89bio Initiates Phase 2 Trial of BIO89-100 in Patients with Severe Hypertriglyceridemia

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- Multi-center, randomized, double-blind, placebo-controlled study will evaluate the safety and efficacy of BIO89-100 administered weekly or every two weeks for 8 weeks -

SAN FRANCISCO, Sept. 03, 2020 (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 initiation of a Phase 2 trial evaluating its product candidate BIO89-100 in patients with severe hypertriglyceridemia (“SHTG”). BIO89-100 is a glycoPEGylated analog of fibroblast growth factor 21 (“FGF21”) in clinical development for the treatment of nonalcoholic steatohepatitis (“NASH”) and SHTG.

"This new program builds on our strategy to leverage the biology of FGF21 to bring meaningful benefit to patients across a range of serious diseases with high unmet needs," said Hank Mansbach, Chief Medical Officer of 89bio. “Existing therapies for SHTG do not address the range of metabolic issues faced by these patients, that result in the increased risk of cardiovascular events and NASH. Our early clinical data indicate that BIO89-100 could offer robust and durable reductions in triglycerides as well as deliver broad metabolic benefits. This suggests BIO89-100 has the potential to be a highly differentiated new therapy for this condition."

The Phase 2 trial is a multi-center, randomized, double-blind, placebo-controlled study designed to evaluate the safety, efficacy, and tolerability of BIO89-100 in patients with SHTG. The study will enroll approximately 90 patients who will be treated with BIO89-100 in one of four treatment groups or placebo administered in either weekly or every two weeks doses for a period of 8 weeks. The primary endpoint is the reduction in fasting triglycerides from baseline. Key secondary endpoints include the effect of BIO89-100 on other lipids and metabolic markers and change in liver fat measured by magnetic resonance imaging proton density fat fraction (MRI-PDFF). Patients who meet screening criteria will undergo a lifestyle stabilization and triglyceride qualification period prior to randomization and will receive lifestyle counseling during the study.

About Severe Hypertriglyceridemia
SHTG is a condition identified by severely elevated levels of triglycerides (greater than or equal to 500 mg/dL). It is associated with an increased risk of NASH, cardiovascular events, and acute pancreatitis. It is estimated that up to 4 million patients in the United States have SHTG. Of these patients, it is estimated that 56% have hepatic fat, 42% have dyslipidemias and 27% have diabetes. This patient population is expected to increase due to the triple epidemic of obesity, metabolic syndrome, and Type 2 diabetes. While existing therapies may decrease triglyceride levels, they generally do not have broader metabolic benefits underscoring the urgent need for additional therapeutic options.

About BIO89-100
BIO89-100 is a glycoPEGylated analog of FGF21 being developed for the treatment of NASH and SHTG. 89bio has optimally engineered BIO89-100 using a proprietary glycoPEGylation technology to balance efficacy and longer dosing interval. In preclinical studies, BIO89-100 demonstrated significant improvements in hepatic steatosis, injury, and fibrosis. In 89bio's Phase 1a clinical trial of BIO89-100 in healthy volunteers, BIO89-100 demonstrated robust and durable improvements in key lipid markers, a favorable tolerability profile, and a long half-life that supports the potential for weekly or once every two weeks dosing.

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. 89bio’s lead product candidate is BIO89-100, a specifically engineered glycoPEGylated analog of FGF21. BIO89-100 is being developed for the treatment of NASH and SHTG with ongoing proof of concept studies in both indications. 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, 89bio's expectations regarding its new clinical program and clinical trials, the association of early data with potential clinical benefit, and the results and timing of anticipated endpoints. 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: expectations regarding the timing, completion and outcome of 89bio’s proof of concept Phase 2 clinical trial evaluating BIO89-100 in patients with SHTG; the unpredictable relationship between preclinical study results and clinical study results; 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 Annual Report on Form 10-K for the year ended December 31, 2019 and its Quarterly Report on Form 10-Q for the quarter ended June 30, 2020 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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