89bio Reports Positive Top-line Data from Phase 1 Single-Ascending Dose Clinical Trial of BIO89-100, an Investigational Medicine for NASH

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- BIO89-100 was generally safe and well tolerated at all dose levels -

- Robust and durable pharmacodynamic effects observed across key lipid parameters -

SAN FRANCISCO and HERZLIYA, Israel, May 22, 2019 /PRNewswire/ -- 89bio LTD, a clinical-stage biopharmaceutical company focused on nonalcoholic steatohepatitis (NASH) and other liver and metabolic disorders, today announced positive top-line results from a Phase 1 single ascending dose (SAD) study of its investigational medicine, BIO89-100, in healthy volunteers. BIO89-100 is a novel long-acting glycopegylated fibroblast growth factor 21 (FGF21) analogue in clinical development for the treatment of patients with NASH.

"BIO89-100 data from this first-in-human trial were consistent with results from preclinical studies," said Hank Mansbach, M.D., chief medical officer, 89bio. "In this study, BIO89-100 demonstrated a favorable safety and biomarker profile with a durable response after a single dose. We believe these findings support both weekly and every 2-week subcutaneous (SC) dosing. Even more encouraging are the robust pharmacodynamic effects demonstrated across multiple lipid parameters, given the subjects were healthy volunteers with most mean lipid parameters in the normal range at baseline."

BIO89-100 was generally safe and well tolerated in the Phase 1 study. The most commonly observed treatment-related adverse events were injection site reactions and headache, all of which were reported as mild. The pharmacokinetic (PK) profile of BIO89-100 was generally dose proportional with a half-life ranging from approximately 53-100 hours. Furthermore, at single doses of 9.1 mg and higher, BIO89-100 demonstrated significant improvements versus baseline in key lipid parameters measured at 8 and 15 days. The mean changes versus baseline include reductions in triglycerides (up to 51%) and LDL-C (up to 37%) and increase in HDL-C (up to 36%).

"These data support the advancement of BIO89-100 into a study in patients with liver disease to evaluate its potential to address the complex nature of NASH, especially in patients with metabolic comorbidities," said Rohan Palekar, CEO, 89bio.

This first-in-human trial was a randomized, double-blind, placebo-controlled, SAD study designed to evaluate the safety, tolerability, PK profile, and immunogenicity of BIO89-100. Seven cohorts with SC doses of BIO89-100 were tested against placebo in 58 healthy adult volunteers. Prespecified exploratory biomarkers were also measured during the study.

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 significant improvements in body weight, liver fat, hepatic injury and fibrosis and biomarkers including triglycerides, LDL and HDL cholesterol, and glycemic control parameters. In a Phase 1 clinical trial in healthy volunteers, BIO89-100 demonstrated a favorable safety and biomarker profile and predictable pharmacokinetic profile. BIO89-100 also demonstrated robust and durable improvements in key lipid parameters after a single dose which supports the potential for once a week or once every two-week dosing.

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.

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