Metacrine Provides Business Update and Reports Fourth Quarter and Full Year 2020 Financial Results

March 18, 2021

Interim Data from the Phase 2a Trial of MET642 in NASH Patients On-Track to be Reported in the Fourth Quarter of 2021

Topline Results from a Phase 2a Trial of MET409 in Combination with Empagliflozin in Patients with NASH and Type 2 Diabetes Expected in the First Half of 2022

Industry Veteran, Jeff Jonker, Appointed to Board of Directors

Conference Call to be Held Today at 8:30 a.m. ET

SAN DIEGO, March 18, 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 reported recent business highlights and fourth quarter and full year 2020 financial results.

“We have made significant progress with our potential best-in-class FXR agonist program, and given the strength of our scientific capabilities, remain diligently focused on both the advancement and expansion of our pipeline,” said Preston Klassen, M.D., MHS, president and chief executive officer of Metacrine. “Importantly, by the end of this year, we expect to have data from the MET642 trial in NASH patients, and select the optimal candidate to advance into late-stage development for this significant indication, with no approved treatment today. We also expect to have progressed our Phase 2a trial evaluating MET409 in combination with empagliflozin in patients with both type 2 diabetes mellitus and NASH and begun preparation for our planned expansion into IBD. 2021 is set to be a year of meaningful clinical progression with milestones that bring us closer to achieving our vision of transforming human health for patients with liver and GI diseases.”

MET409 Program Highlights

- **MET409 NASH Proof-of-Concept Trial Results Published in the Journal of Hepatology:** In February 2021, results from a 12-week, randomized, placebo-controlled Phase 1b trial of MET409, one of two novel farnesoid X receptor (FXR) agonists developed by Metacrine, in patients with non-alcoholic steatohepatitis (NASH) were published in the Journal of Hepatology. In the trial, MET409, at 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.

- **MET409 Phase 2a Combination Trial with Empagliflozin in Patients with Type 2 Diabetes and NASH Initiated:** In January 2021, the first patient was treated in Metacrine’s Phase 2a trial evaluating MET409 (50 mg) in combination with empagliflozin (Jardiance®), a sodium-glucose cotransport-2 (SGLT2) inhibitor, in patients with both type 2 diabetes mellitus and NASH. The 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. Metacrine expects to report topline data in the first half of 2022.

MET642 Program Highlights

- **MET642 Phase 1 Data Presented at the 2021 NASH-TAG Conference:** A poster highlighting the final results from Metacrine’s Phase 1 trial of MET642, the company’s second FXR agonist, in healthy volunteers was presented at the 2021 NASH-TAG Conference. These data build upon the preliminary Phase 1 results reported in December 2020, which showed that treatment with MET642 was generally well-tolerated, with no incidence of pruritus or increases in LDL-cholesterol at all doses evaluated. MET642 also demonstrated a sustained pharmacokinetic profile and robust FXR target engagement after 14 days of daily oral dosing in healthy volunteers.

- **Initiated a Phase 2a Monotherapy Trial of MET642 in Patients with NASH:** In March 2021, the first patient was treated in Metacrine’s Phase 2a trial evaluating MET642 in patients with NASH. 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 MRI-PDFF, at 3 mg and 6 mg dose levels. The two doses are projected to suppress 7α-hydroxy-4-cholesten-3-one (C4), a blood biomarker of bile acid synthesis that decreases with FXR activation, to levels that are likely to result in meaningful reductions in liver fat content. The trial will enroll up to 180 patients in the United States. An interim analysis is planned in the fourth quarter of 2021, after approximately 60 patients have completed 16 weeks of treatment, with topline trial results of up to 180 patients expected to be reported in the first half of 2022.

- **MET642 Granted Fast Track Designation as a Treatment for NASH:** In January 2021, the U.S. Food & Drug

Administration (FDA) granted Fast Track designation to MET642 for the treatment of NASH. 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.

Business Highlights

- **Industry Veteran, Jeff Jonker, Appointed to Board of Directors:** In March 2021, Metacrine appointed Jeff Jonker to its board of directors. Mr. Jonker currently serves as a senior advisor for Ambys Medicines, where he was previously the president and chief executive officer and a director. During his tenure at Ambys Medicines, Mr. Jonker leveraged the company's $140 million Series A financing and strategic partnership with Takeda to establish a pioneering cell therapy platform, including the build out of a cGMP cell therapy manufacturing facility to enable clinical and commercial supply of human hepatocytes. Prior to Ambys Medicines, Mr. Jonker served as president of NGM Biopharmaceuticals, where he led the advancement of the company's robust pipeline, including therapeutics for immune-oncology, retinal, liver and metabolic diseases. Mr. Jonker holds a J.D. from Columbia University School of Law, an M.LITT. from the University of St. Andrews and a B.A. from Claremont McKenna College.

