Madrigal to Present New Data from the Company's MASH Program at AASLD's The Liver Meeting 2025

October 28, 2025

- *Two oral presentations to highlight biomarker, imaging and quality-of-life data from the open-label compensated MASH cirrhosis (F4c) arm of the Phase 3 MAESTRO-NAFLD-1 trial of Rezdiffra*
- *Poster of distinction examines the impact of Rezdiffra interruption on patients, underscoring the need for continued treatment to prevent disease progression*
- *Further poster presentations examine early real-world experience with Rezdiffra and the clinical burden of MASH*

CONSHOHOCKEN, Pa., Oct. 28, 2025 (GLOBE NEWSWIRE) -- Madrigal Pharmaceuticals, Inc. (NASDAQ: MDGL), a biopharmaceutical company focused on delivering novel therapeutics for metabolic dysfunction-associated steatohepatitis (MASH), today announced multiple MASH and Rezdiffra® (resmetirom) data presentations at the American Association for the Study of Liver Diseases (AASLD) The Liver Meeting®, taking place from November 7-11, 2025, in Washington, D.C. Highlights include new analyses from the open-label compensated MASH cirrhosis (F4c) arm of the Phase 3 MAESTRO-NAFLD-1 trial, evaluating the use of Rezdiffra in an advanced, difficult-to-treat patient population with no approved therapies.

"The pace of scientific innovation in MASH continues to accelerate, but there remains an urgent need for an approved therapy to treat patients with compensated cirrhosis," said David Soergel, M.D., Chief Medical Officer of Madrigal. "At this year's Liver Meeting, Madrigal will present important new data that reinforce our confidence in Rezdiffra's potential, if approved in this indication, to benefit even the most advanced patients with compensated cirrhosis, a population we are studying in the ongoing, fully enrolled Phase 3 MAESTRO-NASH-OUTCOMES trial. Additionally, we look forward to sharing multiple posters that examine early real-world experience with Rezdiffra, regression of MASH biomarkers when Rezdiffra treatment is interrupted, and the burden of uncontrolled MASH across health systems."

Madrigal Data Presentations at AASLD's The Liver Meeting, 2025

- Oral Presentation: "Two-Year Time Course of Biomarker and Imaging Responses in Well-Compensated MASH Cirrhosis Patients Treated with Resmetirom" [Abstract #0167, Sunday, November 9 at 5:30 p.m. EST, Presenter: Naim Alkhouri]
- Oral Presentation: "Improvement in Health-Related Quality of Life in Non-Cirrhotic and Cirrhotic Patients with Metabolic Dysfunction-Associated Steatotic Liver Disease Treated with Resmetirom: Data from MAESTRO-NAFLD" [Abstract #0181, Monday, November 10 at 6:00 p.m. EST, Presenter: Zobair Younossi]
- Poster of Distinction: "Durability of Resmetirom Response in MASLD Patients After Two Years of Treatment in MAESTRO-NAFLD-OLE" [Abstract #4003, Presenter: Naim Alkhouri]
- Poster: "Analysis of MAESTRO-NASH, Resmetirom Relative to Placebo Patients, on Primary and Secondary Liver Biopsy Endpoints Based on Aligned Biopsy Endpoints and Statistical Methods from MASH Clinical Trials" [Abstract #4093, Presenter: Rohit Loomba]
- Poster: "Analysis of Biomarkers PRO-C3 and ELF Components in Baseline MASH/MASLD and MASH Cirrhosis Patients; Correlations Between Change in PRO-C3 and ELF in Resmetirom-Treated Patients from The MAESTRO-NASH Trial" [Abstract #4074, Presenter: Meena Bansal]
- Poster: "Novel Multiparametric MRI Imaging Predicts Histologic Response in Resmetirom Versus Placebo (Perspectum) in The Multicentre, International, MAESTRO-NASH Phase 3 Trial" [Abstract #2053, Presenter: Rohit Loomba]
- Poster: "Role of Metabolic Dysfunction-Associated Steatohepatitis (MASH) as a Risk Factor for Hepatocellular Carcinoma (HCC) Development" [Abstract #2639, Presenter: Robert Gish]
- Poster: "Evaluating the Early Real-World Impact of Resmetirom in Patients with Metabolic Dysfunction-Associated Steatohepatitis (MASH): A United States Cohort Study Using Electronic Medical Records" [Abstract #4073, Presenter: Yestle Kim]
- Poster of Distinction: "Semaglutide Discontinuation Among Patients with Metabolic Dysfunction-Associated Steatotic Liver Disease (MASLD)" [Abstract #2499, Presenter: Francis Lobo]
- Poster: "Semaglutide Titration Patterns Among Patients with Metabolic Dysfunction-Associated Steatotic Liver Disease (MASLD)" [Abstract #2527, Presenter: Samantha Clark]
- Poster: "Semaglutide Use Among Individuals Diagnosed with Metabolic Dysfunction-Associated Steatotic Liver Disease in a Medicare Advantage Population" [Abstract #2613, Presenter: Francis Lobo]
- Poster: "An Innovative Screening and Treatment Pathway for Metabolic Dysfunction-Associated Steatotic Liver Disease: The UK-CURES Approach" [Abstract #2535, Presenter: Lindsey Sheehan]
- Poster: "Characterizing Healthcare Costs in Medicare Beneficiaries with a New Diagnosis of Non-Cirrhotic Metabolic Dysfunction-Associated Steatohepatitis" [Abstract #3092, Presenter: Nipun Atreja]
- Poster: "Resmetirom Improves Mortality, Liver and Cardio-Renal-Metabolic Outcomes in Individuals with MASLD in Routine Clinical Practice" [Abstract #4052, Presenter: Vinay Jahagirdar]
- Poster: "Patient Characteristics and Treatment Patterns Among Patients Using Resmetirom in The Real-World Setting"

