Metacrine Initiates Phase 2a Trial of MET642 for the Treatment of Patients with NASH

March 9, 2021

On-track for Interim Analysis Readout in the Fourth Quarter of 2021

SAN DIEGO, March 09, 2021 (GLOBE NEWSWIRE) -- Metacrine, Inc. (Nasdaq: MTCR), a clinical-stage biopharmaceutical company focused on discovering and developing differentiated therapies for patients with liver and gastrointestinal diseases, today announced that the first patient has been treated in its Phase 2a trial of MET642, a potent, sustained, non-bile acid farnesoid x-receptor (FXR) agonist, for the treatment of patients with non-alcoholic steatohepatitis (NASH).

“NASH is a devastating disease, for which an optimized FXR agonist could play a foundational role in the treatment paradigm,” said Hubert C. Chen, M.D., chief medical officer of Metacrine. “MET642 has demonstrated an encouraging profile - including sustained pharmacodynamic effects without pruritus or low-density lipoprotein cholesterol increase - after 14 days of daily oral dosing in our Phase 1 study in healthy volunteers. We are pleased to start this important proof-of-concept study in patients with NASH and look forward to sharing interim results in the fourth quarter of 2021.”

Metacrine has developed a proprietary FXR platform utilizing a unique chemical scaffold, which has demonstrated a clinically differentiated and improved therapeutic profile. The company’s lead FXR clinical candidate, MET409, has successfully completed a 12-week trial in patients with NASH. MET642 is derived from the same chemical scaffold as MET409, with comparable FXR target engagement and pharmacology in preclinical studies, while demonstrating increased potency and differentiated pharmaceutical properties relative to MET409.

The Phase 2a clinical trial is a 16-week, randomized, placebo-controlled, multi-center trial evaluating the safety, tolerability and pharmacological activity (as measured by liver fat reduction) of MET642 (3 mg and 6 mg) vs placebo. An interim analysis is planned in the fourth quarter of 2021, after approximately 60 patients have completed 16 weeks of treatment. Topline trial results of up to 180 patients are expected to be reported in the first half of 2022.

About Metacrine
Metacrine, Inc. (Nasdaq: MTCR) is a clinical-stage biopharmaceutical company building a differentiated pipeline of therapies to treat liver and gastrointestinal (GI) diseases. Metacrine has developed a proprietary farnesoid X receptor (FXR) platform utilizing a unique chemical scaffold, which has demonstrated a differentiated and improved therapeutic profile in clinical trials. The company’s two product candidates, MET409 and MET642, are currently being investigated in clinical trials as potential new treatments for non-alcoholic steatohepatitis (NASH). MET409 has completed a 12-week monotherapy trial in patients with NASH and is being evaluated in a 12-week combination trial with empagliflozin in patients with both NASH and type 2 diabetes. MET642 has completed a 14-day Phase 1 trial in healthy volunteers and is being evaluated in a 16-week monotherapy trial in patients with NASH.

Forward-Looking Statements
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Statements in this press release that are not purely historical are forward-looking statements. Forward-looking statements contained in this press release include statements regarding the therapeutic potential of MET642; the differentiated nature of Metacrine’s FXR program; plans underlying Metacrine’s clinical trials; anticipated study timelines; plans for advancing the clinical development of Metacrine’s FXR program; and the potential for its FXR product candidates to be long-term therapies for NASH. Many factors may cause differences between current expectations and actual results, including unexpected safety or efficacy data observed during preclinical or clinical studies and uncertainties related to the regulatory approval path for the NASH indication. Words such as “may,” “could,” “will,” “encourage,” “expect,” “plan,” “aim,” “anticipate,” “estimate,” “intend,” “potential,” “prepare” and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. These forward-looking statements are based on Metacrine’s expectations and assumptions that may never materialize or prove to be incorrect. Each of these forward-looking statements involves risks and uncertainties. Actual results may differ materially from those projected in any forward-looking statements due to numerous risks and uncertainties, including but not limited to: risks and uncertainties regarding regulatory approvals for MET409 or MET642; potential delays in initiating, enrolling or completing any clinical trials; potential adverse side effects or other safety risks associated with Metacrine’s product candidates; competition from third parties that are developing products for similar uses; and Metacrine’s ability to obtain, maintain and protect its intellectual property. Information regarding the foregoing and additional risks may be found in the section entitled “Risk Factors” in Metacrine’s Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (the “SEC”) on November 12, 2020, and in Metacrine’s other filings with the SEC. All forward-looking statements contained in this press release speak only as of the date on which they were made. Except as required by law, Metacrine assumes no obligation to update any forward-looking statements contained herein to reflect any change in expectations, even as new information becomes available.

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