



Rezdiffra™ (resmetirom) FDA Approval Conference Call

March 2024

NASDAQ: MDGL

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Forward Looking Statements

This presentation includes “forward-looking statements” made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, that are based on Madrigal’s beliefs and assumptions and on information currently available to it, but are subject to factors beyond its control. Forward-looking statements reflect management’s current knowledge, assumptions, judgment and expectations regarding future performance or events. Forward-looking statements include all statements that are not historical facts; statements referenced by forward-looking statement identifiers; and statements regarding: Rezdiffra (resmetirom) and its expected use for treating NASH with moderate to advanced fibrosis; the initiation of the commercial launch of Rezdiffra including statements regarding commercial insurance and the anticipated time to fill prescriptions; estimates of patients diagnosed with NASH and market opportunities; the relationship between NASH progression and adverse patient outcomes; the estimated clinical burden of uncontrolled NASH; analyses for patients with NASH with moderate to advanced fibrosis concerning potential progression to cirrhosis, decompensated cirrhosis, liver transplant or death; cardiovascular risks, comorbidities and outcomes; health economics assessments or projections; indicating Rezdiffra has been shown to improve the fibrosis that is associated with progression to cirrhosis and its complications and resolve the underlying inflammation that drives the disease; projections or objectives for obtaining full approval for Rezdiffra (resmetirom), including those concerning potential clinical benefit to support potential full approval; regarding post-approval requirements and commitments; reduced risk of progression to cirrhosis, liver failure, need for liver transplant and premature mortality; treatment paradigm; improved liver enzymes, fibrosis biomarkers and imaging tests; the potential efficacy and safety of Rezdiffra (resmetirom) for noncirrhotic NASH patients and cirrhotic NASH patients; possible or assumed future results of operations and expenses, business strategies and plans (including ex-US. Launch/partnering plans); research and development activities, the timing and results associated with the future development of Rezdiffra (resmetirom), the timing and completion of projected future clinical milestone events, including enrollment, additional studies, the potential to support an additional indication for Rezdiffra (resmetirom) in patients with well-compensated NASH cirrhosis; optimal dosing levels for Rezdiffra (resmetirom); potential NASH or NAFLD and potential patient benefits with Rezdiffra (resmetirom), including future NASH resolution, safety, fibrosis treatment, cardiovascular effects, lipid treatment, and/or biomarker effects with Rezdiffra (resmetirom); and strategies, objectives and commercial opportunities, including potential prospects or results.

Forward-looking statements can be identified by terms such as “accelerate,” “achieve,” “allow,” “anticipates,” “appear,” “be,” “believes,” “can,” “confidence,” “continue,” “could,” “demonstrates,” “design,” “estimates,” “expectation,” “expects,” “forecasts,” “future,” “goal,” “help,” “hopeful,” “inform,” “intended,” “intends,” “may,” “might,” “on track,” “planned,” “planning,” “plans,” “positions,” “potential,” “powers,” “predicts,” “predictive,” “projects,” “seeks,” “should,” “will,” “will achieve,” “will be,” “would” or similar expressions and the negatives of those terms.

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 does not have commercial experience; 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 our product; the potential inability to raise sufficient capital to fund ongoing operations as currently planned or to obtain financings on terms similar to those arranged in the past; 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; and uncertainties concerning analyses or assessments outside of a controlled clinical trial. 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 as updated from time to time by Madrigal’s other filings with the SEC.

Agenda



1 Introduction

Bill Sibold
Chief Executive Officer
Madrigal Pharmaceuticals

2 Disease Overview and Current Treatment Paradigm

Stephen Harrison, M.D.
Medical Director, Pinnacle Clinical Research; Visiting Professor of Hepatology, Oxford; Lead Principal Investigator of the MAESTRO studies

3 Review of Rezdiffra Label and Clinical Data

Becky Taub, M.D.
Chief Medical Officer and President of R&D
Madrigal Pharmaceuticals

4 Rezdiffra Commercial Strategy

Bill Sibold

5 Q&A

Bill Sibold, Stephen Harrison, Becky Taub and Mardi Dier
Chief Financial Officer
Madrigal Pharmaceuticals

Terri's Story



Terri is a patient leader in the NASH community

Her story illustrates the serious burden of NASH progression

- She was told: *“You have fatty liver, but don’t worry about it”*
- NASH cirrhosis was later detected during gallbladder surgery
- Developed ascites, hepatic encephalopathy and then hepatocellular carcinoma
- Ultimately had liver transplant, but difficult post-transplant experience



NASH, nonalcoholic steatohepatitis. **Ascites**, excess abdominal fluid and swelling. **Hepatic encephalopathy**, impaired cognitive function due to the liver’s inability to filter toxins from the blood. **Hepatocellular carcinoma**, liver cancer.

