



## **Madrigal Pharmaceuticals Announces Support of Fatty Liver Foundation's Screening Fund to Improve Diagnosis and Staging of Non-Alcoholic Fatty Liver Disease (NAFLD) and Non-Alcoholic Steatohepatitis (NASH)**

October 4, 2021

**In recognition of Liver Awareness Month, Madrigal and Fatty Liver Foundation Ring Nasdaq Closing Bell to Increase Awareness of NAFLD/NASH**

CONSHOHOCKEN, Pa., Oct. 04, 2021 (GLOBE NEWSWIRE) -- Madrigal Pharmaceuticals (NASDAQ:MDGL), a clinical-stage biopharmaceutical company pursuing novel therapeutics for fatty liver diseases, announces its support of the Fatty Liver Foundation, the leading patient advocacy organization focused on the diagnosis, treatment and support of Americans with non-alcoholic fatty liver disease (NAFLD), including non-alcoholic steatohepatitis (NASH). Today, Madrigal and the Fatty Liver Foundation will ring the Nasdaq closing bell to raise awareness of the need for more evidence-based screening and testing to improve diagnosis and staging of NAFLD/NASH.

NAFLD is estimated to afflict more than 16 million Americans. NASH is the more severe form of NAFLD. There are more than 5 million NASH patients with significant fibrosis in the U.S. Once NASH progresses to significant liver fibrosis, the risk of adverse liver outcomes increases dramatically. In fact, NASH is currently the leading cause of liver transplants in the U.S. Additionally, patients with NASH and/or advanced fibrosis, as well as NAFLD patients with concomitant type 2 diabetes, are at high risk for adverse cardiovascular events and increased mortality.

Paul Friedman, CEO of Madrigal said, "In recognition of Liver Awareness Month, we want to highlight the high unmet need of the millions of Americans who suffer from NAFLD and NASH. NASH is known as a 'silent disease' because many people don't know they have it until it has progressed to a dangerous stage. By supporting FLF, our objective is to improve the medical and patient community's understanding of the disease, better identify NAFLD/NASH patients, and communicate the growing body of clinical evidence demonstrating the utility of non-invasive tools and techniques to screen and diagnose patients."

Madrigal is providing an unrestricted grant to support FLF's NAFLD Screening Fund whose primary objective is to scale-up evidence-based screening and testing for NAFLD in a community setting. These efforts would support, and potentially boost, the non-invasive screening needed to identify asymptomatic disease and diagnosing NAFLD/NASH patients at various points of progression.

Wayne Eskridge, Co-Founder and CEO of FLF, added, "In partnership with industry, advocates and affected communities, we are launching the NAFLD Screening Fund, a public private partnership with the goal of further investigating the findings from our SUNN-1 Study (Screening for Undiagnosed NAFLD and NASH). In this study, we identified a cohort of people who sought to assess their risk of NAFLD and NASH through non-invasive testing, ultimately demonstrating a high incidence of unidentified liver pathology. We are grateful for Madrigal's support, which will contribute to our collective effort to identify and guide patients in need." Eskridge also noted, "The fund will

seek collaboration with local patient-focused organizations to facilitate the outreach and education goals of FLF through collective action. We encourage any interested parties to join us in this important outreach.”

Meena Bansal, M.D., Fellow of the American Association for the Study of Liver Diseases (FAASLD) and Professor of Medicine at the Icahn School of Medicine at Mount Sinai noted, “NASH is an asymptomatic disease that increases the risk of hepatic failure and cancer as it progresses. Incorporating non-invasive, evidence-based screening and diagnostic approaches is paramount to catching the disease in patients sufficiently early so that behavior modifications and therapeutic care can help improve their health and clinical outcomes.”

The Nasdaq closing bell ceremony will begin at approximately 3:45 p.m. ET on Monday, October 4, 2021, and can be viewed live at <https://livestream.com/accounts/27896496/events/9807812>.

### **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 fatty liver and cardio-metabolic diseases with high unmet medical need. Madrigal’s lead candidate, resmetirom, is a first-in-class, orally administered, small-molecule, liver-directed, thyroid hormone receptor (THR)- $\beta$  selective agonist that is currently in two Phase 3 clinical studies, MAESTRO-NASH and MAESTRO-NAFLD-1, designed to demonstrate multiple benefits in NASH (non-alcoholic steatohepatitis) patients. For more information, visit [www.madrigalpharma.com](http://www.madrigalpharma.com).

