89bio Announces Plans for Phase 2b (ENLIVEN) Trial in NASH

April 5, 2021

- Received written guidance from FDA related to trial design and agreement to use liquid formulation -
- ENLIVEN trial to initiate as planned in 2Q21 -

SAN FRANCISCO, April 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 announced it has received written guidance from the U.S. Food and Drug Administration (FDA) on the company's design of its planned Phase 2b ENLIVEN trial evaluating BIO89-100 for the treatment of patients with fibrosis stage 2 or 3 non-alcoholic steatohepatitis (NASH), including agreement on the use of a liquid formulation.

"We look forward to advancing our NASH program with the ENLIVEN trial following our promising Phase 1b/2a data," said Rohan Palekar, Chief Executive Officer of 89bio. "With its differentiated profile, uniquely engineered structure, and convenient dosing schedule, we believe BIO89-100 has the potential to be a best-in-class FGF21 analog for the treatment of NASH. We believe the liquid formulation will provide a more convenient administration method which we know is critical for compliance for patients living with chronic conditions like NASH."

ENLIVEN will be a multicenter, randomized, double-blind, placebo-controlled Phase 2b study designed to evaluate the safety and efficacy of BIO89-100 in biopsy-confirmed NASH patients with fibrosis stage 2 or 3. A total of approximately 200 patients will receive either one of two different weekly doses or an every two-week dose of BIO89-100 or placebo for 24 weeks followed by a blinded extension phase of an additional 24 weeks for a total treatment period of 48 weeks. The primary efficacy outcome measures at Week 24 will include the two key histology-based endpoints of NASH resolution without worsening of fibrosis and the improvement of fibrosis ≥ 1 stage without worsening of NASH. The ENLIVEN trial will utilize a liquid formulation of BIO89-100 instead of the frozen formulation used in the Phase 1b/2a 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.

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 and timing for BIO89-100, including the Phase 2b (ENLIVEN) trial, the expected trial design for the ENLIVEN trial, including patient enrollment, dosing schedules and trial 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 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, 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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