89bio Announces Publication of Results of Phase 1b/2a Study of Pegozafermin for the Treatment of NASH in The Lancet Gastroenterology & Hepatology

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– Data from cohorts 1-6 in the proof-of-concept study showed pegozafermin was generally well tolerated and had beneficial therapeutic effect in reducing liver fat and improving markers of liver injury, fibrosis and lipids –

– Pegozafermin has the potential to be a best-in-class treatment for individuals with NASH, a patient population in need of effective and well-tolerated therapies –

SAN FRANCISCO, Dec. 12, 2022 (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 cardio-metabolic diseases, today announced that data from cohorts 1-6 in the the Phase 1b/2a proof-of-concept study evaluating pegozafermin for the treatment of nonalcoholic steatohepatitis (NASH) was published online in *The Lancet Gastroenterology & Hepatology.* Study results showed statistically significant absolute reductions in hepatic fat fraction at week 13 with pegozafermin administered every week or every two weeks compared to placebo. Up to 88% of patients had at least a 30% reduction in hepatic fat fraction, which has been shown to correlate with reduced fibrosis progression.[1,2] Furthermore, improvements in liver transaminases (measures of liver injury), measures of fibrosis and lipids were observed with pegozafermin compared to placebo. In this study, pegozafermin was well tolerated with no treatment-related serious adverse events observed.

“Patients with NASH, a complex disease, are in urgent need of disease-modifying treatments that are effective in improving their overall liver health and address key underlying metabolic issues and cardiovascular disease risk factors,” said Rohit Loomba MD, MHSc, Director, NAFLD Research Center, University of California San Diego, primary investigator of the Phase 1b/2a study and lead author of *The Lancet Gastroenterology & Hepatology* paper. “I am very encouraged by the published study results showing pegozafermin was highly potent in reducing liver fat and was associated with clinically meaningful changes in liver health and beneficial effects on lipids and cardiovascular markers. The benefits of pegozafermin were observed across all doses and most prominently at the highest tested doses.”

NASH is a key risk factor for cirrhosis, hepatocellular carcinoma and cardiovascular events and is a leading cause of liver transplantation. In the United States, the prevalence of NASH is expected to increase to 27 million in 2030.[3] Management of this chronic disease is based primarily on lifestyle modification as no FDA-approved disease-modifying therapies are available.

“Based on the published proof-of-concept study, we are encouraged by the potential of pegozafermin to become a new treatment option for people living with NASH and potentially transform the treatment paradigm for this chronic, progressive fatty liver disease,” said Hank Mansbach, Chief Medical Officer of 89bio. “As part of our commitment to address the high medical need in NASH and bring patients a tolerable and highly effective treatment option, we are continuing to advance the clinical development of pegozafermin in our Phase 2b ENLIVEN trial, with topline results expected in the first quarter of next year.”

In the Phase 1b/2a study, participants were randomized to 12 weeks of placebo or one of two subcutaneously administered pegozafermin dosing regimens: 3, 9, 18 or 27 mg weekly or 18 or 36 mg every two weeks.

About the Phase 1b/2a Study
The multicenter, randomized, double-blind, placebo-controlled Phase 1b/2a multiple ascending dose study assessed the safety, tolerability, pharmacokinetic and pharmacodynamic effects of pegozafermin in patients with biopsy-confirmed NASH with fibrosis or at high risk of NASH (phenotypic NASH (PNASH), defined as obesity with either Type 2 diabetes or evidence of liver injury). The study also assessed change in liver fat measured by magnetic resonance imaging-proton density fat fraction (MRI-PDFF) and key biomarker assessments. A total of 81 adults, age 21 to 75 years, were randomized to subcutaneously administered pegozafermin (3, 9, 18 or 27 mg weekly or 18 or 36 mg every two weeks) or placebo for up to 12 weeks. Overall, baseline characteristics were similar among the placebo and pegozafermin groups. The study was conducted at 12 clinical sites in the United States.

About Pegozafermin
Pegozafermin is a specifically engineered glycoPEGylated analog of fibroblast growth factor 21 (FGF21) being developed for the treatment of non-alcoholic steatohepatitis (NASH) and severe hypertriglyceridemia (SHTG). FGF21 is an endogenous hormone that modulates important drivers of lipid metabolism and NASH including triglyceride reduction, glycemic control, steatosis, inflammation and fibrosis. Pegozafermin was specifically engineered using a unique glycoPEGylated technology to extend the half-life while maintaining potency.

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 non-alcoholic steatohepatitis (NASH) 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 with operations in Herzliya, Israel. 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, the therapeutic potential and clinical benefits of pegozafermin, the clinical benefit, safety and tolerability profile of pegozafermin and clinical development plans and timing for pegozafermin. 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 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 timing and outcome of the Phase 2b ENLIVEN trial in NASH; expectations regarding the timing of topline data; 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; 89bio’s substantial dependence on the success of it lead product candidate; competition from competing products; the effect of the COVID-19 pandemic on 89bio’s clinical trials and business operations, and 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, 2022 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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[2] Tamaki N, Ajmera V, Loomba R. Non-invasive methods for imaging hepatic steatosis and their clinical importance in NAFLD. Nat Rev Endocrinol 2022; 18: 55–66.

[3] Estes C, Razavi H, Loomba R, Younossi Z, Sanyal AJ. Modeling the epidemic of nonalcoholic fatty liver disease demonstrates an exponential increase in burden of disease. Hepatology. 2018;67(1):123-133. doi:10.1002/hep.29466.