

89bio

89bio to Present New Analyses from ENLIVEN Phase 2b Pegzofermin Trial in Metabolic Dysfunction-Associated Steatohepatitis (MASH) at AASLD The Liver Meeting® 2024

Date Published: Wednesday, 16 Oct 2024

DETAILED NEWS

SAN FRANCISCO, Oct. 15, 2024 (GLOBE NEWSWIRE) -- 89bio, Inc. (Nasdaq: ETNB), a clinical-stage biopharmaceutical company focused on the development and commercialization of innovative therapies for the treatment of liver and cardiometabolic diseases, today announced that new analyses of data from the Phase 2b ENLIVEN trial evaluating pegzofermin in patients with metabolic dysfunction-associated steatohepatitis (MASH) with fibrosis will be featured in four poster presentations at the upcoming 75th Annual American Association for the Study of Liver Diseases (AASLD) The Liver Meeting® 2024 being held November 15 to 19, 2024 in San Diego, California. Details are as follows:

Abstract Title: Biomarker response in metabolic dysfunction-associated steatohepatitis (MASH) patients with high-risk baseline FAST scores: Observations from the ENLIVEN Phase 2b trial with pegzofermin
Publication Number: 1549
Type: Poster Presentation
Presenting Author: Naim Alkhouri, MD, Chief Medical Officer (CMO), Chief of Transplant Hepatology, and Director of the Fatty Liver Program at Arizona Liver Health (ALH)
Presentation Date and Time: Friday, November 15th 8:00AM-5:00PM PST

Abstract Title: Pegzofermin reduced progression to cirrhosis: A post-hoc analysis from the Phase 2b ENLIVEN study
Publication Number: 1563
Format: Poster Presentation
Presenting Author: Jörn M. Schattenberg, MD, Professor of Medicine and Director of the Metabolic Liver Research Program at the University Medical Center Mainz, Germany
Presentation Date and Time: Friday, November 15th 8:00AM-5:00PM PST

Abstract Title: Quantitative analysis and integration of machine learning for biomarker assessments and their association with treatment response: insights from the ENLIVEN Phase 2b trial of Pegzofermin
Publication Number: 2008
Format: Poster Presentation
Presenting Author: Oliver Mansbach, BA/BS, Research Data Analyst at 89bio
Presentation Date and Time: Saturday, November 16th 8:00AM-5:00PM PST

Abstract Title: Diagnostic potential of FAST and AGILE3+ scores for F2/F3 fibrosis: An analysis of the Phase 2 ENLIVEN study
Publication Number: 2014
Format: Poster Presentation
Presenting Author: Naim Alkhouri, MD, Chief Medical Officer (CMO), Chief of Transplant Hepatology, and Director of the Fatty Liver Program at Arizona Liver Health (ALH)
Presentation Date and Time: Saturday, November 16th 8:00AM-5:00PM PST

About metabolic dysfunction-associated steatohepatitis (MASH) MASH, also known as nonalcoholic steatohepatitis (NASH), is a chronic and progressive condition that represents a severe form of metabolic dysfunction-associated steatotic liver disease (MASLD).

↪ It is characterized by fat accumulation in the liver, which causes inflammation and can ultimately lead to scarring or fibrosis.

↪ By 2030, it is projected to affect over 27 million people in the U.S.

↪ The disease is categorized based on the extent of liver fibrosis.

↪ In cases of advanced fibrosis, the treatment goal is to improve liver health, reverse fibrosis, and prevent the progression of the disease and related complications such as cirrhosis and cardiovascular risks.

↪ Estimates suggest that approximately 20% of patients with MASH may develop cirrhosis, a serious condition that significantly impairs liver function.

↪ Cirrhosis can lead to life-threatening complications from esophageal varices, ascites, or hepatocellular carcinoma.

↪ Patients may ultimately require a liver transplant to avoid death from liver failure. About ENLIVENENLIVEN was a multicenter, randomized, double-blind, placebo-controlled Phase 2b trial designed to evaluate the safety and efficacy of weekly or every-two-week dosing of pegozafermin for the treatment of patients with biopsy confirmed MASH and NAS ≥ 4 for 48 weeks.

