stockholders' equity (deficit)	$ 285,037	$ (31,323)

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 http://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 study and the timing thereof; the design and initiation of the ALKOVE-1 Phase 1/2 study 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; capital allocation; and Nuvalent's future financial and operating results and its expectations related thereto. 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 associated with: risks that Nuvalent may not fully enroll the ARROS-1 study or it 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; the impact of COVID-19 on countries or regions in which Nuvalent has operations or does business, as well as on the timing and anticipated timing and results of its clinical trials, strategy, and future operations, including the global ARROS-1 study and the planned initiation of the ALKOVE-1 Phase 1/2 study; 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 quarter ended September 30, 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.

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