



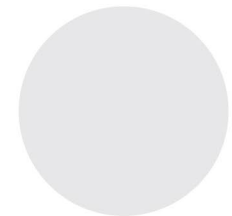
Restoring Balance. Renewing Life.

# JP Morgan Presentation

Andrew Cheng, MD, PhD  
President & CEO



January 10, 2023



This presentation may contain “forward-looking statements” of Akero Therapeutics, Inc. (“we,” “us,” “our,” “Akero” or the “Company”) within the meaning of the Private Securities Litigation Reform Act of 1995 relating to our business, operations, and financial conditions, including but not limited to current express or implied beliefs, expectations and assumptions regarding: the future of our business; future plans and strategies, including our expectations around the therapeutic potential and clinical benefits of Efruxifermin (“EFX”); our development plans for EFX, including our belief in the unique potential of EFX as a foundational NASH therapy; our preclinical and clinical results, including our safety/tolerability, laboratory measures and histology data from our Phase 2a BALANCED study and Phase 2b HARMONY study; the potential benefits resulting from the PRIME, Breakthrough Therapy and Fast Track designations of EFX; the Phase 2b SYMMETRY study, including the Cohort D expansion and expected timing to report preliminary results, and other related milestones; the availability of a new drug product formulation to support Phase 3 clinical trials; risks related to the competitive landscape; the timing and potential benefits of our regulatory interactions; our use of capital, expenses and other future financial results; and the potential impact of COVID-19 on strategy, our employees, supply chain, future operations and clinical trials. Words such as, but not limited to, “look forward to,” “believe,” “expect,” “anticipate,” “estimate,” “intend,” “plan,” “would,” “should” and “could,” and similar expressions or words, identify forward-looking statements. New risks and uncertainties may emerge from time to time, and it is not possible to predict all risks and uncertainties. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in the forward-looking statements, even if new information becomes available in the future. For a discussion of these and other risks and uncertainties, and other important factors, any of which could cause our actual results to differ from those contained in the forward-looking statements, see the section entitled “Risk Factors” in our most recent annual report on Form 10-K filed with the Securities and Exchange Commission, as well as discussions of potential risks, uncertainties, and other important factors in our other subsequent filings with the Securities and Exchange Commission. All information in this presentation is as of the date hereof, and we undertake no duty to update this information unless required by law.

Certain information contained in this presentation relates to or is based on studies, publications, surveys and other data obtained from third-party sources and the Company’s own internal estimates and research. While the Company believes these third-party sources to be reliable as of the date of this presentation, it has not independently verified, and makes no representation as to the adequacy, fairness, accuracy or completeness of, any information obtained from third-party sources. In addition, all of the market data included in this presentation involves a number of assumptions and limitations, and there can be no guarantee as to the accuracy or reliability of such assumptions. Finally, while we believe our own internal research is reliable, such research has not been verified by any independent source.

1

### Potential First-in-Class & Best-in-Class NASH Drug

- Substantial potential market opportunity
- Differentiated mechanism of action
- Strongest reported efficacy data among FGF21s, including:
  - Fibrosis improvement
  - NASH Resolution
  - Improved glyceimic control

FDA Meeting (F2-F3) in March 2023

2

### Building Momentum Toward Phase 3 Pivotal Trials

- Two parallel Phase 2b trials underway
  - HARMONY (F2-F3)
  - SYMMETRY (F4, compensated)
- Regulatory designations
  - Breakthrough Therapy (US FDA)
  - Fast Track (US FDA)
  - PRIME (European EMA)
- Commercial product-device for Ph3