[Abstract #4067, Presenter: Nipun Atreja]

Rezdiffra (resmetirom) is a once-daily, oral, liver-directed thyroid hormone receptor (THR)-β agonist designed to target key underlying causes of MASH. It is the first approved medication for the treatment of MASH in the U.S. and Europe. In the pivotal Phase 3 MAESTRO-NASH biopsy trial, Rezdiffra achieved both fibrosis improvement and MASH resolution primary endpoints. Rezdiffra also reduced liver stiffness, liver fat, liver enzymes, and atherogenic lipids in the MAESTRO-NASH trial and improved health-related quality of life. At one year, 91% of patients treated with Rezdiffra 100mg achieved improvement or stabilization of liver stiffness as measured by vibrational-controlled transient elastography (VCTE), a test that is frequently used to monitor treatment response in clinical practice.

Rezdiffra is indicated in conjunction with diet and exercise for the treatment of adults with noncirrhotic MASH with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis). Continued approval for this indication may be contingent upon verification and description of clinical benefit in ongoing confirmatory trials. Rezdiffra is not approved in any geography for the treatment of patients with cirrhosis.

About MASH
Metabolic dysfunction-associated steatohepatitis (MASH), formerly known as nonalcoholic steatohepatitis (NASH), is a serious liver disease that can progress to cirrhosis, liver failure, liver cancer, need for liver transplantation, and premature mortality. MASH is the leading cause of liver transplantation in women and the second leading cause of all liver transplantation in the U.S., and the fastest-growing indication for liver transplantation in Europe.

Once patients progress to MASH with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis), the risk of adverse liver outcomes increases dramatically: these patients have a 10-17 times higher risk of liver-related mortality as compared to patients without fibrosis. Those who progress to cirrhosis face a 42 times higher risk of liver-related mortality, underscoring the need to treat MASH before complications of cirrhosis develop. MASH is also an independent driver of cardiovascular disease, the leading cause of mortality for patients.

As MASH disease awareness improves and disease prevalence increases, the number of diagnosed patients with MASH with moderate to advanced fibrosis or compensated MASH cirrhosis (F2-F4c) is expected to grow.

About Rezdiffra
What is Rezdiffra?
Rezdiffra is a prescribed medicine used along with diet and exercise to treat adults with nonalcoholic steatohepatitis (NASH) with moderate to advanced liver scarring (fibrosis), but not with cirrhosis of the liver.

