Metacrine Demonstrates Best-in-Class FXR Drug Program with Positive Clinical Results in NASH Patients

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- Randomized, placebo-controlled 12-week study showed mean liver fat reduction of up to 55% with MET409

- 93% of patients showed liver fat reduction of at least 30% from baseline

SAN DIEGO, Jan. 22, 2020 /PRNewswire/ -- Metacrine, Inc., a clinical-stage biotechnology company focused on building an innovative pipeline of best-in-class drugs to treat liver and gastrointestinal (GI) diseases, announced topline results from a 12-week, randomized, placebo-controlled study of MET409 in patients with non-alcoholic steatohepatitis (NASH). MET409 is a purposefully designed farnesoid X receptor (FXR) agonist with two key features: non-bile acid chemical scaffold and sustained FXR activation.

MET409 was dosed orally once daily at 50 mg and 80 mg alongside placebo to evaluate safety, pharmacokinetics, pharmacodynamics and efficacy in 58 patients with NASH. Treatment with MET409 resulted in statistically significant reductions in relative mean liver fat content relative to placebo: 55% for 80 mg, 38% for 50 mg, and 6% for placebo. Approximately 93% and 75% of patients, with 80mg and 50mg treatment, respectively, had 30% or greater liver fat reduction from baseline. Significant reduction in alanine aminotransferase was observed at 80 mg, and meaningful response rates in other liver tests relative to placebo were also observed in both dose cohorts.

"The initial clinical results with Metacrine's FXR program are impressive and unprecedented for the FXR class of drugs," said Stephen A. Harrison, MD, Medical Director of Pinnacle Clinical Research, founder of Summit Clinical Research and a Principal Investigator of the study. "Based on publicly presented data, MET409 shows at least double the efficacy of liver fat reduction at 12 weeks, as compared to other FXR agonists in development."

Overall, MET409 was safe and well tolerated with no treatment-related serious adverse events. Dose-dependent pruritus of moderate grade was seen in 5% and 10% in the 50 mg and 80 mg treated groups, respectively, which appears better than reported rates of moderate pruritus with other FXR drugs. Overall pruritus rates (10-35%) with MET409 were similar or better than that reported in clinical studies with other FXR drugs. Serum cholesterol changes with MET409 were consistent with on-target FXR activation.

"We are very encouraged with the statistically significant and dose-responsive efficacy seen with just 12 weeks of treatment with MET409," said Hubert C. Chen, MD, Chief Medical Officer of Metacrine. "Combined with a differentiated safety and tolerability profile, we believe our FXR program is well positioned to be a best-in-class monotherapy, as well as combination therapy for NASH patients."

Additional details from this 12-week NASH study with MET409 will be presented at an upcoming conference.

About NASH

NASH is a liver disease that exists along a continuum of progressive liver deterioration and is characterized by fatty deposits, inflammation and cellular damage. NASH is expected to be the #1 reason for liver transplant in 2020. There are currently no therapies approved for NASH.

About Metacrine

Metacrine is a clinical-stage biopharmaceutical company focused on building an innovative pipeline of best-in-class drugs to treat liver and gastrointestinal (GI) diseases. The most advanced program is focused on the farnesoid X receptor (FXR) an important drug target in multiple liver and GI diseases. Beyond the FXR program, a pipeline of novel drug candidates against other drug targets is being explored by taking advantage of internal drug discovery and development capabilities. Privately held Metacrine is headquartered in San Diego, California. For additional information, please visit www.metacrine.com.

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