89bio Announces Closing of Enrollment in its Phase 1b/2a NASH Trial and Reports New Preclinical Data Confirming BIO89-100's Mechanism of Action Via Potent FGF Receptor Agonism

April 13, 2020

- Closed enrollment in its Phase 1b/2a NASH trial with 98% of patients enrolled and delays initiation of its SHTG trial due to the COVID-19 pandemic; Reaffirms guidance for NASH trial topline data in 2H20 -

- BIO89-100 demonstrated low nanomolar potency against FGF receptors 1c, 2c and 3c similar to recombinant human FGF21 (rhFGF21) -

SAN FRANCISCO, April 13, 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 that it closed enrollment in its Phase 1b/2a trial for nonalcoholic steatohepatitis (NASH) with 98% of patients enrolled and has delayed initiation of its severe hypertriglyceridemia (SHTG) trial due to the ongoing COVID-19 pandemic. 89bio also reported new preclinical data confirming BIO89-100's mechanism of action via potent FGF receptor agonism.

"I am extremely proud that our team was able to close enrollment in our Phase 1b/2a NASH trial with 98% of patients enrolled, despite the challenging environment related to the ongoing COVID-19 pandemic. We are monitoring the situation and will adjust plans if needed to minimize any trial disruption due to COVID-19. We continue to expect topline data in the second half of 2020," said Rohan Palekar, Chief Executive Officer of 89bio. "In addition, we will delay initiation of our Phase 2 trial of BIO89-100 in SHTG until conditions improve to allow us to execute the trial safely and efficiently. In the interim, we plan to complete all preparatory work to enable enrollment as soon as conditions enable it. We plan to follow the guidelines put forth by the U.S. Centers for Disease Control and Prevention, as well as national, state and local governments and make the proactive decisions necessary to protect the health and safety of all of our stakeholders."

The Phase 1b/2a proof-of-concept trial in NASH is a multicenter, randomized, double-blind, placebo-controlled, multiple ascending dose-ranging trial in patients with NASH or patients with NAFLD and a high risk of NASH. In this trial, 81 patients were randomized to receive weekly or every other week subcutaneous dosing of BIO89-100 or placebo for 12 weeks. The trial is designed to assess the safety, tolerability and PK properties of BIO89-100 as well as absolute change from baseline in hepatic fat fraction measured by magnetic resonance imaging – proton density fat fraction (MRI-PDFF). MRI-PDFF will be assessed at week 7 and at end of the trial along with other key biomarkers that will be evaluated more frequently. 89bio is working closely with its contract research organization partners and clinical sites to mitigate any potential impact of the COVID-19 pandemic on the trial. Topline data is still expected in the second half of 2020 and the Company plans to initiate the Phase 2b trial in the first half of 2021.

89bio is delaying the initiation of its Phase 2 trial of BIO89-100 for the treatment of SHTG, which was planned for the first half of 2020. The Company plans to complete all activities to be operationally prepared to enroll the trial once the external environment is conducive to executing the trial safely and effectively.

The Company has adequate clinical supplies for the ongoing NASH trial and the planned SHTG trial.

New BIO89-100 Preclinical Data

"Our new preclinical data demonstrates that BIO89-100 has similar activity to rhFGF21 at FGF receptors 1c, 2c and 3c, suggesting that BIO89-100 could reproduce the beneficial metabolic benefits of the native hormone, which may translate into clinical benefits for patients with NASH and SHTG," said Dr. Hank Mansbach, Chief Medical Officer of 89bio.

Activation of the FGF receptors 1c, 2c and 3c, together with the co-receptor β-klotho, are critical to the signaling of FGF21 and are believed to be responsible for the beneficial metabolic effects observed. In an in vitro study of receptor agonism, BIO89-100 was shown to have activity at very low nanomolar concentrations in cells co-expressing β-klotho and each of FGF receptors 1c, 2c or 3c. The EC50 (concentration at which one half of the maximal FGF receptor agonist effect is observed) for BIO89-100 was similar across FGF receptors 1c, 2c and 3c and comparable or superior to that of rhFGF21 in this functional assay. An EC50 could not be calculated for rhFGF21 or BIO89-100 at FGF receptor R4.

Investors are encouraged to review the Company's updated Corporate Presentation slide deck that provides an overview of the Company's business and is available under the "Investors" tab of the Company's website at www.89bio.com, or by request to the Company.

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 being developed for the treatment of NASH. The company also intends to develop BIO89-100 for the treatment of SHTG. BIO89-100 is a specifically engineered glycoPEGylated analog of FGF21 that is currently in a proof of concept Phase 1b/2a clinical trial in patients with NASH or NAFLD and a high risk of NASH. 89bio is headquartered in San Francisco with operations in Herzliya, Israel. Visit 89bio.com for more information.

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 plans for its clinical programs and clinical trials, the association of preclinical data with potential clinical benefit and timing of anticipated milestones. 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 U.S. Securities and Exchange Commission (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 completion and outcome of 89bio's Phase 1b/2a proof of concept clinical trial evaluating BIO89-100 in patients with NASH or patients with NAFLD and a high risk of NASH; 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 other risks and uncertainties identified in 89bio's Annual Report on Form 10-K for the year ended December 31, 2019, filed March 18, 2020 with the SEC 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.

Investor Contact:
Ryan Martins
Chief Financial Officer
investors@89bio.com

Media Contact:
Lori Rosen
LDR Communications
917-553-6808
lori@ldrcommunications.com