



Enliven Therapeutics Announces FDA Alignment on ENABLE-2 Phase 3 Trial Design for Relcobatinib (ELVN-001) in Previously Treated Chronic Myeloid Leukemia

October 6, 2026

Enliven remains on track to initiate ENABLE-2 before year-end 2026

BURLINGAME, Calif., Oct. 6, 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 that it has reached alignment with the U.S. Food and Drug Administration (FDA) on the final design of the ENABLE-2 pivotal trial, a Phase 3 trial of relcobatinib (ELVN-001) in patients with previously treated chronic myeloid leukemia (CML).

United States Adopted Names (USAN) Council has adopted relcobatinib as the nonproprietary name for ELVN-001. Relcobatinib is an investigational, potent, highly selective, potentially best-in-class small molecule kinase inhibitor designed to specifically target the BCR::ABL1 gene fusion, the oncogenic driver of CML.

"We are pleased to have reached alignment with the FDA on the design of the ENABLE-2 pivotal Phase 3 trial, providing a clear path to initiate the trial before year-end," said Helen Collins, M.D., Chief Medical Officer of Enliven. "ENABLE-2 is designed to directly compare relcobatinib to the second-generation TKIs and evaluate its potential to be the best-in-class ATP-competitive inhibitor for patients with CML. We are encouraged by the enthusiasm from physicians and the broader CML community as we prepare to initiate the trial."

ENABLE-2 Phase 3 Trial Design: A 2L+ Pivotal Trial for Patients with CML

ENABLE-2 is a planned randomized 2L+ phase 3 trial expected to enroll approximately 450 adults with CML previously treated with one or more tyrosine kinase inhibitors (TKIs). Participants will be randomized 1:1 to receive either relcobatinib 80 mg once daily or an investigator-selected second-generation TKI (dasatinib, nilotinib, or bosutinib). The primary endpoint is major molecular response (MMR) at Week 24, with the key secondary endpoint of MMR at Week 96.

With approximately 450 patients, the trial is designed such that an improvement in MMR rate of at least 10 percentage points over the control arm would be sufficient to demonstrate statistical superiority. We believe this difference would represent a clinically meaningful improvement over currently available second-generation TKIs.

The Company remains on track to initiate ENABLE-2 before year-end 2026.

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. Enliven is based in Burlingame, California. 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 of, and plans regarding, market opportunities, and expectations regarding relcobatinib (ELVN-001); statements regarding the potential profile, activity, selectivity, safety, tolerability, efficacy, differentiated attributes, therapeutic benefit and potential best-in-class or complementary profile of relcobatinib 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 relcobatinib, including the planned ENABLE-2 Phase 3 trial, the statistical power, sample size assumptions and expected treatment effect sizes for ENABLE-2 and the belief that such treatment benefit would be clinically meaningful, 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. 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 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 relcobatinib to differ from the results of earlier trials of relcobatinib; relcobatinib 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 relcobatinib 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 relcobatinib 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; the risk that statistical assumptions underlying the ENABLE-2 trial design may not hold, including assumptions regarding treatment effect sizes, comparator arm performance and statistical power; 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 relcobatinib; and the potential inability of Enliven to obtain regulatory approval for, or ultimately commercialize or license, relcobatinib or other product candidates; Enliven's limited resources; Enliven's limited experience as a company in designing and conducting clinical trials; 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; geopolitical 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.



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SOURCE Enliven Therapeutics, Inc.

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