Madrigal Pharmaceuticals Presents Five Health Economics Outcomes Research Abstracts at the NASH-TAG Annual Conference

January 4, 2024 at 8:00 AM EST

- *Abstracts highlight the serious clinical burden of uncontrolled NASH and identify opportunities to improve patient care*
- *In an analysis of patient records from a large claims database, the risk of progressing to cirrhosis, decompensated cirrhosis, liver transplant, or all-cause death increased from 10.5% after one year to 31.4% after 5 years in patients with noncirrhotic NASH*

CONSHOHOCKEN, Pa., Jan. 04, 2024 (GLOBE NEWSWIRE) -- Madrigal Pharmaceuticals, Inc. (NASDAQ:MDGL), a clinical-stage biopharmaceutical company pursuing novel therapeutics for nonalcoholic steatohepatitis (NASH), today announced five health economics abstracts being presented at the NASH-TAG Conference, taking place from January 4-6, 2024 in Park City, Utah.

Jesse Fishman, Senior Director, Health Economics and Outcomes Research at Madrigal, stated, “We are gaining important new insights about the serious risks and complications associated with uncontrolled NASH through analyses of real-world data from patient registries and health system databases. The abstracts being presented at NASH-TAG underscore the relationship between NASH progression and adverse patient outcomes, reinforce previous evidence suggesting NASH independently contributes to cardiovascular risk, and indicate that many patients with NASH are not being monitored at the frequency recommended by clinical guidelines. These analyses also suggest opportunities to improve care through noninvasive testing strategies and a more holistic approach to assessing cardiovascular risk in patients with NASH.”

Bill Sibold, Chief Executive Officer of Madrigal, stated, “Madrigal’s health economics outcomes research efforts are part of a long-term strategy to provide healthcare decision-makers with data and insights to improve patient care and contextualize the potential value of resmetirom as a foundational therapy for patients with NASH. The serious burden of uncontrolled NASH on patients and the health system is coming into focus: as the disease progresses to cirrhosis, patients face markedly elevated risk of liver-related and cardiovascular outcomes. This is why it is essential to treat NASH with significant fibrosis before patients progress to cirrhosis.”

A summary of the health economics outcomes research abstracts being presented at NASH-TAG follows:

Abstract #21: “Non-invasive tests as a prediction tool to assess MASH resolution score” [Presenter: Jesse Fishman]
In an evaluation of biopsy and noninvasive test data from patients included in the TARGET-NASH registry, the FibroScan-AST score (FAST), FibroScan vibration-controlled transient elastography (VCTE), and the aspartate aminotransferase-to-platelet ratio index (APRI) demonstrated a strong ability to predict NASH resolution. Overall, patients without NASH resolution had larger baseline median FIB-4 (1.7 vs. 1.4, $p<0.003$), APRI (0.7 vs. 0.5, $p<.0001$) and VCTE (12.5 vs. 8.4, $p=0.0054$) scores. Sequential testing with two or three noninvasive tests helped reduce indeterminate results.

Abstract #25: “Characterizing the management of patients with NASH (with versus without cirrhosis) in real-world clinical practice – Low utilization of gastroenterology and hepatology specialty care” [Presenter: Michael Charlton]
In a review of patient records from an Optum database, researchers found that a substantial proportion of patients with NASH were not assessed by a gastroenterologist or hepatologist at the frequency recommended in medical guidelines, even when diagnosed with cirrhosis. Among patients with cirrhosis, ≥25% were not seen by a specialist at the recommended frequency of once per year. Among those without cirrhosis, ≥50% were not assessed by a specialist at the recommended frequency of every 2-3 years. Screening for hepatocellular carcinoma for most patients with cirrhosis occurred less than the recommended frequency. The findings suggest a need to improve clinical practice to align with clinical guidelines.