SYMMETRY readout expected 4Q'23

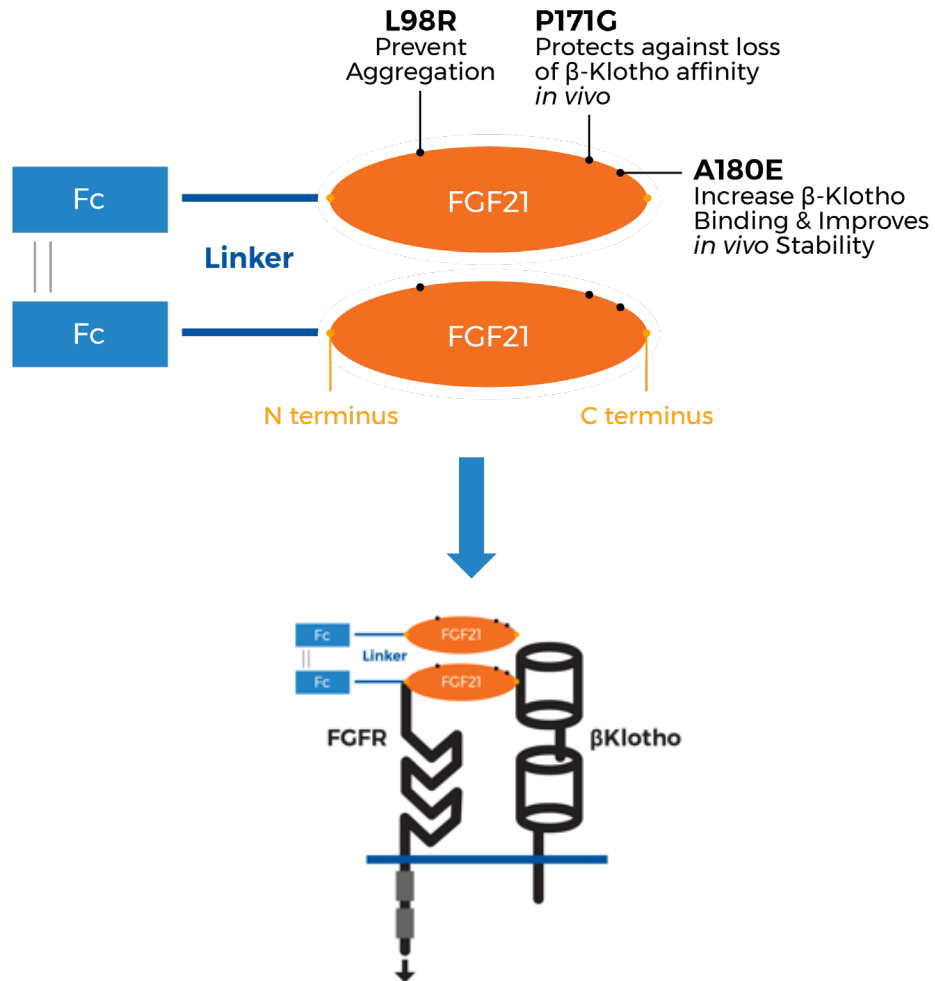
3

### Experienced & Validated Team with Substantial Resources

- Involved in 20+ FDA approvals
- ~\$374M cash on hand as of 3Q'22
  - Includes \$25M Pfizer investment (Q2'22)
  - Includes \$230M Follow-on offering (Q3'22)

Cash runway into 2025

# EFX Engineering Potentially Optimal for NASH Efficacy, With Convenient Once-weekly Dosing



## Key attributes



Akero proprietary Fc-FGF21, Point mutations



Increases half-life from **< 2 hours** to **~3-4 days**



**High affinity** for  $\beta$ -Klotho



Better translation to **human** pharmacology



**Balanced potency** at FGFR1c, 2c, 3c



**Inactive** at FGFR4

Stanislaus, S *et al.* (2017) *Endocrinology* 158(5): 1314-27; Lee, S *et al.* (2018) *Nature* 553: 501-505; Kharitonov, A *et al.* (2007) *Endocrinology* 148(2):774-781

## Breakthrough Therapy (US FDA - 2022)

- Enables expedited development
- Signifies potential for substantial improvement over available therapy on clinically significant endpoints
- Based on Phase 2b HARMONY data

