89bio Initiates Phase 2b ENLIVEN Trial of BIO89-100 for the Treatment of NASH

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SAN FRANCISCO, June 10, 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 initiation of ENLIVEN, a Phase 2b trial evaluating BIO89-100 for the treatment of patients with fibrosis stage 2 or 3 non-alcoholic steatohepatitis (NASH). 89bio is also pleased to announce that a distinguished group of clinicians and scientists will provide their deep expertise and valuable insight as part of the steering committee for ENLIVEN.

“We are pleased to initiate the ENLIVEN trial, an important milestone in our clinical development program for NASH,” said Hank Mansbach, Chief Medical Officer of 89bio. “ENLIVEN is a well-powered trial that builds on positive data from the Phase 1b/2a trial, which demonstrated that BIO89-100 has the potential to combine strong efficacy, a favorable safety and tolerability profile, and potentially best-in-class dosing convenience. We are encouraged by the robust responses that were observed across various efficacy measures and believe these improvements will translate into histology benefits in ENLIVEN.”

ENLIVEN is a multicenter, randomized, double-blind, placebo-controlled Phase 2b study in biopsy-confirmed NASH patients with fibrosis stage 2 or 3. A total of 216 patients will receive either one of two weekly doses (15mg or 30mg) or an every two-week dose (44mg) of BIO89-100 in a liquid formulation or placebo for 24 weeks. All patients will continue treatment in a blinded extension phase for 24 weeks for a total treatment period of 48 weeks, with some of the placebo patients re-randomized to receive BIO89-100 in the extension phase. The primary endpoints at Week 24 are NASH resolution without worsening of fibrosis and the improvement of fibrosis ≥ 1 stage without worsening of NASH.

Concurrent with the initiation of ENLIVEN, 89bio has established a steering committee for the trial comprising a distinguished group of clinicians, researchers, and experts in NASH. Members of the steering committee include:

- Manal Abdalmalek, M.D., Professor of Medicine and Director of NAFLD Clinical Research Program at Duke University
- Naim Alkhouri, M.D., VP of Academic Affairs and Director of Fatty Liver Program at Arizona Liver Health
- Deepak L. Bhatt, M.D., MPH, Executive Director of Interventional Cardiovascular Programs at Brigham and Women's Hospital, and Professor of Medicine at Harvard Medical School
- Juan Frias, M.D., Medical Director and Principal Investigator at National Research Institute, Los Angeles
- Kris V. Kowdley, M.D., Director of Liver Institute Northwest and Clinical Professor at Elson S. Floyd College of Medicine and Washington State University
- Rohit Loomba, M.D., MHSc, Director of NAFLD Research Center, Professor of Medicine in the Division of Gastroenterology, and Adjunct Professor in the Division of Epidemiology at the University of California San Diego

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 ENLIVEN Phase 2b trial, 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 ENLIVEN 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, 2020 and its Quarterly Report on Form 10-Q for the quarter ended March 30, 2021 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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