# 89bio Announces Completion of Enrollment in ENLIVEN, the Phase 2b Trial of Pegozafermin for the Treatment of NASH

August 18, 2022

**219 total patients enrolled; topline data expected in the first quarter of 2023**

SAN FRANCISCO, Aug. 18, 2022 (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 enrollment in ENLIVEN, the Phase 2b trial of pegozafermin for the treatment of NASH.

“We are very pleased to have successfully completed enrollment of 219 total patients in ENLIVEN, a well-powered trial that builds on positive data demonstrating pegozafermin’s broad metabolic effects and favorable safety/tolerability profile,” said Hank Mansbach, Chief Medical Officer of 89bio. “The impressive pace of enrollment is a testament to both the high level of engagement by our clinical trial sites and our team’s strategic execution and brings us one step closer to addressing the need for new treatment options for patients suffering from NASH. We see this as a significant milestone in the pegozafermin clinical program and, building on this momentum, we expect to report topline data from ENLIVEN in the first quarter of 2023.”

ENLIVEN is a multicenter, randomized, double-blind, placebo-controlled Phase 2b trial in biopsy-confirmed NASH patients with fibrosis stage 2 or 3. The trial enrolled a total of 219 patients who will receive either one of two weekly doses (15mg or 30mg) or an every two-week dose (44mg) of pegozafermin in a liquid formulation or placebo for 24 weeks with a randomization schema of 4: 4: 2.5: 1 (placebo: 30mg QW: 44mg Q2W: 15mg QW). 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 pegozafermin in the extension phase. More information about the study is available at ClinicalTrials.gov (NCT Number: NCT04929483).

**About 89bio**
89bio is a clinical-stage biopharmaceutical company dedicated to the development of best-in-class therapies for patients with liver and cardio-metabolic diseases who lack optimal treatment options. The company is focused on rapidly advancing its lead candidate, pegozafermin, through clinical development for the treatment of non-alcoholic steatohepatitis (NASH) and severe hypertriglyceridemia (SHTG). Pegozafermin is a specifically engineered, potentially best-in-class fibroblast growth factor 21 (FGF21) analog with unique glycoPEGylated technology that optimizes biological activity through an extended half-life. The company is headquartered in San Francisco with operations in Herzliya, Israel. For more information, visit www.89bio.com or follow the company on LinkedIn.

**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 pegozafermin, the safety and tolerability profile of pegozafermin, clinical development plans and timing for pegozafermin, including the Phase 2b ENLIVEN trial, the expected trial design for the ENLIVEN trial, dosing schedules and trial endpoints, the timing for topline data for the ENLIVEN trial and expectations regarding the time period over which 89bio’s capital resources will be sufficient to fund its anticipated operations. Words such as “may,” “might,” “will,” “objective,” “intend,” “should,” “could,” “can,” “would,” “expect,” “believe,” “design,” “estimate,” “predict,” “potential,” “anticipate,” “goal,” “opportunity,” “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 the Phase 2b ENLIVEN trial in NASH; 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; 89bio’s substantial dependence on the success of it lead product candidate; competition from competing products; 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 Quarterly Report on Form 10-Q for the quarter ended June 30, 2022 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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