Enliven Therapeutics Reports Third Quarter Financial Results and Provides a Business Update

November 13, 2024

Announced positive data from the Phase 1 clinical trial of ELVN-001 in CML, reporting a cumulative MMR rate of 44% (8/18) by 24 weeks and showing that ELVN-001 remains well-tolerated with no dose reductions

Continued to progress ELVN-002 with a focus on recently initiated combination clinical trials evaluating patients with HER2+ MBC and CRC

Strong balance sheet with $292 million in cash, cash equivalents and marketable securities, which is expected to provide cash runway into late 2026

BOULDER, Colo., Nov. 13, 2024 /PRNewswire/ -- Enliven Therapeutics, Inc. (Enliven or the Company) (Nasdaq: ELVN), a clinical-stage biopharmaceutical company focused on the discovery and development of small molecule therapeutics, today reported financial results for the third quarter ended September 30, 2024, and provided a business update, including highlights of pipeline progress.

"We are thrilled by the progress that we made in the third quarter of 2024. We reported updated clinical data for ELVN-001, which continues to compare favorably to precedent Phase 1 trials of approved BCR::ABL1 TKIs despite a more heavily pre-treated patient population. Since our data release, we have seen strong enrollment and momentum for the program," said Sam Kintz, Co-founder and Chief Executive Officer of Enliven. "Additionally, we are encouraged by the recent accelerated approval of Scemblix in 1L CML, which we believe will pave the way for earlier line use of this new treatment option, thereby creating a potentially large, 2L+ opportunity for ELVN-001. It has been an exciting year for Enliven, and I look forward to sharing additional updates in 2025."

Pipeline Updates

ELVN-001 is a potent, highly selective, potentially best-in-class small molecule kinase inhibitor designed to specifically target the BCR-ABL gene fusion, the oncogenic driver for patients with chronic myeloid leukemia (CML).

- The Company announced positive updated data from the Phase 1 clinical trial evaluating ELVN-001 in patients with CML that have failed, or are intolerant to or not a candidate for, available therapies known to be active for treatment of their CML (NCT05304377).
  - As of the cutoff date, June 25, 2024, ELVN-001 achieved a cumulative major molecular response (MMR) rate of 44.4% (8/18) by 24 weeks with stable or deepening responses between weeks 12 and 24.
  - ELVN-001 remains well-tolerated, consistent with its selective kinase profile, and there have been no dose reductions or discontinuations at ≥ 40 mg due to treatment-related adverse events (TRAE).
  - These data continued to compare favorably to precedent Phase 1 cumulative MMRs for approved BCR::ABL1 TKIs, particularly given the more heavily pre-treated patient population in the ELVN-001 clinical trial. Further details can be found on the Enliven website.
- The Company plans to report additional Phase 1 data in 2025 and is expected to include between approximately 60-100 patients across various lines of therapy with significant follow-up.

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

- Enliven continued to progress its Phase 1 trial evaluating ELVN-002 as a monotherapy agent in patients with HER2+ and HER2 mutant tumors and its exploratory cohort in combination with Kadcyla® (an approved HER2 antibody drug conjugate) in patients with HER2+ metastatic breast cancer (MBC) (NCT05650879).
- Additionally, the Company continues to enroll its Phase 1 trial evaluating ELVN-002 in combination with trastuzumab +/- chemotherapeutic agents in patients with HER2+ MBC and colorectal cancer (CRC) (NCT06328738).
- Enliven plans to report Phase 1 data from the ongoing trials in 2025.

Third Quarter 2024 Financial Results

- **Cash Position:** As of September 30, 2024, the Company had cash, cash equivalents and marketable securities totaling $291.8 million, which is expected to provide cash runway into late 2026.
- **Research and development (R&D) expenses:** R&D expenses were $21.3 million for the third quarter of 2024, compared to $19.6 million for the third quarter of 2023.
- **General and administrative (G&A) expenses:** G&A expenses were $5.8 million for the third quarter of 2024, compared to $4.6 million for the third quarter of 2023.
- **Net Loss:** Net loss was $23.2 million for the third quarter of 2024, compared to $20.8 million for the third quarter of 2023.

About Enliven Therapeutics
Enliven is a clinical-stage biopharmaceutical company focused on the discovery and development of small molecule therapeutics to help people 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 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, market opportunities, and expectations regarding Enliven's programs, including ELVN-001 and ELVN-002; Enliven's pipeline of product candidates; expected milestones for ELVN-001 and ELVN-002, including the expected timing of data from the clinical trials of ELVN-001 and ELVN-002 and the number of patients included in such data; statements relating to Enliven's expected cash runway; 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 risks and uncertainties, including, without limitation: the limited operating history of Enliven; 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; the potential for interim, topline, and preliminary data from Enliven's preclinical studies and clinical trials to materially change from the final data; 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), which may be found in the section titled "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.

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

Statements of Operations	**Three Months Ended September 30,**		**Nine Months Ended September 30,**	
	2024	**2023**	**2024**	**2023**
Operating expenses:				
Research and development	$ 21,258	$ 19,606	$ 60,054	$ 46,669
General and administrative	5,810	4,642	17,604	14,131
Total operating expenses	27,068	24,248	77,658	60,800
Loss from operations	(27,068)	(24,248)	(77,658)	(60,800)
Other income (expense), net	3,912	3,479	11,814	8,586
Net loss	$ (23,156)	$ (20,769)	$ (65,844)	$ (52,214)
Net loss per share, basic and diluted	$ (0.48)	$ (0.51)	$ (1.43)	$ (1.55)
Weighted-average shares outstanding, basic and diluted	48,267	41,031	46,137	33,665

Balance Sheets	**September 30, 2024**	**December 31, 2023**
Assets		
Current assets:		
Cash, cash equivalents and marketable securities	$ 291,834	$ 253,148
Restricted cash	54	54
Prepaid expenses and other current assets	5,109	2,949
Contingent value right asset	—	10,000
Total current assets	296,997	266,151
Property and equipment, net	549	742
Operating lease right-of-use assets	81	320

Deferred offering costs		563		563
Other long-term assets		7,240		4,091
Total assets	$	305,430	$	271,867
Liabilities and Stockholders' Equity				
Current liabilities:				
Accounts payable	$	1,019	$	532
Accrued expenses and other current liabilities		16,008		15,362
Contingent value right liability		—		10,000
Total current liabilities		17,027		25,894
Long-term liabilities		—		67
Total liabilities		17,027		25,961
Stockholders' equity		288,403		245,906
Total liabilities and stockholders' equity	$	305,430	$	271,867

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Investors, ir@enliventherapeutics.com; Media, media@enliventherapeutics.com