Madrigal Pharmaceuticals Announces Preliminary* Fourth-Quarter and Full-Year 2024 Net Sales, Year-End Cash and Total Patients on Rezdiffra

- *Preliminary fourth-quarter and full-year 2024 Rezdiffra™ (resmetirom) net sales ranges of $100 million to $103 million and $177 million to $180 million, respectively*
- *Preliminary year-end 2024 cash, cash equivalents, restricted cash and marketable securities of approximately $931 million*
- *As of year-end 2024, more than 11,800 patients on Rezdiffra*
- *Madrigal to present at the 43rd Annual J.P. Morgan Healthcare Conference at 2:15 p.m. PST (5:15 p.m. EST) on Wednesday January 15, 2025*

CONSHOHOCKEN, Pa., Jan. 13, 2025 – Madrigal Pharmaceuticals, Inc. (NASDAQ:MDGL), a biopharmaceutical company focused on delivering novel therapeutics for metabolic dysfunction-associated steatohepatitis (MASH), today announced an update on its business performance, including preliminary* fourth-quarter and year-end net sales, year-end cash and patients on Rezdiffra.

Bill Sibold, Chief Executive Officer of Madrigal, stated, "2024 was a transformational year for Madrigal and the MASH field. Rezdiffra received U.S. FDA approval as the first and only treatment for MASH; we built an expert team for launch; and now more than 11,800 patients are on therapy. Our success reflects exceptional execution and the urgent need for treatments for this serious liver disease, expected to become the leading cause of liver transplants in the U.S."

Sibold continued, "As we build momentum in the U.S., we are pursuing additional growth opportunities, including preparing for European expansion in the second half of 2025. Looking ahead, the MAESTRO-NASH OUTCOMES trial in compensated cirrhosis could unlock further growth, positioning Rezdiffra as the only treatment for F2 to F4 MASH and the only therapy with outcomes data this decade."

Preliminary Fourth-Quarter and Full-Year 2024 Financial Performance and Rezdiffra Patients

- Preliminary fourth-quarter and full-year 2024 Rezdiffra net sales ranges of $100 million to $103 million and $177 million to $180 million, respectively.
- Preliminary year-end 2024 cash, cash equivalents, restricted cash and marketable securities of approximately $931 million.
- More than 11,800 patients on Rezdifrra as of year-end 2024.

2024 Accomplishments

- On February 8, the Rezdiffra Phase 3 MAESTRO-NASH trial results were published in *The New England Journal of Medicine*; the paper was subsequently chosen as one of the journal's 14 notable scientific research articles of 2024.

- On March 5, announced EMA validation of the Marketing Authorization Application (MAA) for Rezdiffra; Company anticipates EMA decision mid-2025 with a country-by-country launch in Europe expected to commence with Germany in second-half 2025, subject to EMA approval.
- On March 14, received U.S. FDA approval for Rezdiffra, the first and only approved MASH therapy, and subsequently launched the medicine.
- On October 21, announced completion of enrollment in the MAESTRO-NASH OUTCOMES study, an event-driven trial evaluating Rezdiffra in patients with compensated MASH cirrhosis. Positive results could position Rezdiffra to become the first treatment available for this advanced and underserved population.

J.P. Morgan Healthcare Conference Presentation and Webcast
Bill Sibold, Chief Executive Officer of Madrigal, will discuss these updates as part of a webcast presentation at the 43rd annual J.P. Morgan Healthcare Conference in San Francisco on Wednesday, January 15 at 2:15 p.m. PST (5:15 p.m. EST). The event will be available via live webcast on Madrigal's Investor Relations page [LINK HERE].

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 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. 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 preliminary selected financial results, Madrigal's ability to execute its strategy, the planned commercial launch of Rezdiffra in Europe and expectations regarding the MAESTRO NASH OUTCOMES trial. Forward-looking statements are subject to a number of risks and uncertainties including, but not limited to: the assumptions underlying the forward-looking statements; the finalization and audit of Madrigal's fourth quarter and 2024 fiscal year financial results which could potentially result in changes or adjustments to the selected preliminary financial results presented herein; 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 does not have commercial experience; 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 studies, 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 studies; 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; enrollment and trial conclusion uncertainties; 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; the ability to service indebtedness and otherwise comply with debt covenants; outcomes or trends from competitive studies; future topline data timing or results; our ability to prevent and/or mitigate cyber-attacks; the timing and outcomes of clinical studies 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, or 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, 2023, filed with the SEC on February 28, 2024, and Part II, Item 1A of its Quarterly Report on Form 10-Q for the quarter ended September 30, 2024, filed with the SEC on October 31, 2024, and as updated from time to time by Madrigal's other filings with the SEC.

** Fourth quarter and full-year 2024 financial results are preliminary, unaudited, subject to adjustment, and provided as an approximation in advance of the Company's announcement of complete financial results in February 2025. This information is based on currently available information. Madrigal has provided estimated ranges primarily because financial closing controls and procedures for the quarter are not yet completed and final results may therefore vary from these estimates. These preliminary estimates have not been audited by Madrigal's independent registered public accounting firm.*

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