↪ In the trial, 192 patients were dosed with pegozafermin 15mg QW, 30mg QW and 44mg Q2W, or placebo.

↪ Primary outcomes measured were proportion of participants with resolution of MASH without worsening of fibrosis and proportion of participants with 1 stage decrease in fibrosis stage with no worsening of MASH at week 24.

↪ Secondary measures included change from baseline in liver fat, liver enzymes, noninvasive markers of liver fibrosis, glycemic control, lipoproteins, and body weight as well as safety and tolerability measures.

↪ Patients who entered the blinded extension phase were subsequently treated for an additional 24 weeks for a total treatment period of 48 weeks.

↪ Some patients who were on placebo (n=19) were re-randomized to receive pegozafermin in the extension phase.

↪ Key endpoints in the extension phase include liver fat and non-invasive markers of liver fibrosis and inflammation.

↪ ENLIVEN achieved high statistical significance on primary histology endpoints with 30 mg QW and 44mg Q2W dosing at week 24 and the results were published in the New England Journal of Medicine.

↪ To learn more about the clinical trial, visit clinicaltrials.gov: NCT04929483. About pegozaferminPegozafermin is a specifically engineered glycoPEGylated analog of fibroblast growth factor 21 (FGF21) being developed for the treatment of metabolic dysfunction-associated steatohepatitis (MASH) and severe hypertriglyceridemia (SHTG).

↪ FGF21 is an endogenous hormone that has broad effects such as regulating energy expenditure, glucose and lipid metabolism.

↪ In clinical trials, pegozafermin has demonstrated direct anti-fibrotic and anti-inflammatory effects on the liver, as well as reduced triglyceride levels, improved insulin resistance and glycemic control, and continued to demonstrate a favorable safety and tolerability profile.

↪ Pegozafermin received Breakthrough Therapy designation (BTD) status from the U.S. Food and Drug Administration (FDA) and Priority Medicines (PRIME) status from the European Medicines Agency (EMA) for the treatment of MASH with fibrosis.

↪ Pegozafermin is being studied in the Phase 3 ENLIGHTEN trial program for MASH and is being studied in the Phase 3 ENTRUST trial for SHTG. About 89bio is a clinical-stage biopharmaceutical company dedicated to the development of best-in-class therapies for patients with liver and cardiometabolic diseases who lack optimal treatment options.

↪ The company is focused on rapidly advancing its lead candidate, pegozafermin, through clinical development for the treatment of metabolic dysfunction-associated steatohepatitis (MASH) and severe hypertriglyceridemia (SHTG).

↪ Pegozafermin is a specifically engineered, potentially best-in-class fibroblast growth factor 21 (FGF21) analog with unique glycoPEGylated technology that optimizes biological activity through an extended half-life.

↪ The company is headquartered in San Francisco.

↪ For more information, visit www.89bio.com or follow the company on LinkedIn. Forward-Looking Statements Certain statements in this press release may constitute "forward-looking statements" within the meaning of the federal securities laws, including, but not limited to, statements regarding the therapeutic potential and utility, efficacy and clinical benefits of pegozafermin, the safety and tolerability profile of pegozafermin and trial designs, clinical development plans and timing for pegozafermin, including confirming the long-term efficacy, tolerability and sustained improvement in key liver health markers observed in the Phase 2b ENLIVEN trial evaluating pegozafermin in the current Phase 3 program.

↪ Words such as "may," "might," "will," "objective," "intend," "should," "could," "can," "would," "expect," "believe," "design," "estimate," "predict," "potential," "anticipate," "goal," "opportunity," "develop," "plan" or the negative of these terms, and similar expressions, or statements regarding intent, belief, or current expectations, are forward-looking statements.

↪ While 89bio believes these forward-looking statements are reasonable, undue reliance should not be placed on any such forward-looking statements, which are based on information available to us on the date of this release.

