89bio Presents New Analyses Evaluating Pegozafermin and Potential Benefit of Non-Invasive Tests from the ENLIVEN Phase 2b Trial in MASH Patients at AASLD The Liver Meeting® 2024

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New post-hoc analyses reinforce pegozafermin's potential anti-fibrotic effects and the potential utility of non-invasive tests which correlate to histological endpoints

SAN FRANCISCO, Nov. 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, announced new analyses of data from the Phase 2b ENLIVEN trial evaluating pegozafermin in metabolic dysfunction-associated steatohepatitis (MASH) patients with advanced fibrosis. The findings were presented in four poster sessions at The American Association for the Study of Liver Diseases (AASLD) The Liver Meeting® being held in San Diego, California.

"We are excited to present additional analyses from our Phase 2b ENLIVEN trial at this year's Liver Meeting, which reinforce pegozafermin's potential effectiveness in reversing fibrosis and preventing progression to cirrhosis in patients with advanced MASH," said Hank Mansbach, Chief Medical Officer of 89bio. "These analyses strengthen our confidence in the design of our Phase 3 trials for both cirrhotic and non-cirrhotic MASH, and we look forward to building on this momentum as we advance these trials."

"MASH is often underdiagnosed and undertreated, which can lead to cirrhosis and severe complications like the need for liver transplantation," said Naim Alkhouri, MD, Chief Medical Officer, Chief of Transplant Hepatology, and Director of the Fatty Liver Program at Arizona Liver Health (ALH). "These post-hoc analyses demonstrate the potential of NITs like FAST and AGILE3+ to identify high-risk patients more conveniently, potentially reducing the need for liver biopsy. The results show that pegozafermin not only improved patients' FAST scores but also achieved both MASH resolution and fibrosis improvement, indicating its potential as a treatment option for patients with advanced MASH."

Publications Presented at the Meeting:

- Pegozafermin reduced progression to cirrhosis: A post-hoc analysis from the Phase 2b ENLIVEN study (Publication 1563).
- Biomarker response in metabolic dysfunction-associated steatohepatitis (MASH) patients with high-risk baseline FAST scores: Observations from the ENLIVEN Phase 2b trial with pegozafermin (Publication 1549).
- Diagnostic potential of FAST and AGILE3+ scores for F2/F3 fibrosis: An analysis of the Phase 2 ENLIVEN study (Publication 2014).
- Analysis and integration of machine learning for biomarker assessments and their association with treatment response: Insights from the ENLIVEN Phase 2b trial of pegozafermin (Publication 2008)

A copy of the AASLD posters will be accessible under "Scientific Publications" in the pipeline section of 89bio's website.

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 noninvasive 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 Agency (EMA) for the treatment of MASH with fibrosis. Pegozafermin is being studied in the Phase 3 ENLIGHTEN trial program for MASH and 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 trials for both cirrhotic and non-cirrhotic MASH. 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 September 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.

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