A Randomized, Placebo-Controlled, Phase 2 Study of the Safety and Efficacy of Combination Treatment with Semaglutide, Cilofexor and Firsocostat in Patients With Compensated Cirrhosis Due to Metabolic Dysfunction-Associated Steatohepatitis (WAYFIND)

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Background and Aims

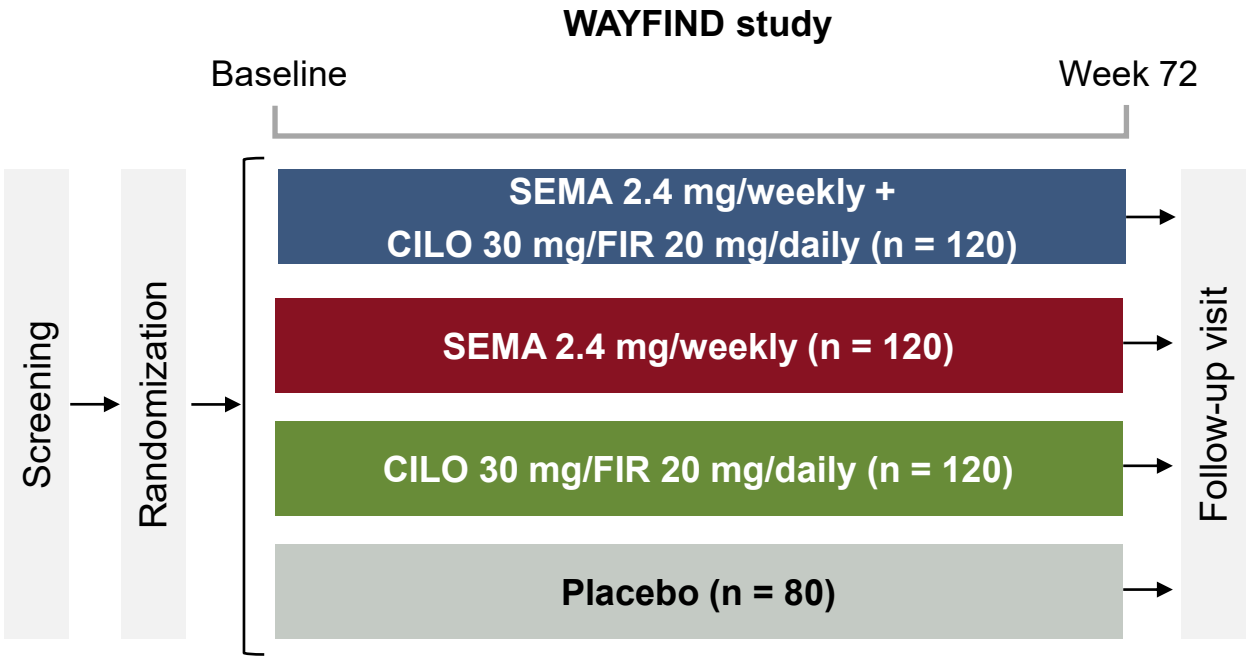
- Combination therapies may be needed to achieve meaningful therapeutic gains in patients with cirrhotic (F4c) MASH, for which no approved treatments exist and where the greatest disease burden for MASH still lies[1,2]
- The glucagon-like peptide-1 receptor agonist semaglutide (SEMA) recently received approval for treating MASH with moderate to advanced liver fibrosis (F2–F3), based on positive results from the phase 3 ESSENCE trial[3,4]
- Fixed-dose combination treatment with cilofexor (CILO), a non-steroidal, gut-restricted, selective farnesoid X receptor agonist, and firsocostat (FIR), a liver-targeted acetyl-coenzyme A carboxylase inhibitor, may have anti-fibrotic effects in F3–F4 MASH[5]

Aim: To evaluate the efficacy and safety of SEMA + CILO/FIR in patients with compensated cirrhosis due to MASH (phase 2 WAYFIND study; NCT04971785)

1. Sanyal AJ, *et al. N Engl J Med*. 2021;385:1559–69. **2.** Ratziu V, *et al. Gastroenterology*. 2023;165:5–10. **3.** Sanyal AJ, *et al. N Engl J Med*. 2025;392:2089–99. **4.** US FDA. 2025. WEGOVY (semaglutide) injection, for subcutaneous use: Prescribing Information. Accessed September 12, 2025. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/215256s024lbl.pdf. **5.** Loomba R, *et al. Hepatology*. 2021;73:625–43.
CILO, cilofexor; **FDA**, Food and Drug Administration; **FIR**, firsocostat; **MASH**, metabolic dysfunction-associated steatohepatitis; **SEMA**, semaglutide.

Study Design

- Adults (aged 18–80 years) with compensated cirrhosis (F4c) due to MASH[a] were randomized 3:3:3:2 (target enrollment: n = 440) to receive SEMA + CILO/FIR, SEMA, CILO/FIR or placebo for 72 weeks
  - SEMA was administered with dose escalation from 0.24–2.4 mg/weekly over the first 16 weeks



Efficacy analyses at Week 72

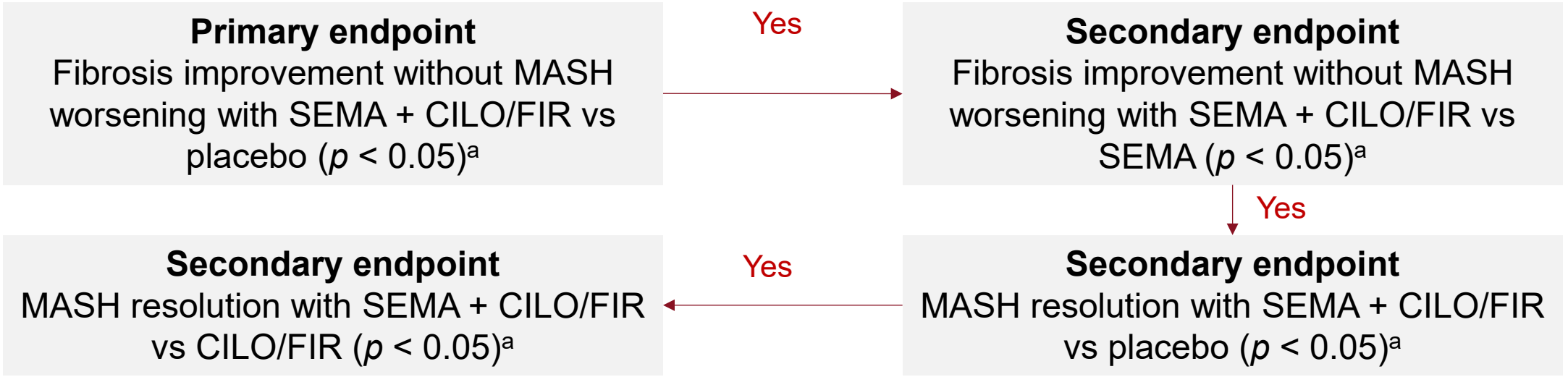
- Proportion of patients with ≥ 1-stage improvement in fibrosis[b] without MASH worsening[c]
- Proportion of patients with MASH resolution[d]

Liver biopsies were read by central pathologists and AIM-MASH AI Assist from PathAI

[a]Defined as the presence of Grade ≥ 1 steatosis, Grade ≥ 1 hepatocellular ballooning, and Grade ≥ 1 lobular inflammation (based on NAS).
[b]Based on MASH CRN classification. [c]Defined as a ≥ 1-point increase in hepatocellular ballooning or lobular inflammation. [d]Defined as lobular inflammation = 0 or 1 and hepatocellular ballooning = 0.
CILO, cilofexor; **CRN**, Clinical Research Network; **FIR**, firsocostat; **MASH**, metabolic dysfunction-associated steatohepatitis; **NAS**, nonalcoholic fatty liver disease activity score; **SEMA**, semaglutide.

