Enliven Therapeutics Announces Oral Presentation at the EHA 2026 Congress Featuring Additional Positive Phase 1 Clinical Trial Data for ELVN-001 in CML

May 12, 2026

Abstract includes previously reported data: cumulative MMR rate of 47% with 38% of patients achieving MMR by 24 weeks in mature, heavily pretreated 80 mg QD Phase 1b cohort

In patients who previously received asciminib, cumulative MMR rate was 52%, with 38% of patients achieving MMR by 24 weeks

ELVN-001 maintained a favorable safety and tolerability profile with 141 patients enrolled and a median treatment duration of ~32 weeks

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

BOULDER, Colo., May 12, 2026 /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 additional, 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) 2026 Congress taking place June 11-14 in Stockholm, Sweden and virtually. Updated data will be presented during an oral presentation at the conference on Thursday, June 11, at 5:45 p.m. CEST /11:45 a.m. ET.

ELVN-001 is a potent, highly selective, potentially best-in-class small molecule kinase inhibitor designed to specifically target the BCR::ABL1 gene fusion, the oncogenic driver for patients living with CML. Data presented at EHA will be from the ongoing ENABLE Phase 1 clinical trial, which enrolled patients with CML that is relapsed, refractory or intolerant to available tyrosine kinase inhibitors (TKIs) (NCT05304377).

"As we treat more patients and extend follow-up, ELVN-001 continues to demonstrate robust anti-CML activity in a heavily pretreated patient population," said Helen Collins, M.D., Chief Medical Officer of Enliven. "These results are consistent with our earlier findings demonstrating a favorable safety and tolerability profile, reinforcing ELVN-001's highly selective design. We believe these data and the overall profile of ELVN-001 support its potential to be the best-in-class ATP-competitive inhibitor for patients living with CML. Importantly, ELVN-001's distinct binding mode compared to ATP-competitive inhibitors and complementary mechanism of action to allosteric inhibitors supports its use across lines of treatment. We look forward to sharing additional updates at the EHA Congress in June."

Abstract Highlights

Patient Demographics

- As of the cutoff date of December 22, 2025, 141 patients were enrolled in the ongoing Phase 1 trial across dose levels from 10-160 mg once daily (QD), and most patients (76%) remain on study with a median treatment duration of 31.7 weeks.
- Patients enrolled continue to be heavily pretreated, with 67% having received three or more prior unique TKIs and 24% having received five or more unique TKIs.
    - 61% of patients had received prior asciminib, and of those patients, 92% had received three or more prior unique TKIs, and 37% had received five or more unique TKIs.
    - 9% of patients enrolled with mutations associated with resistance to asciminib.

Efficacy

- As previously reported in January 2026:
    - In the initial 80 mg QD Phase 1b cohort (n=19), all patients were evaluable for efficacy by 24 weeks. Of these, 9/19 (47%) were in major molecular response (MMR), with 6/16 (38%) achieving MMR.
    - In the randomized 60 mg and 120 mg QD Phase 1b cohorts (n=41), 26 patients were evaluable for efficacy by 24 weeks, reflecting their more recent enrollment. Of these, 18/26 (69%) were in MMR, with 9/17 (53%) achieving MMR.
- All patients who received prior asciminib in Phase 1b had an improved or stable response category by week 24. Of these, 14/27 (52%) were in MMR, with 8/21 (38%) achieving MMR.
- Across all Phase 1b cohorts, 100% of evaluable patients in MMR at enrollment maintained or deepened their response.
- These data continued to compare favorably to precedent Phase 1 MMR rates for approved BCR::ABL1 TKIs, particularly given the more heavily pretreated patient population in the ELVN-001 clinical trial.

Safety Profile

- ELVN-001 remains well-tolerated, consistent with its highly selective kinase profile.
- Less than 10% of patients had dose reductions due to treatment-emergent adverse events, and 6.4% of patients discontinued due to adverse events.

Details of the oral presentation are as follows:
Title: *ENABLE: Updated Efficacy and Safety Results of ELVN-001, a Novel Selective ATP-Competitive Inhibitor of BCR::ABL1, in Patients with Previously Treated CP-CML*
Presenter: Dennis Kim, M.D.
Session Title: s416 Chronic myeloid leukemia – Clinical
Location: A12 Hall
Abstract Number: S164
Presentation Date/Time: June 11, 5:45 p.m. - 6:00 p.m. CEST / 11:45 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.

About the ENABLE Trial
The ENABLE study (NCT05304377) is a Phase 1 study of ELVN-001 in patients with previously treated CML. ENABLE 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.

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 TKI, 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 medicine approach that improves survival and enhances overall well-being. Enliven's discovery process combines deep insights into clinically validated biological targets and differentiated chemistry to design potentially first-in-class or best-in-class therapies. To learn more, visit www.enliventherapeutics.com and connect with us on LinkedIn and X.

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 Enliven's management, as well as assumptions made by, and information currently available to, Enliven's management. 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 profile, activity, selectivity, safety, tolerability, efficacy, differentiated attributes, therapeutic benefit and potential best-in-class or complementary profile of ELVN-001; the interpretation of data from the ongoing ENABLE trial, including MMR rate, safety and tolerability data; comparisons to historical or precedent clinical trial results; the timing, content and availability of additional clinical data and presentation materials; the continued conduct, design, objectives, endpoints, dose selection and future clinical evaluation of 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 potential for interim, topline and preliminary results from Enliven's clinical trials to materially change as additional patient data become available or following more comprehensive review; the potential for results from the ongoing or any future clinical trial of ELVN-001 to differ from the results of earlier trials of ELVN-001; ELVN- failing to demonstrate sufficient safety, efficacy, tolerability, durability, differentiated attributes or therapeutic benefit in current or future clinical trials; risks associated with unexpected events during the remainder of the ENABLE trial including serious adverse events, toxicities, dose reductions, discontinuations or other undesirable side effects; delays or difficulties in recruiting, enrolling or maintaining patients in ELVN-001 clinical trials; the risks of delays in completing the ongoing ENABLE trial; Enliven failing to complete the ongoing ENABLE trial, to present additional data or to advance ELVN-001 through clinical development; regulatory authorities disagreeing with Enliven's clinical trial design, dose selection, endpoints or interpretation of data, or requiring additional studies or diagnostics; lack of reliability of cross-trial comparisons because the referenced data are derived from different clinical trials at different points in time, with differences in trial design and patient populations, and results may differ in head-to-head studies; developments relating to Enliven's competitors and industry which may affect the development or potential market opportunity for ELVN-001; and the potential inability of Enliven to obtain regulatory approval for, or ultimately commercialize or license, ELVN-001 or other product candidates; Enliven's limited resources; 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 are more fully described in Enliven's filings with the Securities and Exchange Commission (SEC), including under the heading "Risk Factors" in Enliven's Annual and Quarterly Reports on Form 10-K and Form 10-Q filed with the SEC and in Enliven's future SEC filings. 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.

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-oral-presentation-at-the-eha-2026-congress-featuring-additional-positive-phase-1-clinical-trial-data-for-elvn-001-in-cml-302769668.html

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