Madrigal Announces Acceptance of MGL-3196 Abstract for a Main Plenary Presentation at The International Liver Congress™ 2018

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CONSHOHOCKEN, Pa., Jan. 30, 2018 (GLOBE NEWSWIRE) -- **Madrigal Pharmaceuticals, Inc.**(Nasdaq:MDGL) today announced that Week 12 Phase 2 results for MGL-3196, its first-in-class, oral, once-daily, liver-directed, thyroid hormone receptor (THR) β-selective agonist, will be presented during a main plenary session at the Annual Meeting of the European Association for the Study of the Liver (EASL) during The International Liver Congress™ 2018. TheCongress is being held April 11-15 in Paris, France.

The presentation will be made on April 13 by Stephen Harrison, M.D., Principal Investigator of the study, and Medical Director for Pinnacle Clinical Research, San Antonio, Texas, and Visiting Professor of Hepatology, Oxford University, and will include results from an ongoing MGL-3196 Phase 2 clinical trial in patients with biopsy-proven non-alcoholic steatohepatitis (NASH). As previously reported, in this trial, MGL-3196, demonstrated statistically significant results for the primary endpoint at 12 weeks, the percent change in hepatic fat versus placebo as measured by MRI-PDFF, a non-invasive imaging test.

The abstract for this presentation is entitled, *GS2 MGL-3196, a selective thyroid hormone receptor-beta agonist significantly decreases hepatic fat in NASH patients at 12 weeks, the primary endpoint in a 36 week serial liver biopsy study*, and is expected to be available March 28, 2018 at 10:00 am CET.

About the Ongoing 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.

As previously reported, the primary endpoint of the study was achieved, the reduction of liver fat at 12 weeks compared with baseline (relative change), assessed by MRI-PDFF. Liver fat was reduced by 36.3% and 42.0% relative reduction in MGL-3196 treated patients, e.g., all MGL-3196 treated patients (78) and all high exposure MGL-3196 treated patients (44/78), respectively, as compared with 9.6% median reduction in liver fat in 38 placebo treated patients. These results were statistically significant ($p<0.0001$) for both MGL-3196 treatment groups). MGL-3196 was well-tolerated with few serious adverse events noted during the 12-week portion of the study, none of which were related to MGL-3196 (http://www.madrigalpharma.com/wp-content/uploads/2017/12/Madrigal-Announces-Phase-2-NASH-Results-FINAL-20171206.pdf). The study remains blinded. Additional efficacy endpoints are being assessed at the end of the 36-week treatment period by repeat MRI-PDFF and conventional liver biopsy to examine histologic evidence for the resolution of and improvement in NASH. Results of the 36-week endpoints are expected in the second quarter of 2018. In addition, based on liver enzyme inclusion criteria, some patients (blinded as to whether they were on placebo or MGL-3196 in the main 36-week portion of the study) are receiving extended treatment beyond 36 weeks for up to 36 additional weeks. All patients in the extension study will receive MGL-3196 and only non-invasive assessments will be made, including serial MRI-PDFF, safety labs, and circulating biomarkers.

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 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 the preferred treatment option for NASH.

About Madrigal Pharmaceuticals
Madrigal Pharmaceuticals, Inc. (Nasdaq:MDGL) 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. Madrigal'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 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.Such statements contain words such as "expect," "could," "may," "will," "believe," "estimate," "continue," "future," or the negative thereof or comparable terminology and the use of future dates. 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.

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