Statistical Analysis

Prespecified Testing Hierarchy

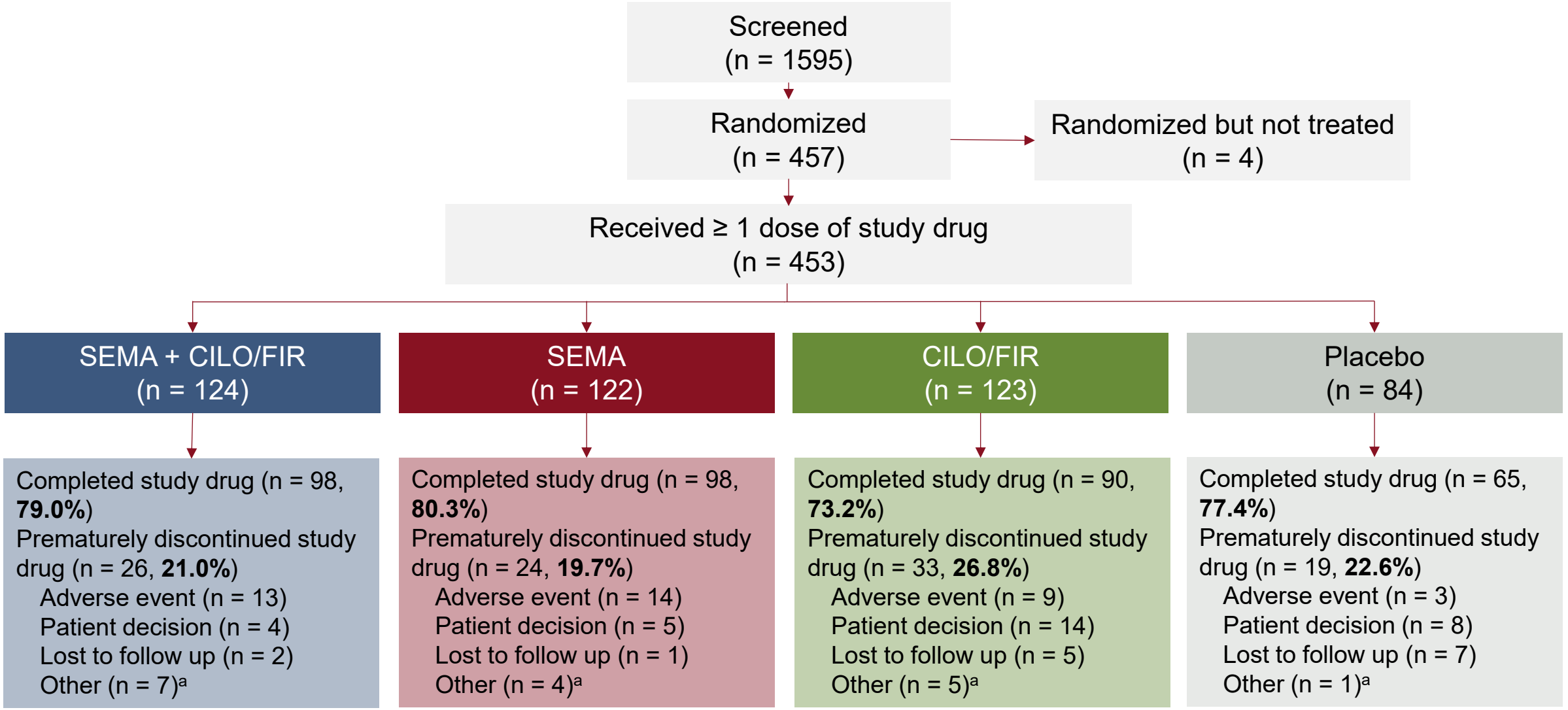


- A stratified Mantel–Haenszel test was used to compare differences between treatment groups in proportions of patients achieving study endpoints based on baseline re-read and week-72 biopsies, with baseline diabetes status and enhanced liver fibrosis (ELF) test score category as stratification factors
- The primary endpoint was tested at a 2-sided significance level of 0.05
- If the primary endpoint was achieved, secondary efficacy endpoints were tested sequentially at a 2-sided significance level of 0.05

[a]Based on central pathologist reading.

CILO, cilofexor; **ELF**, enhanced liver fibrosis; **FIR**, firsocostat; **MASH**, metabolic dysfunction-associated steatohepatitis; **SEMA**, semaglutide.

Patient Disposition



[a]Reasons recorded as "Other" include protocol violation (SEMA + CILO/FIR, n = 3; SEMA, n = 2; CILO/FIR, n = 1; placebo, n = 1), investigator's discretion (2;1;1;0), non-compliance with study drug (0;0;2;0), study terminated by sponsor (1;1;0;0), death (0;0;1;0) and pregnancy (1;0;0;0).
CILO, cilofexor; **FIR**, firsocostat; **SEMA**, semaglutide.

Baseline Characteristics (1/2)[a]

	Total (N = 453)	SEMA + CILO/FIR (N = 124)	SEMA (N = 122)	CILO/FIR (N = 123)	Placebo (N = 84)
Age, years, mean (SD)	62 (9.6)	61 (10.4)	61 (9.2)	62 (9.5)	63 (9.1)
Female, n (%)	292 (64.5)	83 (66.9)	85 (69.7)	74 (60.2)	50 (59.5)
Race, n (%)					
White	372 (82.1)	100 (80.6)	108 (88.5)	98 (79.7)	66 (78.6)
Asian	38 (8.4)	11 (8.9)	9 (7.4)	15 (12.2)	3 (3.6)
Black	9 (2.0)	2 (1.6)	1 (0.8)	1 (0.8)	5 (6.0)
Other or not permitted[b]	34 (7.5)	11 (8.9)	4 (3.3)	9 (7.3)	10 (11.9)
Ethnicity, n (%)					
Not Hispanic or Latino	346 (76.4)	95 (76.6)	99 (81.1)	90 (73.2)	62 (73.8)
Hispanic or Latino	100 (22.1)	28 (22.6)	23 (18.9)	30 (24.4)	19 (22.6)
Not permitted[b]	7 (1.5)	1 (0.8)	0	3 (2.4)	3 (3.6)
BMI, kg/m^2, mean (SD)	34.5 (6.8)	34.7 (6.2)	34.8 (6.9)	34.0 (7.5)	34.4 (6.6)
Waist circumference, cm, mean (SD)	114 (15.0)	114 (13.8)	115 (15.0)	112 (15.8)	114 (15.3)