Abstract #26: “Characterizing the real-world clinical outcomes of patients with NASH without cirrhosis versus with cirrhosis” [Presenter: Michael Charlton]
In another review of patient records from an Optum database, researchers examined the relationship between NASH disease progression and risk of clinical outcomes. For patients with NASH without cirrhosis at baseline, the risk of experiencing all-cause death, progression to cirrhosis or decompensated cirrhosis, or a liver transplant increased from 10.5% in year one to 31.4% by year five. The risk of death was several-fold higher for those with cirrhosis. This study also found that the risk of death and progression increased significantly with age and presence of comorbidities of cardiovascular disease and type 2 diabetes, highlighting the importance of delaying liver disease progression.

Abstract #27: “A longitudinal assessment of cardiovascular risk for patients enrolled in TARGET-NASH” [Presenter: Jesse Fishman]
In an analysis of patient data from the TARGET-NASH registry, patients with NASH with cirrhosis were found to be at an increased risk of cardiovascular events compared to patients with noncirrhotic NASH, even after adjusting for traditional cardiovascular risk factors: this finding supports the notion that the severity of liver disease impacts the level of cardiovascular risk and suggests that treatments that could delay progression to cirrhosis may potentially reduce health events like cardiovascular outcomes, morbidity, and mortality in patients with NASH.

Abstract #41: “Enhancing ASCVD Risk Prediction in NASH/NAFLD Patients” [Presenter: Jesse Fishman]
In an analysis of a retrospective dataset from a large U.S. integrated delivery network health system, researchers compared observed events to a model that predicted events and found that a cardiovascular risk model that included liver-specific biomarkers improved the prediction of cardiovascular mortality and myocardial infarction events in patients with NASH relative to the American Heart Association's Atherosclerotic Cardiovascular Disease Risk Estimator Plus. This finding underscores the necessity of revisiting current cardiovascular risk models for patients with NASH to incorporate more holistic and liver-specific variables.

About NASH

Nonalcoholic steatohepatitis (NASH) is a more advanced form of nonalcoholic fatty liver disease (NAFLD). NASH is a leading cause of liver related mortality and an increasing burden on healthcare systems globally. Additionally, patients with NASH, especially those with more advanced metabolic risk factors (hypertension, concomitant type 2 diabetes), are at increased risk for adverse cardiovascular events and increased morbidity and mortality.

Once patients progress to NASH with significant fibrosis (consistent with F2/F3), the risk of adverse liver outcomes increases dramatically. NASH is rapidly becoming the leading cause of liver transplantation in the U.S. There are currently no FDA-approved therapies available for the treatment of NASH.

NASH is also known as “metabolic dysfunction-associated steatohepatitis (MASH)” following a change in disease nomenclature introduced by hepatology medical societies in 2023.

About Madrigal Pharmaceuticals

Madrigal Pharmaceuticals, Inc. (Nasdaq: MDGL) is a clinical-stage biopharmaceutical company pursuing novel therapeutics for nonalcoholic steatohepatitis (NASH), a liver disease with high unmet medical need. Madrigal’s lead candidate, resmetirom, is a liver-directed THR-β agonist oral therapy that is designed to target key underlying causes of NASH. For more information, visit www.madrigalpharma.com.

