89bio Presents Additional Exploratory Analyses from the Phase 1b/2a NASH Study of Pegozafermin at AASLD The Liver Meeting® 2022

November 5, 2022

- New analysis of cohort 7 data using a three-reader pathologist panel showed that 6/19 patients scored as having fibrosis stage 4 at baseline (putative F4); excluding these patients resulted in higher histological response rates in the patients with F2-F3 fibrosis than previously reported -

SAN FRANCISCO, Nov. 05, 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 the presentation of post-hoc exploratory analyses of additional data from the paired-biopsy, open-label expansion cohort (Cohort 7) in the Phase 1b/2a proof-of-concept study evaluating pegozafermin in patients with nonalcoholic steatohepatitis (NASH). These data were featured in a poster presentation (abstract #36901) at the American Association for the Study of Liver Diseases (AASLD) The Liver Meeting® 2022, being held virtually and in Washington, D.C., from November 4 – 8, 2022. A copy of the poster presentation will be accessible under “Scientific Publications” in the pipeline section of 89bio’s website .

In this open-label cohort, NASH patients were treated once weekly for 20 weeks with 27 mg of pegozafermin. For the primary analysis, biopsies were read centrally at baseline and at end of treatment by a single expert liver pathologist (central reader). In a post-hoc exploratory analysis, a panel of three additional expert NASH pathologists (three-reader panel) assessed the same baseline and end of treatment slides that had been evaluated by the central reader. The expected inter-reader variability common in NASH studies was observed.

The three-reader panel scored six of the 19 patients as having F4 fibrosis at baseline (putative F4), which was an exclusion criterion for the Phase 1b/2a study. Excluding the putative F4 patients resulted in a higher proportion of patients meeting the registration enabling histological endpoints compared to the primary analysis based on the central reader, as shown below.

Parameter	All patients (n=19)	Excluding patients with putative F4 fibrosis at baseline (n=13*)
≥ 2 point reduction in NAS (%)	74%	77%
NASH resolution without worsening of fibrosis (%)	32%	46%
Fibrosis improvement ≥ 1 stage without worsening of NASH (%)	26%	38%

*Post-hoc analysis excluding patients with putative F4 fibrosis (n=6) based on scoring by 2 or more of the three-panel pathologists; cirrhosis was an exclusion criterion in this study

“These latest data showcase pegozafermin’s ability to drive meaningful changes on histology endpoints despite the inherent variability in liver biopsy assessments,” said Dr. Hank Mansbach, Chief Medical Officer of 89bio. “We have incorporated a three-panel consensus read to reduce variability in our ongoing Phase 2b ENLIVEN trial and remain on track to report topline data in the first quarter of 2023. We were also encouraged to observe pharmacological activity with pegozafermin in the small group of F4 patients.”

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. Pegozafermin is currently being evaluated in the Phase 2b ENLIVEN trial in NASH and is expected to move into Phase 3 program for SHTG in 2023.

Recent Phase 2 data with pegozafermin in SHTG patients demonstrated significant and clinically meaningful reductions in triglycerides as well as improvements in other cardiometabolic measures. Additionally, Phase 1b/2a data with pegozafermin in biopsy-confirmed NASH patients demonstrated clinically meaningful changes on histology endpoints and non-invasive measures of total liver health as well as many of the underlying metabolic comorbidities commonly associated with NASH.

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, clinical development plans and timing for pegozafermin, including the Phase 2b ENLIVEN trial and the Phase 3 program for SHTG, and the timing for topline data for the ENLIVEN trial will be sufficient to fund its

anticipated operations. 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; 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; and other risks and uncertainties identified in 89bio’s Quarterly Report on Form 10-Q for the quarter ended June 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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