Madrigal Pharmaceuticals Enters into Exclusive Global License Agreement for Oral GLP-1 Receptor Agonist with CSPC Pharmaceutical Group Limited

July 30, 2025

- *License agreement supports Madrigal's pipeline strategy to develop innovative combination treatments for MASH, anchored by its foundational therapy Rezdiffra™ (resmetirom)*
- *Combining Rezdiffra with the oral GLP-1, SYH2086, offers potential for a best-in-class MASH treatment in a once-a-day, well-tolerated pill*

CONSHOHOCKEN, Pa., July 30, 2025 (GLOBE NEWSWIRE) -- Madrigal Pharmaceuticals, Inc. (NASDAQ: MDGL) ("Madrigal") today announced that it has entered into an exclusive global license agreement with CSPC Pharmaceutical Group Limited (HKEX Stock CodeL 1093) ("CSPC") for SYH2086, a preclinical oral small molecule glucagon-like peptide-1 (GLP-1) receptor agonist and orforglipron derivative. Madrigal plans to initiate clinical development in the first half of 2026.

"We've made remarkable progress this year advancing our strategic priorities – from the continued successful launch of Rezdiffra, to securing new IP protection through 2044, to laying the groundwork for Rezdiffra's next stages of growth in F4c and Europe," said Bill Sibold, Chief Executive Officer of Madrigal. "This agreement to acquire global rights to SYH2086 aligns perfectly with our long-term goal to extend our leadership in MASH by building a pipeline anchored by Rezdiffra. We believe a combination of Rezdiffra and SYH2086 has the potential to deliver a best-in-class oral treatment for patients with MASH."

David Soergel, M.D., Chief Medical Officer of Madrigal, added, "The clinical rationale for developing a combination therapy with Rezdiffra and an oral GLP-1 is clear: we want to optimize efficacy and tolerability in MASH by balancing the weight loss from a GLP-1 with the fibrosis and lipid reduction of Rezdiffra in a once-a-day pill. In the pivotal Phase 3 MAESTRO-NASH trial, even modest weight loss of five percent or more enhanced Rezdiffra's antifibrotic benefit, so we are confident that combination therapy with SYH2086 has the potential to provide increased efficacy for patients with MASH."

"We are pleased to announce the in-license of our oral GLP-1 by Madrigal, an innovative company that pioneered the first approved treatment for MASH," said Dongchen Cai, Chairman of the Board, CSPC. "We believe Madrigal's strong clinical development and commercial capabilities will help unlock the full potential of SYH2086 to benefit patients."

Financial Considerations
Under the agreement, CSPC has granted Madrigal an exclusive global license to develop, manufacture, and commercialize SYH2086. CSPC will receive an upfront payment of $120 million and is eligible to receive up to $2 billion in milestone payments if certain development, regulatory and commercial milestones are achieved, as well as royalties on net sales. CSPC may develop and commercialize other oral GLP-1 agonists in China subject to certain conditions. The transaction is anticipated to close in the fourth quarter of 2025, subject to the applicable regulatory clearance.

About CSPC Pharmaceutical Group's SYH2086
SYH2086, a preclinical candidate developed by the CSPC with complete global intellectual property rights, is a novel oral small molecule GLP-1 receptor agonist. GLP-1 receptor agonists are a class of drugs that exert their effects through the GLP-1 receptor and have been developed as treatments for the management of type 2 diabetes and obesity. Their core mechanisms of action include enhancing insulin secretion, suppressing glucagon release, delaying gastric emptying, and reducing appetite, thereby offering both glycemic control and weight loss benefits. Preclinical data demonstrated that SYH2086 exhibited excellent in vitro agonistic activity as well as in vivo glucose-lowering and weight-loss effects, with a linear pharmacokinetic (PK) profile over a wide dose range across multiple animal species, with no significant safety risks observed.

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 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 Statement
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 Madrigal's expected development timelines for SYH2086, the potential benefit of SYH2086 in combination with Rezdiffra, the anticipated timeline to close the licensing transaction and Madrigal's leadership position in the MASH sector. 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 related to the parties ability to close the transaction in a timely manner or at all; risks associated with development of early stage candidates; risks related to obtaining and maintaining regulatory approvals, including, but not limited to, potential regulatory delays or rejections; 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 timing and outcomes of clinical trials of Rezdiffra (resmetirom); 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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