89bio Completed Target Enrollment in Histology Cohort to Evaluate BIO89-100 for the Treatment of NASH

August 2, 2021

- Study designed to build upon positive Phase 1b/2a data and provide an early opportunity to demonstrate BIO89-100's potential benefits on histology endpoints -

SAN FRANCISCO, Aug. 02, 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 that it has completed target enrollment of 20 patients in the paired-biopsy, open-label histology cohort in biopsy-confirmed fibrosis stage F2 – F3 NASH patients.

"This is an important clinical milestone and step forward in advancing BIO89-100 as a new treatment option for patients suffering from NASH," said Hank Mansbach, Chief Medical Officer of 89bio. "We believe assessing histology endpoints could reinforce the robust efficacy improvements we previously observed in our proof-of-concept study and will provide further validation of the FGF21 class. In addition, this cohort is intended to support both the clinical utility of BIO89-100 and our overall clinical development strategy in NASH. We look forward to sharing topline data by year-end 2021."

The paired-biopsy, open-label histology cohort is an expansion of the Phase 1b/2a trial of BIO89-100 in NASH. In this cohort, biopsy-confirmed NASH patients are treated for 20 weeks with 27 mg of BIO89-100 once weekly. The key efficacy endpoints include a 2-point or greater improvement in the NAFLD Activity Score (NAS), NASH resolution without worsening of fibrosis, and the improvement of fibrosis ≥ 1 stage without worsening of NASH.

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 potential efficacy of BIO89-100, clinical development plans for BIO89-100, and the anticipated timing for topline data. 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 of topline data; 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 31, 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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