89bio Presents New Data from Phase 1b/2a NASH Study Showing BIO89-100 Reduces Spleen Volume

November 14, 2021

New sub-analysis presented at The Liver Meeting® 2021 shows treatment with BIO89-100 reduced spleen volume by an average of 11.8% in NASH patients

Oral presentation was highlighted by the AASLD Scientific Program Committee as a key presentation in The Liver Meeting® 2021

SAN FRANCISCO, Nov. 14, 2021 (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 new data from a post-hoc analysis of the Phase 1b/2a proof-of-concept study evaluating BIO89-100 in patients with nonalcoholic steatohepatitis (NASH) at The Liver Meeting® 2021 of the American Association for the Study of Liver Diseases (AASLD). The sub-analysis, which assessed the correlation between liver fat and spleen volume (SV), demonstrated that treatment with BIO89-100 reduced spleen volume by an average of 11.8% in patients with NASH. These data will be presented virtually on Sunday, November 14, as an oral presentation entitled “Treatment with BIO89-100 Led to Decreased Spleen Volume That was Correlated with Relative Change in Liver Fat Volume and Pro-C3 Level in a Phase 1b/2a, Placebo-controlled, Double-blind, NASH Proof of Concept (POC) Study” during the Parallel 21: NAFLD and NASH: Clinical Trials of Novel Therapeutics session.

“Prior to this study, correlations between increased spleen volume and improvements in NASH had not been systematically evaluated,” said Rohit Loomba, MD, MHSc, Director of the NAFLD Research Center and Director of Hepatology at UC San Diego School of Medicine. “These exciting data from the BIO89-100 study demonstrate that improvement in liver fat and liver volume result in decreasing spleen volume likely due to improved portal flow.”

The post-hoc analysis of the Phase 1b/2a study assessed the effect of BIO89-100 on SV in NASH patients without advanced fibrosis. SV was evaluated in all eligible patients on BIO89-100 27mg every week dose (n=8), BIO89-100 36mg every two-week dose (n=8) and 16 patients on placebo. These patients were assessed by MRI at baseline, on Day 50 and on Day 92. At baseline, it was observed that SV was correlated with liver volume, vibration-controlled transient elastography (VCTE) score and body mass index (BMI), and negatively correlated with platelet count. Findings at study Day 50 and Day 92 demonstrated that treatment with BIO89-100 led to a progressive and significant decrease in spleen volume compared to placebo (on Day 50, treated patients saw an average of 7.4% decrease in SV and by Day 92 patients saw an average 11.8% decrease in SV).

These preliminary observations suggest that increased fat in the liver and inflammation may lead to subclinical worsening of portal blood flow, which in turn leads to increased spleen volume in NASH patients without advanced fibrosis. Based on these study findings, portal flow may be improved with treatment that significantly reduces liver fat.

“We are encouraged by the preliminary findings that suggest BIO89-100 has the potential to promote meaningful reductions in spleen volume, which correlate with reductions in liver fat by MRI-PDFF and liver fat volume,” said Hank Mansbach, Chief Medical Officer of 89bio. “These exciting data continue to advance our understanding of fatty liver disease and provide new insights about evaluating treatment response in NASH.”

In addition to being presented at the meeting, the abstract has been selected by members of the AASLD Scientific Program Committee as a key presentation in The Best of Liver Meeting 2021. A copy of the oral presentation will be accessible under ‘Scientific Publications’ in the pipeline section of 89bio’s website .

About the Phase 1b/2a Study
This multicenter, randomized, double-blind, placebo-controlled, multiple ascending dose-ranging trial was designed to assess the safety, tolerability and pharmacokinetic (PK) properties of BIO89-100 as well as change in liver fat measured by MRI-PDFF and key biomarker assessments in patients with biopsy-proven NASH with fibrosis or patients with phenotypical NASH (PNASH). PNASH was defined as patients with steatosis greater than 10% who have central obesity and Type 2 diabetes or central obesity and evidence of liver injury. Both patient populations had similar disease characteristics at baseline. A total of 81 patients were randomized to receive weekly or every-two-week subcutaneous dosing of BIO89-100 or placebo for up to 12 weeks. Results showed robust reductions in liver fat and key liver markers, a strong efficacy profile, and favorable tolerability with weekly and every-two-week dosing. These findings highlight the promising clinical profile of BIO89-100 and add to the growing body of evidence suggesting it could be a leading FGF21 analog in a class that could become the backbone of treatment for NASH.

About 89bio
89bio is a clinical-stage biopharmaceutical company focused on the development and commercialization of innovative therapies for the treatment of liver and cardio-metabolic diseases. The company’s lead product candidate, BIO89-100, is a specifically engineered glycoPEGylated analog of FGF21. BIO89-100 is being developed for the treatment of nonalcoholic steatohepatitis (NASH) and severe hypertriglyceridemia (SHTG). 89bio is headquartered in San Francisco with operations in Herzliya, Israel.

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 BIO89-100 with respect to spleen volume and the potential efficacy of BIO89-100 in reducing spleen volume. Words such as "may," "might," "will," "objective," "intend," "should," "could," "can," "would," "expect," "believe," "design," "estimate," "predict," "potential," "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: positive results from a clinical study may not necessarily be predictive of the results of future or ongoing clinical studies; and other risks and uncertainties identified in 89bio's Annual Report on Form 10-K for the year ended December 31, 2020, its Quarterly Reports on Form 10-Q 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.

Investor Contact:
Ryan Martins
Chief Financial Officer
investors@89bio.com

Media Contact:
Peter Duckler
773-343-3069
pduckler@w2ogroup.com

Source: 89bio, Inc.