89bio Presents Additional Analysis of Phase 1b/2a NASH Study at the Annual ENDO 2021 Conference

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New analysis shows BIO89-100 meaningfully reduces liver fat volume and liver volume in patients with NASH

SAN FRANCISCO, March 20, 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 additional positive data from its Phase 1b/2a study of BIO89-100, a long-acting glycoPEGylated FGF21 analog, in patients with nonalcoholic steatohepatitis (NASH). The data will be presented in an on-demand poster presentation at ENDO 2021, the Endocrine Society's annual meeting taking place virtually from March 20-23, 2021.

"Excess liver fat is an important driver of disease progression for people living with NASH and can be associated with increased risk for cardiovascular events and even death," said Hank Mansbach, chief medical officer of 89bio. "We are encouraged by new analyses from our Phase 1b/2a study that show BIO89-100 demonstrated clinically meaningful reductions in both liver fat volume and liver volume overall across all dosing groups. The data continues to highlight the promising clinical profile of BIO89-100 and supports further development of BIO89-100 in NASH and also severe hypertriglyceridemia."

New analyses of the Phase 1b/2a study data showed BIO89-100 treatment resulted in significant reductions in liver volume of up to 15% and liver fat volume of up to 65% in treated patients at 13 weeks compared to baseline, as measured by magnetic resonance imaging-proton density fat fraction (MRI-PDFF). These data extend the previously reported MRI-PDFF data in which BIO89-100 treatment resulted in up to 70% relative reduction in liver fat fraction relative to placebo treatment. Additionally, BIO89-100, as previously reported, demonstrated a favorable safety and tolerability profile, with rates of gastrointestinal side effects such as nausea, diarrhea and vomiting similar to placebo.

The poster presentation details are as follows:

Session: P02 - Integrated Physiology of Obesity and Metabolic Disease
Poster Presentation: #53
Poster Title: BIO89-100 Demonstrated Robust Reductions in Liver Fat and Liver Fat Volume (LFV) by MRI-PDFF, Favorable Tolerability and Potential for Weekly (QW) or Every 2 Weeks (Q2W) Dosing in a Phase 1b/2a Placebo-Controlled, Double-Blind, Multiple Ascending Dose Study in NASH
Presenting Author: Juan Pablo Frias, M.D.

A copy of the poster presentation is also available for download via the 89bio website.

About NASH
NASH is the most advanced stage of nonalcoholic fatty liver disease (NAFLD). It is a complex metabolic disorder that causes fat buildup in the liver, as well as inflammation and eventually fibrosis, and it can worsen to cirrhosis and liver failure. NASH affects more than 16 million adults in the United States, and by 2030 its prevalence is predicted to increase by 63 percent. The exact cause of NASH is unknown, but it is commonly found in people with obesity and type 2 diabetes. While there are currently no approved treatments, the biopharmaceutical industry is actively involved in addressing this unmet medical need.

About the Phase 1b/2a Study
This clinical study was a multicenter, randomized, double-blind, placebo-controlled, multiple ascending dose-ranging trial. It was designed to assess the safety, tolerability, and 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 populations that were enrolled had similar disease characteristics at baseline. A total of 81 patients were randomized to receive weekly or every two weeks subcutaneous dosing of BIO89-100 or placebo for up to 12 weeks. Results observed across all dose groups from the trial add to a growing body of evidence demonstrating the promise of BIO89-100 for the treatment of NASH. Results showed robust reductions in liver fat and key liver markers. A strong efficacy profile and favorable tolerability were observed with weekly and every two-week dosing.

About BIO89-100
BIO89-100 is a glycoPEGylated analog of FGF21 being developed for the treatment of NASH. 89bio has optimally engineered BIO89-100 using a proprietary glycoPEGylation technology to balance efficacy and longer dosing interval. Recent Phase 1b/2a data show BIO89-100 demonstrated a favorable safety and tolerability profile and robust reductions in liver fat and key lipid markers when dosed weekly (QW) or once every two weeks (Q2W). BIO89-100 is also being developed for the treatment of severe hypertriglyceridemia (SHTG) and is currently in a Phase 2 trial.

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.

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