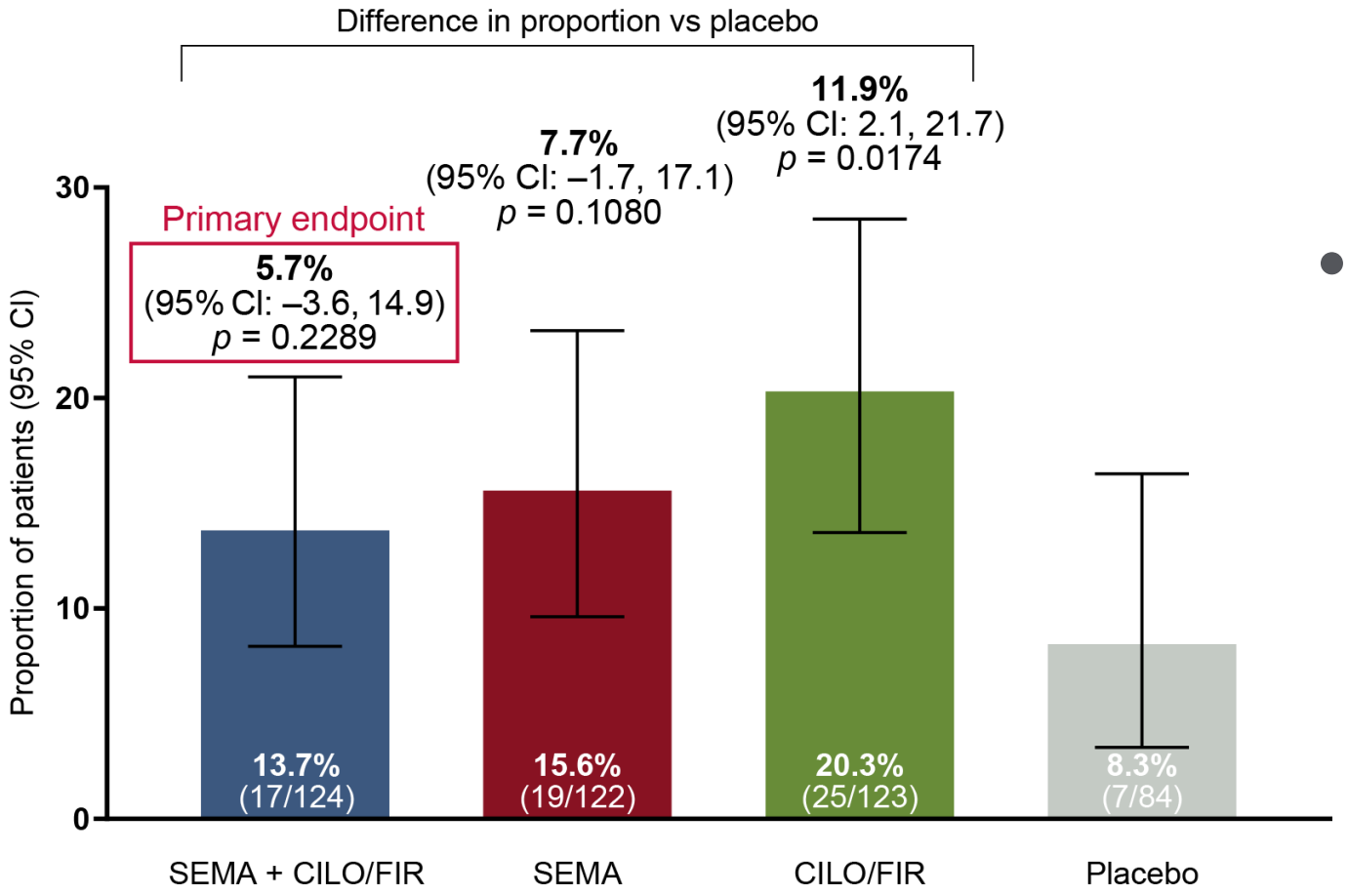
[a]Reported for evaluable patients in the Safety Analysis Set, which included all patients who received at least one dose of study drug. [b]Information was unable to be collected due to local regulations or participant refusal.
BMI, body mass index; **CILO**, cilofexor; **FIR**, firsocostat; **SD**, standard deviation; **SEMA**, semaglutide.

Baseline Characteristics (2/2)[a]

	Total (N = 453)	SEMA + CILO/FIR (N = 124)	SEMA (N = 122)	CILO/FIR (N = 123)	Placebo (N = 84)
Comorbidities, n (%)					
Diabetes mellitus	309 (68.2)	81 (65.3)	85 (69.7)	86 (69.9)	57 (67.9)
Obesity[b]	317 (70.0)	91 (73.4)	89 (73.0)	79 (64.2)	58 (69.0)
NAS, mean (SD)	4 (1.1)	4 (1.2)	4 (1.1)	4 (1.1)	4 (1.1)
Platelet count, × 10^3/μL, mean (SD)	191 (55.3)	190 (55.0)	195 (66.8)	191 (45.1)	189 (51.7)
ALT, U/L, mean (SD)	49 (28.8)	49 (25.8)	46 (25.9)	54 (35.5)	47 (25.7)
AST, U/L, mean (SD)	49 (24.1)	50 (25.2)	48 (23.1)	52 (26.0)	45 (20.6)
Total bilirubin, mg/dL, mean (SD)	0.7 (0.3)	0.7 (0.4)	0.7 (0.3)	0.7 (0.3)	0.6 (0.3)
MELD score, mean (SD)	7 (1.5)	7 (1.6)	7 (1.7)	7 (1.3)	7 (1.4)
ELF test score, mean (SD)	10.6 (0.9)	10.6 (0.9)	10.6 (0.9)	10.7 (0.9)	10.6 (1.1)
Albumin, g/dL, mean (SD)	4.6 (0.3)	4.6 (0.3)	4.5 (0.3)	4.6 (0.3)	4.6 (0.3)
VCTE (FibroScan), kPa, mean (SD)	22.6 (12.1)	21.9 (12.0)	23.7 (12.9)	22.8 (12.2)	21.7 (11.0)
VCTE (FibroScan) < 15 kPa, n/N (%)	130/442 (29.4)	40/123 (32.5)	32/119 (26.9)	34/117 (29.1)	24/83 (28.9)

[a]Reported for evaluable patients in the Safety Analysis Set, which included all patients who received at least one dose of study drug. [b]Defined as a BMI ≥ 30 kg/m^2.
ALT, alanine aminotransferase; **AST**, aspartate aminotransferase; **BMI**, body mass index; **CILO**, cilofexor; **ELF**, enhanced liver fibrosis; **FIR**, firsocostat; **NAS**, nonalcoholic fatty liver disease activity score; **MELD**, Model for End-Stage Liver disease; **SD**, standard deviation; **SEMA**, semaglutide; **VCTE**, vibration-controlled transient elastography.