Key Takeaways for Today's Call

➤ Rezdifra approval is an **unprecedented milestone**

➤ **First-in-class label** positions Rezdifra as **foundational therapy**

➤ Set to deliver **successful launch** and **maximize potential**

Strong Label Positions Rezdifra as Foundational Therapy



NOW APPROVED
Rezdifra[™]
resmetirom tablets
60mg · 80mg · 100mg



Indicated for the treatment of NASH with moderate to advanced liver fibrosis (F2/F3)



No biopsy requirement in label



Once-daily, oral; simple dosing



No contraindications; no boxed warning; no monitoring requirements beyond SOC

Landmark label for first FDA-approved medicine for NASH
sets standard for potential future treatments



Disease Overview and Current Treatment Paradigm

NASH is a Chronic and Progressive Liver Disease



NAFLD: Nonalcoholic Fatty Liver Disease:
Entire spectrum of fatty liver disease in individuals without significant alcohol consumption

Normal Liver	NAFL: Nonalcoholic Fatty Liver	NASH: Nonalcoholic Steatohepatitis	NASH with Fibrosis	Cirrhosis
 <p>→ Fat accumulation</p>	 <ul style="list-style-type: none"> Isolated steatosis (fat in ≥5% of hepatocytes) 	 <ul style="list-style-type: none"> Steatosis Ballooning Inflammation 	 <ul style="list-style-type: none"> F1: fibrosis stage 1 = Mild <div style="border: 1px solid blue; padding: 5px;"> <p><i>Moderate to Advanced</i></p> <ul style="list-style-type: none"> F2: fibrosis stage 2 F3: fibrosis stage 3 </div>	 <ul style="list-style-type: none"> F4: fibrosis stage 4 = Cirrhosis

NASH is the more advanced form of NAFLD, which can progress to cirrhosis, liver failure, or result in premature death¹⁻⁵

Hepatocytes, liver cells. **Steatosis**, excess fat in liver cells. **Steatohepatitis**, build up of excess fat in liver cells causing inflammation and damage.

1. Sheka AC, et al. JAMA. 2020;323(12):1175-83. 2. Alkhoury N, McCullough AJ. Gastroenterol Hepatol (N Y). 2012;8(10):661-8. 3. EASL-EASD-EASO. J Hepatol. 2016;64:1388-402. 4. Diehl AM, Day C. NEJM. 2017;377:3063-72. 5. Honda et al. Int J Mol Sci. 2020;21:4039.

The NASH Patient Journey, Diagnosis and Treatment



Initial Suspicion & Referral



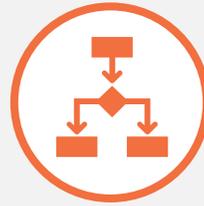
Initial suspicion at primary care



Referral to a specialist (Hep/GI)



Diagnosis & Risk Assessment at Hep/GI



Confirmation of NASH diagnosis and fibrosis using NITs

Treatment for Moderate to Advanced (F2/F3) NASH Patients

+ Ongoing Diet, Exercise and Co-morbidity management

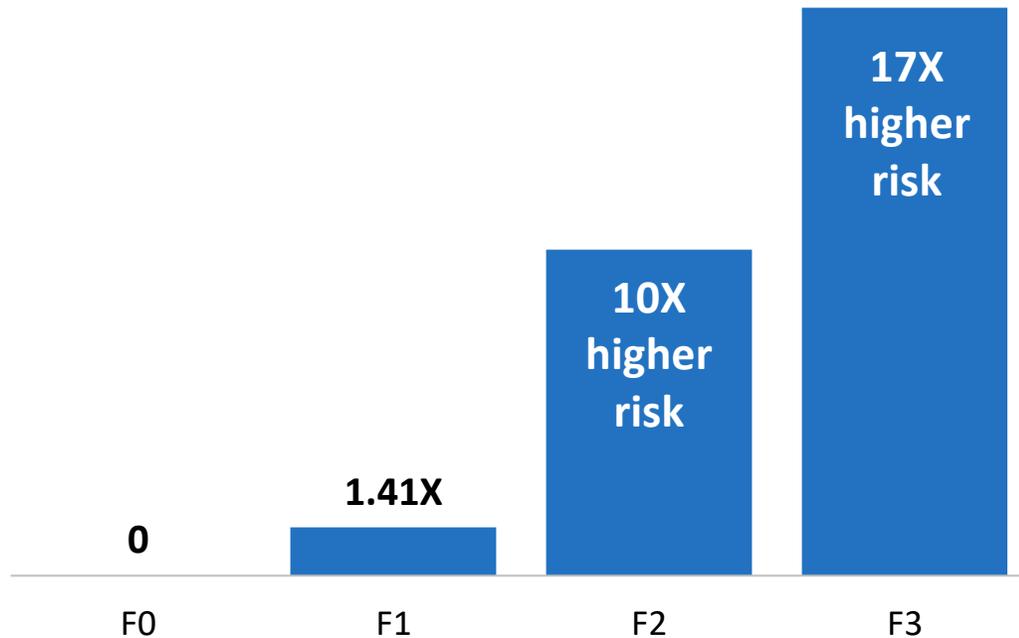
Prior Approach:
No treatments available to halt or improve fibrosis; resolve NASH