Forward Looking Statements

This communication includes “forward-looking statements” made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, that are based on Madrigal’s beliefs and assumptions and on information currently available to it, but are subject to factors beyond its control. Forward-looking statements reflect management’s current knowledge, assumptions, judgment and expectations regarding future performance or events. Forward-looking statements include: all statements that are not historical facts; statements referenced by forward-looking statement identifiers, including the examples in the paragraph below; the relationship between NASH progression and adverse patient outcomes; the estimated clinical burden of uncontrolled NASH; analyses for patients with NASH with significant fibrosis concerning potential progression to cirrhosis, decompensated cirrhosis, liver transplant or death, and cardiovascular risks, comorbidities and outcomes; health economics assessments or projections; resmetirom’s potential to be the first specialty therapy for NASH patients with significant liver fibrosis; projections or objectives for obtaining accelerated or full approval for resmetirom, including all statements concerning potential clinical benefit to support accelerated approval and/or potential approval; and statements or references concerning - the potential efficacy and safety of resmetirom for noncirrhotic NASH patients and cirrhotic NASH patients, possible or assumed future results of operations and expenses, business strategies and plans (including ex-US. Launch/partnering plans), research and development activities, and the timing and results associated with the future development of resmetirom, the timing and completion of projected future clinical milestone events, including enrollment, additional studies, top-line data and open label projections, plans, Madrigal’s primary and key secondary study endpoints for resmetirom and the potential for achieving such endpoints and projections, the potential to support an additional indication for resmetirom in patients with well-compensated NASH cirrhosis, optimal dosing levels for resmetirom, projections regarding potential NASH or NAFLD and potential patient benefits with resmetirom, including future NASH resolution, safety, fibrosis treatment, cardiovascular effects, lipid treatment, and/or biomarker effects with resmetirom, and strategies, objectives and commercial opportunities, including potential prospects or results.

Forward-looking statements can be identified by terms such as “accelerate,” “achieve,” “allow,” “anticipates,” “appear,” “be,” “believes,” “can,” “confidence,” “continue,” “could,” “demonstrates,” ”design,” “estimates,” “expectation,” “expects,” “forecasts,” “future,” “goal,” “help,” “hopeful,” “inform,” inform,” “intended,” “intends,” “may,” “might,” “on track,” “planned,” “planning,” “plans,” “positions,” “potential,” “powers,” “predicts,” ”predictive,” “projects,” “seeks,” “should,” “will,” “will achieve,” “will be,” “would” or similar expressions and the negatives of those terms.

Forward-looking statements are subject to a number of risks and uncertainties including, but not limited to: the assumptions underlying the forward-looking statements; risks of obtaining and maintaining regulatory approvals, including, but not limited to, potential regulatory delays or rejections; risks associated with meeting the objectives of Madrigal’s clinical studies, including, but not limited to Madrigal’s ability to achieve enrollment objectives concerning patient numbers (including an adequate safety database), outcomes objectives and/or timing objectives for Madrigal’s studies; any delays or failures in enrollment, and the occurrence of adverse safety events; risks related to the effects of resmetirom’s mechanism of action; the achievement of enrollment objectives concerning patient number, safety database and/or timing for Madrigal’s studies; enrollment and trial conclusion uncertainties; market demand for and acceptance of our products; the potential inability to raise sufficient capital to fund ongoing operations as currently planned or to obtain financings on terms similar to those arranged in the past; the ability to service indebtedness and otherwise comply with debt covenants; outcomes or trends from competitive studies; future topline data timing or results; our ability to prevent and/or mitigate cyber-attacks, unauthorized exfiltration of data or other security incidents; the risks of achieving potential benefits in studies that includes substantially more patients, and patients with different disease states, than prior studies; the timing and outcomes of clinical studies of resmetirom; the uncertainties inherent in clinical testing; and uncertainties concerning analyses or assessments outside of a controlled clinical trial. 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 submissions filed with the U.S. Securities and Exchange Commission, or SEC, 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. Madrigal specifically discusses these risks and uncertainties in greater detail in the sections appearing in Part I, Item 1A of its Annual Report on Form 10-K for the year ended December 31, 2022, filed with the SEC on February 23, 2023, as amended by our Form 10-K/A filed with the SEC on March 3, 2023, and Part II, Item 1A of its Quarterly Reports on Form 10-Q for the quarters ended June 30, 2023 and September 30, 2023, and as updated from time to time by Madrigal’s other filings with the SEC.

Investor Contact
Alex Howarth, Madrigal Pharmaceuticals, Inc., IR@madrigalpharma.com

Media Contact
Christopher Frates, Madrigal Pharmaceuticals, Inc., media@madrigalpharma.com

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