Assessing the Clinical Characteristics and Outcomes of Patients Prescribed Resmetirom in a Real-World EHR Database

Sammy Saab, MD, MPH[1], Yestle Kim, PharmD[2], Dave Lewandowski, MBA[3], Jessamine P. Winer-Jones, PhD[3], Maryam Ajose, MPH[3], Machaon Bonafede, PhD, MPH[3], John O'Donnell, PhD[2], Taylor Ryan, MHI[3]

Pfleger Liver Institute, Los Angeles, CA, USA[1]; Madrigal Pharmaceuticals, Inc., West Conshohocken, PA, USA[2]; Veradigm, Chicago, IL, USA[3]

INTRODUCTION

- Resmetirom is an oral thyroid hormone receptors (THR) β-selective agonist approved, as an adjunct to diet and exercise management, for treating fibrosis among patients with noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH) with moderate to advanced fibrosis in the United States[1-3]
- A recent phase III clinical trial, MAESTRO-NASH, has shown the efficacy of resmetirom (compared with placebo) on MASH resolution and liver fibrosis improvement, at both 80mg and 100mg doses[4]
- However, data are limited on the real-world prescribing practices and outcomes of MASH patients on resmetirom

OBJECTIVE

- This non-interventional, retrospective study aimed to describe the clinical characteristics and outcomes among adults with noncirrhotic MASH initiating resmetirom in the US real-world setting

METHODS

Data Source & Study Population

- Using the Veradigm Network EHR linked to Komodo Health claims, this study identified adult patients (18+ years) with ≥1 prescription record for resmetirom (earliest record=index date) between 03/14/2024-04/30/2025. Study inclusion/exclusion criteria are described in **Figure 1**

Patient Characteristics

- Patient demographics and cardiometabolic comorbidities were captured on the index date or anytime in the 12 months prior to the first resmetirom prescription (baseline)
  - 98% of patients had 24 months of pre-index activity
- Liver stiffness as measured by vibration-controlled transient elastography (VCTE) and liver enzyme levels, including alanine transaminase (ALT) and aspartate transaminase (AST) were captured in baseline (including index) and post-resmetirom initiation (follow-up), based on data availability
- Low-density lipoprotein cholesterol (LDL-C) and triglyceride levels were captured in baseline (including index) and follow-up and later stratified by evidence of concomitant statin use in follow-up only (including index)
- Body mass index (BMI) was captured in baseline (including index) and follow-up and later stratified by concomitant glucagon-like peptide-1 receptor agonists (GLP-1 RAs) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) agonists use in follow-up only (including index)
- Resmetirom treatment duration was assessed during the 6-month follow-up period (including the index) by leveraging written prescription data in patient medical records. The most recent prescription was considered to be the treatment end date if gap between prescriptions was <45 days. Treatment discontinuation was defined as a gap ≥45 days (end date=last prescription prior to gap)

Figure 1. Inclusion/Exclusion Criteria

≥1 prescription record for resmetirom between 03/14/2024 and 04/30/2025. Index date earliest claim for resmetirom
N=1,690

↓

No missing age or sex data
N=1,689

↓

≥18 years old on the index date
N=1,689

↓

Patients without evidence of cirrhosis†[5], decompensated cirrhosis, other ascites, hepatic encephalopathy, unspecified encephalopathy, lactulose treatment, liver transplant, or hepatocellular carcinoma in the year prior to initiating resmetirom
N=1,527

↓

Patients with activity in the EHR during the 6 months after the index date
N=579

NOTES

†This study identified patients with cirrhosis in electronic health records data using a validated algorithm proposed by Khalifa et al[5]

REFERENCES

1. Rezdiffra [package insert]. West Conshohocken, PA; Madrigal Pharmaceuticals, Inc. **2.** Liss KH, Finck BN. *Biochimie.* 2017;136:65-74. **3.** Pharmaceuticals M. Resmetirom. 2022; https://www.madrigalpharma.com/our-programs/resmetirom/.**4.** Harrison SA, et al. *N Engl J Med.* 2024;390(6):497-509. **5.** Khalifa A, et al. *Dig DisSci.* 2023; 68(6):2360–2369.