Fibrosis Improvement Without MASH Worsening at Week 72 (Central Pathologists)[a]

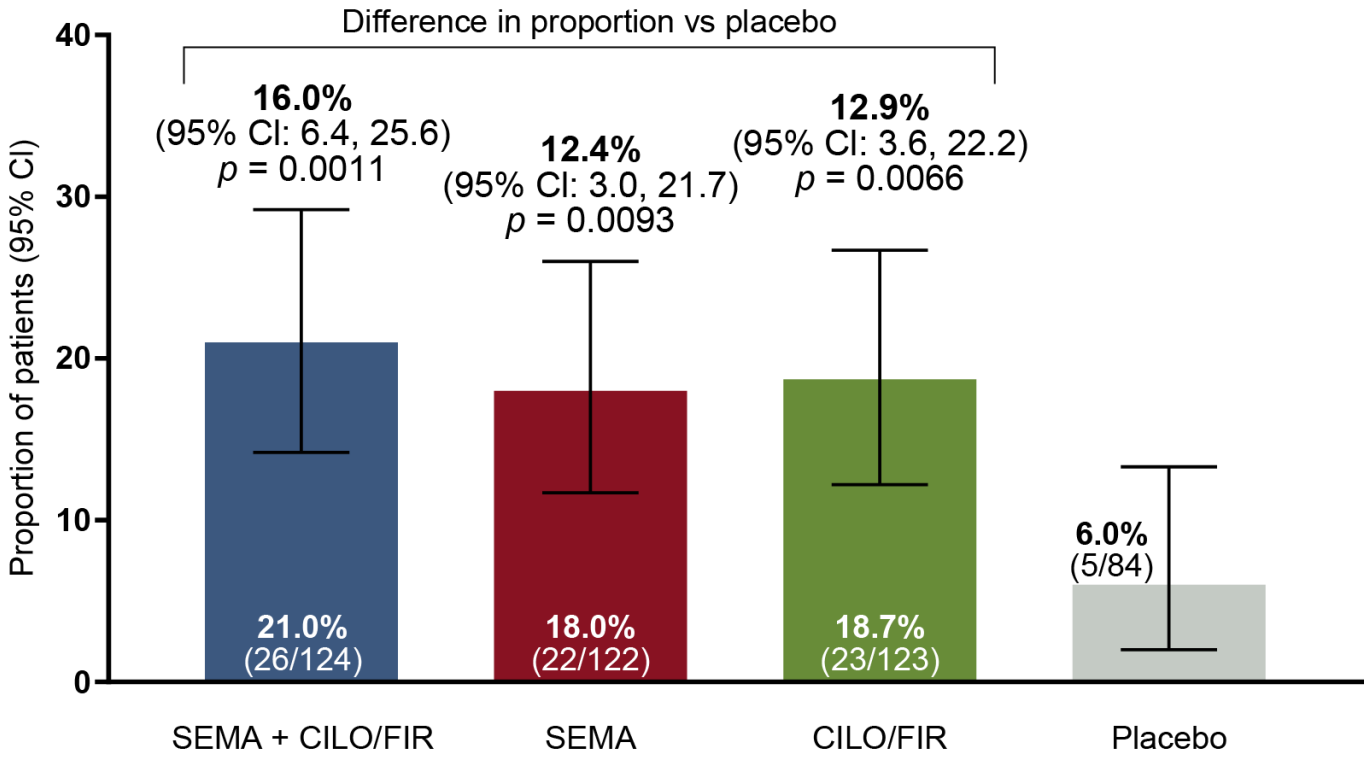


- The primary endpoint was not achieved; therefore, *p* values for all secondary and exploratory endpoints presented henceforth are nominal based on the prespecified testing hierarchy

[a]Missing data were analyzed as treatment failures (non-responder imputation). Data are reported for the Full Analysis Set, which included all randomized patients who received at least one dose of study drug. The proportion difference, 95% CI and *p* value between each treatment group versus placebo are from stratified Mantel-Haenszel tests with baseline diabetes status and baseline ELF category as stratification factor.

CI, confidence interval; **CILO**, cilofexor; **ELF**, enhanced liver fibrosis; **FIR**, firsocostat; **MASH**, metabolic dysfunction-associated steatohepatitis; **PBO**, placebo; **SEMA**, semaglutide.

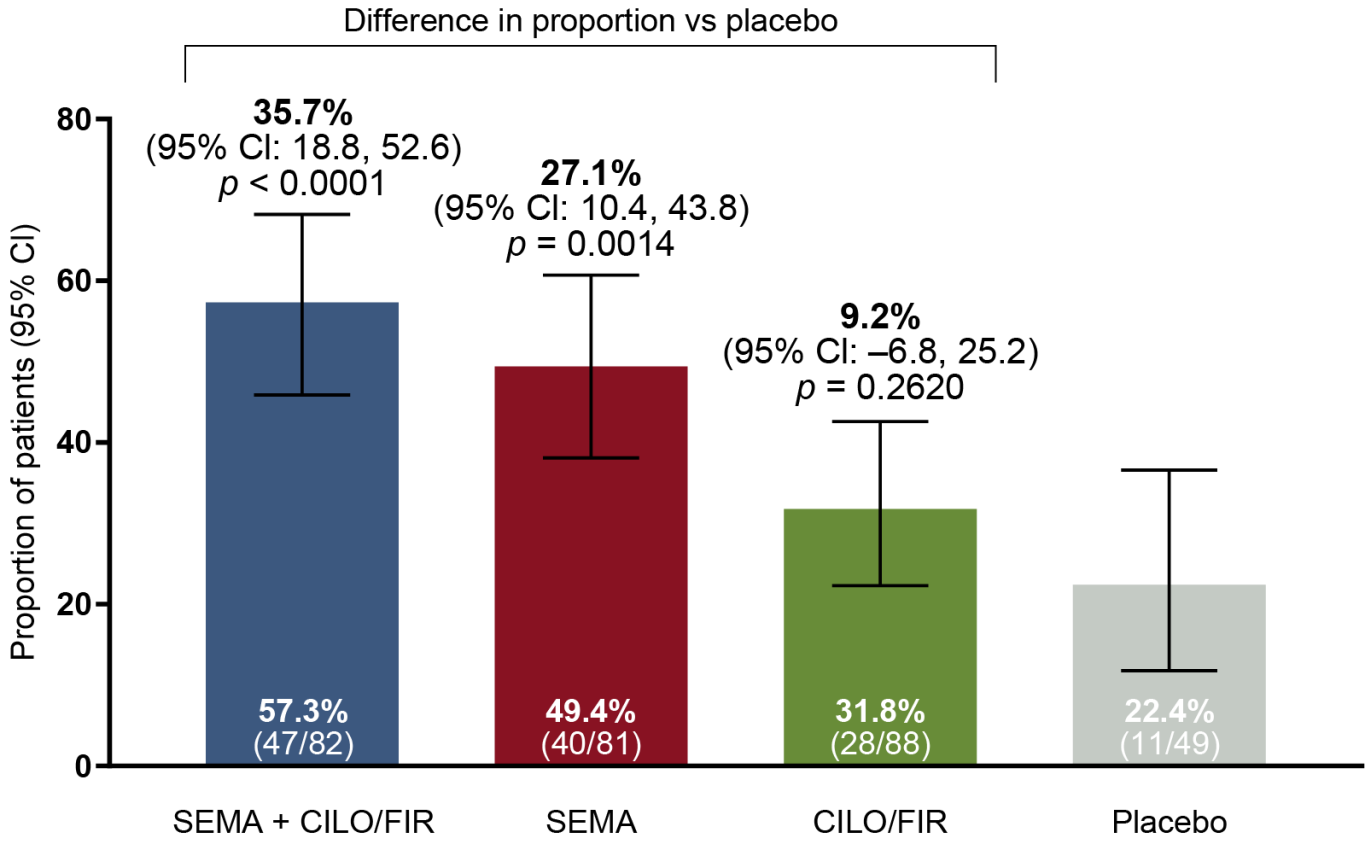
Fibrosis Improvement Without MASH Worsening at Week 72 (PathAI)[a]



[a]Missing data were analyzed as treatment failures (non-responder imputation). Data are reported for the Full Analysis Set, which included all randomized patients who received at least one dose of study drug. The proportion difference, 95% CI and *p* value between each treatment group versus placebo are from stratified Mantel-Haenszel tests with baseline diabetes status and baseline ELF category as stratification factor.

