89bio Announces Preclinical Data That Demonstrate Potential Utility of BIO89-100 for Treatment of NASH

April 12, 2019

Data presented in Late-Breaking Presentation at the EASL International Liver Congress™

SAN FRANCISCO and HERZLIYA, Israel, April 11, 2019 /PRNewswire/ -- 89bio LTD, a clinical-stage biopharmaceutical company focused on nonalcoholic steatohepatitis (NASH) and other liver and metabolic disorders, today announced that preclinical data of its investigational drug BIO89-100 were featured in a late-breaking poster presentation at The International Liver Congress™ 2019, the Annual Meeting of the European Association for the Study of the Liver (EASL) in Vienna, Austria. BIO89-100 is a novel long-acting glycopegylated fibroblast growth factor 21 (FGF21) analogue in clinical development for the treatment of patients with NASH.

In this preclinical study in spontaneously diabetic obese cynomolgus monkeys, BIO89-100 demonstrated statistically significant pharmacodynamic effects on key metabolic and liver parameters associated with NASH following weekly and every 2-week subcutaneous dosing. In earlier preclinical studies, BIO89-100 was shown to improve liver-related and key metabolic parameters in 2 different mouse models of NASH as well as in a previous study in the same monkey model using a subcutaneous weekly dosing regimen.

"We are encouraged by these preclinical data that collectively demonstrate the potential of BIO89-100 to address the complex clinical condition of patients with NASH," said Hank Mansbach, M.D., chief medical officer, 89bio. "Furthermore, based on the effects seen in the every 2-week dosing groups, BIO89-100 may be well-suited for extended-interval dosing in patients."

All BIO89-100 treatment groups achieved statistically significant reductions in body weight, fasting plasma glucose, LDL cholesterol, triglycerides, and hemoglobin A1c compared to the vehicle group. Change in median alanine aminotransferase (ALT) levels from baseline to Day 28 was between -15.4% to - 42.7% in the BIO89-100 treated groups versus +8.9% in the vehicle group. The exposure profile of the weekly and every 2-week dosing regimens was similar, except for higher trough levels on Day 14 and Day 28 with the weekly dose.

Dr. Mansbach added, "In addition to the preclinical evaluation of BIO89-100, we've made important progress advancing the clinical development of BIO89-100, which is currently being evaluated in a single ascending dose study in healthy volunteers."

About NASH
NASH is the most advanced stage of nonalcoholic fatty liver disease (NAFLD). It is a complex metabolic disorder that causes fat buildup in the liver, as well as inflammation and eventually fibrosis, and it can worsen to cirrhosis and liver failure. NASH affects more than 16 million adults in the United States. The exact cause of NASH is unknown, but it is commonly found in people with obesity and type 2 diabetes. It is predicted that by 2020, NASH will surpass hepatitis C as the leading cause of liver transplant, and by 2030 its prevalence will increase by 63 percent. While there are currently no approved treatments, the biopharmaceutical industry is actively involved in addressing this unmet medical need.

About BIO89-100
BIO89-100 is a novel long-acting glycopegylated FGF21 analogue for the treatment of NASH. It was engineered using a proprietary glycopegylation technology to prolong the biological activity of native FGF21. In preclinical studies BIO89-100 demonstrated a long half-life, potentially enabling extended-interval dosing. BIO89-100 also showed significant improvements in liver fat, hepatic injury and fibrosis and metabolic biomarkers including triglycerides, cholesterol, body weight, and glycemic control parameters.

About 89bio
89bio is a privately held biopharmaceutical company building a pipeline of biologic and small molecule treatments for liver and metabolic disorders. The company's lead product candidate for the treatment of NASH is BIO89-100. Currently in Phase 1, BIO89-100 is a novel long-acting glycopegylated FGF21 analogue. 89bio is headquartered in San Francisco with R&D and operations in Herzliya, Israel. Visit 89bio.com for more information.

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

SOURCE 89bio