Enliven Therapeutics Reports Fourth Quarter and Full Year 2023 Financial Results and Provides a Business Update

March 14, 2024

Initial proof of concept data from Phase 1a trial evaluating ELVN-001 in adults with chronic myeloid leukemia (CML) is expected in the second quarter of 2024

IND application to evaluate ELVN-002 in combination with trastuzumab in patients with HER2+ metastatic breast cancer and colorectal cancer received U.S. FDA clearance

Strong balance sheet, closing the year with $253 million in cash, cash equivalents and marketable securities

BOULDER, Colo., March 14, 2024 (GLOBE NEWSWIRE) -- Enliven Therapeutics, Inc. (Enliven or the Company) (Nasdaq: ELVN), a clinical-stage precision oncology company focused on the discovery and development of next-generation small molecule kinase inhibitors, today reported financial results for the fourth quarter and full year ended December 31, 2023, provided updated guidance on parallel lead product candidates and highlighted pipeline progress.

"We are pleased with the ongoing momentum of our clinical pipeline. Our Phase 1 trial of ELVN-001 is on track, and we are excited to share our initial proof of concept data in the second quarter of 2024," said Sam Kintz, MBA, Enliven's Co-founder and Chief Executive Officer. "Furthermore, the FDA's acceptance of our second ELVN-002 IND application paves the way to evaluate combination therapy in patients with HER2+ cancers, for which there remains a significant unmet need, particularly in patients who progress on or are intolerant to Enhertu. We are focused on getting the trial up and running and dosing the first patient by mid-2024."

Recent Research and Development Highlights and Upcoming Milestones

ELVN-001, a highly selective, small molecule kinase inhibitor designed to specifically target the BCR-ABL gene fusion

- Patient enrollment in the Phase 1 clinical trial in adults with CML (NCT05304377) remains ongoing, and the Company has nearly completed the Phase 1a dose escalation portion of the trial.
- The first clinical data disclosure is expected in the second quarter of 2024. The Company expects this data to include more than 20 patients enrolled at an efficacious dose range, with 10 to 20 of those patients having been treated for over three months at the time of disclosure.

ELVN-002, a potent, highly selective, central nervous system (CNS) penetrant and irreversible HER2 inhibitor with activity against wild type HER2 and various HER2 mutations

- The Company's Investigational New Drug (IND) application to evaluate ELVN-002 in combination with trastuzumab +/- chemotherapeutic agents in adults with HER2+ metastatic breast cancer (MBC) and colorectal cancer (CRC) received U.S. Food and Drug Administration (FDA) clearance. Dosing of the first patient is expected by mid-2024.
- Precedent clinical evidence suggests that dual HER2 targeting results in clinically meaningful improvements in patients with HER2+ MBC and CRC.
- The ongoing Phase 1a dose escalation (NCT05650879) is nearly complete, and the data from that ongoing trial supports the additional Phase 1 combination trial. The initial data disclosure for ELVN-002 is expected in 2024.

Full Year and Fourth Quarter 2023 Financial Results

- **Cash Position:** As of December 31, 2023, the Company had cash, cash equivalents and marketable securities totaling $253.1 million, which is expected to provide cash runway into early 2026.
- **Research and development (R&D) expenses:** R&D expenses were $17.9 million for the fourth quarter of 2023, compared to $8.2 million for the fourth quarter of 2022. R&D expenses were $64.6 million for the full year 2023, compared to $31.0 million for the full year 2022.
- **General and administrative (G&A) expenses:** G&A expenses for the fourth quarter of 2023 were $4.8 million, compared to $2.0 million for the fourth quarter of 2022. G&A expenses were $19.0 million for the full year 2023, compared to $7.8 million for the full year 2022.

- **Net Loss:** Enliven reported a net loss of $19.4 million for the fourth quarter of 2023, compared to a net loss of $9.6 million for the fourth quarter of 2022. Total net loss for the full year 2023 was $71.6 million, compared to $37.7 million for the full year 2022.

About Enliven Therapeutics

Enliven Therapeutics is a clinical-stage biopharmaceutical company focused on the discovery and development of small molecule inhibitors to help patients with cancer not only live longer, but live better. Enliven aims to address existing and emerging unmet needs with a precision oncology approach that improves survival and enhances overall patient well-being. Enliven's discovery process combines deep insights in clinically validated biological targets and differentiated chemistry to design potentially first-in-class or best-in-class therapies. Enliven is based in Boulder, Colorado.