CI, confidence interval; **CILO**, cilofexor; **ELF**, enhanced liver fibrosis; **FIR**, firsocostat; **MASH**, metabolic dysfunction-associated steatohepatitis; **PBO**, placebo; **SEMA**, semaglutide.

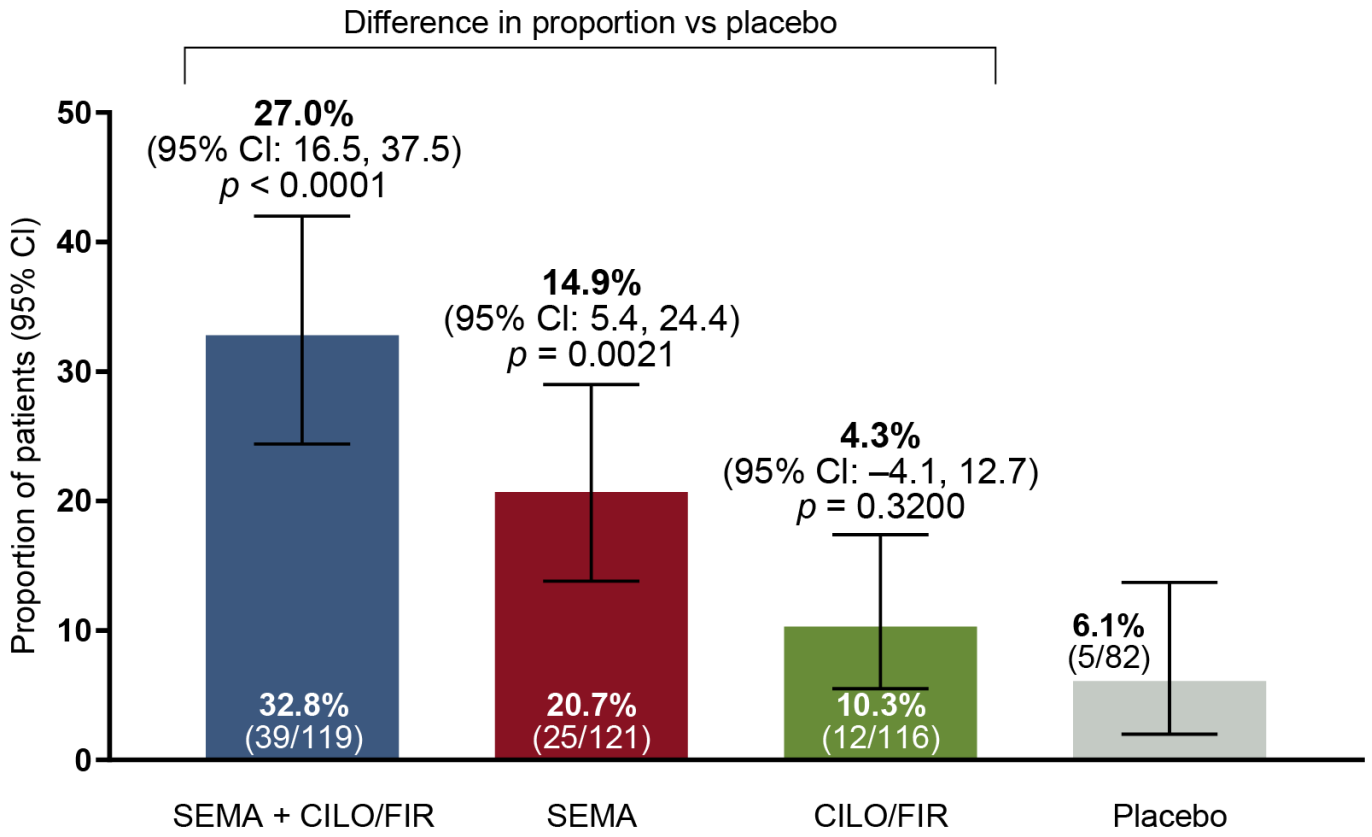
MASH Resolution Without Worsening of Fibrosis at Week 72 (Central Pathologists)[a]



[a]Endpoint included 'without worsening of fibrosis' because 86/453 patients had fibrosis F3 or below at baseline re-read. Missing data were analyzed as treatment failures (non-responder imputation). Data are reported for evaluable patients (hepatocellular ballooning and lobular inflammation of grades ≥ 1 at baseline re-read) from the Full Analysis Set, which included all randomized patients who received at least one dose of study drug. The proportion difference, 95% CI and *p* value between each treatment group versus placebo are from stratified Mantel-Haenszel tests with baseline diabetes status and baseline ELF category as stratification factor.

CI, confidence interval; **CILO**, cilofexor; **ELF**, enhanced liver fibrosis; **FIR**, firsocostat; **MASH**, metabolic dysfunction-associated steatohepatitis; **PBO**, placebo; **SEMA**, semaglutide.

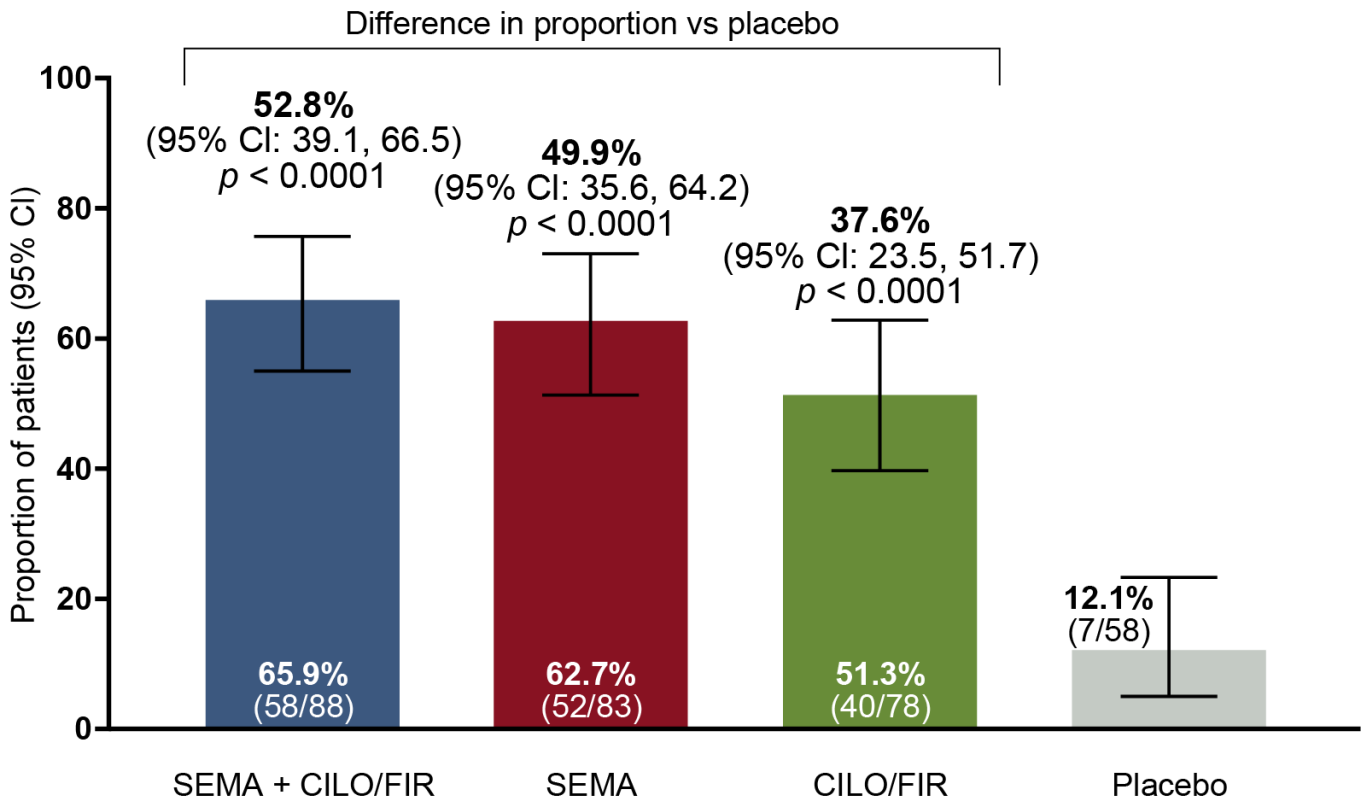
MASH Resolution Without Worsening of Fibrosis at Week 72 (PathAI)[a]



