89bio to Present 48-Week Data from ENLIVEN Phase 2b Pegozafermin Trial in Metabolic Dysfunction-Associated Steatohepatitis (MASH) at EASL International Liver Congress

May 22, 2024

-Poster presentation selected for the EASL Poster Tour, a dedicated discussion session-

SAN FRANCISCO, May 22, 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 data from the 48-week extension phase of the Phase 2b ENLIVEN trial evaluating pegozafermin in patients with metabolic dysfunction-associated steatohepatitis (MASH) with fibrosis will be presented in an oral and poster presentation at the European Association for the Study of the Liver (EASL) Congress to be held June 5 to 8, 2024 in Milan, Italy.

“These data, which are being presented for the first time in a scientific setting, establish pegozafermin as the first FGF21 analog candidate to demonstrate positive, sustained benefits over a 48-week period in patients with advanced MASH,” said Hank Mansbach, Chief Medical Officer of 89bio. “In addition, these data highlight the observed long-term efficacy, tolerability and sustained improvement in key liver health markers, that we aim to confirm in our ongoing Phase 3 program.”

Presentation details are as follows:

Abstract Title: Week 48 results from the Phase 2b ENLIVEN extension study investigating pegozafermin for the treatment of metabolic dysfunction-associated steatohepatitis with fibrosis
Abstract Number: 943
Format: Oral presentation
Presenting Author: Rohit Loomba, M.D., MHSc, Chief of the Division of Gastroenterology and Hepatology at University of California San Diego School of Medicine, and lead investigator of the ENLIGHTEN program
Presentation Date and Time: Saturday, June 8th 10:45-12:00 CET
About the Abstract: The Phase 2b ENLIVEN trial evaluated the efficacy and safety of pegozafermin in MASH patients with biopsy-proven F2/F3 fibrosis. After the main study, patients began a 24-week blinded extension phase for a total of 48 weeks of treatment. At week 48, both the 30mg weekly and 44mg every-two-week dosing schedules of pegozafermin demonstrated statistically significant improvements across key markers of liver health. The benefits observed at week 48 were consistent with the results observed at week 24, indicating sustained benefits over time.

Abstract Title: Pegozafermin added to background GLP-1 therapy in patients with metabolic dysfunction-associated steatohepatitis with F2/F3 fibrosis: ENLIVEN 48-week extension data
Abstract Number: 1268
Format: Poster presentation
Presenting Author: Arun J. Sanyal, MBBS, M.D., Professor, Departments of Medicine, Physiology, and Molecular Pathology, Virginia Commonwealth University and lead investigator of the ENLIVEN trial
Presentation Date and Time: Saturday, June 8th 8:30-17:00 CET
About the Abstract: A sub analysis of the Phase 2b ENLIVEN trial extension phase was conducted for patients on background GLP-1 therapy. Patients entering ENLIVEN on background GLP-1 therapies were required to have been on a stable regimen for at least six months. Consistent with results observed in the Main Study, patients on background GLP-1 therapy who received pegozafermin continue to derive a greater benefit on markers of liver fibrosis, liver injury/inflammation, liver fat and lipids, compared to patients who continued GLP-1 therapy in the placebo group.
Poster Tour: The poster presentation has been selected by members of the EASL communications committee to be featured in a dedicated discussion during the “Metabolism-Alcohol & Toxicity” session, being held on Thursday, June 6 th 12:45-13:45 CET.

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 ENLIVEN
ENLIVEN 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 30mg 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 pegozafermin
Pegozafermin 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 Agenda (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
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 March 31, 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.

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