89bio Provides Business Update and Outlook for 2023

January 4, 2023

– Topline results from ENLIVEN Phase 2b NASH trial on track for first quarter of 2023 –

– Feedback from FDA supports advancement of Phase 3 program for pegozafermin in SHTG; plan to initiate first of two SHTG Phase 3 trials in the first half of 2023 –

– Secured $100 million credit facility with K2 HealthVentures; pro forma cash of $188.4 million as of December 31, 2022 –

SAN FRANCISCO, Jan. 04, 2023 (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 provided a corporate update, including its roadmap for advancing pegozafermin in 2023.

Key 2023 Milestones

- Topline data from ENLIVEN, the Phase 2b non-alcoholic steatohepatitis (NASH) trial, expected in the first quarter of 2023
- Initiation of the first Phase 3 severe hypertriglyceridemia (SHTG) trial expected in the first half of 2023

“In 2022, we delivered key data in both SHTG and NASH that has allowed us to enter 2023 poised to move pegozafermin forward into Phase 3 development,” said Rohan Palekar, Chief Executive Officer of 89bio. “We remain on track to deliver topline results from ENLIVEN later this quarter. Based on the results from our previous trials and recent data from other NASH product candidates, we remain confident that the trial outcome could support the transition into Phase 3. In SHTG we received feedback from the FDA supporting the advancement of pegozafermin into Phase 3. We have incorporated the agency’s feedback into our protocol and plan to initiate the first of two recommended Phase 3 trials in SHTG in the first half of this year. In parallel, we have developed plans to optimize the clinical development program across both indications that would leverage the safety database from the SHTG Phase 3 program to support the NASH program. We expect to finalize these plans after we have reviewed results from the ENLIVEN trial later this quarter.”

“In addition, we are very pleased to have secured a new $100 million credit facility from K2 HealthVentures,” continued Mr. Palekar. “This additional financing reflects confidence in our program and extends our cash runway by giving us additional resources to deliver on important milestones across our clinical development programs.”

Clinical Development Overview

Non-alcoholic Steatohepatitis (NASH)
ENLIVEN Phase 2b trial topline data expected in the first quarter of 2023

- ENLIVEN is a Phase 2b trial designed to evaluate the safety and efficacy of weekly (15mg and 30mg) or every two-week (44mg) pegozafermin for the treatment of patients with fibrosis stage F2 - F3 NASH and NAS ≥ 4 for 48 weeks. Enrollment in the trial was completed in August 2022.
- The primary analysis will evaluate the effect of pegozafermin on the two FDA approvable histology endpoints [1-point fibrosis improvement with no worsening of NASH and NASH resolution with no worsening of fibrosis] and will include patients who met histologic entry criteria [F2/F3 patients and NAS ≥4] based on the three-panel consensus read of biopsies at baseline to ensure consistency between baseline and end of treatment biopsy reading methods. This three-panel consensus read was instituted after receipt of data from the expansion cohort of the Phase 1b/2a trial (cohort 7) to address biopsy reading variability and increase the likelihood of showing the true benefit of pegozafermin while maintaining adequate study power. Prior to this change, biopsy entry criteria for ENLIVEN was based on a single reader.
- The company plans to hold a regulatory meeting in 2023 to discuss Phase 3 development assuming positive data from the ENLIVEN study.

Severe Hypertriglyceridemia (SHTG)
Initiation of the first Phase 3 trial planned in the first half of 2023 based on feedback from the FDA

- In 2022, 89bio reported topline results from the Phase 2 ENTRIGUE trial with statistically significant results on the primary endpoint [triglyceride reduction of 63% from baseline at 27 mg QW, $p<0.001$ vs. placebo] and on key secondary endpoints including reduction in liver fat.
- The FDA agreed that the pre-clinical and clinical data package support the advancement of pegozafermin into Phase 3 with the proposed primary endpoint of reduction in TG from baseline without the need for a clinical outcome study. The FDA also agreed to the proposed doses, proposed secondary endpoints and were generally aligned with other study

parameters. Since SHTG is a common, chronic condition and pegozafermin is a novel investigational biologic therapy, the agency recommended conducting two Phase 3 trials in SHTG, each of one year duration as part of the efficacy and safety database required to support the registration package. The primary endpoint in the planned Phase 3 trials is anticipated to be assessed at week 26.

- The company has developed plans to optimize clinical development across both SHTG and NASH and will finalize these plans after reviewing the ENLIVEN trial results. The company anticipates there will be efficiencies in leveraging the safety database across the two indications with a potential reduction in the costs of the NASH program.
- SHTG represents a large market with approximately 800,000 patients who are inadequately treated with existing therapies and thereby at increased risk for acute pancreatitis and atherosclerotic cardiovascular events. Physician and payor research also support a significant patient need for a drug like pegozafermin based on results from the ENTRIGUE trial. Pegozafermin has a highly differentiated profile relative to currently available therapies as well as new therapies in development.

Technical Operations

- 89bio has developed a new pre-filled syringe using its approved liquid formulation and has filed this pre-filled syringe presentation for approval with the agency. The company expects to receive FDA approval in 2023 and plans to utilize this presentation in its planned SHTG Phase 3 trial in the first half of 2023.

Financial Update

- 89bio reported pro forma cash of $188.4 million as of Dec. 31, 2022 which includes the $20 million drawn under the company’s term loan facility with Silicon Valley Bank. Today, the company entered into a loan and security agreement with K2 HealthVentures, a healthcare focused specialty finance company, which provides for an aggregate principal amount of up to $100 million of which $25 million was drawn at closing. 89bio may draw an additional $25 million in two separate tranches upon achievement of clinical and regulatory milestones. An additional $50 million may be drawn in a fourth tranche subject to the approval of K2 HealthVentures. This credit facility increases 89bio’s financial strength and provides the company with significant strategic and operational flexibility by securing access to an immediately available financing option to support the continued development of pegozafermin.

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 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. For more information, visit www.89bio.com or follow the company on LinkedIn.

About K2 HealthVentures
K2 HealthVentures is an alternative investment firm focused on providing flexible, long-term financing solutions to innovative private and public companies in the life sciences and healthcare industries. The investment team comprises collaborative, experienced professionals with diverse backgrounds in finance and operations, as well as deep domain knowledge across various healthcare sectors. A uniquely flexible, permanent capital structure enables the firm to provide creative, adaptive financing solutions and meet the evolving capital needs of its portfolio companies as they grow. K2HV is driven by dual goals of Profit and Purpose—aiming to fuel the growth of innovative companies that will ultimately improve the lives of patients and giving a percentage of investment profits back to underserved areas in healthcare. www.k2hv.com

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, the timing of clinical development plans, including the Phase 2b ENLIVEN trial, the timing for topline data for the ENLIVEN trial, the timing for the initiation of the first Phase 3 trial in SHTG, cost of the NASH program, potential market size for SHTG patients, and timing for FDA approval of the pre-filled syringe, financial strength and access to capital. 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; expectations regarding the initiation of the first 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; expectations regarding FDA approval and feedback; 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; 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, 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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