[a]Endpoint included 'without worsening of fibrosis' because 138/453 patients had fibrosis F3 at PathAI baseline reading. Missing data were analyzed as treatment failures (non-responder imputation). Data are reported for evaluable patients (PathAI baseline hepatocellular ballooning and lobular inflammation of grades ≥ 1) from the Full Analysis Set, which included all randomized patients who received at least one dose of study drug. The proportion difference, 95% CI and *p* value between each treatment group versus placebo are from stratified Mantel-Haenszel tests with baseline diabetes status and baseline ELF category as stratification factor.

CI, confidence interval; **CILO**, cilofexor; **ELF**, enhanced liver fibrosis; **FIR**, firsocostat; **MASH**, metabolic dysfunction-associated steatohepatitis; **PBO**, placebo; **SEMA**, semaglutide.

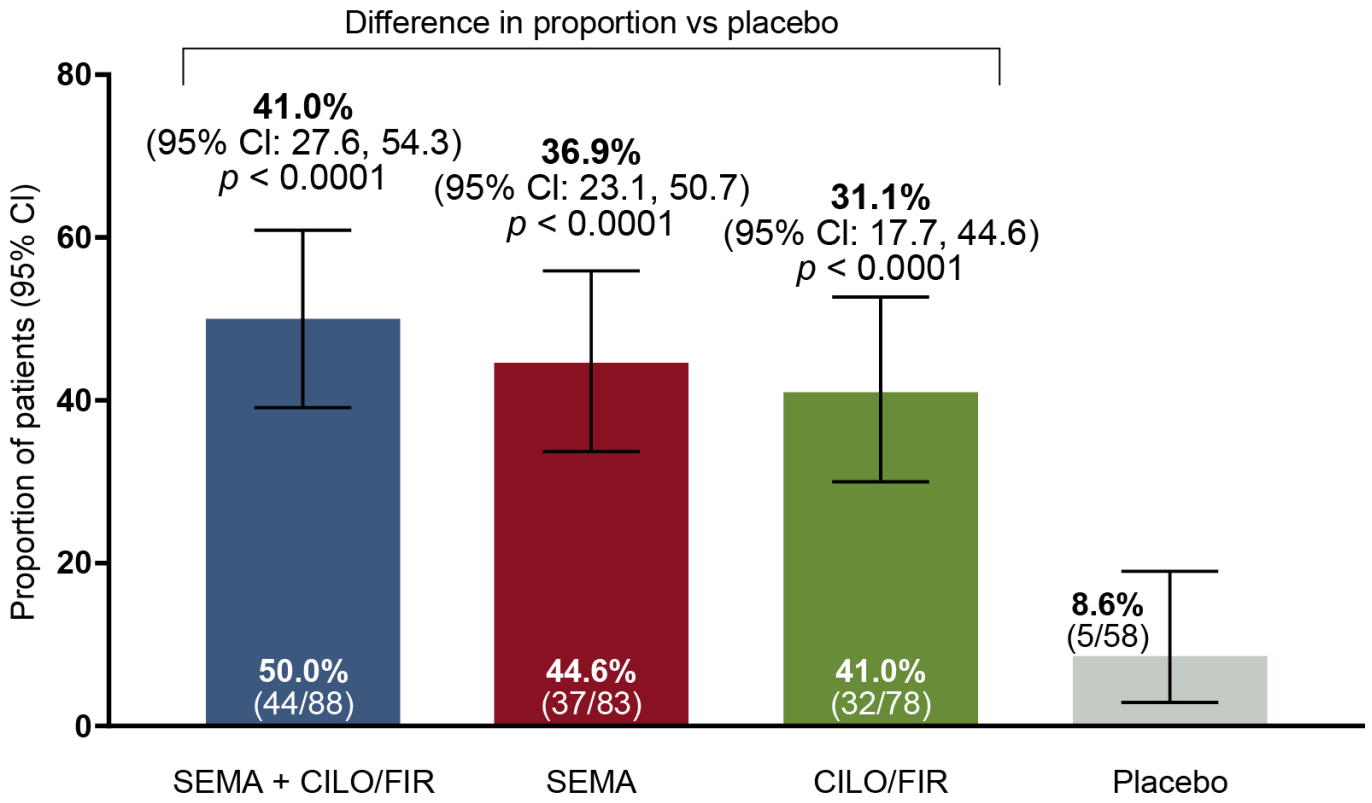
VCTE (FibroScan) Reduction ≥ 30% at Week 72[a]



[a]Data are reported for evaluable patients with observed data at both baseline and Week 72 (observed case analysis) from the Full Analysis Set, which included all randomized patients who received at least one dose of study drug. The proportion difference, 95% CI and *p* value between each treatment group versus placebo are from stratified Mantel-Haenszel tests with baseline diabetes status and baseline ELF category as stratification factor.

CI, confidence interval; **CILO**, cilofexor; **ELF**, enhanced liver fibrosis; **FIR**, firsocostat; **MASH**, metabolic dysfunction-associated steatohepatitis; **PBO**, placebo; **SEMA**, semaglutide; **VCTE**, vibration-controlled transient elastography.

