Enliven Therapeutics Announces Updated Positive Phase 1 Clinical Data and Alignment with FDA on Key Phase 3 Trial Design Components

June 11, 2026

61% overall MMR and 48% MMR achievement by 24 weeks in the 80 mg QD Phase 1b cohort

67% overall MMR and 55% MMR achievement by 24 weeks in all Phase 1b patients who had previously received 1 or 2 prior unique TKIs

Favorable safety and tolerability profile with 161 patients enrolled and a median treatment duration of 35 weeks

Alignment with the FDA on 80 mg QD as the recommended Phase 3 dose and on the 2L+ patient population for the ENABLE-2 pivotal trial, which is expected to initiate in the second half of this year

BURLINGAME, Calif., June 11, 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 presented updated positive data from the Phase 1 ENABLE clinical trial evaluating ELVN-001 in patients with previously treated chronic myeloid leukemia (CML). An oral presentation will be delivered later today at the European Hematology Association (EHA) 2026 Congress, taking place June 11-15 in Stockholm, Sweden, and virtually. The Company also provided an update on recent regulatory interactions with the Food and Drug Administration (FDA). Enliven will host a webcast and conference call today, June 11, at 8:30 a.m. ET / 2:30 p.m. CEST.

"Despite recent advances in CML treatment, there remains a need for highly effective therapies with excellent safety and tolerability profiles optimized for long-term treatment and capable of deep and durable molecular responses," said Dennis Kim, M.D., Professor of Medicine in the Department of Medical Oncology and Hematology at the Princess Margaret Cancer Centre, Canada. "The updated data from the ENABLE trial are very promising and encouraging. The trial demonstrated meaningful responses across lines of therapy in heavily pretreated patients, including responses in patients who had shown a lack of efficacy to the most effective approved therapies. Further, ELVN-001 demonstrated a favorable safety and tolerability profile, reflecting its high selectivity. I look forward to the initiation of the planned Phase 3 ENABLE-2 trial, which could establish ELVN-001 as an important new treatment option for patients with previously treated CML."

"These promising results continue to showcase the consistency of ELVN-001's overall profile and reinforce its potential to be a best-in-class ATP-competitive inhibitor with differentiated activity relative to allosteric inhibitors," said Helen Collins, M.D., Chief Medical Officer of Enliven. "In these data, we observed higher response rates in patients treated in earlier lines of therapy, and comparable response rates regardless of prior asciminib exposure. We are also thrilled by the outcome of our recent End-of-Phase 1 meeting with the FDA, where we reached alignment on the 80 mg once daily dose and the inclusion of patients who have received at least one prior TKI in the planned ENABLE-2 Phase 3 trial. This is an important milestone as we advance towards initiating ENABLE-2 later this year."

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 are 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).

ELVN-001 Updated Data Highlights

ENABLE Has Enrolled a Heavily Pretreated Patient Population

- As of the cutoff date of March 10, 2026, 161 patients were enrolled in the ongoing Phase 1 trial across dose levels ranging from 10-240 mg daily.
- Most patients (76%) remain on study with a median treatment duration of 35 weeks.
- Patients enrolled were heavily pretreated, with 70% having received three or more prior unique TKIs and 23% having received five or more unique TKIs.
    - 62% of patients received prior asciminib, and these patients were more heavily pretreated than the overall trial population: 93% received three or more prior unique TKIs, and 34% received five or more unique TKIs.
    - 8% of patients enrolled with mutations associated with resistance to allosteric inhibitors, increasing from 4% in Phase 1a to 11% in Phase 1b.

Encouraging ELVN-001 Efficacy Data by 24 Weeks

- Of the 90 patients enrolled in the Phase 1b, 78 had typical BCR::ABL1 transcripts and had at least one post-baseline transcript; 69 patients were evaluable for major molecular response (MMR) by 24 weeks.
- Additionally, of the 49 patients enrolled in the 80 mg once daily (QD) Phase 1b cohort, 37 had typical BCR::ABL1 transcripts and had at least one post-baseline transcript; 28 patients were evaluable for MMR by 24 weeks.