TODAY'S Approach:



Goal: Treat Before Negative Patient Outcomes Occur

Up to 17X Higher Risk of Liver-Related Mortality in Patients with NASH with Moderate to Advanced Fibrosis¹



~22%

of patients with F3
fibrosis **progress to
cirrhosis within 2 years²**



Goal: Treat NASH with moderate to advanced fibrosis **before negative patient outcomes occur**

1. Angulo P, et al. Gastroenterology. 2015;149:389-397. 2. Loomba R, Adams L. Hepatology. 2019;70(6):1885-1888.



Review of Rezdiffra Label and Clinical Data

Rezdiffra Approval Supported by One of the Most Comprehensive Clinical Development Programs in NASH



MAESTRO-NAFLD-1 Safety

Evaluates safety and tolerability as measured by incidence of adverse events

52 weeks (completed)

~**1,200** patients, including 200 with compensated cirrhosis



MAESTRO-NASH Moderate to Advanced Fibrosis

Evaluates NASH resolution and/or fibrosis improvement on liver biopsy and composite clinical events

52 weeks biopsy (completed)
54 months clinical outcomes

~**1,750** patients (ongoing)



MAESTRO-NASH OUTCOMES Compensated Cirrhosis

Event-driven trial evaluating progression to hepatic decompensation

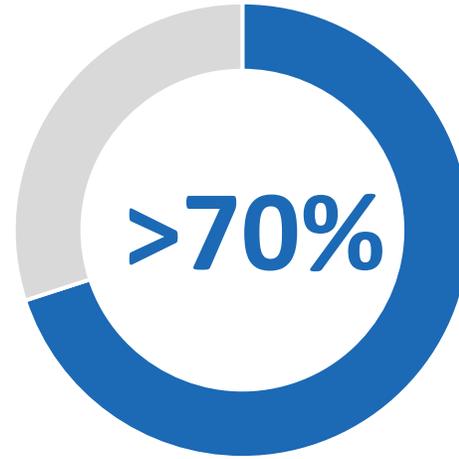
~36 months

~**700** patients (recruiting)

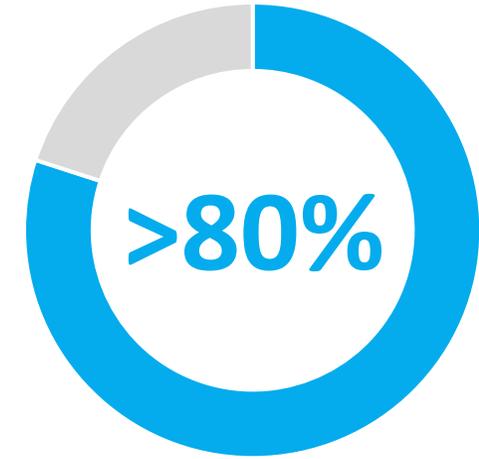
Phase 3 Data in *New England Journal of Medicine* Demonstrate Broad Response



50% of Rezdiffra-treated patients showed either **NASH resolution or fibrosis improvement**¹



>70% of patients achieved a **>30% reduction in non-invasive test results (MRI-PDFF)**²



> 80% of Rezdiffra-treated patients achieved **fibrosis reversal or no fibrosis progression**³

MRI-PDFF, magnetic resonance imaging-proton density fat fraction. Source: Harrison S, et al. *N Engl J Med*. 2024 Feb;390(6):497-509. 1. 50% of patients on 100mg with eligible biopsies at 52 weeks achieved NASH resolution or fibrosis improvement. *NEJM* supplement Table S9. 2. >70% of patients on 100mg achieved >30% reduction in MRI-PDFF at 52 weeks. *NEJM* supplement Table S10. 3. >80% of Rezdiffra-treated patients (F1B or F2 at baseline) achieved fibrosis reversal or no fibrosis progression at 52 weeks. *NEJM* supplement Figure S5.

Rezdiffra Indication: No Biopsy; Defined Patient Population

INDICATIONS AND USAGE¹

REZDIFFRA is a thyroid hormone receptor beta (THR-beta) agonist indicated in conjunction with diet and exercise for the treatment of adults with noncirrhotic nonalcoholic steatohepatitis (NASH) with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis).

This indication is approved under accelerated approval based on improvement of NASH and fibrosis. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.



NASH with moderate to advanced liver fibrosis (consistent with F2/F3)



No biopsy requirement



No contraindications; no boxed warning; no monitoring requirements beyond SOC

1. Rezdiffra prescribing information. West Conshohocken, PA: Madrigal Pharmaceuticals, Inc.; 2024. **SOC**, standard of care.

