Madrigal Pharmaceuticals Completes Enrollment in Phase 2 Proof-of-Concept Study with MGL-3196 for Treatment of NASH

-- Primary endpoint is the reduction of liver fat, assessed by MRI-PDFF, at 12 weeks --

-- Company expects to report top-line results by year-end --

CONSHOHOCKEN, Pa., August 1, 2017 -- Madrigal Pharmaceuticals, Inc. (Nasdaq:MDGL) today announced that it has completed patient enrollment of 125 patients, exceeding its targeted enrollment of 117 patients, in its Phase 2 proof-of-concept study evaluating MGL-3196 for the treatment of non-alcoholic steatohepatitis (NASH). MGL-3196 is a first-in-class, oral, once-daily, liver-directed, thyroid hormone receptor (THR) β-selective agonist medication.

“I am pleased to be participating in this important study as the results will confirm if MGL-3196 is safe and well-tolerated and shows efficacy in NASH patients,” stated Stephen A. Harrison, M.D., Medical Director of Pinnacle Clinical Research, San Antonio, Texas and Principal Investigator of the study. “Additionally, since the study incorporates both magnetic resonance imaging-estimated proton density fat fraction (MRI-PDFF), a non-invasive measure of liver fat, along with liver biopsy, there is the potential to provide additional evidence for a correlation between improvement in non-invasive imaging and the histopathologic components associated with NASH on biopsy.”

“As we completed patient recruitment within the timeframe we had anticipated, we are on track to release top-line results for the primary endpoint, the reduction of liver fat assessed by MRI-PDFF at 12 weeks, by the end of this year,” stated Rebecca Taub, M.D., Chief Medical Officer, Executive Vice President and Founding Scientist of Madrigal. “This also means that we will be on track to provide top-line 36 week results, which include a final MRI-PDFF and an end-of-study liver biopsy in the second quarter of 2018.”

“Data from this study will help us better design our phase 3 trial, planning for which is already underway,” stated Paul Friedman, M.D., Chief Executive Officer of Madrigal. “I also point out that top-line data from our phase 2 study with MGL-3196 in heterozygous familial hypercholesterolemia will also become available by year end or very early in 2018.”

About the Phase 2 NASH Study
The randomized, double-blind, placebo-controlled, multi-center Phase 2 study enrolled 125 patients 18 years of age and older with liver biopsy-confirmed NASH and included approximately 25 clinical sites in the United States. Patients were randomized to receive

either placebo or MGL-3196 with twice as many patients receiving MGL-3196 as placebo.

The primary endpoint of the study is the reduction of liver fat at 12 weeks, assessed by MRI-PDFF, with efficacy 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. Recent published data show a high correlation of reduction of liver fat measured by MRI-PDFF to NASH scoring on liver biopsy.

Other secondary endpoints include changes in clinically relevant biomarkers at 12 and 36 weeks, improvement in fibrosis by at least one stage with no worsening of steatohepatitis, and safety and tolerability. Additional information about the study [NCT02912260] can be obtained at www.ClinicalTrials.gov.

About MGL-3196

Among its many functions in the human body, thyroid hormone, through activation of its beta receptor, plays a central role in controlling lipid metabolism, impacting a range of health parameters from levels of serum cholesterol and triglycerides to the pathological buildup of fat in the liver. Attempts to exploit this pathway for therapeutic purposes in cardio-metabolic and liver diseases have been hampered by the lack of selectivity of older compounds for the thyroid hormone receptor (THR)-β, chemically-related toxicities and undesirable distribution in the body.

Madrigal recognized that greater selectivity for thyroid hormone receptor (THR)-β and liver targeting might overcome these challenges and deliver the full therapeutic potential of THR-β agonism. Madrigal believes that MGL-3196 is the first orally administered, small-molecule, liver-directed, truly β-selective thyroid THR agonist. MGL-3196 has demonstrated the potential for a broad array of therapeutically beneficial effects, improving components of both metabolic syndrome, such as insulin resistance and dyslipidemia, and fatty liver disease, including lipotoxicity and inflammation. These pleiotropic actions, coupled with an excellent safety profile, suggest that MGL-3196 could be an ideal drug for NASH. MGL-3196 has the unique potential to address the root causes of the underlying disease process in NASH and ultimately, the accompanying liver fibrosis, while also lowering associated cardiovascular risk.

About NASH

Non-alcoholic steatohepatitis (NASH) is a common liver disease unrelated to alcohol use, characterized by a build-up of fat in the liver, inflammation 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. According to the National Institutes of Health (NIH), NASH affects approximately six percent of American adults.[1] It is the fastest growing reason for liver transplants and is also associated with an increasing incidence of liver cancer. There are currently no treatments approved by the U.S. Food and Drug Administration (FDA) for NASH.

About Madrigal Pharmaceutical
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) β-selective agonist that is currently in Phase 2 development for NASH and heterozygous familial hypercholesterolemia (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.

[1] National Institutes of Diabetes and Digestive and Kidney Disorders. Defintion and Facts of NAFLD and NASH. Available at https://www.niddk.nih.gov/health-information/health-topics/liver-disease/nonalcoholic-steatohepatitis/Pages/facts.aspx Accessed July 31, 2017.

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