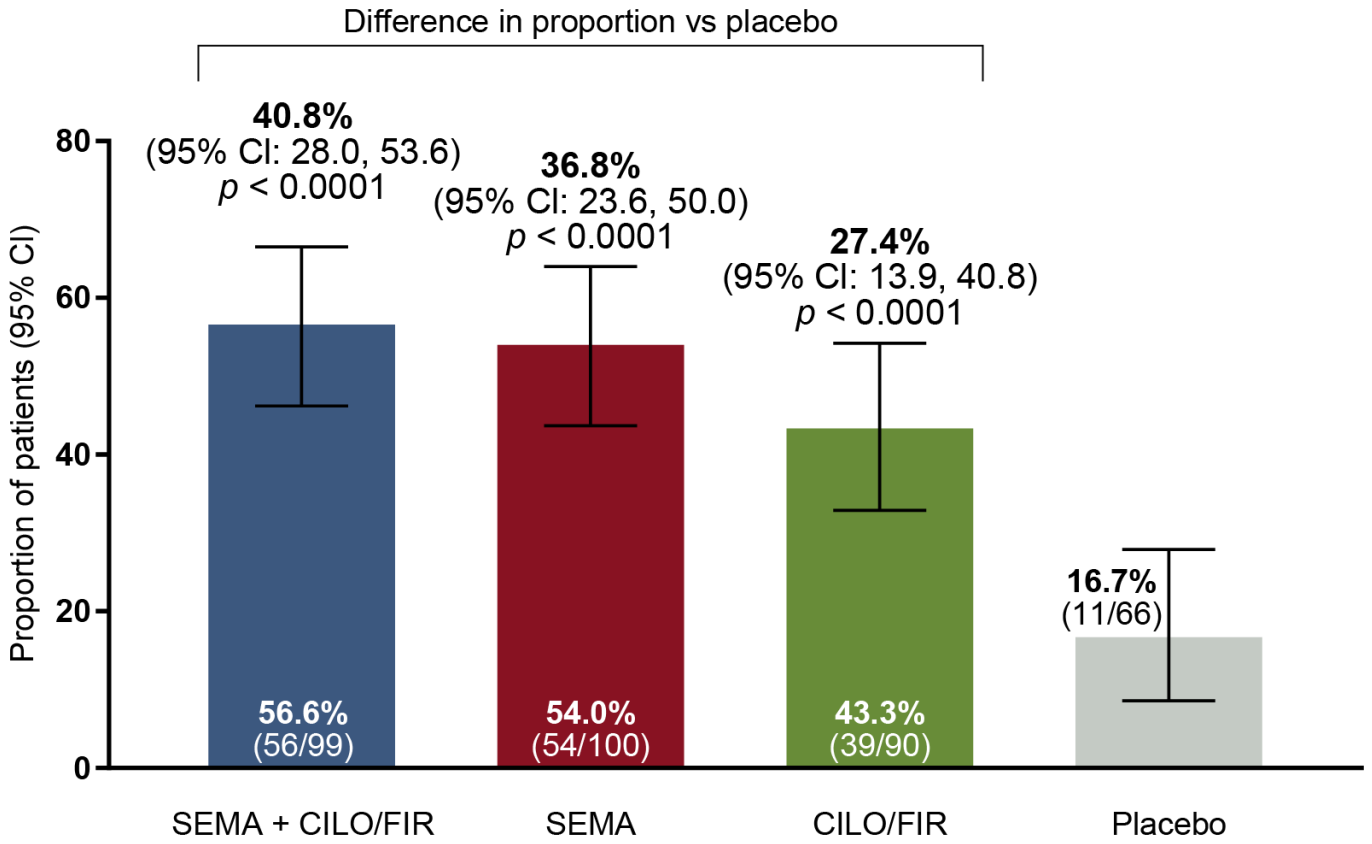
VCTE (FibroScan) ≥ 30% Reduction and Liver Stiffness Measurement < 15 kPa at Week 72[a]



[a]Data are reported for evaluable patients with observed data at both baseline and Week 72 (observed case analysis) from the Full Analysis Set, which included all randomized patients who received at least one dose of study drug. The proportion difference, 95% CI and *p* value between each treatment group versus placebo are from stratified Mantel-Haenszel tests with baseline diabetes status and baseline ELF category as stratification factor.

CI, confidence interval; **CILO**, cilofexor; **ELF**, enhanced liver fibrosis; **FIR**, firsocostat; **MASH**, metabolic dysfunction-associated steatohepatitis; **PBO**, placebo; **SEMA**, semaglutide; **VCTE**, vibration-controlled transient elastography.

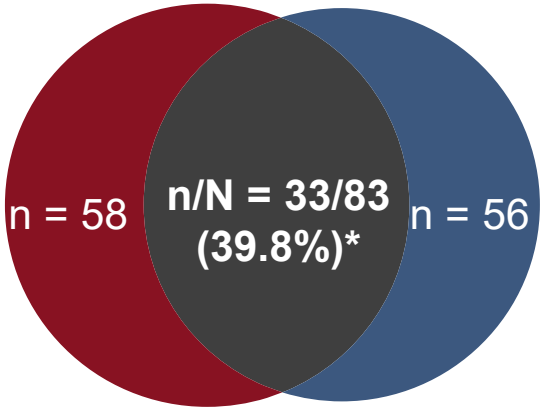
ELF Score Reduction ≥ 0.5 Units at Week 72[a]



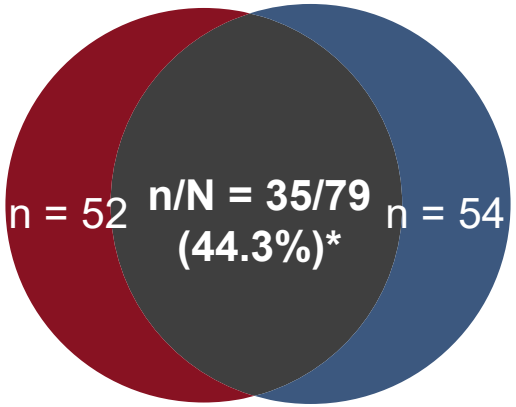
[a]Data are reported for evaluable patients with observed data at both baseline and Week 72 (observed case analysis) from the Full Analysis Set, which included all randomized patients who received at least one dose of study drug. The proportion difference, 95% CI and *p* value between each treatment group versus placebo are from stratified Mantel-Haenszel tests with baseline diabetes status and baseline ELF category as stratification factor.

CI, confidence interval; **CILO**, cilofexor; **ELF**, enhanced liver fibrosis; **FIR**, firsocostat; **MASH**, metabolic dysfunction-associated steatohepatitis; **PBO**, placebo; **SEMA**, semaglutide.

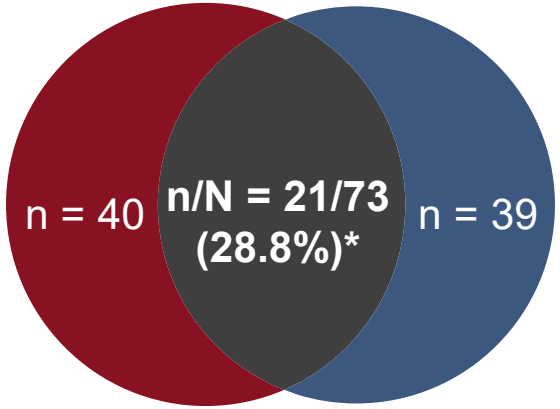
VCTE (FibroScan) Reduction ≥ 30% and ELF Score Reduction ≥ 0.5 Units at Week 72[a]