Cohort (n = evaluable for MMR)	Phase 1b	Phase 1b 80 mg QD Cohort
Overall MMR	54% (n=69)	61% (n=28)

Achieved MMR	40% (n=53)	48% (n=21)
Maintained MMR	100% (n=16)	100% (n=7)

- Deep Molecular Response (DMR) achievement rates were also encouraging.
  - By 24 weeks, DMR was achieved in 22% of patients in the overall Phase 1b and 30% of patients in the 80 mg QD Phase 1b cohort.
- Response rates were higher in less heavily pretreated patients, and prior asciminib exposure did not meaningfully impact response rates.

Achieved Response Rates by 24-weeks (n = evaluable for MMR)		
Prior number of unique TKIs:	**Phase 1b (n=69)**	**Phase 1b post-asciminib (n=43)**
1-2	55% (n=27)	60% (n=6)
3-4	32% (n=26)	28% (n=22)
5+	29% (n=16)	29% (n=15)

ELVN-001's Safety Profile Consistent with High Selectivity for ABL1

- ELVN-001 was generally well-tolerated, consistent with its high selectivity.
- 6% of patients discontinued due to adverse events.
- The majority of treatment-emergent adverse events (TEAEs) were Grade 1 or 2.
- Grade ≥3 TEAEs were reported in 53/158 (34%) patients overall; with thrombocytopenia (6%), neutropenia (6%) and lipase elevation (6%) as the most common.
  - At the biologically optimal dose of 80 mg QD (n=62), Grade ≥3 TEAEs were reported in 15/62 (24%) patients, with thrombocytopenia (6%) being the only Grade ≥3 TEAE reported in >5% of patients.

Key Outcomes from the End-of-Phase 1 Meeting with the FDA

- 80 mg QD selected as the recommended dose for Phase 3 ENABLE-2 trial.
- ENABLE-2 is expected to enroll patients with CML previously treated with one or more TKIs, and to be randomized to receive either ELVN-001 or physician's choice of an ATP-competitive TKI.
- Additional details of the Phase 3 trial design are expected to be finalized following further discussions with the FDA, including at a planned End-of-Phase 2 meeting anticipated in the third quarter of 2026.

The oral presentation titled: "*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*" will be presented today at 5:45 p.m. CEST during the European Hematology Association Congress in Stockholm, Sweden, by Dennis Kim, M.D., Professor of Medicine, Department of Medical Oncology and Hematology at the Princess Margaret Cancer Centre, Canada. A copy of the presentation 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 live webcast and conference call today at 8:30 a.m. ET / 2:30 p.m. CEST. To participate in the live event, please register using this link. Following registration, participants will have access to dial in numbers and a unique passcode should they prefer to participate by phone. The event and accompanying slides can also be accessed by visiting the investor relations section of the Company's website at https://ir.enliventherapeutics.com. An archived webcast will be available on the Company's website 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. 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. ELVN-001, a highly selective active-site TKI, 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 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 to allosteric inhibitors; 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, including the planned ENABLE-2 Phase 3 trial, the potential timing of initiation of ENABLE-2, the potential timing and outcome of further FDA discussions and the finalization of additional Phase 3 trial design details; and statements by Enliven's Chief Medical Officer, and Dennis Kim, M.D., Professor of Medicine, Department of Medical Oncology and Hematology at the Princess Margaret Cancer Centre, Canada. 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-001 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 or initiating ENABLE-2; Enliven failing to complete the ongoing ENABLE trial, to present additional data, to initiate ENABLE-2 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 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 are 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-phase-1-clinical-data-and-alignment-with-fda-on-key-phase-3-trial-design-components-302797424.html

SOURCE Enliven Therapeutics, Inc.

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