## Fast Track (US FDA - 2021)

- Enables more frequent regulatory interactions to resolve development issues with potential eligibility for priority review
- Signifies potential to fill an unmet medical need
- Based on Phase 2a BALANCED data

## PRIME (EMA - 2020)

- Enables enhanced regulatory support
- Signifies potential to offer a major therapeutic advantage over existing treatments or benefit patients without treatment options
- Based on Phase 2a BALANCED data

**Efruxifermin is the first investigational NASH drug to receive all three designations**

◀ Combination End-of-Phase 2 (F2-F3) / Breakthrough Therapy meeting in March 2023 ▶

# HARMONY

STATISTICALLY SIGNIFICANT EFFECTS AFTER 24 WEEKS

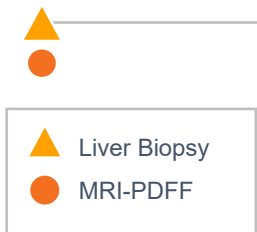
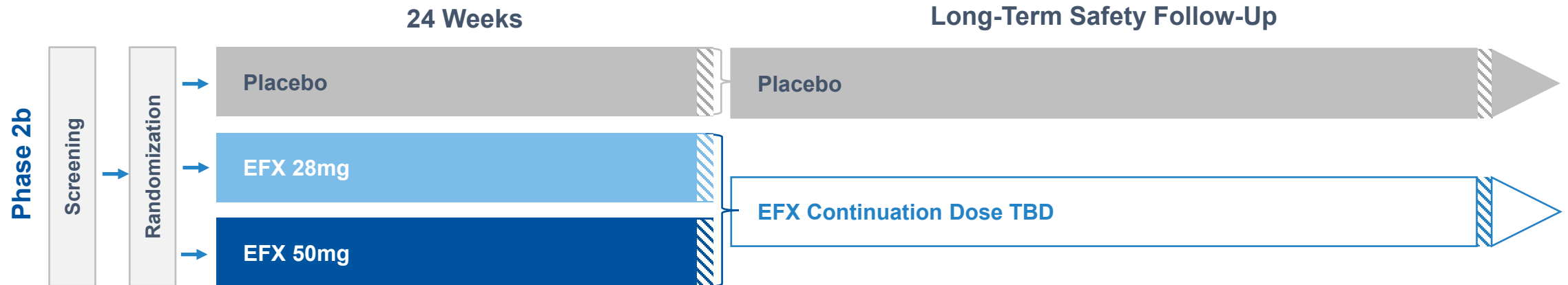
FIBROSIS  
IMPROVEMENT

NASH  
RESOLUTION

FIBROSIS IMPROVEMENT  
AND  
NASH RESOLUTION

# » HARMONY Trial Design: Pre-Cirrhotic (F2-F3) NASH

<p><b>Key Inclusion Criteria</b></p> <ul style="list-style-type: none"> <li>• F2-F3 NASH</li> <li>• NAS <math>\geq 4</math></li> <li>• Liver Fat (MRI-PDFF) <math>\geq 8\%</math></li> </ul>	<p><b>Phase 2b Primary Endpoint</b></p> <ul style="list-style-type: none"> <li>• <math>\geq 1</math>-stage fibrosis improvement without worsening of NASH</li> </ul>	<p><b>Key Secondary Efficacy Endpoints</b></p> <ul style="list-style-type: none"> <li>• NASH Resolution &amp; No Worsening of Fibrosis</li> <li>• Fibrosis Markers</li> <li>• Lipoproteins</li> <li>• Glycemic Control</li> <li>• Weight Change</li> <li>• MRI-PDFF</li> <li>• Liver Injury Markers</li> </ul>
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**Regulatory Requirements for Phase 3 Trials**