Rezdiffra Indication: Clearly States Where Rezdiffra Should Not Be Used



INDICATIONS AND USAGE¹

REZDIFFRA is a thyroid hormone receptor beta (THR-beta) agonist indicated in conjunction with diet and exercise for the treatment of adults with noncirrhotic nonalcoholic steatohepatitis (NASH) with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis).

This indication is approved under accelerated approval based on improvement of NASH and fibrosis. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Limitations of Use

Avoid use of REZDIFFRA in patients with decompensated cirrhosis



Avoid use of Rezdiffra in patients with decompensated cirrhosis

1. Rezdiffra prescribing information. West Conshohocken, PA: Madrigal Pharmaceuticals, Inc.; 2024.

Rezdiffra Label: Simple Dosing Profile

DOSING AND ADMINISTRATION¹

The recommended dosage of REZDIFFRA is based on actual body weight. For patients weighing:

- <100 kg, the recommended dosage is 80 mg orally once daily.
- ≥100 kg, the recommended dosage is 100 mg orally once daily.

Administer REZDIFFRA with or without food.

DOSING FORMS AND STRENGTHS¹

Tablets: 60 mg, 80 mg, or 100 mg



Simple, weight-based, no titration



Oral, once-daily



3 strengths: 60 mg, 80 mg, 100 mg

1. Rezdiffra prescribing information. West Conshohocken, PA: Madrigal Pharmaceuticals, Inc.; 2024.

Rezdiffra Label: No Contraindications; Warnings and Precautions Reinforce Standard of Care



CONTRAINDICATIONS¹

None.

WARNINGS AND PRECAUTIONS¹

- Hepatotoxicity: Monitor patients during treatment with REZDIFFRA for elevations in liver tests and for the development of liver-related adverse reactions. Discontinue REZDIFFRA and continue to monitor the patient if hepatotoxicity is suspected.
- Gallbladder-Related Adverse Reactions: Cholelithiasis and cholecystitis were observed more often in REZDIFFRA-treated patients. If cholelithiasis is suspected, gallbladder diagnostic studies and appropriate clinical follow-up are indicated. If an acute gallbladder event such as acute cholecystitis is suspected, interrupt REZDIFFRA treatment until the event is resolved.



No contraindications; no boxed warning



Hepatotoxicity; one patient from safety trial (did not have NASH); label reinforces standard of care



Gallbladder-related AEs; higher incidence in NASH patients; overall incidence low with Rezdiffra (<1%)

1. Rezdiffra prescribing information. West Conshohocken, PA: Madrigal Pharmaceuticals, Inc.; 2024.

Rezdiffra Label: Strong Clinical Efficacy on Fibrosis Improvement and NASH Resolution



Clinical Efficacy in Rezdiffra Label¹

	Placebo N=294	80 mg N=298	100 mg N=296
Improvement in liver fibrosis and no worsening of steatohepatitis			
Response rate, Pathologist A (%)	15	23	28
<i>Difference in response rate vs. placebo (95% CI)</i>		8 (2, 14)	13 (7, 20)
Response rate, Pathologist B (%)	13	23	24
<i>Difference in response rate vs. placebo (95% CI)</i>		11 (5, 17)	11 (5, 17)
Resolution of steatohepatitis and no worsening of liver fibrosis			
Response rate, Pathologist A (%)	13	27	36
<i>Difference in response rate vs. placebo (95% CI)</i>		14 (8, 20)	23 (16, 30)
Response rate, Pathologist B (%)	9	26	24
<i>Difference in response rate vs. placebo (95% CI)</i>		17 (11, 23)	15 (9, 21)

From Rezdiffra Label¹

- *Two pathologists, Pathologist A and Pathologist B, independently read the liver biopsies for each patient.*
 - *Both the 80 mg once daily and the 100 mg once daily dosages of REZDIFFRA demonstrated improvement on these histopathology endpoints at Month 12 compared to placebo.*
- *In a statistical analysis incorporating both pathologists' independent readings, REZDIFFRA achieved statistical significance on both histopathology endpoints for both doses.*

1. Rezdiffra prescribing information. West Conshohocken, PA: Madrigal Pharmaceuticals, Inc.; 2024. Label: The 888 population was based on patients determined to be F2/F3 based on scoring of the baseline liver biopsy by a central reviewer at the time of randomization into the study. FDA Endpoints: Liver fibrosis was evaluated on the NASH Clinical Research Network (CRN) fibrosis score as 0 to 4. Resolution of steatohepatitis was defined as a score of 0–1 for inflammation, 0 for ballooning, and any value for steatosis. No worsening of steatohepatitis was defined as no increase in score for ballooning, inflammation, or steatosis. Estimated using the Mantel-Haenszel method stratified by baseline type 2 diabetes status (presence or absence) and fibrosis stage (F2 or F3). 95% stratified Newcombe confidence intervals (CIs) are provided. Patients with missing liver biopsy at Month 12 are considered a non-responder.

