Metacrine Achieves Full Enrollment for MET409 Phase 2a Combination Trial in Patients With Type 2 Diabetes and NASH

June 2, 2021

- *Topline data expected to be reported in the fourth quarter of 2021*

SAN DIEGO, June 02, 2021 (GLOBE NEWSWIRE) -- Metacrine, Inc. (NASDAQ:MTCR), a clinical-stage biopharmaceutical company pioneering differentiated therapies for patients with liver and gastrointestinal diseases, today announced that it has completed enrollment for its Phase 2a trial evaluating MET409 in combination with empagliflozin (Jardiance®), a sodium-glucose cotransport-2 (SGLT2) inhibitor, in patients with type 2 diabetes and non-alcoholic steatohepatitis (NASH). The Company plans to report topline data in the fourth quarter of 2021.

“NASH is closely linked to several co-morbidities including type 2 diabetes and treating patients holistically will likely require combination therapies,” said Hubert C. Chen, M.D., chief medical officer, Metacrine. “We are encouraged by the enthusiasm of investigators, and most importantly patients, in recognizing the potential benefits of our differentiated combinatorial approach. We’re also grateful for the efforts of our clinical operations team in achieving this key milestone.”

SGLT-2 inhibitors, in addition to affording glycemic control, cardiovascular benefits and renal protection, have demonstrated positive effects on liver fat reduction. A daily oral combination treatment with an FXR agonist and SGLT-2 inhibitor could benefit patients with NASH and type 2 diabetes, a population that may be at greater risk for liver disease progression.

The Phase 2a study (NCT04702490) is a 12-week, randomized, placebo-controlled, multi-center trial that enrolled over 120 patients to evaluate the safety, tolerability and pharmacological activity, as measured by reductions in liver fat content with magnetic resonance imaging-derived proton density fat fraction (MRI-PDFF), of MET409 (50 mg) and empagliflozin (10 mg) vs individual monotherapy components and placebo.

About Metacrine

Metacrine, Inc. is a clinical-stage biopharmaceutical company building a pipeline of differentiated therapies to treat liver and gastrointestinal diseases. Metacrine has developed a proprietary farnesoid X receptor (FXR) platform utilizing a unique chemical scaffold, which has demonstrated an 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 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. To learn more, visit www.metacrine.com.

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. Such forward-looking statements include, among other things, statements about the design, progress, timing, scope and results of clinical trials; the anticipated timing of disclosure of results of clinical trials; statements regarding the therapeutic potential of MET409; 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; and the potential for its FXR product candidates to be therapies for patients with both NASH and type 2 diabetes. Words such as “may,” “will,” “expect,” “plan,” “aim,” “projected,” “likely,” “anticipate,” “estimate,” “intend,” “potential,” “prepare,” “perceived,” “believes” 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 Annual Report on Form 10-K filed with the Securities and Exchange Commission (the “SEC”) on March 18, 2021, 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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