Madrigal Pharmaceuticals to Present Multiple Rezdiffra™ (resmetirom) Abstracts in NASH/MASH at the AASLD Liver Meeting®

October 30, 2024

CONSHOHOCKEN, Pa., Oct. 30, 2024 (GLOBE NEWSWIRE) -- Madrigal Pharmaceuticals, Inc. (NASDAQ:MDGL), a biopharmaceutical company focused on delivering novel therapeutics for nonalcoholic steatohepatitis (NASH)/metabolic dysfunction-associated steatohepatitis (MASH), today announced multiple resmetirom data presentations at the upcoming American Association for the Study of Liver Diseases (AASLD) Liver Meeting, taking place from November 15-19, 2024 in San Diego.

Bill Sibold, Chief Executive Officer of Madrigal, stated, “This will be the first AASLD Liver Meeting following the approval of Rezdiffra earlier this year, and the entire NASH community feels energized with new momentum. It is an exciting moment for Madrigal and for the field as a whole. At the same time, we recognize that NASH remains the leading cause of liver transplant among women in the U.S. and second-leading cause in men, so there is an urgent need to continue advancing patient care. The Liver Meeting will provide a valuable opportunity to share the latest resmetirom clinical research, engage with healthcare providers, and reinforce Madrigal’s leadership position in NASH.”

Becky Taub, M.D., Chief Medical Officer and President of Research & Development of Madrigal, added, “The eleven abstracts Madrigal will be presenting at The Liver Meeting support Rezdiffra’s position as the foundational therapy for NASH with moderate to advanced fibrosis and offer important insights into the burden of the disease on patients and the health system. We look forward to sharing two oral presentations of new results from the Phase 3 MAESTRO-NASH trial and multiple posters from our clinical development program that will help guide patient care and further NASH research.”

Rezdiffra (resmetirom) is a once-daily, oral, liver-directed thyroid hormone receptor THR-β agonist designed to target key underlying causes of NASH. It is the first approved medication for the treatment of NASH. In the pivotal Phase 3 MAESTRO-NASH biopsy trial, Rezdiffra achieved both fibrosis improvement and NASH resolution primary endpoints, and 80% of patients treated with Rezdiffra 100 mg experienced improvement or stabilization of fibrosis. Rezdiffra is indicated in conjunction with diet and exercise for the treatment of adults with noncirrhotic NASH 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.

Madrigal data presentations at AASLD The Liver Meeting, 2024

- Oral presentation: “Effect of resmetirom or placebo in NASH fibrosis patients with <5% or ≥5% weight loss and/or on baseline GLP-1 therapy in the MAESTRO-NASH 52-week serial liver biopsy study” [Sunday, Nov. 17 at 9:15 a.m. PST. Presenter: Mazen Noureddin]
- Oral presentation: “Resmetirom effects on NASH with liver fibrosis in patients with NASH genetic risk alleles” [Sunday, Nov. 17 at 11:30 a.m. PST. Presenter: Naga Chalasani]
- Poster: “Resmetirom therapy of MASH-associated Child Pugh A cirrhosis reduces estimated risk for clinical outcome based on HepQuant RISK ACE model” [Presenter: Gregory Everson]
- 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: Meena Bansal]
- Poster: “Use of non-invasive tests to diagnose and follow NASH with liver fibrosis patients treated with resmetirom” [Presenter: Naim Alkhouri]
- Poster: “Liver enzymes reductions from baseline over time in resmetirom treated patients in a Phase 3 study, MAESTRO-NASH” [Presenter: Seth Baum]
- Poster: “Validating pre-identified morphological baseline features for predicting fibrosis progression in MAESTRO-NASH” [Presenter: Jörn Schattenberg]
- Poster: “Impact of resmetirom on statin pharmacokinetics and safety in Phase 1 studies and MAESTRO-NASH” [Presenter: Seth Baum]
- Poster: “Assessment of resmetirom efficacy (80 mg vs. 100 mg) stratified by baseline body mass index and weight in patients from the MAESTRO-NASH trial” [Presenter: Mazen Noureddin]
- Poster: “Risk of incident extrahepatic cancers among Medicare patients with non-alcoholic steatohepatitis (NASH)” [Presenter: Robert Gish]
- Poster: “Current multi-dimensional view of non-alcoholic steatohepatitis (NASH)/ metabolic dysfunction-associated steatohepatitis (MASH) global epidemiological rates” [Presenter: Michael Charlton]

Additionally, Madrigal will be exhibiting at booth #1239 and hosting two product theaters on Sunday and Monday, November 17 and 18, at 10:00 a.m. PST.

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 moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis), the risk of adverse liver outcomes increases dramatically. When a patient with NASH progresses to cirrhosis, their risk of liver-related mortality increases by more than 42 percent. NASH is rapidly becoming the leading cause of liver transplantation in the U.S.

Madrigal estimates that approximately 1.5 million patients have been diagnosed with NASH in the U.S., of which approximately 525,000 have NASH with moderate to advanced liver fibrosis. Madrigal is focusing on approximately 315,000 diagnosed patients with NASH with moderate to advanced liver fibrosis under the care of liver specialist physicians during the launch of Rezdiffra.

NASH is also known as metabolic dysfunction-associated steatohepatitis (MASH). In 2023, global liver disease medical societies and patient groups came together to rename the disease, with the goal of establishing an affirmative, non-stigmatizing name and diagnosis. Nonalcoholic fatty liver disease (NAFLD) was renamed metabolic dysfunction-associated steatotic liver disease (MASLD); NASH was renamed MASH; and an overarching term, steatotic liver disease (SLD), was established to capture multiple types of liver diseases associated with fat buildup in the liver. In addition to liver disease, patients with MASH have at least one related comorbid condition (e.g., obesity, hypertension, dyslipidemia, or type 2 diabetes).

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 Pharmaceuticals
Madrigal Pharmaceuticals, Inc. (Nasdaq: MDGL) is a biopharmaceutical company focused on delivering novel therapeutics for nonalcoholic steatohepatitis (NASH), 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 NASH. For more information, visit www.madrigalpharma.com.

Forward-Looking Statements
Certain statements in this press release, other than purely historical information, may constitute "forward-looking statements" made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, including statements regarding: Rezdiffra and its expected use for treating NASH with moderate to advanced fibrosis. The forward-looking statements in this press release are neither promises nor guarantees, and you should not place undue reliance on these forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, many of which are beyond Madrigal's control, and which could cause actual results to differ materially from those expressed or implied by these forward-looking statements.

These risks, uncertainties and other factors are described under the heading "Risk Factors" in Madrigal's Annual Report on Form 10-K for the year ended December 31, 2023, and Quarterly Report on Form 10-Q for the quarter ended June 30, 2024, and in subsequent filings made by Madrigal with the Securities and Exchange Commission from time to time. These forward-looking statements are based on Madrigal's current expectations and speak only as of the date of this press release. Except as required by law, 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.

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