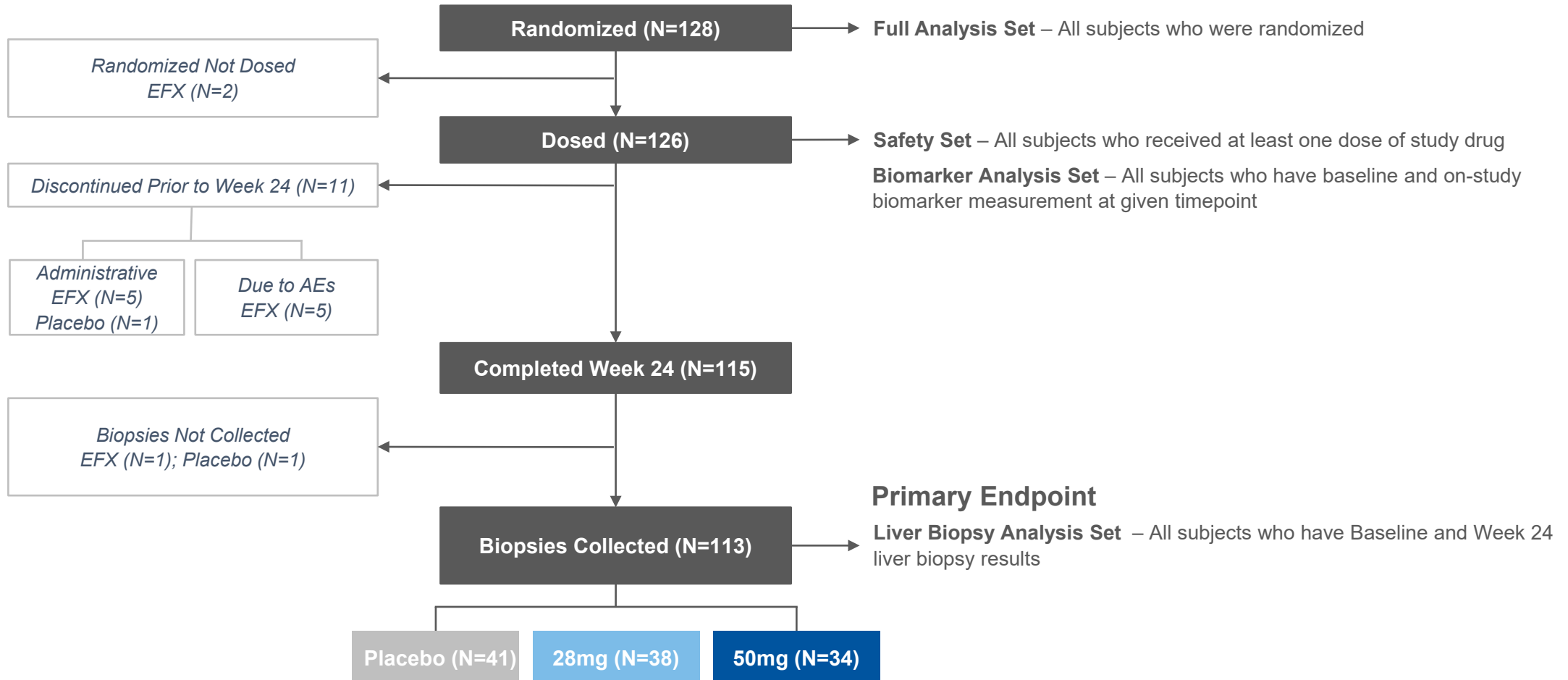
- FDA accepts one of two endpoints for Phase 3 registrational trials: (1) Fibrosis improvement  $\geq 1$  stage & no worsening of NASH or (2) NASH resolution and no worsening of fibrosis<sup>1</sup>
- EMA requires both endpoints to be met for marketing approval<sup>2</sup>

<sup>1</sup> FDA Draft Guidance, Noncirrhotic Nonalcoholic Steatohepatitis With Liver Fibrosis: Developing Drugs for Treatment (2018)

