Metacrine Doses First Patient in 12-Week NASH Proof-of-Concept Trial with a Sustained FXR Agonist

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Placebo-controlled, multi-center trial will evaluate safety, tolerability and efficacy biomarkers to assess potential best-in-class FXR agonist

SAN DIEGO, July 09, 2019 (GLOBE NEWSWIRE) -- 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, today announced that the first patient has been dosed in its 12-week, Phase 1b trial of MET409, a potent, sustained, non-bile acid farnesoid x-receptor (FXR) agonist small molecule, in patients with non-alcoholic steatohepatitis (NASH).

“The 12-week portion of our NASH proof-of-concept study is designed to evaluate the safety and benefits of sustained FXR activation – a best-in-class thesis we proposed two years ago in differentiating Metacrine’s FXR program from others,” said Hubert C. Chen, MD, Chief Medical Officer of Metacrine. “We will also gain insight into how sustained FXR activation can impact liver health.”

The company recently completed the 4-week portion of the Phase 1b clinical trial, which evaluated 50mg of MET409 in 10 NASH patients. Topline results of that study showed MET409 was well tolerated with no reports of pruritis, no adverse changes in LDL cholesterol, and favorable trends in liver fat reduction and overall liver function.

The 12-week portion of the Phase 1b clinical trial is designed to evaluate the safety, tolerability and change in liver fat content with 80mg of MET409. The study is a multi-center, placebo-controlled trial led by Stephen A. Harrison, MD, Medical Director of Pinnacle Clinical Research, founder of Summit Clinical Research and the principal coordinating investigator of the study. Key additional analysis will include evaluating the effects of treatment with MET409 on liver function and overall liver health, changes in serum cholesterol levels, and the drug’s ability to remain biologically active throughout a 24-hour period.

NASH is a liver disease caused by excessive fat accumulation in the liver that induces chronic inflammation and ballooning, resulting in progressive fibrosis that can lead to cirrhosis and eventual liver failure requiring liver transplant. There are currently no medications approved for the treatment of NASH. The proportion of liver transplants attributable to NASH has increased significantly in past years and is projected to be the leading cause of liver transplant by the end of 2020.

Metacrine has developed an extensive portfolio of oral FXR agonists that are taken once a day and have sustained activation of the target over 24 hours. MET409 is a representative non-bile acid sustained FXR agonist. The company is developing a new and improved FXR agonist from its library of over 2,500 compounds and plans to initiate human clinical studies in early 2020.

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. Metacrine has purposefully designed a series of compounds to be optimized, next-generation FXR agonists. 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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