89bio Receives EMA PRIME Status for Pegozafermin in the Treatment of Metabolic Dysfunction-Associated Steatohepatitis (MASH) with Fibrosis and Compensated Cirrhosis

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–PRIME status is supported by positive data from the Phase 2b ENLIVEN trial of pegozafermin–

–Phase 3 ENLIGHTEN-Fibrosis trial in non-cirrhotic MASH (fibrosis stage F2-F3) patients is enrolling and ENLIGHTEN-Cirrhosis in MASH patients with compensated cirrhosis (F4) is planned to initiate in the second quarter of 2024–

SAN FRANCISCO, March 27, 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 the European Medicines Agency (EMA) has granted Priority Medicines (PRIME) status to pegozafermin in patients with MASH. The PRIME status was supported by positive data from the Phase 2b ENLIVEN trial of pegozafermin in patients with non-cirrhotic MASH with fibrosis (F2-F3) and MASH with compensated cirrhosis (F4).

“The EMA PRIME status further supports pegozafermin’s positioning as a leading FGF21 analog for the treatment of MASH, which has demonstrated robust anti-fibrotic and metabolic benefits as seen in our Phase 2b ENLIVEN trial,” said Rohan Palekar, Chief Executive Officer of 89bio. “This status recognizes the urgent need for effective treatment options for MASH patients with advanced fibrosis and underscores pegozafermin’s potential to address the targeted unmet medical need. We look forward to working closely with regulatory agencies as we continue to advance our Phase 3 clinical development program, ENLIGHTEN, aimed at potentially benefiting advanced MASH patients and MASH patients with compensated cirrhosis.”

The PRIME status is granted by the EMA to provide early and proactive support to developers of promising medicines that, based on clinical data, may offer a major therapeutic advantage over existing treatments, or benefit patients without treatment options. PRIME aims to provide multiple benefits so that these medicines can reach patients earlier including, enhanced interaction and early dialogue with EMA, guidance on the overall development plan and regulatory strategy, and the potential for accelerated assessment of the time of marketing authorization application.

For more information on the PRIME status, please visit the EMA website at www.ema.europa.eu.

About Metabolic dysfunction-associated steatohepatitis (MASH)
MASH, formerly known as nonalcoholic steatohepatitis (NASH), is a more advanced form of metabolic dysfunction-associated steatotic liver disease (MASLD) which is a chronic, progressive disease in which fat accumulates in the liver, ultimately leading to scarring or fibrosis. Fibrosis damages the liver and can lead to more severe liver-related complications, including cirrhosis, liver failure, and hepatocellular cancer (HCC) and is associated with increased risk for cardiovascular disease. In later stages, MASH can cause cirrhosis which increases the risk for serious intervention such as a liver transplant, with MASH being a leading cause of liver transplants among adults. Most people with MASH experience few or no symptoms until they’ve progressed to an advanced stage, and as a result, the disease often goes undetected for years, or even decades.

About The ENLIGHTEN Program
The ENLIGHTEN program is comprised of two Phase 3 global, multi-center, randomized, double-blind, placebo-controlled trials, evaluating the efficacy and safety of pegozafermin in patients with MASH. The ENLIGHTEN-Fibrosis trial, the first of two Phase 3 trials in the program, will enroll approximately 1,000 patients with non-cirrhotic MASH (fibrosis stage F2-F3) to evaluate the efficacy and safety of pegozafermin. The co-primary endpoints, for which demonstration of an effect on each is needed to support regulatory approval, measured at week 52 are a one-point improvement in fibrosis with no worsening of MASH and MASH resolution with no worsening of fibrosis, assessed at week 52. ENLIGHTEN-Cirrhosis, the second of the two Phase 3 trials in the program, will evaluate the efficacy and safety of pegozafermin in MASH patients with compensated cirrhosis (F4).

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. The FDA granted pegozafermin Breakthrough Therapy designation (BTD) for the treatment of MASH with fibrosis. Pegozafermin is advancing into 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 the anticipated design and advancement of our Phase 3 ENLIGHTEN program and timing of initiation of the ENLIGHTEN-Cirrhosis Phase 3 trial in MASH patients with compensated cirrhosis (F4). 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 and advancement of our Phase 3 ENLIGHTEN program and initiation of the ENLIGHTEN-Cirrhosis Phase 3 trial in MASH patients with compensated cirrhosis (F4); 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 and PRIME designation for pegozafermin in MASH may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA or EMA procedures, respectively, and does not assure ultimate approval by the FDA or EMA, respectively; 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 Annual Report on Form 10-K for the year ended December 31, 2023 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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