SCAN QR CODE
FOR DIGITAL POSTER

Madrigal

RESULTS

TABLE 1. Patient Characteristics, Baseline

	Rezdiffra Patients N= 579
Age, Index, mean (SD)	59.1 (12.8)
Sex, Female, N (%)	349 (60.3%)
Race, N (%)	
Asian	31 (5.4%)
African American/Black	30 (5.2%)
White	417 (72.0%)
Other	66 (11.4%)
Unknown/Not Reported	35 (6.0%)
Hyperlipidemia†, N (%)	297 (51.3%)
Hypertension, N (%)	305 (52.7%)
Obesity, N (%)	429 (74.1%)
Type 2 Diabetes, N (%)	308 (53.2%)

SD: standard deviation †Inclusive of hypercholesterolemia, hyperglyceridemia, hyperlipidemia, and elevated lipoprotein(a)

TABLE 2. Clinical Characteristics, Follow-Up

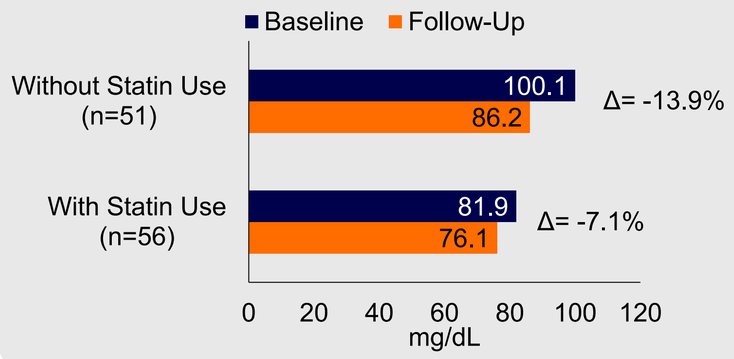
	Rezdiffra Patients N= 579
Index Prescription Strength†, N (%)	
60 mg	39 (6.7%)
80 mg	300 (51.8%)
100 mg	243 (42.0%)
Index Treatment Duration‡, days, mean (SD)	117.7 (67.3)
Treated Through 6 months Post-Index, N (%)	284 (49.1%)
Concomitant Medication Use	
Statin Therapy, N (%)	210 (36.3%)
GLP-1 RA or GLP-1/GIP, N (%)	177 (30.6%)

GLP-1 RA: glucagon-like peptide-1 receptor agonists. GLP-1/GIP: GLP-1/glucose-dependent insulinotropic polypeptide. SD: standard deviation
†3 patients had more than 1 dose documented on their index date
‡Treatment duration was determined from prescription data in the EHR. Discontinuation was defined as a gap ≥45 days (end date=last prescription prior to gap). End date for patients with gap <45 was considered to be the most recently available prescription

Results

- Of the 1,690 patients initiating resmetirom identified in the linked database, 579 were eligible for the analysis
- Patients were ~59 years old and majority were female (60.3%), and White (72.0%) **(Table 1)**
- In the baseline period, the proportion of patients with 2+ and 3+ cardiometabolic comorbidities was 71.2% and 45.9%, respectively (not mutually exclusive)
- At index, most patients were prescribed resmetirom 80 mg (51.8%) or 100 mg (42.0%) dose **(Table 2)**
- Concomitant use of statin therapy during follow-up was seen in 210 (36.3%) patients; 195 (92.9%) of whom had baseline use
- Similarly, in follow-up, concurrent use of GLP-1 RAs or dual GLP-1/GIPs was seen in 177 (30.6%) patients; 130 (73.4%) of whom had baseline use
- Between baseline and follow-up, the mean liver enzyme levels decreased in ALT (60.7 U/L to 53.7 U/L; n= 296) and AST (46.9 U/L to 43.2 U/L; n= 289)
- Among 107 (18.5%) patients with ≥1 LDL-C value in baseline and follow-up, patients without evidence of concomitant statin use in follow-up (n= 51) saw a greater magnitude of change in LDL-C over the study period (from 100.1 mg/dL to 86.2 mg/dL, Δ= -13.9%) (**Figure 2**)
- Among 109 (18.8%) patients with ≥1 triglyceride value in baseline and follow-up, patients without evidence of concomitant statin use in follow-up (n= 51) saw a greater magnitude of change in over the study period (from 169.8 mg/dL to 138.5 mg/dL, Δ= -18.4%) (**Figure 3**)

FIGURE 2. Change in Mean LDL-C Values: Stratified by Concomitant Statin Use in Follow-Up



LDL-C: low-density lipoprotein cholesterol

FIGURE 3. Change in Mean Triglyceride Values: Stratified by Concomitant Statin Use in Follow-Up

