89bio Announces U.S. FDA has Granted Breakthrough Therapy Designation for Pegozafermin in Nonalcoholic Steatohepatitis (NASH)

September 21, 2023

–Supported by positive data in F2/F3 and F4 NASH patients from the ENLIVEN Phase 2b trial of pegozafermin–

–Discussions with regulatory agencies regarding the NASH Phase 3 program planned for the fourth quarter of 2023–

SAN FRANCISCO, Sept. 21, 2023 (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 the U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy Designation (BTD) to pegozafermin in patients with nonalcoholic steatohepatitis (NASH).

“We are thrilled with this validation from the FDA awarding pegozafermin with Breakthrough Therapy Designation, which we expect will be advantageous for finalizing our Phase 3 development strategy in NASH following planned discussions with regulatory agencies in the fourth quarter of 2023,” said Rohan Palekar, Chief Executive Officer of 89bio. “We believe pegozafermin is well positioned as a leading FGF21 analog treatment option with demonstrated strong histology data, best-in-class tolerability, and dosing convenience to date. It has the potential to meet the treatment needs for F2/3 patients as well as compensated cirrhotic (F4) patients. The benefits of this designation include more comprehensive guidance from the FDA on the development program, ability to discuss innovative development plan options, access to a scientific liaison, and potential eligibility for Priority Review.”

BTD was supported by data from the ENLIVEN Phase 2b trial of pegozafermin in patients with NASH. In the study, both the 44mg every-two-week (Q2W) and 30mg weekly (QW) doses met — with high statistical significance — the primary histology endpoints per the FDA guidance regarding endpoints and statistical analysis. The 44mg Q2W and 30mg QW dose groups also demonstrated statistically significant and clinically meaningful improvements in liver fat, non-invasive markers of liver fibrosis and inflammation, and meaningful improvements in other metabolic and lipid markers. The ENLIVEN trial also included biopsy-confirmed F4 patients who were not part of the primary analysis but continued in the study. In a descriptive analysis of these data, 45% of pegozafermin-treated patients experienced at least one-stage improvement in liver fibrosis with no worsening of NASH by week 24 compared with zero out of one patient on placebo. Overall, pegozafermin was generally well-tolerated with a favorable safety profile consistent with prior studies.

BTD is an FDA program designed to expedite the development and review of product candidates intended for serious or life-threatening conditions. To qualify for this designation, preliminary clinical evidence must indicate that the product candidate may demonstrate substantial improvement over currently available options on at least one clinically significant endpoint.

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 therapeutic candidate, pegozafermin, through clinical development for the treatment of non-alcoholic steatohepatitis (NASH) and severe hypertriglyceridemia (SHTG). 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, the timing for meeting with regulatory authorities and the benefits of BTD for the development 89bio’s Phase 3 development strategy. 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 initiation of the Phase 3 trial in NASH; 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 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 Annual Report on Form 10-K for the year ended December 31, 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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