

Nuvalent Announces Anticipated Timing of Preliminary Phase 1 Dose-Escalation Data for NVL-655 and Reports First Quarter 2023 Financial Results

Preliminary dose-escalation data anticipated in second half of 2023 from ongoing ALKOVE-1 Phase 1/2 clinical trial of NVL-655 for patients with advanced ALK-positive

NSCLC and other solid tumors

Strong financial position with expected operating runway into the second half of 2025

CAMBRIDGE, Mass., May 11, 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 announced plans to share preliminary data from the dose-escalation portion of its ongoing ALKOVE-1 Phase 1/2 clinical trial for NVL-655, a novel ALK-selective inhibitor, in the second half of 2023, and reported first quarter 2023 financial results.

ALKOVE-1 is a Phase 1/2, multicenter, open-label, dose-escalation and expansion trial evaluating NVL-655 in patients with advanced ALK-positive non-small cell lung cancer (NSCLC) and other solid tumors. The Phase 1 dose-escalation portion of the study is enrolling patients with previously treated ALK-positive solid tumors and will evaluate the overall safety and tolerability of NVL-655. Additional objectives include determination of the recommended Phase 2 dose (RP2D), characterization of the pharmacokinetic profile, and evaluation of preliminary anti-tumor activity. Preclinical data, including those [presented recently](#) at the American Association for Cancer Research (AACR) Annual Meeting 2023, demonstrated that NVL-655 had broad preclinical activity across diverse ALK oncoproteins, single and compound resistance mutations, and tumor types while maintaining strong selectivity for ALK over TRKB and CNS penetrance.

"2023 is a year of focused, data-driven execution towards our goal of delivering a pipeline of novel kinase inhibitors to patients as efficiently as possible," said James Porter, Ph.D., Chief Executive Officer at Nuvalent. "We plan to report preliminary data from our ALKOVE-1 trial of NVL-655 for patients with advanced ALK-positive NSCLC and other solid tumors in the second half of the year. We continue to enroll patients in the Phase 1 portion of the ARROS-1 trial of NVL-520 for advanced ROS1-positive NSCLC and other solid tumors in support of RP2D selection, and to advance NVL-330, our novel HER2-selective inhibitor for patients with HER2 exon 20 insertion-positive cancers, through IND-enabling studies. With a solid cash position and an expert team, we are well-positioned to deliver on both our near- and long-term goals."

First Quarter 2023 Financial Results

- **Cash Position & Operating Runway:** Cash, cash equivalents and marketable securities were \$450.5 million as of March 31, 2023. 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 \$22.1 million for the first quarter of 2023.
- **G&A Expenses:** General and administrative (G&A) expenses were \$8.1 million for the first quarter of 2023.
- **Net Loss:** Net loss for the first quarter of 2023 was \$25.2 million, or \$0.44 per share.

About NVL-655

NVL-655 is a novel brain-penetrant ALK-selective inhibitor created to overcome limitations observed with currently available ALK inhibitors. NVL-655 is designed to remain active in tumors that have developed

Three Months Ended March 31,

Operating expenses:		
Research and development	\$ 22,125	\$ 12,693
General and administrative	8,085	4,995
Total operating expenses	30,210	17,688
Loss from operations	(30,210)	(17,688)
Other income (expense):		
Interest income and other income, net	5,018	139
Total other income, net	5,018	139
Net loss	\$ (25,192)	\$ (17,549)
Net loss per share attributable to		
common stockholders, basic and diluted	\$ (0.44)	\$ (0.36)
Weighted average shares of common stock		
outstanding, basic and diluted	56,703,873	48,284,778

SELECTED BALANCE SHEET DATA
(In thousands)
(Unaudited)

	March 31, 2023	December 31, 2022
Cash, cash equivalents and marketable securities	\$ 450,462	\$ 472,163
Working capital	\$ 439,272	\$ 458,510
Total assets	\$ 460,989	\$ 482,459
Total liabilities	\$ 17,021	\$ 19,481
Total stockholders' equity	\$ 443,968	\$ 462,978

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