Forward-Looking Statements

This press release contains forward-looking statements (including within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended) concerning Enliven and other matters. These statements may discuss goals, intentions and expectations as to future plans, trends, events, results of operations or financial condition, or otherwise, based on current beliefs of the management of Enliven, as well as assumptions made by, and information currently available to, management of Enliven. Forward-looking statements generally include statements that are predictive in nature and depend upon or refer to future events or conditions, and include words such as "may," "will," "should," "would," "expect," "anticipate," "plan," "likely," "believe," "estimate," "project," "intend," and other similar expressions or the negative or plural of these words, or other similar expressions that are predictions or indicate future events or prospects, although not all forward-looking statements contain these words. Statements that are not historical facts are forward-looking statements. Forward-looking statements in this press release include, but are not limited to, statements regarding the potential of, and plans and expectations regarding, Enliven's programs, including ELVN-001 and ELVN-002; the expected timing of initial data for the Phase 1a trials of ELVN-001 and ELVN-002; Enliven's pipeline of product candidates; the expected timing of dosing of the first patient for the ELVN-002 combination trial; the expected timing of the completion of the Phase 1a dose escalation for the ELVN-002 monotherapy trial; the expected timing of disclosure of more information on Enliven's pipeline; the strength of Enliven's balance sheet and the sufficiency of cash, cash equivalents and marketable securities to fund its current operating plan into early 2026; and statements by Enliven's Co-founder and Chief Executive Officer. Forward-looking statements are based on current beliefs and assumptions that are subject to risks and uncertainties and are not guarantees of future performance. Actual results could differ materially from those contained in any forward-looking statement as a result of various factors, including, without limitation: the limited operating history of Enliven; the significant net losses incurred since its inception; the ability to advance product candidates through preclinical and clinical development; the ability to obtain regulatory approval for, and ultimately commercialize, product candidates; the outcome of preclinical testing and early clinical trials for product candidates and the potential that the outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials; Enliven's limited resources; the risk of failing to demonstrate safety and efficacy of product candidates; Enliven's limited experience as a company in designing and conducting clinical trials; potential delays or difficulties in the enrollment or maintenance of patients in clinical trials; developments relating to Enliven's competitors and its industry, including competing product candidates and therapies; the decision to develop or seek strategic collaborations to develop Enliven's current or future product candidates in combination with other therapies and the cost of combination therapies; the ability to attract, hire, and retain highly skilled executive officers and employees; the ability of Enliven to protect its intellectual property and proprietary technologies; the scope of any patent protection Enliven obtains or the loss of any of Enliven's patent protection; reliance on third parties, including contract manufacturing organizations, contract research organizations and strategic partners; general market or macroeconomic conditions; Enliven's ability to obtain additional capital to fund Enliven's general corporate activities and to fund Enliven's research and development; and other risks and uncertainties, including those more fully described in Enliven's filings with the Securities and Exchange Commission (SEC), including additional risks which may be found in the section entitled "Risk Factors" in Enliven's Annual and Quarterly Reports on Form 10-K and 10-Q filed with the SEC and in Enliven's future reports to be filed with the SEC. Except as required by applicable law, Enliven undertakes no obligation to revise or update any forward-looking statement, or to make any other forward-looking statements, whether as a result of new information, future events or otherwise.

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

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Enliven Therapeutics, Inc.
Selected Condensed Consolidated Financial Information
(in thousands, except per share data)
(unaudited)

Statements of Operations	Three Months Ended December 31,		Year Ended December 31,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 17,905	$ 8,197	$ 64,574	$ 31,022
General and administrative	4,824	1,966	18,955	7,769
Total operating expenses	22,729	10,163	83,529	38,791
Loss from operations	(22,729)	(10,163)	(83,529)	(38,791)
Other income (expense), net	3,359	613	11,945	1,129
Net loss	$ (19,370)	$ (9,550)	$ (71,584)	$ (37,662)

Net loss per share, basic and diluted	$ (0.47)	$ (2.91)	$ (2.01)	$ (12.05)
Weighted-average shares outstanding, basic and diluted	41,128	3,283	35,546	3,124

Balance Sheets	**December 31,**	
	2023	**2022**
Assets		
Current assets:		
Cash, cash equivalents and marketable securities	$ 253,148	$ 75,536
Restricted cash	54	—
Prepaid expenses and other current assets	2,949	2,217
Contingent value right asset	10,000	—
Total current assets	266,151	77,753
Property and equipment, net	742	890
Operating lease right-of-use assets	320	626
Deferred offering costs	563	3,975
Restricted cash	—	54
Other long-term assets	4,091	—
Total assets	$ 271,867	$ 83,298
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 532	$ 3,438
Accrued expenses and other current liabilities	15,362	6,277
Contingent value right liability	10,000	—
Total current liabilities	25,894	9,715
Long-term liabilities	67	659
Total liabilities	25,961	10,374
Convertible preferred stock	—	149,749
Stockholders' equity (deficit)	245,906	(76,825)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 271,867	$ 83,298