# Enliven Reports Positive Initial Phase 1b Data for ELVN-001 in CML and Outlines 2026 Clinical Milestones

January 8, 2026

*Cumulative major molecular response (MMR) rate of 69% by 24 weeks, with 53% of patients achieving MMR by 24 weeks in ongoing randomized Phase 1b cohorts*

*ELVN-001 continues to demonstrate a favorable safety and tolerability profile across all dose levels evaluated, consistent with previously reported data*

*Data further reinforce ELVN-001's positioning as the potentially best-in-class active-site TKI in CML*

*Multiple key data, regulatory and operational catalysts expected in 2026*

BOULDER, Colo., Jan. 8, 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 positive initial data from the ongoing Phase 1b ENABLE clinical trial evaluating ELVN-001 in patients with chronic myeloid leukemia (CML) that is relapsed, refractory or intolerant to available tyrosine kinase inhibitors (TKIs) (NCT05304377).

"We are excited about these initial Phase 1b data, the progress we made throughout 2025 and the year ahead. Our data continue to demonstrate that ELVN-001 has the potential to be the best-in-class active-site TKI for the treatment of CML and an important treatment option across all lines of therapy," said Helen Collins, M.D., Chief Medical Officer of Enliven. "Momentum has been building over the last year leading to significant interest in our Phase 3 clinical trial from sites all around the world. We are preparing for upcoming regulatory interactions with the FDA to align on dose selection and support initiation of the Phase 3 trial in the second half of 2026."

**ELVN-001 Program 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 CML.*

**Encouraging ELVN-001 Phase 1b Data by 24 Weeks**

- As of the cutoff date of December 22, 2025, 60 patients were enrolled in the initial cohorts of the Phase 1b trial. Patients were first enrolled in the 80 mg once daily (QD) cohort. Subsequent patients were randomized to either 60 mg QD or 120 mg QD.
- Patients enrolled were heavily pretreated, consistent with patients from previously reported datasets. In these 60 patients:
  - 53% of patients received four or more unique prior TKIs.
  - 67% of patients received prior asciminib and 32% received prior ponatinib.
- Despite the heavily pretreated patient population, the efficacy data below highlights that ELVN-001 continues to demonstrate the profile of a best-in-class active-site TKI.

| Dose (number of patients) | 80 mg QD (n=19) | 60/120 mg QD (n=41) |
|---|---|---|
| Cumulative MMR | 47% (n=19) | 69% (n=26) |
| Achieved MMR | 38% (n=16) | 53% (n=17) |
| Maintained MMR | 100% (n=3) | 100% (n=9) |
| Deep Molecular Response (DMR) | 16% (n=19) | 35% (n=26) |

As of the data cutoff in December:

- In the 80 mg QD Phase 1b cohort (n=19), all patients were evaluable for efficacy by 24 weeks. In these mature data, rates of MMR achievement (38%) and DMR (16%) compare favorably to precedent Phase 1 trials of approved BCR::ABL1 TKIs, including asciminib.
- In the randomized 60 mg and 120 mg cohorts (n=41), 26 patients were evaluable for efficacy by 24 weeks, reflecting their more recent enrollment. In this cohort, highly encouraging rates of MMR achievement (53%) and DMR (35%) were observed.
- Across all Phase 1b cohorts, 100% of evaluable patients in MMR at enrollment maintained, or deepened, their response.
- As expected, robust clinical activity was observed at doses from 60 mg to 120 mg QD, with no clear evidence of dose response (efficacy or safety) within this range.
- ELVN-001 continues to demonstrate a favorable safety and tolerability profile across all evaluated doses. The safety profile observed in these Phase 1b cohorts remained consistent with previously reported data, with no maximum tolerated dose and no new safety signals identified.

**Expected 2026 Clinical Milestones for ELVN-001**

- Mid-year presentation of additional Phase 1 data from the ongoing ENABLE trial
- Regulatory alignment with the FDA on dose selection and Phase 3 trial design
- Initiation of ENABLE-2, the Phase 3 clinical trial of ELVN-001, in the second half of 2026

**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 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 the presentation of additional Phase 1 data from the ongoing ENABLE trial, the potential timing of regulatory and operational catalysts including regulatory alignment with the FDA on dose selection and Phase 3 trial design, and potential timing of the initiation of ENABLE-2; 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 the results of the ongoing or any future clinical trial of ELVN-001 to differ from the results from earlier trials of ELVN-001; the risk of delays in completing the ongoing ENABLE trial or initiation of a Phase 3 trial of ELVN-001; risks associated with unexpected events during the remainder of the ongoing ENABLE trial, including serious adverse events, toxicities or other undesirable side effects; the risk of difficulties in enrolling or maintaining patients in clinical trials of ELVN-001; 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 or license, or identify and complete strategic alternatives for, 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, including extrapolations or predictions regarding the safety and efficacy of ELVN-001 based on comparisons to published results of trials of other products, which may be different when evaluated in head-to-head studies; 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 potential market opportunity for any of Enliven's programs; 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.

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

View original content to download multimedia:https://www.prnewswire.com/news-releases/enliven-reports-positive-initial-phase-1b-data-for-elvn-001-in-cml-and-outlines-2026-clinical-milestones-302655863.html

SOURCE Enliven Therapeutics, Inc.

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