Metacrine Announces Publication of MET409 NASH Proof-of-Concept Study Results in the Journal of Hepatology

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Publication highlights the first clinical evidence that the risk-benefit profile of FXR agonists can be enhanced through structural optimization

SAN DIEGO, Feb. 16, 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 Journal of Hepatology has published the results from the company's 12-week, randomized, placebo-controlled Phase 1b study of MET409, the company's lead farnesoid X receptor (FXR) agonist, in patients with non-alcoholic steatohepatitis (NASH).

"The publication of our Phase 1b study data in this highly regarded, peer-reviewed journal further underscores the promise of an optimized FXR to treat patients with NASH, a potentially life-threatening liver disease with no approved treatments," said Hubert C. Chen, M.D., chief medical officer of Metacrine. "MET409 has demonstrated improvements in the efficacy and tolerability profile for the FXR class. These findings highlight its potential as both a front-line monotherapy and backbone of combination therapies, including with anti-diabetic medications in patients with both NASH and type 2 diabetes, who represent a patient segment with significant unmet needs. We are excited about the broad potential for MET409."

Metacrine has developed a proprietary FXR platform utilizing a unique chemical scaffold, which has demonstrated a differentiated and improved therapeutic profile in the clinic. MET409 is a once-daily, orally administered FXR agonist that is being evaluated as both a monotherapy and a combination therapy for the treatment of NASH. In the 12-week Phase 1b trial in patients with NASH, MET409 (50 mg) achieved approximately 38% mean relative liver fat reduction and was associated with a 16% overall pruritus rate, with no discontinuations due to pruritus, and a 7% LDL-cholesterol increase, findings that are favorable and perceived as class-leading for FXR agonists.

About the Publication
The Journal of Hepatology article, entitled "A structurally optimized FXR agonist, MET409, reduced liver fat content over 12 weeks in patients with non-alcoholic steatohepatitis", was published online on February 11, 2021. Authors include Stephen A. Harrison, M.D., University of Oxford and Pinnacle Clinical Research; Mustafa R. Bashir, M.D., Duke University Medical Center; and Eric J. Lawitz, M.D., University of Texas Health San Antonio and Texas Liver Institute.

About Non-alcoholic Steatohepatitis (NASH)
Non-alcoholic steatohepatitis, or NASH, is a liver disease characterized by excess liver fat, inflammation and fibrosis. In 2015, there were an estimated 17 million people in the United States with NASH, which is expected to increase to an estimated 27 million people by 2030. Left untreated, patients' disease may progress to liver failure, which is life-threatening without a successful liver transplant. NASH is expected to become the leading cause for liver transplants in the United States. Additionally, patients with NASH often present with metabolic disease and other co-morbidities, which is likely to require combination therapy. Currently, there are no approved therapies for NASH.

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 advanced into 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 MET409; statements regarding Metacrine's timelines; the differentiated nature of Metacrine's FXR program; plans underlying Metacrine's clinical trials; plans for advancing the clinical development of Metacrine's FXR program; the potential for its FXR product candidates to be long-term therapies for NASH; the potential for its FXR product candidates to be used in combination therapies with anti-diabetic medications; and the potential for its FXR product candidates to be therapies for patients with both NASH and type 2 diabetes. 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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