### **About the Fatty Liver Foundation**

The Fatty Liver Foundation is the only national, non-profit patient organization dedicated to improving the identification, diagnosis, treatment & support of Americans with fatty liver, NAFLD or NASH through awareness, screening, education and patient outreach. FLF’s goal is to improve the lives of both asymptomatic and diagnosed patients by raising awareness, developing wellness screening, educating patients and championing the development of a responsive support system for individuals of the growing epidemic of fatty liver disease. For more information, visit [www.fattyliverfoundation.org](http://www.fattyliverfoundation.org).

### **About the Fatty Liver Foundation NAFLD Screening Fund**

With recent advancements in the diagnostics and potential treatments for NAFLD, screening and testing are now the critical nexus between identification of disease and effective intervention. To meet this need, the NAFLD Screening Fund’s primary objective is to scale-up evidence-based screening and testing for NAFLD. Funded activities would boost the screening practices needed to identify asymptomatic disease and staging of NAFLD/NASH patients.

The expansion of screening and staging of fatty liver disease is a model of community outreach that has been proven by FLF in medical and non-medical settings. The Fund’s impact will be expanded education and awareness of NAFLD, achieved through screening, which has been shown to empower individuals’ ownership and participation in their health and healthcare. Through multiple site collaborations, new screening technologies, improved data management systems, and more trained personnel, the Fund will be leveraged to rapidly scale up community screening efforts. The

NAFLD Screening fund will be the catalyst for greater patient engagement in research and development, including treatment preparedness as new therapies become available. It is a mechanism through which many streams of financial support, both public and private, can be coordinated and focused on this rapidly growing health threat.

## **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, that are based on our beliefs and assumptions and on information currently available to us but are subject to factors beyond our control. Forward-looking statements include but are not limited to statements or references concerning: our clinical trials; research and development activities; market size estimates for NASH and NAFLD patients; the timing and results associated with the future development of our lead product candidate, MGL-3196 (resmetirom); our primary and secondary study endpoints for resmetirom and the potential for achieving such endpoints and projections; plans, objectives and timing for making a Subpart H (Accelerated Approval of New Drugs for Serious or Life-Threatening Illnesses) submission to FDA; optimal dosing levels for resmetirom; projections regarding potential future NASH resolution, safety, fibrosis treatment, cardiovascular effects, lipid treatment or biomarker effects with resmetirom; the efficacy and safety of resmetirom for non-cirrhotic NASH patients and cirrhotic NASH patients; the predictive power of liver fat reduction measured by non-invasive tests on NASH resolution with fibrosis reduction or improvement, the achievement of enrollment objectives concerning patient number, safety database and/or timing for our studies; the predictive power of NASH resolution and/or liver fibrosis reduction with resmetirom using non-invasive tests, including the use of ELF, FibroScan, MRE and/or MRI-PDFF; the ability to develop clinical evidence demonstrating the utility of non-invasive tools and techniques to screen and diagnose NASH and/or NAFLD patients; the predictive power of non-invasive tests generally, including for purposes of diagnosing NASH, monitoring patient response to resmetirom, or recruiting a NASH clinical trial; potential NASH or NAFLD patient risk profile benefits with resmetirom; the potential for resmetirom to become the best-in-class and/or first-to-market treatment option for patients with NASH; and our possible or assumed future results of operations and expenses, business strategies and plans, capital needs and financing plans, trends, market sizing, competitive position, industry environment and potential growth opportunities, among other things. Forward-looking statements: reflect management’s current knowledge, assumptions, judgment and expectations regarding future performance or events; include all statements that are not historical facts; and can be identified by terms such as “allow,” “anticipates,” “be,” “believes,” “continue,” “could,” “demonstrates,” “design,” “estimates,” “expects,” “forecasts,” “future,” “goal,” “hopeful,” “inform,” “intends,” “may,” “might,” “planned”, “plans,” “positions,” “potential,” “powers,” “predicts,” “predictive,” “projects,” “seeks,” “should,” “will,” “will be,” “would” or similar expressions and the negatives of those terms. Although management presently believes that the expectations reflected in such forward-looking statements are reasonable, it can 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: our clinical development of resmetirom; enrollment uncertainties, generally and in relation to COVID-19-related measures that may be continued for an uncertain period of time or implemented; outcomes or trends from competitive studies; future topline data timing or results; the risks of achieving potential benefits in studies that include substantially more patients than our prior*

*studies; limitations associated with early stage, non-placebo controlled study data; the timing and outcomes of clinical studies of resmetirom; 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. We specifically discuss these risks and uncertainties in greater detail in the section entitled "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2020, as well as in our other filings with the SEC.*

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