Metacrine Announces FDA Fast Track Designation for MET642 as a Treatment of NASH

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SAN DIEGO, Jan. 19, 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 U.S. Food & Drug Administration (FDA) has granted Fast Track designation to MET642, the company's second farnesoid X receptor (FXR) agonist, for the treatment of non-alcoholic steatohepatitis (NASH).

"We are pleased to have received a second fast track designation for product candidates from our proprietary FXR platform and believe this further demonstrates the recognition of significant unmet needs in patients with NASH by regulatory authorities," said Hubert C. Chen, M.D., chief medical officer of Metacrine. "Given our recently reported, favorable Phase 1 data for MET642, we are excited about its potential and look forward to advancing it into the Phase 2a study in the first half of this year."

Fast Track is a process designed to facilitate the development and expedite the review of drugs designed to treat serious diseases or conditions that have the potential to fill an unmet medical need for such diseases or conditions. Through the Fast Track designation, the company may be eligible to submit sections of its New Drug Application on a rolling basis, and there are opportunities for more frequent interactions and written communications with the FDA around the drug's development plan. A Fast Track-designated product may also be eligible for accelerated approval and priority review if the criteria for those programs are satisfied.

Metacrine recently completed a Phase 1 clinical trial of MET642 in healthy volunteers, in which MET642 was safe and generally well-tolerated and demonstrated a sustained pharmacokinetic profile and robust FXR target engagement after 14 days of daily oral dosing. Importantly, pruritus and LDL-cholesterol increases were not seen at any dose level. The company plans to further evaluate MET642 in a Phase 2a, 16-week, randomized, placebo-controlled trial in patients with NASH, which is expected to begin in the first half of 2021.

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 MET642; 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 MET642; 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," "look forward," "will," "expect," "plan," "estimate," "intend," "potential," 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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