Madrigal Expands its MASH Pipeline with Exclusive Global License Agreement for Ervogastat, a Phase 2 Oral DGAT-2 Inhibitor

January 9, 2026

- *Agreement expands Madrigal's pipeline and strengthens its leadership in pioneering MASH therapies*
- *DGAT-2 inhibition represents a complementary mechanism of action with Rezdiffra® (resmetirom) for potential additive therapeutic benefit in MASH*
- *Madrigal to present at the 44th Annual J.P. Morgan Healthcare Conference at 1:30 p.m. PST (4:30 p.m. EST) on Monday, January 12, 2026*

CONSHOHOCKEN, Pa., Jan. 09, 2026 (GLOBE NEWSWIRE) -- Madrigal Pharmaceuticals, Inc. (NASDAQ: MDGL), a biopharmaceutical company focused on delivering novel therapeutics for metabolic dysfunction-associated steatohepatitis (MASH), today announced an exclusive global license agreement with Pfizer for ervogastat, a clinical-stage oral DGAT-2 inhibitor, strengthening the company's leadership in shaping the next generation of MASH therapies and combination regimens. DGAT-2 inhibitors work by blocking the final step in triglyceride assembly and storage, resulting in lower hepatic triglycerides, reduced lipotoxic fat and decreased inflammation in the liver.

The company will present more details at the 44th Annual J.P. Morgan Healthcare Conference on Monday, January 12, 2026 at 1:30 p.m. PST. The presentation will be webcast live and can be accessed here or by visiting Madrigal's Investor Relations site, Events and Presentations page.

"Madrigal is committed to building the industry-leading pipeline that will shape the future of MASH care and improve patient outcomes," said Bill Sibold, Chief Executive Officer of Madrigal. "As the next wave of innovation moves toward combination therapies, Rezdiffra's strong profile as a liver-directed, well-tolerated, once-daily oral therapy positions it as the ideal foundation. Our global license agreement for ervogastat aligns with our long-term leadership ambition, and we believe Madrigal is uniquely positioned to advance this promising Phase 2 asset and unlock its full clinical and commercial value through a development program focused on combination therapy with Rezdiffra."

"There is a compelling scientific rationale for studying ervogastat in combination with Rezdiffra," said Professor Quentin Anstee, Ruth & Lionel Jacobson Chair of Personalised Medicine, Faculty of Medical Sciences, Newcastle University, and lead investigator on a prior Phase 2 ervogastat study. "A majority of patients in the Phase 2 study of ervogastat achieved a 50% reduction in liver fat as measured by MRI-PDFF; this is an important measure of efficacy that has been predictive of longer-term fibrosis improvement for other mechanisms, including Rezdiffra. Because Rezdiffra and ervogastat act on distinct yet complementary pathways that drive liver fat accumulation, this combination has potential to produce additive antisteatotic and antifibrotic efficacy."

"MASH is a complex disease that will require multiple treatment approaches to address the full spectrum of patient needs," said David Soergel, M.D., Chief Medical Officer of Madrigal. "With Rezdiffra as the anchor and a world-class R&D team, our broadened portfolio now spans several key pathways that will define the future of MASH treatment. Along with studies of our oral GLP-1 receptor agonist, we look forward to adding ervogastat to our growing clinical program."

Ervogastat (PF-06865571) is a liver-directed, oral diacylglycerol O-acyltransferase 2 (DGAT-2) inhibitor. DGAT-2 inhibitors work by blocking the final step in triglyceride assembly and storage, resulting in lower hepatic triglycerides, reduced lipotoxic fat and decreased inflammation. This differentiated mechanism offers the potential for additive clinical benefit when combined with Rezdiffra, a thyroid hormone receptor-β (THR-β) agonist that increases the cell's ability to process fat via mitochondrial biogenesis. In a published Phase 2 study, 72% of patients treated with ervogastat (150mg) achieved at least a 30% reduction in liver fat, and 61% achieved at least a 50% reduction, as measured by MRI-PDFF. Improvements in liver enzymes and liver stiffness as measured by vibration-controlled transient elastography (VCTE) were also observed, and all active doses studied were well tolerated. In 2026, Madrigal plans to conduct a drug-to-drug interaction study with Rezdiffra and consult with the FDA on design of a Phase 2 combination trial.

Under the agreement, Pfizer has granted Madrigal an exclusive global license to develop, manufacture and commercialize ervogastat, as well as rights to two additional early-stage MASH pipeline assets. Pfizer received an upfront payment of $50 million USD, which will be reflected in Madrigal's fourth quarter 2025 expenses, and is eligible for additional payments if certain milestones are achieved, as well as royalties on net sales.

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 metabolic dysfunction-associated steatohepatitis (MASH) with moderate to advanced liver scarring (fibrosis), but not with cirrhosis of the liver.

This indication is approved based on improvement of MASH 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 MASH.
- 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.
    - A pregnancy safety study for women who take Rezdiffra during pregnancy collects information about the health of you and your baby. You or your healthcare provider can report your pregnancy by visiting https://pregnancyregistry.madrigalpharma.com/ or calling 1-800-905-0324.
- 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, 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) or stomach pain/tenderness.
- gallbladder problems. Gallbladder problems such as gallstones, or inflammation of the gallbladder, or inflammation of the pancreas from gallstones can occur with MASH 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 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 a combination therapy of Rezdiffra and ervogastat for the treatment of MASH, Madrigal’s ability to build its pipeline and Madrigal’s development goals and timelines for ervogastat. 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 or any other product candidate; 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; our ability to enter into strategic transactions and realize the anticipated benefits of any such transaction; our ability to obtain, maintain and protect our intellectual property; 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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Source: Madrigal Pharmaceuticals, Inc.