



Madrigal to Present Late-Breaking Resmetirom Data in Patients with Compensated MASH Cirrhosis at the EASL Congress

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CONSHOHOCKEN, Pa., April 29, 2025 (GLOBE NEWSWIRE) -- Madrigal Pharmaceuticals, Inc. (NASDAQ: MDGL), a biopharmaceutical company focused on delivering novel therapeutics for metabolic dysfunction-associated steatohepatitis (MASH), today announced six presentations at the upcoming European Association for the Study of the Liver (EASL) Congress, taking place from May 7-10, 2025, in Amsterdam, the Netherlands. Madrigal will share detailed two-year data from the open-label compensated MASH cirrhosis (F4c) arm of the Phase 3 MAESTRO-NAFLD-1 trial in a late-breaking oral presentation titled, "Treatment with resmetirom for up to two years led to improvement in liver stiffness, fibrosis biomarkers, fibrosis scores and portal hypertension risk in 122 patients with compensated MASH cirrhosis."

"Patients with compensated MASH cirrhosis who develop clinically significant portal hypertension are at greatly elevated risk of experiencing life-threatening complications of late-stage liver disease so there is an urgent need to advance new treatment strategies for this vulnerable population," said Bill Sibold, Chief Executive Officer of Madrigal. "The late-breaking data we will be presenting at EASL suggest that resmetirom may help halt or reverse disease progression in patients with compensated MASH cirrhosis, and we look forward to sharing important new findings examining the medication's impact on portal hypertension risk. These data reinforce our conviction in resmetirom's potential to become the foundational therapy across F2 to F4c MASH."

"This EASL Congress comes at an ideal time for our growing team in Europe," added Neil Archer, Executive Vice President and Head of International for Madrigal. "As we prepare for a European Commission decision on our marketing authorization application for resmetirom, EASL will provide a valuable opportunity to listen, learn and engage with healthcare providers, patient advocates and other stakeholders who are working to improve care for this serious disease."

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. In the pivotal Phase 3 [MAESTRO-NASH biopsy trial](#), resmetirom achieved both fibrosis improvement and MASH resolution primary endpoints, and 91% of patients treated with resmetirom 100 mg experienced improvement or stabilization of liver stiffness. In the U.S., resmetirom 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.

Resmetirom is not approved in Europe for the treatment of patients with MASH with moderate to advanced liver fibrosis and not approved in any geography for the treatment of patients with cirrhosis. A marketing authorization application (MAA) for resmetirom is under evaluation with the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP). The CHMP opinion and subsequent European Union (EU) decision are expected in mid-2025. Madrigal expects to launch resmetirom in Europe on a country-by-country basis commencing with Germany in the second half of 2025, pending European Commission approval.

Madrigal Data Presentations at the EASL Congress 2025

- Late-Breaking Oral Presentation: "Treatment with resmetirom for up to two years led to improvement in liver stiffness, fibrosis biomarkers, fibrosis scores and portal hypertension risk in 122 patients with compensated MASH cirrhosis" [Saturday, May 10, at 13:15 CEST. Presenter: Naim Alkhouri]
- Poster: "Baseline characteristics in well-compensated NASH cirrhosis patients diagnosed with or without a liver biopsy in MAESTRO-NASH-OUTCOMES, a clinical outcome phase 3 study assessing the effect of resmetirom in well compensated NASH cirrhosis" [Presenter: Jörn M. Schattenberg]
- Poster: "Use of noninvasive tests (NITs) to diagnose and follow non-alcoholic steatohepatitis (NASH) with liver fibrosis patients treated with resmetirom" [Presenter: Jörn M. Schattenberg]
- Poster: "Metabolic dysfunction-associated steatohepatitis (MASH) prevalence in Germany – results from a claims analysis" [Presenter: Thomas Ramezani]
- Poster: "Metabolic dysfunction-associated steatohepatitis as a risk factor for hepatocellular carcinoma mortality" [Presenter: Robert G. Gish]
- Poster: "Use of the LiverRisk score for prediction of moderate to advanced liver fibrosis in United States adults" [Presenter: Mary E. Rinella]

Investor Webcast to Review New F4c Data

At 8 a.m. EDT May 13, 2025, Madrigal will host a webcast to review the detailed two-year data from the compensated MASH cirrhosis (F4c) arm of the Phase 3 MAESTRO-NAFLD-1 trial. To access the webcast, please visit the investor relations section of the Madrigal website or [click here](#) to register.

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 expected to become the leading cause of liver transplantation in the U.S. and is already the leading cause of liver transplantation among women.

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.

An estimated 1.5 million patients have been diagnosed with MASH in the U.S., and Madrigal is focused on reaching approximately 315,000 patients with moderate to advanced fibrosis who are under the care of liver specialists. As MASH disease awareness improves and disease prevalence increases, the number of diagnosed patients with MASH with moderate to advanced fibrosis 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, 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 the FDA for the treatment of MASH with moderate to advanced fibrosis (consistent with stages F2 to F3). An ongoing Phase 3 outcomes trial is evaluating Rezdiffra for the treatment of compensated MASH cirrhosis (consistent with stage 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 Rezdiffra's role as a foundational therapy, the potential benefit of Rezdiffra in patients with compensated MASH cirrhosis and timing for an expected regulatory decision regarding resmetirom in Europe and the expected commencement of commercialization in Germany. 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, particularly for a company that did not have commercial experience prior to 2024; 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; the potential inability to raise sufficient capital to fund ongoing operations as currently planned or to obtain financing on acceptable terms; 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.

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