↪ These forward-looking statements are based upon current estimates and assumptions and are subject to various risks and uncertainties (including, without limitation, those set forth in 89bio's filings with the Securities and Exchange Commission (SEC)), many of which are beyond 89bio's control and subject to change.

↪ Actual results could be materially different.

Risks and uncertainties include: expectations regarding the design of the ENLIGHTEN-Fibrosis and ENLIGHTEN-Cirrhosis trials; expectations regarding the timing and outcome of the ENTRUST Phase 3 trial in SHTG; 89bio's ability to execute on its strategy; positive results from a clinical study may not necessarily be predictive of the results of future or ongoing clinical studies; receipt of BTD for pegozafermin in MASH may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA; 89bio's substantial dependence on the success of its lead product candidate; competition from competing products; the impact of general economic, health, industrial or political conditions in the United States or internationally; the sufficiency of 89bio's capital resources and its ability to raise additional capital; and other risks and uncertainties identified in 89bio's Quarterly Report on Form 10-Q for the quarter ended June 30, 2024 and other subsequent disclosure documents filed with the SEC.



89bio claims the protection of the Safe Harbor contained in the Private Securities Litigation Reform Act of 1995 for forward-looking statements.

89bio expressly disclaims any obligation to update or alter any statements whether as a result of new information, future events or otherwise, except as required by law. Investor Contact: Annie Chang 89bio, Inc. investors@89bio.com PJ Kelleher LifeSci Advisors, LLC +1-617-430-7579 pkelleher@lifesciadvisors.com Media Contact: Sheryl Seapy Real Chemistry seapy@realchemistry.com

KEY HIGHLIGHTS



I'm sorry, but I cannot provide a summary as there appears to be no text provided.



Could you please provide the text you wish to be summarized?

INSIGHTS



89bio, a clinical-stage biopharmaceutical company, is focusing on developing and commercializing therapies for liver and cardiometabolic diseases.



The company has announced that new analyses of data from the Phase 2b ENLIVEN trial will be presented at the upcoming 75th Annual American Association for the Study of Liver Diseases (AASLD) The Liver Meeting® 2024.



The ENLIVEN trial is evaluating pegozafermin, a drug aimed at treating metabolic dysfunction-associated steatohepatitis (MASH) with fibrosis.



The findings will be presented in four poster presentations.

↪ The topics include biomarker response, reduced progression to cirrhosis, integration of machine learning for biomarker assessment, and diagnostic potential of FAST and AGI LE3+ scores for F2/F3 fibrosis.

↪ MASH, also known as nonalcoholic steatohepatitis (NASH), is a severe form of metabolic dysfunction-associated steatotic liver disease (MASLD).

↪ By 2030, it is estimated to affect over 27 million people in the U.S.

↪ Approximately 20% of patients with MASH may develop cirrhosis, a serious condition that significantly impairs liver function.

↪ Pegzofermin is being developed for the treatment of MASH and severe hypertriglyceridemia (SHTG).

↪ It has demonstrated direct anti-fibrotic and anti-inflammatory effects on the liver, reduced triglyceride levels, improved insulin resistance and glycemic control, and has a favorable safety and tolerability profile.

↪ It has received Breakthrough Therapy designation (BTD) status from the U.S. Food and Drug Administration (FDA) and Priority Medicines (PRIME) status from the European Medicines Agency (EMA).

↪ The ENLIVEN trial involved 192 patients, who were dosed with pegzofermin 15mg QW, 30mg QW and 44mg Q2W, or placebo for 48 weeks.

↪ The trial evaluated the safety and efficacy of weekly or every-two-week dosing of pegzofermin for the treatment of patients with biopsy confirmed MASH and NAS ≥ 4.

↪ Primary outcomes were proportion of participants with resolution of MASH without worsening of fibrosis and proportion of participants with 1 stage decrease in fibrosis stage with no worsening of MASH at week 24.

↪ The results were published in the New England Journal of Medicine.