89bio Provides Business Update and Outlook for 2025

January 13, 2025

– Completed enrollment in Phase 3 ENTRUST trial in patients with severe hypertriglyceridemia (SHTG); topline 26-week data expected in the second half of 2025 –

– The Phase 3 ENLIGHTEN program in patients with non-cirrhotic (F2-F3) and compensated cirrhotic (F4) metabolic dysfunction-associated steatohepatitis (MASH) continues to enroll patients across both trials –

– Cash, cash equivalents, and marketable securities totaled approximately $440 million as of December 31, 2024 –

SAN FRANCISCO, Jan. 13, 2025 (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 cardiometabolic diseases, today provided a corporate update and business outlook for 2025.

“Looking ahead to 2025, we are well-positioned to build on the momentum from the initiation and ongoing enrollment of our ENLIGHTEN Phase 3 program in MASH and the successful completion of enrollment in our ENTRUST Phase 3 trial in SHTG and expect to announce topline data from the Company’s first Phase 3 trial in the second half of 2025,” said Rohan Palekar, CEO of 89bio. “We remain confident in pegozafermin’s potential as a potent anti-fibrotic agent with broad cardio-metabolic benefits. With a strengthened leadership team, commercial-scale manufacturing available, and a bolstered financial position, we continue to advance our Phase 3 programs toward potential Biologics License Application (BLA) and Marketing Authorization Application (MAA) filings, aiming to transform care for patients living with MASH and SHTG.”

Key 2024 Highlights

- **Completed enrollment in *ENTRUST***, the Phase 3 trial evaluating the efficacy, safety and tolerability of pegozafermin in patients with SHTG. 89bio expects to report topline 26-week data from this trial in the second half of 2025.
- **Initiated *ENLIGHTEN-Fibrosis* and *ENLIGHTEN-Cirrhosis***, the Phase 3 trials in non-cirrhotic (F2-F3) MASH patients with fibrosis and in compensated cirrhotic (F4) MASH patients, in March and May of 2024, respectively. Both MASH studies continue to enroll patients globally.
- **Obtained regulatory feedback from the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA)** on clinical as well as Chemistry, Manufacturing, and Controls (CMC) requirements for marketing authorization filings for pegozafermin. The Company remains on track for potential BLA and MAA filings, pending positive clinical data.
- **Bolstered its balance sheet** through the completed equity follow-on offering for $143.8 million in gross proceeds and an amended credit facility with K2 HealthVentures, providing an aggregate principal of up to $150.0 million. Cash, cash equivalents, and marketable securities totaled approximately $440 million as of December 31, 2024 (preliminary unaudited).
- **Strengthened its executive leadership team and Board of Directors** with four seasoned industry veterans. Appointments include Teresa Perney, Ph.D., Chief Regulatory and Quality Officer; Francis Sarena, Chief Operating Officer; Charles McWherter, Ph.D., Board of Directors; and Martin Babler, Board of Directors. These additions bring extensive operational, clinical, regulatory, and commercial expertise to 89bio.

About 89bio
89bio is a clinical-stage biopharmaceutical company dedicated to the development of best-in-class therapies for patients with liver and cardiometabolic diseases who lack optimal treatment options. The company is focused on rapidly advancing its lead candidate, pegozafermin, through Phase 3 clinical development for the treatment of metabolic dysfunction-associated steatohepatitis (MASH) 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. 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, statements regarding the therapeutic potential and utility, efficacy and clinical benefits of pegozafermin, the safety and tolerability profile of pegozafermin, trial designs, clinical development plans and timing for pegozafermin, including the topline results from the ENTRUST Phase 3 trial in SHTG and enrollment in clinical trials, including enrollment of the Phase 3 ENLIGHTEN-Fibrosis trial and Phase 3 ENLIGHTEN-Cirrhosis trial in MASH and 89bio’s potential BLA and MAA filings. 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 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 timing and outcome of the ENLIGHTEN-Fibrosis Phase 3 trial and Phase 3 ENLIGHTEN-Cirrhosis trial in MASH and ENTRUST Phase 3 trial in SHTG; 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; 89bio's substantial dependence on the success of it lead product candidate; competition from competing products; the impact of general economic, health, industrial or political conditions in the United States or internationally; the sufficiency of 89bio's capital resources and its ability to raise additional capital; and other risks and uncertainties identified in 89bio's Quarterly Report on Form 10-Q for the quarter ended September 30, 2024 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:
Annie Chang
89bio, Inc.
annie.chang@89bio.com

PJ Kelleher
LifeSci Advisors, LLC
+1-617-430-7579
pkelleher@lifesciadvisors.com

Media Contact:
Sheryl Seapy
Real Chemistry
sseapy@realchemistry.com