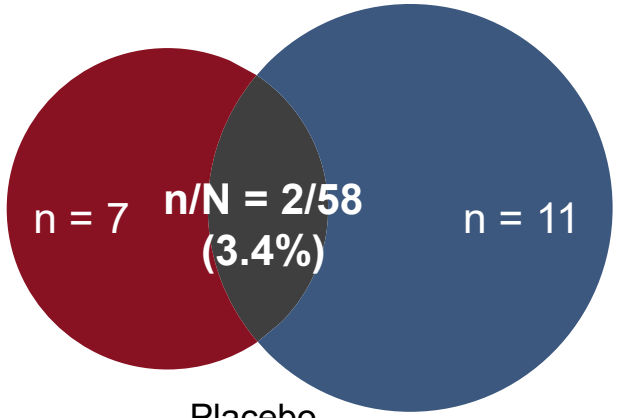
SEMA + CILO/FIR



SEMA



CILO/FIR



Placebo

VCTE (FibroScan) reduction ≥ 30% only

ELF score reduction ≥ 0.5 Units only

VCTE (FibroScan) reduction ≥ 30% and ELF score reduction ≥ 0.5 Units

*$p < 0.0001$ compared with PBO

[a]The size of the Venn diagram for each treatment group is not proportional to the relative size versus other treatment groups. Data are reported for evaluable patients (N) with observed data at both baseline and Week 72 (observed case analysis) for VCTE (FibroScan) reduction ≥ 30% (SEMA + CILO/FIR: N = 88; SEMA: N = 83; CILO/FIR: N = 78; PBO: N = 58), ELF score reduction ≥ 0.5 Units (SEMA + CILO/FIR: N = 99; SEMA: N = 100; CILO/FIR: N = 90; PBO: N = 66), and for the overlap between these outcomes (N values shown in Venn diagrams). Some patients included in the non-overlapping sets did not have evaluable data for both VCTE (FibroScan) reduction ≥ 30% and ELF score reduction ≥ 0.5 Units at Week 72.

CILO, cilofexor; **ELF**, enhanced liver fibrosis; **FIR**, firsocostat; **PBO**, placebo; **SEMA**, semaglutide; **VCTE**, vibration-controlled transient elastography.

Summary of Adverse Events[a]

n (%)	SEMA + CILO/FIR (n = 124)	SEMA (n = 122)	CILO/FIR (n = 123)	Placebo (n = 84)
Any AE[b]	111 (89.5)	107 (87.7)	107 (87.0)	72 (85.7)
Nausea	59 (47.6)	49 (40.2)	29 (23.6)	19 (22.6)
Diarrhea	34 (27.4)	25 (20.5)	16 (13.0)	15 (17.9)
Constipation	30 (24.2)	26 (21.3)	11 (8.9)	7 (8.3)
Vomiting	27 (21.8)	21 (17.2)	7 (5.7)	6 (7.1)
Decreased appetite	19 (15.3)	20 (16.4)	7 (5.7)	5 (6.0)
Serious AEs	17 (13.7)	13 (10.7)	18 (14.6)	11 (13.1)
AE grade ≥ 3	25 (20.2)	17 (13.9)	25 (20.3)	14 (16.7)
AE leading to study discontinuation	8 (6.5)	9 (7.4)	6 (4.9)	3 (3.6)
AE leading to any drug discontinuation	13 (10.5)	14 (11.5)	9 (7.3)	3 (3.6)
Treatment-related serious AE	0	0	0	0
Deaths	0	1 (0.8)	1 (0.8)	0

[a]Reported for the Safety Analysis Set, which included all patients who received at least one dose of study drug.
[b]The most frequent (≥ 15% of patients) AEs occurring in any treatment group excluding COVID-19.
AE, adverse event; **CILO**, cilofexor; **FIR**, firsocostat; **SEMA**, semaglutide.

Summary

- SEMA + CILO/FIR did not achieve the primary endpoint of fibrosis improvement without MASH worsening compared with placebo based on central pathologist biopsy reading
  - CILO/FIR achieved fibrosis improvement without MASH worsening (nominal $p = 0.0174$)
  - SEMA-containing regimens achieved MASH resolution (all nominal $p < 0.01$)
- When assessed using PathAI, SEMA + CILO/FIR achieved fibrosis improvement without MASH worsening, as well as MASH resolution, compared with placebo (all nominal $p < 0.01$)
  - SEMA alone and CILO/FIR alone also achieved fibrosis improvement without MASH worsening based on PathAI assessment (both nominal $p < 0.01$)
- SEMA, CILO/FIR and their combination improved non-invasive fibrosis tests compared with placebo
- SEMA + CILO/FIR was generally well tolerated

CILO, cilofexor; **FIR**, firsocostat; **MASH**, metabolic dysfunction-associated steatohepatitis; **SEMA**, semaglutide.

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United States
Canada
France
Spain
Japan
Australia

Additional Key Inclusion Criteria[a]

- Adults aged 18–80 years with F4c due to MASH were eligible for enrollment if they met the following additional key inclusion criteria:
  - The following laboratory parameters at screening, as determined by the central laboratory:
    - eGFR ≥ 30 mL/min/1.73m^2, as calculated by the Modification of Diet in Renal Disease equation to estimate creatinine clearance
    - HbA_{1c} ≤ 10% (or serum fructosamine ≤ 400 µmol/L if HbA_{1c} is not quantifiable)
    - Hemoglobin > 10.6 g/dL
    - International normalized ratio ≤ 1.4, unless due to therapeutic anticoagulation
    - Total bilirubin ≤ 1.3 × upper limit of normal (unless due to an alternative etiology such as Gilbert's syndrome or hemolytic anemia)
    - Serum albumin ≥ 3.5 g/dL
    - Serum ALP ≤ 2 × upper limit of normal
    - Platelet count ≥ 125,000/µL
    - Serum triglyceride level ≤ 250 mg/dL[b]
    - ALT < 5 × upper limit of normal
  - BMI ≥ 23 kg/m^2 at screening

[a]Additional protocol-defined inclusion criteria apply. [b]If initial screening value is > 250 mg/dL, triglycerides may be retested during the screening period. Fasting serum triglycerides must be confirmed to be ≤ 250 mg/dL prior to Day 1. Management of hypertriglyceridemia may be initiated or modified at investigator discretion during the screening period.

ALP, alkaline phosphatase; **ALT**, alanine aminotransferase; **BMI**, body mass index; **eGFR**, estimated glomerular filtration rate; **HbA_{1c}**, hemoglobin A_{1c}; **MASH**, metabolic dysfunction-associated steatohepatitis.

Key Exclusion Criteria[a]

- Patients were not eligible for enrollment if they met any of the following key exclusion criteria:
  - Any history of decompensated liver disease including ascites, hepatic encephalopathy, and variceal bleeding
  - Child–Pugh score > 6 at screening[b]
  - MELD score > 12 at screening[b]
  - Presence of chronic hepatitis B virus or chronic hepatitis C virus infection[c]
  - History of liver transplantation
  - Current or prior history of hepatocellular carcinoma
  - Other causes of liver disease, including but not limited to, alcoholic liver disease, primary biliary cholangitis, primary sclerosing cholangitis, autoimmune hepatitis, drug-induced hepatotoxicity, Wilson disease, clinically significant iron overload, or alpha-1-antitrypsin deficiency
  - Men who habitually drink more than 21 units/week of alcohol or women who habitually drink more than 14 units/week of alcohol[d]

[a]Additional protocol-defined exclusion criteria apply. [b]Unless due to an alternative etiology. [c]Patients cured of hepatitis C virus infection < 2 years before screening were excluded. [d]1 unit is equivalent to 12 oz/360 mL of beer, a 4 oz/120 mL glass of wine, or 1 oz/30 mL of hard liquor.
MELD, Model for End-Stage Liver disease.