<sup>2</sup> EMA, Draft Reflection paper on regulatory requirements for the development of medicinal products for chronic non-infectious liver diseases (PBC, PSC, NASH) (2018)

# » Week 24 Patient Disposition & Analysis Sets

## Key Analysis Sets





## » Baseline Demographics

Parameter (Mean)	Placebo (N=43)	EFX 28mg (N=42)	EFX 50mg (N=43)
Age (Years)	55	57	52
Sex (% Female)	63	69	53
Weight (kg)	108	104	103
Type 2 Diabetes (%)	65	76	70
Fibrosis Stage (% F3) <sup>1</sup>	70	64	63
Enhanced Liver Fibrosis (ELF) Score	9.8	9.7	9.8
Pro-C3 <sup>2</sup> (µg/L)	16.5	15.3	18.4
Liver Stiffness by VCTE <sup>3</sup> (FibroScan) (kPa)	15	14	16
Hepatic Fat Fraction by MRI-PDFF <sup>4</sup> (%)	17.1	18.5	17.5
NAFLD Activity Score (NAS)	5.4	5.1	5.6
Alanine Aminotransferase (ALT) (U/L)	62	50	63
Aspartate Aminotransferase (AST) (U/L)	57	42	52
HbA1c (%)	6.8	6.8	6.7
Triglycerides (mg/dL)	170	158	154
LDL-Cholesterol (mg/dL)	94	96	111

<sup>1</sup> All patients either fibrosis stage 2 (F2) or stage 3 (F3); <sup>2</sup> Procollagen 3 N-Terminal Propeptide; <sup>3</sup> Vibration-controlled transient elastography; <sup>4</sup> Magnetic Resonance Imaging Proton Density Fat Fraction

