89bio Announces Dosing of First Patients in NASH Study and Issuance of Composition of Matter Patent -

September 25, 2019

-New Patent Provides Coverage through 2038-

SAN FRANCISCO and HERZLIYA, Israel, Sept. 25, 2019 /PRNewswire/ -- 89bio, Inc. (89bio or the company), a clinical-stage biopharmaceutical company, has initiated dosing in its proof of concept Phase 1b/2a clinical trial evaluating its product candidate, BIO89-100, in patients with nonalcoholic steatohepatitis (NASH) or patients with nonalcoholic fatty liver disease (NAFLD) and a high risk of NASH. BIO89-100 is a glycoPEGylated analog of fibroblast growth factor 21 (FGF21) in clinical development for the treatment of NASH.

The company also announced that the United States Patent and Trademark Office has issued US Patent 10,407,479, entitled "Mutant FGF-21 Peptide Pegylated Conjugates and Uses Thereof." The patent expires in 2038 and covers the composition of BIO89-100 as well as methods for making and using BIO89-100 for a variety of therapeutic indications including NASH or metabolic syndrome. The new patent further strengthens the company's intellectual property (IP) position that also includes granted patents that cover glycoPEGylated FGF21 and other constructs in the United States and 38 additional countries.

"Today's announcement highlights the progress 89bio is making in developing novel medicines for patients with NASH and other liver and cardio-metabolic diseases. We believe BIO89-100 may be a differentiated FGF21 therapy based on its robust and durable biological effects and a favorable tolerability profile, as well its potential for a longer dosing interval," said Rohan Palekar, CEO, 89bio. "Our goal is to advance BIO89-100 rapidly through clinical development and continue to fortify the company's global IP position."

About the Phase 1b/2a Clinical Trial
The proof of concept clinical trial is designed to evaluate the safety, tolerability and pharmacokinetic properties of BIO89-100 as well as change in liver fat measured by magnetic resonance imaging proton density fat fraction (MRI-PDFF) and key biomarker assessments. The trial is a multicenter, randomized, double-blind, placebo-controlled, multiple ascending dose-ranging study in patients with NASH or patients with NAFLD and a high risk of NASH. 83 patients will be randomized to receive weekly or once every two weeks subcutaneous dosing of BIO89-100 or placebo for up to 12 weeks.

About BIO89-100
BIO89-100 is a glycoPEGylated analog of FGF21 being developed for the treatment of NASH. 89bio has specifically engineered BIO89-100 using a proprietary glycoPEGylation technology designed to prolong the biological activity of native FGF21. In preclinical studies, BIO89-100 demonstrated consistent beneficial effects across a range of endpoints, including hepatic steatosis, injury, and fibrosis. In 89bio's Phase 1a clinical trial in healthy volunteers, BIO89-100 demonstrated a favorable tolerability profile and dose-proportional pharmacokinetics. BIO89-100 also demonstrated statistically significant improvements in key lipid parameters for two weeks after a single dose, which combined with results from the company's animal studies supports the potential for weekly or once every two weeks dosing.

About 89bio
89bio is a clinical-stage biopharmaceutical company focused on the development and commercialization of innovative therapies for the treatment of liver and cardio-metabolic diseases. The company's lead product candidate is BIO89-100, which is being developed for the treatment of NASH. Currently in a proof of concept Phase 1b/2a clinical trial, BIO89-100 is a specifically engineered glycoPEGylated analog of FGF21. 89bio is headquartered in San Francisco with operations in Herzliya, Israel. Visit 89bio.com for more information.

Investor Contact:
Ryan Martins
Chief Financial Officer
510-390-3407
ryan.martins@89bio.com

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

SOURCE 89Bio