Madrigal Pharmaceuticals Reports 2017 First Quarter Financial Results

May 11, 2017

- Phase 2 clinical studies of MGL-3196, a liver-directed thyroid hormone receptor (THR) beta selective agonist, are underway in patients with non-alcoholic steatohepatitis (NASH) and familial hypercholesterolemia (HeFH)

- Top-line results from these two trials, expected by year-end, have the potential to support the design and initiation of Phase 3 registration trials in 2018 -

CONSHOHOCKEN, Pa., May 11, 2017 (GLOBE NEWSWIRE) -- Madrigal Pharmaceuticals, Inc. (NASDAQ:MDGL) today announced its first quarter 2017 financial results. During the first quarter of 2017, Madrigal initiated Phase 2 clinical development of its lead compound, MGL-3196, a first-in-class, oral, once-daily, liver-directed, thyroid hormone receptor (THR) β-selective agonist, in patients with HeFH. The Company had initiated a Phase 2 clinical study of MGL-3196 in patients with NASH in the fourth quarter of 2016.

"Enrollment is continuing as planned in our two Phase 2 proof-of-concept clinical trials of MGL-3196, for patients with NASH and HeFH," said Paul Friedman, M.D., Chief Executive Officer of Madrigal. "Both indications have serious unmet patient needs that we believe can be safely and effectively addressed by MGL-3196. We look forward to data readouts from these studies which, if positive, should enable us to initiate Phase 3 registration trials in 2018."

"Because MGL-3196 selectively agonizes THR-β, it has the potential to safely address key pathological mechanisms responsible for the progression of liver injury and address the underlying causes of NASH," said Rebecca Taub, M.D., CMO and Executive VP, Research & Development of Madrigal. "Additionally, for the majority of HeFH patients who do not reach their cholesterol reduction goals on standard treatment, MGL-3196 has the potential to provide significant LDL lowering in these patients either as monotherapy or in combination with existing therapies."

Clinical Program Summaries for MGL-3196

NASH
*Non-alcoholic Steatohepatitis (*NASH) is a common liver disease in the United States and worldwide, unrelated to alcohol use, that is characterized by a build-up of fat in the liver, inflammation, damage (ballooning) of hepatocytes and increasing fibrosis. Although people with NASH may feel well and often do not know they have the disease, NASH can lead to permanent damage, including cirrhosis and impaired liver function in a high percentage of NASH patients.

In October 2016, the first patient was treated in Madrigal's Phase 2 trial of MGL-3196 for the treatment of NASH. The randomized, double-blind, placebo-controlled, multi-center study is expected to enroll up to 117 patients 18 years of age and older with biopsy-confirmed NASH and more than 10% liver fat as confirmed by a magnetic resonance imaging-proton density fat fraction (MRI-PDFF).

In this trial, patients are randomized 2:1 to receive either MGL-3196 or placebo. The primary endpoint of the trial is the reduction of liver fat, assessed by MRI-PDFF at 12 weeks. Recent published data show a high correlation of reduction of liver fat measured by MRI-PDFF to NASH scoring on liver biopsy.

Efficacy will be confirmed at the end of the trial (36 weeks) by repeat MRI-PDFF and conventional liver biopsy to examine histological evidence for the resolution of NASH. Additional secondary endpoints include changes in clinically relevant biomarkers at 12 and 36 weeks, improvement in fibrosis by at least one stage, improvement of NASH, and safety and tolerability. Top-line results for the primary endpoint of the trial, the reduction of liver fat, assessed by MRI-PDFF at 12 weeks, are expected by year-end.

HeFH
Heterozygous familial hypercholesterolemia (HeFH) is a severe genetic dyslipidemia, typically caused by an inactivating mutation in one copy of the LDL receptor gene that leads to early onset cardiovascular disease. With conventional therapy, including statins and ezetimibe, the majority of HeFH and virtually all HoFH patients fail to reach their cholesterol (LDL-C) reduction goals. Based on evidence of impressive LDL cholesterol lowering in Phase 1, and data suggesting that MGL-3196 has a mechanism of action that is different from and complementary to statins, Madrigal initiated a Phase 2 proof-of-concept trial in HeFH. Top-line results of this trial are also expected by year-end.

The 12-week, randomized, double-blind, placebo-controlled, multi-center study will enroll up to 105 patients with HeFH randomized in a 2:1 ratio to receive either MGL-3196 or placebo, in addition to their current drug regimen (including high dose statins and ezetimibe). The primary endpoint of the study is reduction of LDL cholesterol, with secondary endpoints including reductions in triglycerides, Lp(a), and ApoB, as well as safety. Lp(a) is a severely atherogenic lipid particle, commonly elevated in familial hypercholesterolemia patients and poorly controlled by existing lipid lowering therapies. THR-β agonism is one of the few

therapeutic approaches that can substantially lower Lp(a). As previously announced, the first patient in this study was dosed in February 2017.