Consistent Efficacy Across All Endpoints, Doses, Patient Populations



	Label F2/F3 Population ^{1,2}						Madrigal F1B/F2/F3 Population ^{1,2}					
	MAESTRO-NASH Label Endpoints			MAESTRO-NASH Prespecified Endpoints			MAESTRO-NASH Label Endpoints			MAESTRO-NASH Prespecified Endpoints (NEJM)		
	Placebo	80 mg	100 mg	Placebo	80 mg	100 mg	Placebo	80 mg	100 mg	Placebo	80 mg	100 mg
Fibrosis Improvement	14%	23% p < 0.001	26% p < 0.001	16%	25% p = 0.002	27% p < 0.001	12%	23% p < 0.001	24% p < 0.001	14%	24% p < 0.001	26% p < 0.001
NASH Resolution	11%	25% p < 0.001	30% p < 0.001	9%	24% p < 0.001	29% p < 0.001	12%	27% p < 0.001	32% p < 0.001	10%	26% p < 0.001	30% p < 0.001
Number of Patients	888			888			966			966		

1. Label: The 888 population was based on patients determined to be F2/F3 based on scoring of the baseline liver biopsy by a central reviewer at the time of randomization into the study. Label Endpoints: Liver fibrosis was evaluated on the NASH Clinical Research Network (CRN) fibrosis score as 0 to 4. Resolution of steatohepatitis was defined as a score of 0–1 for inflammation, 0 for ballooning, and any value for steatosis. No worsening of steatohepatitis was defined as no increase in score for ballooning, inflammation, or steatosis. Estimated using the Mantel-Haenszel method stratified by baseline type 2 diabetes status (presence or absence) and fibrosis stage (F2 or F3). 95% stratified Newcombe confidence intervals (CIs) are provided. Patients with missing liver biopsy at Month 12 are considered a non-responder.

2. MADRIGAL: 966 population of F1B, F2, F3 patients was based on the primary efficacy read of baseline slides that was conducted by Path A and Path B near the Week 52 completion date. Madrigal Endpoints: Resolution of NASH Resolution of steatohepatitis was defined as a score of 0–1 for inflammation, 0 for ballooning, and any value for steatosis with no worsening of fibrosis stage and at least a 2-point reduction in NAS. Fibrosis improvement, at least a 1 stage improvement in fibrosis with no worsening of NAS. NAS, NAFLD Activity Score, the unweighted sum of the scores for steatosis (0-3), lobular inflammation (0-3), and ballooning (0-2); thus ranging from 0 to 8.

Rezdiffra Sets the Safety Bar in NASH



Common Adverse Reactions Reported with Rezdiffra^{1,2}

Adverse Reaction	Placebo	Rezdiffra 80 mg Once Daily	Rezdiffra 100 mg Once Daily
	N=294	N=298	N=296
	n (EAIR ¹)	n (EAIR ¹)	n (EAIR ¹)
Diarrhea	52 (14)	78 (23)	98 (33)
Nausea	36 (9)	65 (18)	51 (15)
Pruritus	18(4)	24(6)	36 (10)
Vomiting	15 (4)	27 (7)	30 (8)
Constipation	18 (4)	20 (5)	28 (8)
Abdominal pain	18 (4)	22 (5)	27 (7)
Dizziness	6 (1)	17 (4)	17 (4)

- Most frequent AEs were GI-related and generally transient with resolution over time
- Diarrhea lasted on average 2-3 weeks often characterized as loose stools or worsening of underlying diarrhea

Pruritus, itchiness of skin; **AEs**, adverse events; **EAIR**, exposure-adjusted incidence rate; **PY**, person-years.

1. The EAIR per 100 PY can be interpreted as an estimated number of first occurrences of the adverse reaction of interest if 100 patients are treated for one year. 2. Rezdiffra prescribing information. West Conshohocken, PA: Madrigal Pharmaceuticals, Inc.; 2024.