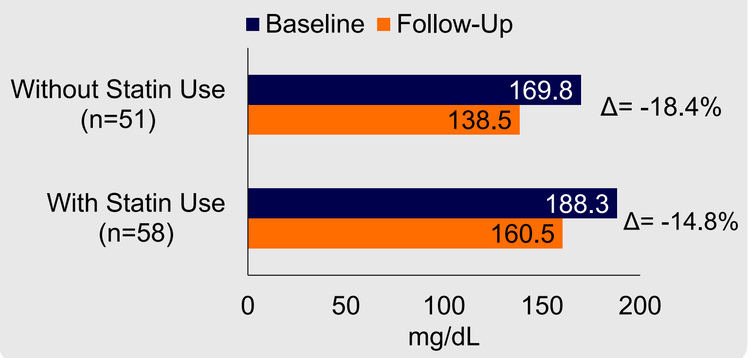
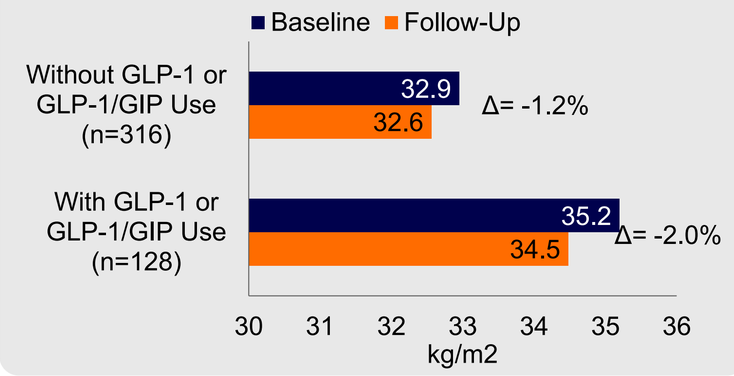


FIGURE 4. Change in Mean BMI Values: Stratified by Concomitant GLP-1 or GLP-1/GIP Use in Follow-Up



BMI: body mass index. GLP-1/GIP: glucose-dependent insulinotropic polypeptide. GLP-1: glucagon-like peptide-1

Results (cont'd)

- Among 444 (76.7%) patients with ≥1 BMI value in baseline and follow-up, the change in BMI amongst patients with (n= 128) vs without (n= 316) evidence of concomitant follow-up GLP-1 or GLP-1/GIP use was similar (**Figure 4**)
- Mean liver stiffness measured by vibration-controlled transient elastography (VCTE) was 11.4 kPa (n=20) in baseline and 9.0 kPa (n=11) in follow-up

LIMITATIONS

- This study used EHRs to capture the start and stop dates for resmetirom and assumed patients took their medication as documented
- This analysis did not account for restarts, switches, or dosage changes in statins, GLP-1 RAs, or GLP-1/GIPs
- The Veradigm Network is commonly used by practitioners in small to mid-size practices, the results may not be generalizable to those in large practices or hospital systems
- These findings are preliminary due to the recent approval of resmetirom and short duration of follow-up
- Interpretation of these findings should consider that some patients in a real world clinical setting may receive resmetirom outside of its labeled indication, which was not systematically evaluated in this analysis

CONCLUSION

- **In this descriptive real-world analysis, among the 579 patients who initiated resmetirom, mean reductions in liver enzyme levels and VCTE results after approximately 6 months of follow-up were observed**
  - **Despite differences in baseline patient characteristics and a shorter follow-up time, changes in lipid and liver enzyme levels trended in the same direction as the results in MAESTRO-NASH**
- **While patients with no evidence of statin use had high LDL-C and borderline high triglyceride levels at baseline, the magnitude of LDL-C and triglyceride reductions were greatest in these patients**
- **Additional assessment with a longer follow-up period is required to better understand the real-world long-term effectiveness of resmetirom among patients with noncirrhotic MASH**

DISCLOSURES

This study was funded by Madrigal Pharmaceuticals, Inc. S Saab is employed by the University of California Los Angeles and is a consultant/speaker for Madrigal Pharmaceuticals, Inc. and a consultant for Gilead, Ipsen, Kezar, Orphalan, Madrigal, Mallinckrodt, Salix. He is on the speaker bureau for Gilead, Ipsen, Mallinckrodt, Salix, and Gore. Y Kim, and J O'Donnell are employees of Madrigal Pharmaceuticals, Inc. D Lewandowski, JP Winer-Jones, M Ajose, M Bonafede, and T Ryan are employees of Veradigm, which received fees from Madrigal Pharmaceuticals, Inc. related to this work.