Enliven Therapeutics Announces Updated Positive Data from Phase 1 Clinical Trial of ELVN-001 in CML and Oral Presentation at the EHA 2025 Congress

May 14, 2025

Reported cumulative MMR rate of 44% (16 of 36) by 24 weeks with 26% (7 of 27) of patients achieving MMR by 24 weeks, which continues to compare favorably to precedent Phase 1 trials of approved BCR::ABL1 TKIs

ELVN-001 continues to demonstrate a favorable safety and tolerability profile across all dose levels with 74 patients enrolled and a median treatment duration of ~26 weeks at cutoff

Presentation at EHA will include updated data with additional patients and longer treatment duration

Enliven will host a webcast and conference call on June 13 at 1:30 p.m. ET

BOULDER, Colo., May 14, 2025 /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 announced updated, positive data from the Phase 1 ENABLE clinical trial evaluating ELVN-001 in patients with chronic myeloid leukemia (CML) in an abstract accepted for an oral presentation at the European Hematology Association (EHA) 2025 Congress taking place June 12-15 in Milan, Italy, and virtually. Updated data will be presented during an oral presentation at the conference on Friday, June 13, at 5 p.m. CEST/11 a.m. ET. Enliven management will host a webcast and conference call to discuss the data on Friday, June 13, at 7:30 p.m. CEST/1:30 p.m. ET.

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 CML. Data presented at EHA will be from the ongoing ENABLE Phase 1a/1b clinical trial, which enrolled patients with CML that have failed, are intolerant to, or are not a candidate for, available therapies known to be active for treatment of their CML (NCT05304377).

"We are strongly encouraged by the consistent efficacy, safety and tolerability data from the ongoing ENABLE trial in heavily pretreated patients with CML," said Helen Collins, M.D., Chief Medical Officer of Enliven. "These data continue to demonstrate the potential for ELVN-001 to achieve a best-in-class profile compared to the available active-site TKIs. We look forward to providing additional updates at the EHA Congress in June."

Abstract Highlights

Patient Demographics

- As of the cutoff date of January 21, 2025, 74 patients have been enrolled in the ongoing Phase 1 trial across dose levels from 10-160 mg daily and the vast majority of patients (82%) remain on study with a median treatment duration of ~26 weeks.
- Patients enrolled continue to be heavily pretreated, with 66% having received three or more prior tyrosine kinase inhibitors (TKIs), including ponatinib (45%) and asciminib (57%).

Updated Efficacy

- Of the enrolled patients, 36 with typical transcripts and without T315I mutations were evaluable for molecular response by 24 weeks.
- 16 of 36 (44%) evaluable patients were in major molecular response (MMR) by 24 weeks, with 7 of 27 (26%) achieving and 9 of 9 (100%) maintaining MMR.
    - Of those resistant to their last TKI, 10 of 25 (40%) were in MMR by 24 weeks.
    - Of those previously treated with asciminib or ponatinib, 9 of 25 (36%) were in MMR by 24 weeks, including one with a known asciminib resistance mutation (A337T).
    - All patients who achieved or maintained MMR were still in MMR at the time of data cutoff.
- These data continued to compare favorably to precedent Phase 1 MMRs for approved BCR::ABL1 TKIs, particularly given the more heavily pre-treated patient population in the ELVN-001 clinical trial.

Updated Safety

- ELVN-001 remains well-tolerated across all doses, consistent with its selective kinase profile.
- Dose interruptions and reductions occurred in less than 10% and less than 5% of patients, respectively.
- The maximum tolerated dose was not reached.

Details of the oral presentation are as follows:
Title: *ENABLE: A Phase 1a/1b Study of ELVN-001, a selective active site inhibitor of BCR::ABL1, in patients with previously treated CML*
Presenter: Andreas Hochhaus, M.D.
Session Title: s425 Novel approaches of CML treatment

Location: Coral 2
Abstract Number: S165
Presentation Date/Time: June 13, 5 p.m. CEST / 11 a.m. ET

The abstract is available on the EHA website. Following the presentation, a copy will be available on the "Program Presentations & Publications" section of the Company's website at www.enliventherapeutics.com.

Webcast and Conference Call Information
Enliven will host a conference call with management on June 13, 2025, at 7:30 p.m. CEST/1:30 p.m. ET. To access the call, please dial +1 (800) 803-6955 (domestic) or (240) 220-9050 (international), and reference participant ID 631-128-259 at least 10 minutes prior to the start time and ask to be joined to the Enliven call. Accompanying slides and a link to the webcast will be available in the Investors section of the Enliven website at https://ir.enliventherapeutics.com/events. To participate in the live event, please register using this link. An archived webcast will be available following the event.

About the ENABLE Trial
The ENABLE study (NCT05304377) is a Phase 1 study of ELVN-001 in patients with previously treated CML. The trial is currently in Phase 1a/1b development and is a dose escalation and expansion trial designed to evaluate safety and tolerability and to determine the recommended dose for further clinical evaluation of ELVN-001 in patients with CML with and without T315I mutations that is relapsed, refractory or intolerant to TKIs. Secondary endpoints include pharmacokinetics, MMR by central quantitative reverse transcriptase polymerase chain reaction, duration of MMR, BCR::ABL1 transcript levels and complete hematologic response. Enliven is preparing for the potential start of a pivotal trial for ELVN-001 in 2026.

About ELVN-001
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. As a highly selective active site inhibitor, ELVN-001 has a mechanism of action that is complementary to allosteric BCR::ABL1 inhibitors, which may play an increasingly important role in the standard of care. ELVN-001 was also designed to have activity against the T315I mutation, the most common BCR::ABL1 mutation, which confers resistance to nearly all approved TKIs, as well as activity against mutations known to confer resistance to allosteric BCR::ABL1 inhibitors.

About Enliven Therapeutics
Enliven is a clinical-stage biopharmaceutical company focused on the discovery and development of small molecule therapeutics to help people 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 that involve substantial risks and uncertainties. These statements may discuss goals, intentions and expectations as to future plans, trends, events, results of operations and 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 regarding, market opportunities, and expectations regarding Enliven's programs, including ELVN-001; expected milestones for ELVN-001, including the potential timing for a start of a pivotal trial for ELVN-001; and statements by Enliven's Chief Medical 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 clinical development; the ability to obtain regulatory approval for, and ultimately commercialize or license, 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 medical institutions, contract manufacturing organizations, contract research organizations and strategic partners; geo-political developments, 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.

Head-to-Head Comparisons

The Company has not performed any head-to-head trials for ELVN-001. As a result, the data referenced in this press release is derived from different clinical trials at different points in time, with differences in trial design and patient populations. As a result, conclusions from cross-trial comparisons cannot be made.

View original content to download multimedia:https://www.prnewswire.com/news-releases/enliven-therapeutics-announces-updated-positive-data-from-phase-1-clinical-trial-of-elvn-001-in-cml-and-oral-presentation-at-the-eha-2025-congress-302455412.html

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