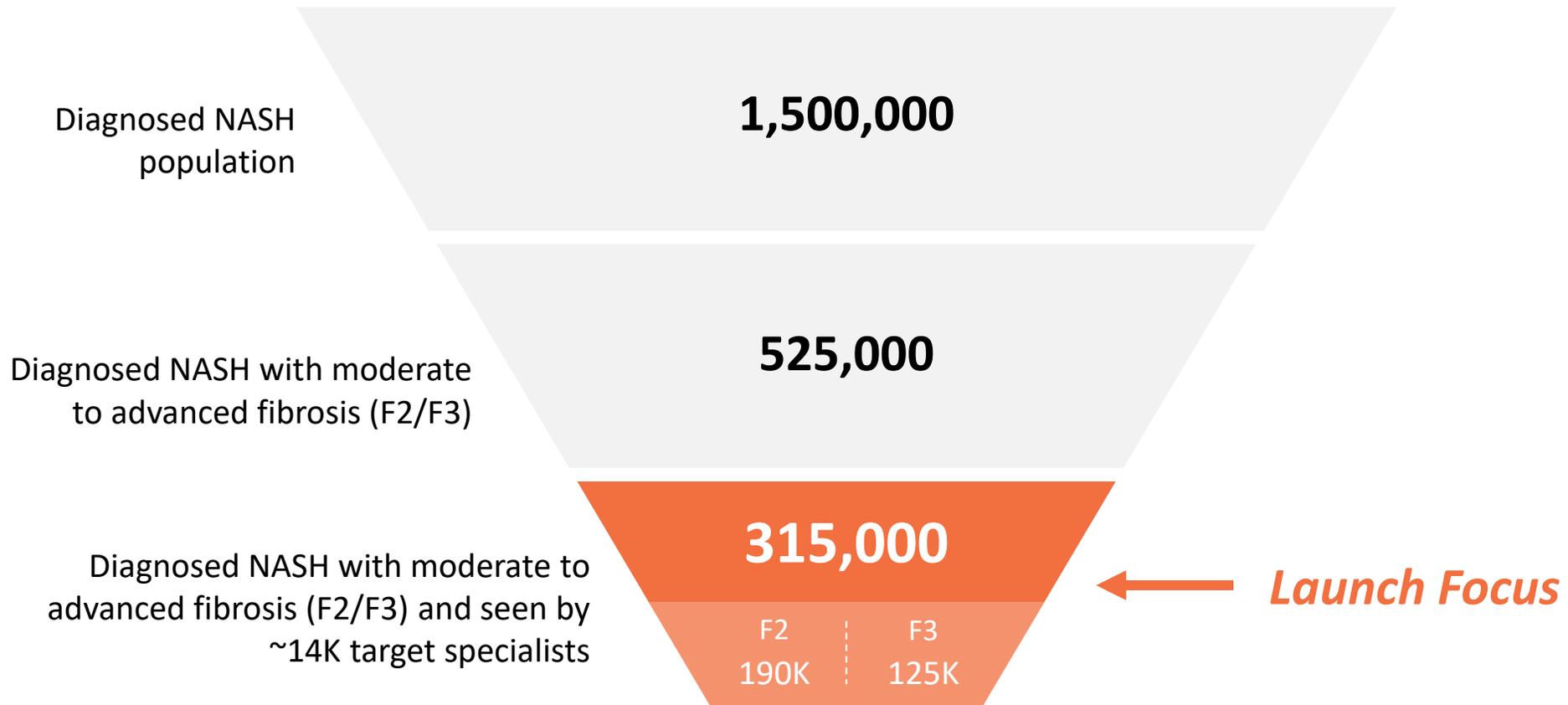


Rezdifra Commercial Strategy

Specialty Launch Designed to Focus on 315,000 U.S. Patients

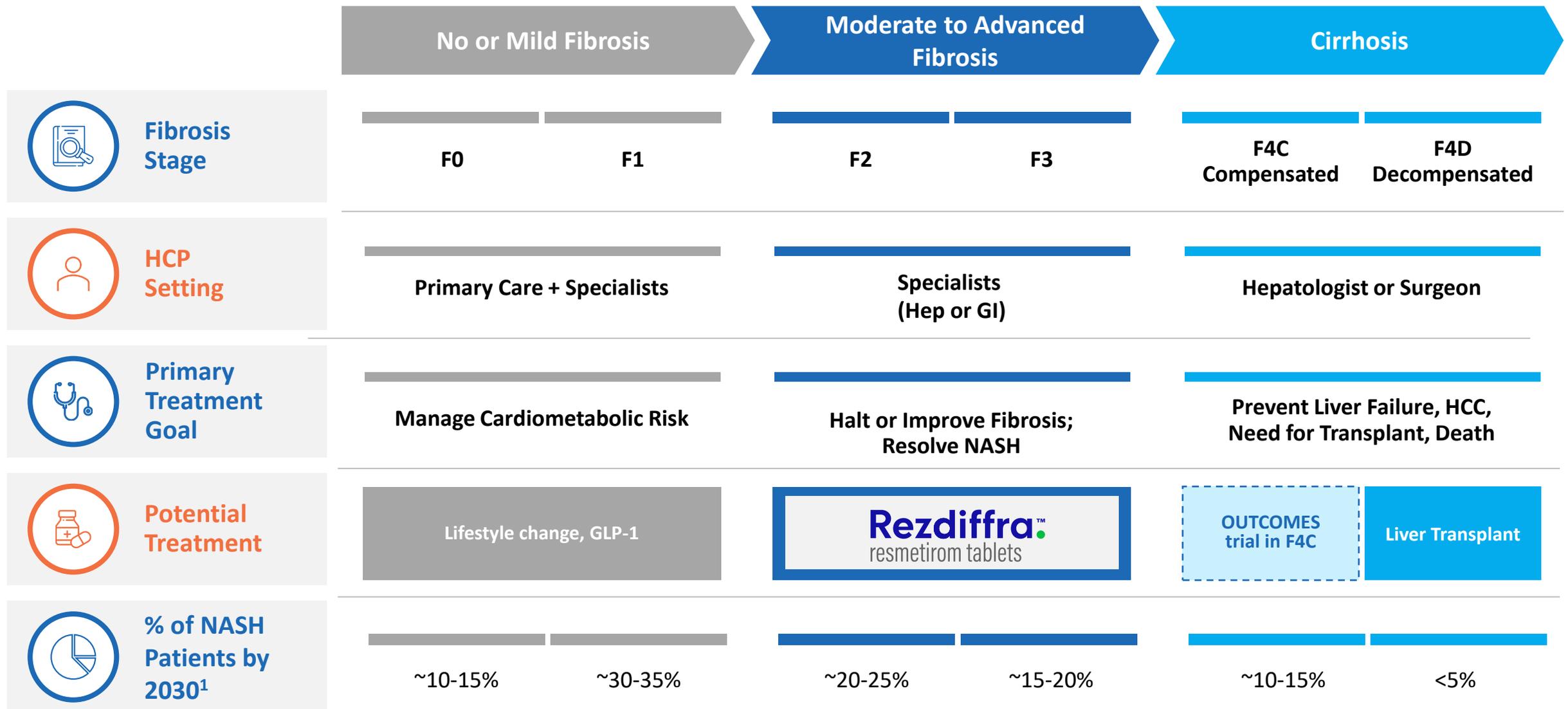


U.S. NASH Waterfall at Launch¹



1. Forian Claims Data; Clearview Analysis; Fishman J, et al. Poster presented at: ISPOR 2023; May 7-10, 2023; Boston, MA. Data on file: REF-00571.

Rezdiffra's Differentiated Position in the NASH Treatment Paradigm



Hep, hepatologist; GI, gastroenterologist; HCC, hepatocellular carcinoma. 1. Estes C, et al. Hepatology. 2018 Jan;67(1):123-133.

Our Stakeholders Are Ready and Waiting for a Therapy Like Rezdiffra



Physicians

In the treatment of NASH with moderate to advanced fibrosis:

~88% of heps/GIs see a high urgency to treat

~85% of heps/GIs see Rezdiffra offering high clinical utility



Patients

When seeking a treatment for NASH with moderate to advanced fibrosis:

89% would proactively seek resmetirom if it were available

“There is a ticking time bomb inside me, I don’t know when it will go off.”