It is not known if Rezdiffra is safe and effective in children (under 18 years old).
This indication is approved based on improvement of NASH and liver scarring (fibrosis). There are ongoing studies to confirm the clinical benefit of Rezdiffra.
Before you take Rezdiffra, tell your healthcare provider about all of your medical conditions, including if you:

- have any liver problems other than NASH.
- have gallbladder problems or have been told you have gallbladder problems, including gallstones.
- are pregnant or plan to become pregnant. It is not known if Rezdiffra will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if Rezdiffra passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you take Rezdiffra.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

- Rezdiffra and other medicines may affect each other, causing side effects. Rezdiffra may affect the way other medicines work, and other medicines may affect how Rezdiffra works.
- Especially tell your healthcare provider if you take medicines that contain gemfibrozil to help lower your triglycerides, or cyclosporine to suppress your immune system, because Rezdiffra is not recommended in patients taking these medicines.
- Tell your healthcare provider if you are taking medicines such as clopidogrel to thin your blood or statin medicines to help lower your cholesterol.
- Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

What are the possible side effects of Rezdiffra?
Rezdiffra may cause serious side effects, including:

- liver injury (hepatotoxicity). Stop taking Rezdiffra and call your healthcare provider right away if you develop the following signs or symptoms of hepatotoxicity: tiredness, nausea, vomiting, fever, rash, your skin or the white part of your eyes turns yellow (jaundice), pain or tenderness in the upper middle or upper right area of your stomach (abdomen).
- gallbladder problems. Gallbladder problems such as gallstones, inflammation of the gallbladder, or inflammation of the pancreas from gallstones can occur with NASH and may occur if you take Rezdiffra. Call your healthcare provider right

away if you develop any signs or symptoms of these conditions including nausea, vomiting, fever, or pain in your stomach area (abdomen) that is severe and will not go away. The pain may be felt going from your abdomen to your back and the pain may happen with or without vomiting.

The most common side effects of Rezdiffra include: diarrhea, nausea, itching, stomach (abdominal) pain, vomiting, dizziness, and constipation.

These are not all the possible side effects of Rezdiffra. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Madrigal at 1-800-905-0324.

Please see the full Prescribing Information, including Patient Information, for Rezdiffra.

About Madrigal
Madrigal Pharmaceuticals, Inc. (Nasdaq: MDGL) is a biopharmaceutical company focused on delivering novel therapeutics for metabolic dysfunction-associated steatohepatitis (MASH), a liver disease with high unmet medical need. Madrigal's medication, Rezdiffra (resmetirom), is a once-daily, oral, liver-directed THR-β agonist designed to target key underlying causes of MASH. Rezdiffra is the first and only medication approved by both the FDA and European Commission for the treatment of MASH with moderate to advanced fibrosis (F2 to F3). An ongoing Phase 3 outcomes trial is evaluating Rezdiffra for the treatment of compensated MASH cirrhosis (F4c). For more information, visit www.madrigalpharma.com.

Forward-Looking Statements
This press release includes "forward-looking statements" made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, as amended, including statements related to the potential benefit of Rezdiffra in patients with compensated MASH cirrhosis. 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; the challenges with the commercial launch of a new product; our history of operating losses and the possibility that we may never achieve or maintain profitability; risks associated with meeting the objectives of Madrigal's clinical trials, 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 trials; any delays or failures in enrollment, and the occurrence of adverse safety events; risks related to the effects of Rezdiffra's (resmetirom's) mechanism of action; market demand for and acceptance of Rezdiffra; our ability to service indebtedness and otherwise comply with debt covenants; outcomes or trends from competitive trials; future topline data timing or results; our ability to prevent and/or mitigate cyber-attacks; the uncertainties inherent in clinical testing; uncertainties concerning analyses or assessments outside of a controlled clinical trial; and changes in laws and regulations applicable to our business and our ability to comply with such laws and regulations. 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 ("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, 2024, filed with the SEC on February 26, 2025, and as updated from time to time by Madrigal's other filings with the SEC.

Madrigal may use its website to comply with its disclosure obligations under Regulation FD. Therefore, investors should monitor Madrigal's website in addition to following its press releases, filings with the SEC, public conference calls, and webcasts.

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