HoFH
Homozygous familial hypercholesterolemia (HoFH) is a much rarer form of severe genetic dyslipidemia, which results from inactivating mutations in both copies of the LDL receptor gene, and can produce cardiovascular disease before age 20. The protocol for a Phase 2, open-label study of MGL-3196 in HoFH is in development. The 12-week trial will have endpoints similar to the HeFH study and is expected to begin enrolling patients by the end of 2017.

Financial Results for the Three Months Ended March 31, 2017

As of March 31, 2017, Madrigal had cash, cash equivalents and marketable securities of $40.1 million.

Operating expenses were $6.1 million for the three month period ended March 31, 2017, compared to $0.7 million in the comparable prior year period.

Research and development expenses for the three month period ended March 31, 2017 increased to approximately $4.4 million, as compared to $0.5 million in the first quarter of 2016. The increases are primarily attributable to higher expenses for personnel, particularly non-cash stock based compensation, and increased expenses for our preclinical and clinical development programs for MGL-3196.

General and administrative expenses for the three month period ended March 31, 2017 increased to approximately $1.7 million, as compared to $0.2 million in the first quarter of 2016. The increase is primarily attributable to higher expenses for personnel, particularly non-cash stock based compensation, and professional services related to Madrigal becoming a public company in mid-2016.

Interest income (expense), net, for the three month period ended March 31, 2017 was $76 thousand, as compared to $(975) thousand for the comparable period in 2016. The decrease in interest expense in 2017 was due to the conversion of convertible debt to shares of common stock in connection with the Company's merger, which closed on July 22, 2016.

About Madrigal Pharmaceuticals

Madrigal Pharmaceuticals, Inc. (Nasdaq:MGDL) is a clinical-stage biopharmaceutical company pursuing novel therapeutics that target a specific thyroid hormone receptor pathway in the liver, which is a key regulatory mechanism common to a spectrum of cardio-metabolic and fatty liver diseases with high unmet medical need. The company's lead candidate, MGL-3196, is a first-in-class, orally administered, small-molecule, liver-directed, thyroid hormone receptor (THR) ß- selective agonist that is currently in Phase 2 development for NASH and HeFH. For more information, visit www.madrigalpharma.com.

Forward-Looking Statements

This communication contains "forward-looking statements" made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements reflect management's current knowledge, assumptions, judgment and expectations regarding future performance or events. Although management believes that the expectations reflected in such statements are reasonable, they give no assurance that such expectations will prove to be correct and you should be aware that actual results could differ materially from those contained in the forward-looking statements. Forward-looking statements are subject to a number of risks and uncertainties including, but not limited to, the company's clinical development of MGL-3196, the timing and outcomes of clinical studies of MGL-3196, and the uncertainties inherent in clinical testing. Undue reliance should not be placed on forward-looking statements, which speak only as of the date they are made. Madrigal undertakes no obligation to update any forward looking statements to reflect new information, events or circumstances after the date they are made, or to reflect the occurrence of unanticipated events. Please refer to Madrigal's filings with the U.S. Securities and Exchange Commission for more detailed information regarding these risks and uncertainties and other factors that may cause actual results to differ materially from those expressed or implied.

(**Tables Follow**)

Madrigal Pharmaceuticals, Inc.
Condensed Consolidated Statements of Operations
(in thousands, except share and per share amounts)
(unaudited)

	Three Months Ended March 31,	
	2017	**2016**
Revenues:		
Total revenues	$ -	$ -
Operating expenses:		

Research and development	4,380	516
General and administrative	1,695	222
Total operating expenses	6,075	738
Loss from operations	(6,075)	(738)
Interest income (expense), net	76	(975)
Net loss	$ (5,999)	$ (1,713)
Basic and diluted net loss per common share	$ (0.50)	$ (9.72)
Basic and diluted weighted average number of common shares outstanding	11,955,739	176,158

Madrigal Pharmaceuticals, Inc.
Condensed Consolidated Balance Sheets
(in thousands)
(unaudited)

	March 31, 2017	December 31, 2016
Assets		
Cash, cash equivalents and marketable securities	$ 40,127	$ 40,499
Other current assets	225	708
Other non-current assets	5	3
Total assets	$ 40,357	$ 41,210
Liabilities and Equity		
Current liabilities	$ 5,906	$ 4,800
Long-term liabilities	-	-
Stockholders' equity	34,451	36,410
Total liabilities and stockholders' equity	$ 40,357	$ 41,210

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