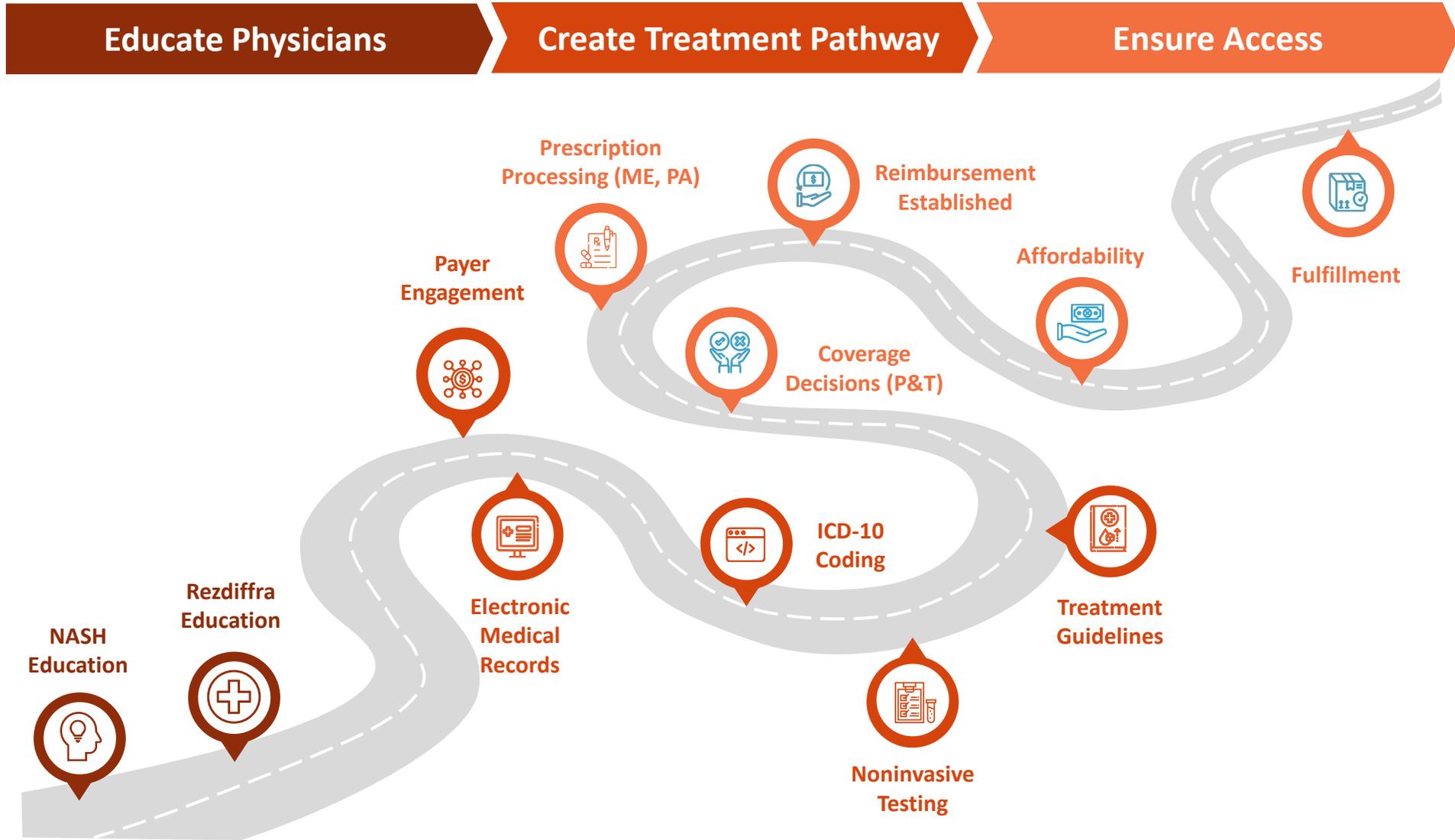
Payers

Vast majority of payers have a good understanding of disease state

Nearly 100% viewed need to treat NASH with moderate to advanced fibrosis as high to very high

Early insights: No biopsy requirement expected

Establishing Pathway for Blockbuster, First-in-Disease Medicine



Key Goals

Commercial coverage to ~80% by YE24

Time to fill Rx from ~60 days to ~30 days at 6 mos. post launch

P&T, pharmacy and therapeutics; ME, medical exception; PA, prior authorization.

Built a Winning Team Ready for Launch

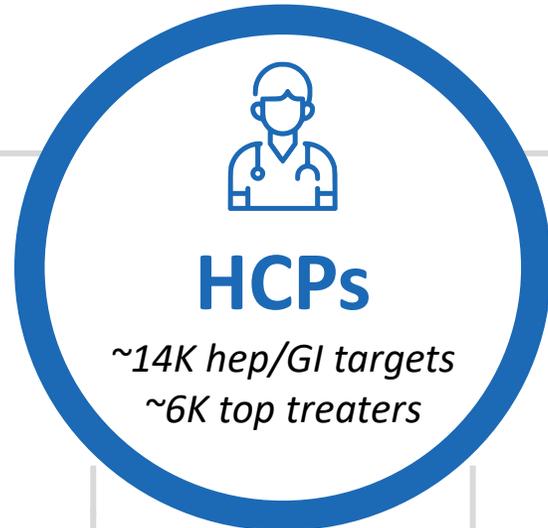
Commercial and Medical leadership team; each with 25+ years industry experience; numerous blockbuster launches

Sales

- 17 yrs. experience
- Top performers
- Hep/GI experience

Patient Support

- 18 yrs. experience
- Expert support in access and affordability solutions



HCPs

~14K hep/GI targets
~6K top treaters

Key Account Team

- IDNs, large GI/hep health systems
- Hep/GI experience

Medical Affairs

- 8 yrs. in practice;
14 yrs. in industry
- M.D.s, Pharm.D.s, Ph.D.s
- Hep/GI experience

Market Access

- 15 yrs. experience
- Best-in-class HEOR data
- Robust disease, cost and NIT education leading up to launch

Right People, Right Skills, Right Size

Pricing is Grounded in Benefit to Patients and Value to the Health System



Targeting a Costly Disease for the Health System

~\$120B Annual direct costs of NASH¹

4X Higher cost of cirrhosis vs. halting NASH at F3²



Delivering a Cost-Effective Therapy

\$76,000

ICER cost-effectiveness assessment

\$39,600 – \$50,100

ICER cost-effectiveness threshold range³



Rezdiffra Price

\$47,400

Annual WAC price

Price reflects value as first-and-only therapy for NASH

Madrigal Patient Support to Provide Access Support and Education

Helping patients, no matter where they are
in the Rezdifra treatment journey

Educational
resources

Coverage navigation

Financial support

Direct-to-patient
delivery



Madrigal plans to focus on equitable access
and affordability as the launch progresses:

- **\$10 co-pays** for **Commercial** patients
- Patients with **no insurance or no coverage for Rezdifra** may be eligible to receive the medication for free

Key Takeaways for Today's Call



➤ Rezdifra approval is an **unprecedented milestone**

➤ **First-in-class label** positions Rezdifra as **foundational therapy**

➤ Set to deliver **successful launch** and **maximize potential**



Q&A



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NASDAQ: MDGL

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