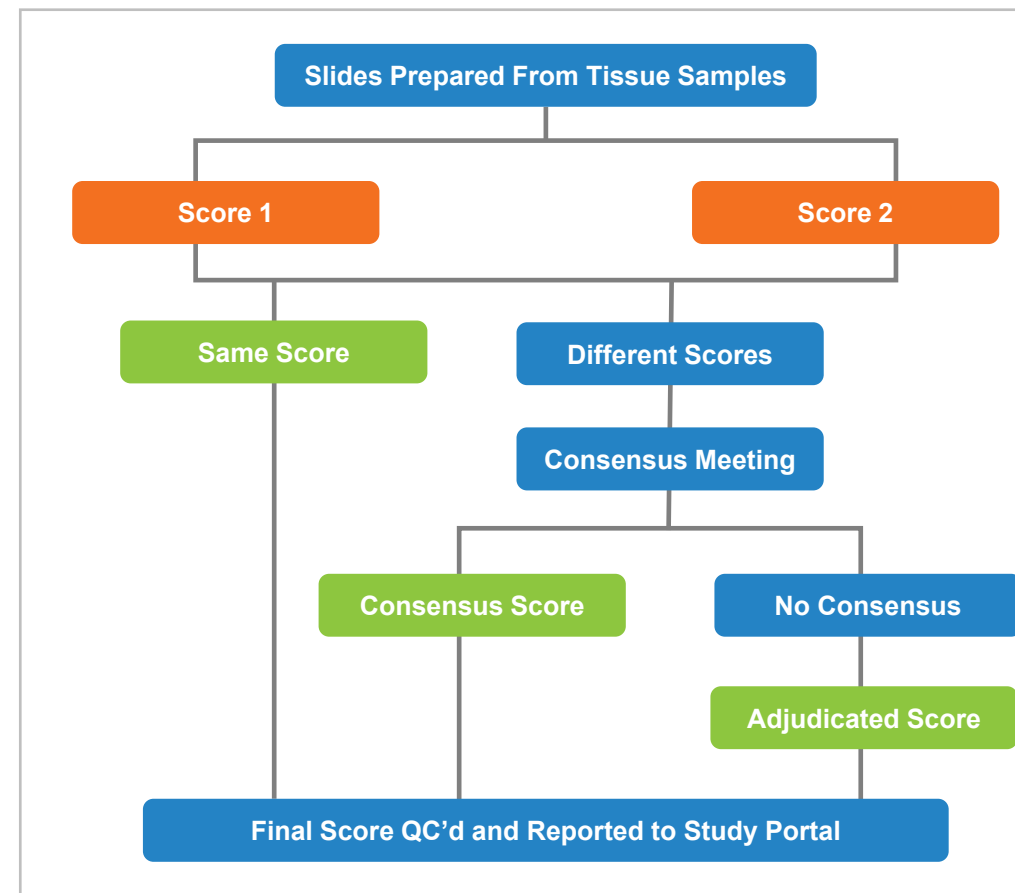


# Consensus Reading of Biopsies: Rigorous Approach to Histopathology Based on FDA Input to Minimize Variability

## Key Features of EFX Biopsy Analysis Plan

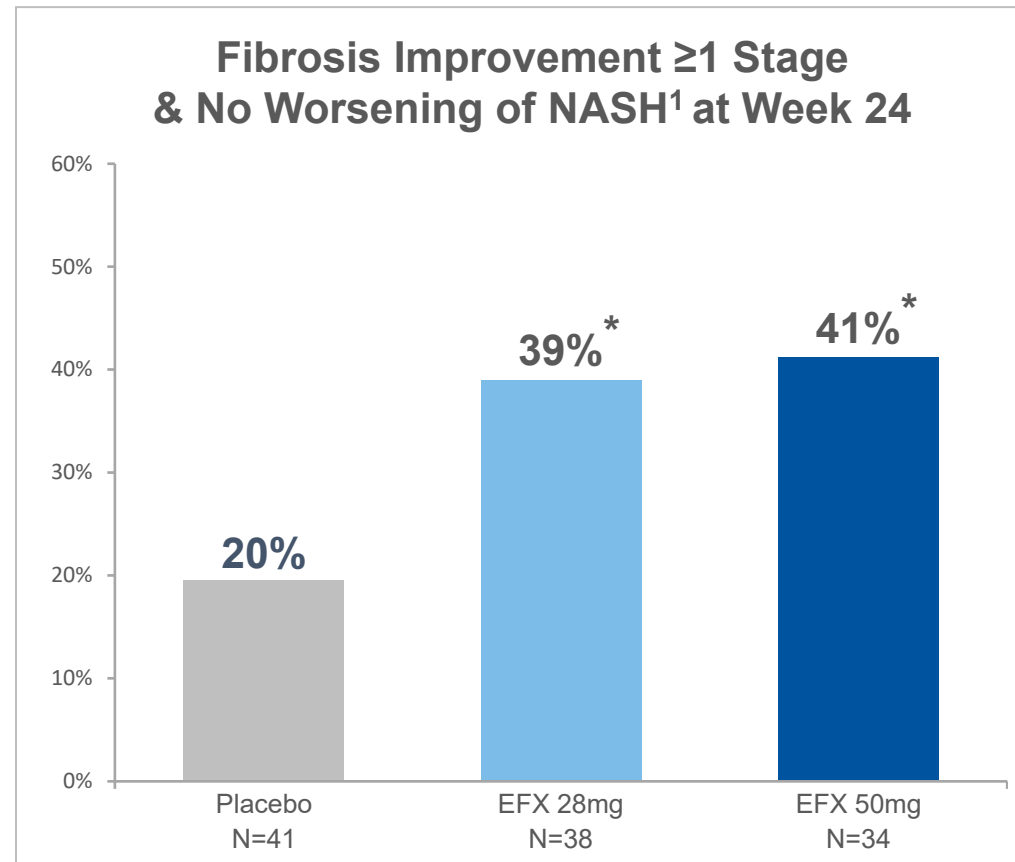
- Biopsies independently scored by two pathologists, with a third pathologist available to adjudicate in absence of consensus
- Pathologists underwent protocol-specific training to align on NASH-CRN scoring interpretation
- Pathologists blinded to subject, treatment, and sequence
- No paired biopsy reads (i.e., pre- and on-treatment biopsies not read side-by-side)