Upcoming Milestones

- Metacrine expects to report topline data of an interim analysis from its Phase 2a, 16-week, randomized, placebo-controlled trial evaluating MET642 in patients with NASH in the fourth quarter of 2021 after approximately 60 patients have completed 16 weeks of treatment, with topline trial results of up to 180 patients expected to be reported in the first half of 2022.
- Metacrine expects to report topline data from its Phase 2a trial evaluating MET409 in combination with empagliflozin in patients with both type 2 diabetes mellitus and NASH in the first half of 2022.

Fourth Quarter and Full Year 2020 Financial Results

- **Capital Position:** Cash, cash equivalents and short-term investments were $96.2 million as of December 31, 2020. The company believes that its cash, cash equivalents and short-term investments as of December 31, 2020 will be sufficient to fund its current operating plan through 2022.
- **R&D Expenses:** Research and development expenses were $6.8 million for the fourth quarter of 2020 and $26.8 million for the full year ended December 31, 2020, compared to $6.5 million for the fourth quarter of 2019 and $26.0 million for the full year ended December 31, 2019. The increase in research and development expenses was primarily attributable to the continued investment in the clinical development and manufacturing activities associated with the advancement of MET409 and MET642.
- **G&A Expenses:** General and administrative expenses were $3.8 million for the fourth quarter of 2020 and $9.9 million for the full year ended December 31, 2020, compared to $1.0 million for the fourth quarter of 2019 and $4.0 million for the full year ended December 31, 2019. The increase in general and administrative expenses was primarily attributable to increased headcount, non-cash stock-based compensation and costs associated with operating as a publicly traded company upon completion of the company's initial public offering in September 2020.
- **Net Loss:** Net loss was $10.8 million for the fourth quarter of 2020 and $37.3 million for the full year ended December 31, 2020, compared to $7.4 million for the fourth quarter of 2019 and $28.9 million for the full year ended December 31, 2019.

Conference Call Information

Metacrine will host a conference call today, March 18, at 8:30 a.m. ET. To participate in the conference call, please dial (833) 614-1526 (domestic) or (520) 809-9922 (international) and refer to conference ID 4995715. A webcast will be available in the investor section of the company's website at www.metacrine.com and will be archived for 60 days following the call.

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. The company's most advanced programs, MET409 and MET642, target the farnesoid X receptor (FXR), which is central to modulating liver and GI diseases. Both MET409 and MET642 are currently being investigated in clinical trials as potential new treatments for non-alcoholic steatohepatitis (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. Such forward-looking statements include, among other things, statements regarding the therapeutic potential of MET409 and 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 Metacrine's FXR program; the potential best-in-class nature of Metacrine's FXR program; the potential for its FXR product candidates to be long-term therapies for NASH; plans for expansion of Metacrine's FXR program into IBD; and the potential benefits of MET642's Fast Track designation. Words such as "may," "will," "expect," "plan," "aim," "anticipate," "estimate," "intend," "potential," "prepare", "perceived" 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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Metacrine, Inc.
Unaudited Condensed Consolidated Statements of Operations
(in thousands)

	Three Months Ended December 31,		Years Ended December 31,	
	2020	**2019**	**2020**	**2019**
Operating expenses:				
Research and development	$ 6,817	$ 6,476	$ 26,790	$ 25,973
General and administrative	3,813	974	9,900	4,031
Total operating expenses	10,630	7,450	36,690	30,004
Loss from operations	(10,630)	(7,450)	(36,690)	(30,004)
Total other income (expense)	(186)	53	(614)	1,071
Net loss	$ (10,816)	$ (7,397)	$ (37,304)	$ (28,933)

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

	December 31,	
	2020	**2019**
Assets		
Current assets:		
Cash, cash equivalents, and short-term investments	$ 96,176	$ 55,651
Prepaid expenses and other current assets	5,847	1,692
Total current assets	102,023	57,343
Property and equipment, net	634	735
Operating lease right-of-use asset	1,579	2,203
Total assets	$ 104,236	$ 60,281
Liabilities, Convertible Preferred Stock, and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 334	$ 239
Accrued and other current liabilities	3,692	4,149
Total current liabilities	4,026	4,388
Long-term debt, net of debt discount	9,372	9,099
Other long-term liabilities	1,559	2,566
Convertible preferred stock	-	122,465
Stockholders' equity (deficit)	89,279	(78,237)
Total liabilities, convertible preferred stock, and stockholders' equity (deficit)	$ 104,236	$ 60,281