



Metacrine Accelerates MET409 Clinical Development Milestone and Reports First-Quarter 2021 Results

May 13, 2021

- *Topline results from a Phase 2a trial of MET409 in combination with empagliflozin in patients with NASH and type 2 diabetes now expected in the fourth quarter of 2021*
- *Interim data from the Phase 2a trial of MET642 in NASH patients on track to be reported in the fourth quarter of 2021*

SAN DIEGO, May 13, 2021 (GLOBE NEWSWIRE) -- Metacrine, Inc. (NASDAQ:MTCR), a clinical-stage biopharmaceutical company pioneering differentiated therapies for patients with liver and gastrointestinal diseases, today updated a key clinical development milestone and reported its first-quarter 2021 financial results.

"As I look ahead to the second half of 2021, we are nearing significant clinical development milestones for both our MET409 and MET642 programs," said Preston Klassen, M.D., MHS, CEO, Metacrine. "Importantly, we moved up our MET409 combination trial readout to the fourth quarter of 2021, and affirmed that we are on track to share data from an interim analysis of the MET642 trial in non-alcoholic steatohepatitis (NASH) patients during the same period. I am proud of our team for rapidly progressing patient enrollment for both of these studies, bringing us closer to advancing our program into late-stage development in both NASH and our planned expansion into IBD in 2022."

Klassen continued, "Our potentially best-in-class FXR agonist platform supports our vision of bringing new therapies to patients that desperately need treatment options. We believe that the wider therapeutic index demonstrated by our NASH program will address the risk/benefit profile necessary to treat patients with the promise of expanded treatment options, including combination with other agents. We are well-capitalized to achieve our next set of objectives and remain focused on advancing and expanding our pipeline in the months ahead."

Key Clinical Development Milestones & Outlook

- **MET409 Phase 2a combination trial results now expected in the fourth quarter of 2021** - Metacrine now expects to report topline data from its Phase 2a trial evaluating MET409 (50mg) in combination with empagliflozin (Jardiance[®]), a sodium-glucose cotransport-2 (SGLT2) inhibitor in patients with both type 2 diabetes and NASH, in the fourth quarter of 2021 (previously first half of 2022). SGLT-2 inhibitors, in addition to affording glycemic control and cardiovascular/renal benefits, 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, who are believed to be at greater risk for liver disease progression. The MET409 Phase 2a clinical trial is a 12-week, randomized, placebo-controlled, multi-center trial evaluating 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). The trial will enroll up to 120 patients in the United States.
- **MET642 Phase 2a monotherapy trial interim analysis on-track for the fourth quarter of 2021** - The Company plans to report topline data of an interim analysis from its Phase 2a, 16-week, randomized, placebo-controlled, multi-centered trial evaluating MET642 in patients with NASH 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 anticipated in the first half of 2022. The MET642 Phase 2a clinical trial is evaluating the safety, tolerability and pharmacological activity, as measured by MRI-PDFF, at 3 mg and 6 mg dose levels.

Recent Business Highlights

- In April 2021, Metacrine appointed Julia C. Owens, Ph.D. to the Company's board of directors. Dr. Owens currently serves as the executive chairperson for Millendo Therapeutics, Inc., a company that she co-founded in 2012. For nine years, she served as the president and chief executive officer of Millendo, establishing its strategy, building its endocrine disease pipeline and attracting a world class team. Under her leadership, the company raised \$195 million from both the private and public markets, and advanced four distinct product candidates into clinical studies in six different indications, including four Phase 2 programs and a pivotal study. Prior to co-founding Millendo, she served as senior vice president, corporate development and strategy at Lycera Corp. Dr. Owens also held business development roles at QuatRx Pharmaceuticals, which was acquired by Shionogi following the approval of Osphena[®], and at Tularik Inc. (acquired by Amgen). She is on the board of the Biotechnology Innovation Organization (BIO), the Leadership Council of the University of Michigan Life Sciences Institute, and the Investment Advisory Board of the Michigan Biomedical Venture Fund. Dr. Owens holds a Ph.D. in biochemistry from the University of California, San Francisco and a B.S. in chemistry and B.A. in molecular and cellular biology from the University of California, Berkeley.

First-Quarter 2021 Financial Results

- **Cash Balance** - Cash, cash equivalents and short-term investments were \$84.5 million as of March 31, 2021.
- **R&D Expenses** - Research and development expenses were \$10.9 million for the three months ended March 31, 2021, as compared to \$6.4 million for the prior-year period. The increase was primarily driven by higher clinical development costs related to the advancement of the Company's MET409 and MET642 programs.
- **G&A Expenses** - General and administrative expenses were \$3.7 million for the three months ended March 31, 2021, as compared to \$1.6 million for the same period in the prior year. The increase was attributable to higher employee-related costs and expenses associated with operating as a publicly traded company.
- **Net Loss** - Net loss was \$14.8 million for the three months ended March 31, 2021, as compared to \$8.1 million for prior-year quarter.

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; plans for initiating future clinical trials and studies; statements regarding the therapeutic potential of MET409 and MET642; 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 best-in-class nature of Metacrine's FXR program; and the potential for its FXR product candidates to be long-term therapies for NASH. 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.

Metacrine, Inc.
Unaudited Condensed Consolidated Statements of Operations
(in thousands)

	Three Months Ended March 31,	
	2021	2020
Operating expenses:		
Research and development	\$10,857	\$6,361
General and administrative	3,696	1,601
Total operating expenses	14,553	7,962
Loss from operations	(14,553)	(7,962)
Total other income (expense)	(215)	(150)
Net loss	\$(14,768)	\$(8,112)

Metacrine, Inc.
Unaudited Condensed Consolidated Balance Sheets
(in thousands)

	March 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash, cash equivalents, and short-term investments	\$84,457	\$96,176
Prepaid expenses and other current assets	6,257	5,847

Total current assets	90,714	102,023
Property and equipment, net	555	634
Operating lease right-of-use asset	1,415	1,579
Total assets	\$92,684	\$104,236
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$325	\$334
Accrued and other current liabilities	4,911	3,692
Total current liabilities	5,236	4,026
Long-term debt, net of debt discount	9,434	9,372
Other long-term liabilities	1,354	1,559
Stockholders' equity	76,660	89,279
Total liabilities and stockholders' equity	\$92,684	\$104,236

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Source: Metacrine, Inc.