89bio Provides Business Outlook for 2021

January 5, 2021

-Phase 2b NASH trial as part of a potential Phase 2b/3 program expected to initiate in 1H21-

-Topline data from recently initiated NASH paired-biopsy, open-label histology cohort expected by YE21-

-Topline data from BIO89-100's Phase 2 SHTG trial expected in 2H21-

SAN FRANCISCO, Jan. 05, 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 provided a corporate update, including its roadmap for advancing BIO89-100 in 2021.

"We are extremely pleased by our 2020 progress across all aspects of the company including clinical, manufacturing and corporate advancements," said Rohan Palekar, chief executive officer of 89bio. "We are steadily executing across our clinical development program for BIO89-100, a potentially best-in-class FGF21 analog engineered to achieve superior efficacy, optimal dosing convenience, as well as favorable safety and tolerability. In 2020, we presented encouraging topline Phase 1b/2a data, which has informed the advancement of our clinical strategy in NASH and we are looking forward to our major anticipated milestones in 2021 in both NASH and SHTG."

Key 2021 Milestones

- Report topline data from the paired-biopsy, open-label histology cohort as part of the Phase 1b/2a trial of BIO89-100 in NASH by year-end 2021
- Initiate the Phase 2b NASH trial as part of a potential Phase 2b/3 program in the first half of 2021
- Report topline data from the Phase 2 trial of BIO89-100 in SHTG in the second half of 2021

Clinical Development Overview
89bio is developing BIO89-100, a glycoPEGylated analog of FGF21 for the treatment of liver and cardio-metabolic diseases. BIO89-100 delivers a compelling risk-benefit profile by improving liver pathology and addressing the underlying metabolic issues while balancing these benefits with favorable tolerability and the dosing convenience necessary for adoption and compliance.

NASH
89bio plans to initiate a Phase 2b NASH trial as part of a potential Phase 2b/3 trial in the first half of 2021. Additionally, the Company recently initiated a paired-biopsy, open-label histology cohort as part of the Phase 1b/2a trial of BIO89-100 in NASH, with data anticipated by the end of 2021. This cohort will enroll approximately 20 patients with biopsy-confirmed NASH and will provide an early opportunity to demonstrate BIO89-100's benefits on histology endpoints. These patients will be treated for 20 weeks with 27 mg of BIO89-100 once weekly. The cohort will build on the recent data from 89bio's Phase 1b/2a multicenter, randomized, double-blind, placebo-controlled, multiple ascending dose-ranging trial. The 13-week trial enrolled a total of 81 patients and demonstrated relative reductions in liver fat of up to 70% versus placebo, as measured by magnetic resonance imaging—proton density fat fraction (MRI-PDFF). A majority of patients achieved a ≥ 30% (up to 88%) or a ≥ 50% (up to 71%) reduction in liver fat. ALT was significantly reduced (up to 44%) in these patients and key lipid markers like triglycerides, LDL, and non-HDL were also significantly improved. Results were consistent across the sub-populations of biopsy-confirmed NASH and phenotypic NASH (PNASH) patients enrolled in the trial and baseline characteristics were similar across these sub-populations as were the reductions in liver fat. The percentage of responders on MRI-PDFF and BIO89-100's effect on reducing ALT and triglycerides were also similar across these sub-populations. Overall, BIO89-100 had a favorable safety and tolerability profile with rates of gastrointestinal side effects such as nausea, diarrhea and vomiting similar to placebo.

SHTG
The ongoing Phase 2 trial investigating BIO89-100 for the treatment of severe hypertriglyceridemia (SHTG) will enroll approximately 90 patients. In this Phase 2 multi-center, randomized, double-blind, placebo-controlled study designed to evaluate safety, efficacy, and tolerability, BIO89-100 or placebo will be administered in one of four treatment groups either weekly or every two 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 MRI-PDFF. Topline data from the study are expected in the second half of 2021.

Participation in the 10th Annual LifeSci Partners Corporate Access Event
Rohan Palekar, chief executive officer of 89bio, will participate in 1x1 meetings with investors at the upcoming Annual LifeSci Partners Corporate Access Event, which will take place January 6-8 and 11-14, 2021.

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, the safety and tolerability of BIO89-100, clinical development plans for BIO89-100, including the Phase 2b trial and open-label paired biopsy histology cohort for NASH and the Phase 2 trial for SHTG, and the anticipated timing for such plans. 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 and outcome of 89bio's initiation of the Phase 2b trial in NASH; expectations regarding the timing of topline data; 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; 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 September 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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