Consensus Biopsy Analysis Flow Chart





# Both EFX Doses Achieved Statistical Significance on Primary Endpoint (Fibrosis Improvement)



<sup>1</sup> Improvement in liver fibrosis greater than or equal to one stage and no worsening of NASH (defined as no increase in NAS for ballooning, inflammation, or steatosis)

\* p<0.05, versus placebo (Cochran–Mantel–Haenszel test [CMH])

# EFX Fibrosis Improvement in Context: Pre-Cirrhotic NASH (≥1 Stage Improvement in Fibrosis and No Worsening of NASH)



**Efruxifermin**  
Phase 2b (F2-F3)  
66% F3  
24 Wks / Completers<sup>1</sup>  
**Consensus Readers**



**Lanifibranor**  
Phase 2b (F1-F3)  
% F3 Not Reported  
24 Wks / Completers<sup>2</sup>  
Single Reader



**Resmetirom**  
Phase 3 (F1-F3)  
62% F3  
52 Wks / ITT<sup>3</sup>  
**Two Readers**  
(Combined Statistically)



**Obeticholic Acid**  
Phase 3 (F2-F3)  
54% F3  
72 Wks / ITT<sup>3</sup>  
**Consensus Readers**

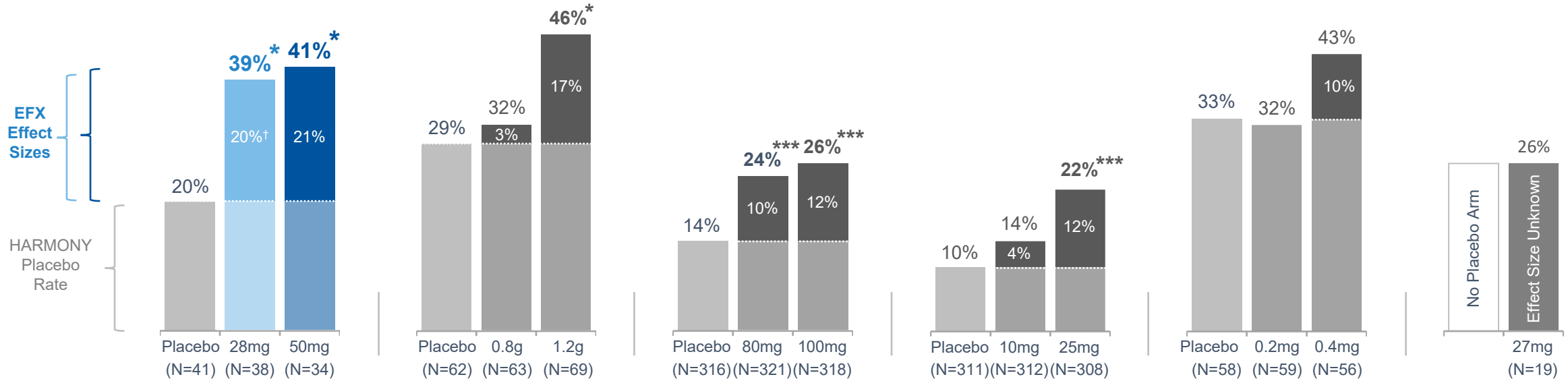


**Semaglutide**  
Phase 2b (F2-F3)  
69% F3  
72 Wks / ITT<sup>3</sup>  
**Consensus Readers**



**Pegozafermin**  
Phase 1b/2a (F2-F3)  
65% F3  
20 Wks / Completers<sup>4</sup>  
Single Reader

By Reported Effect Size (Treatment Minus Placebo)



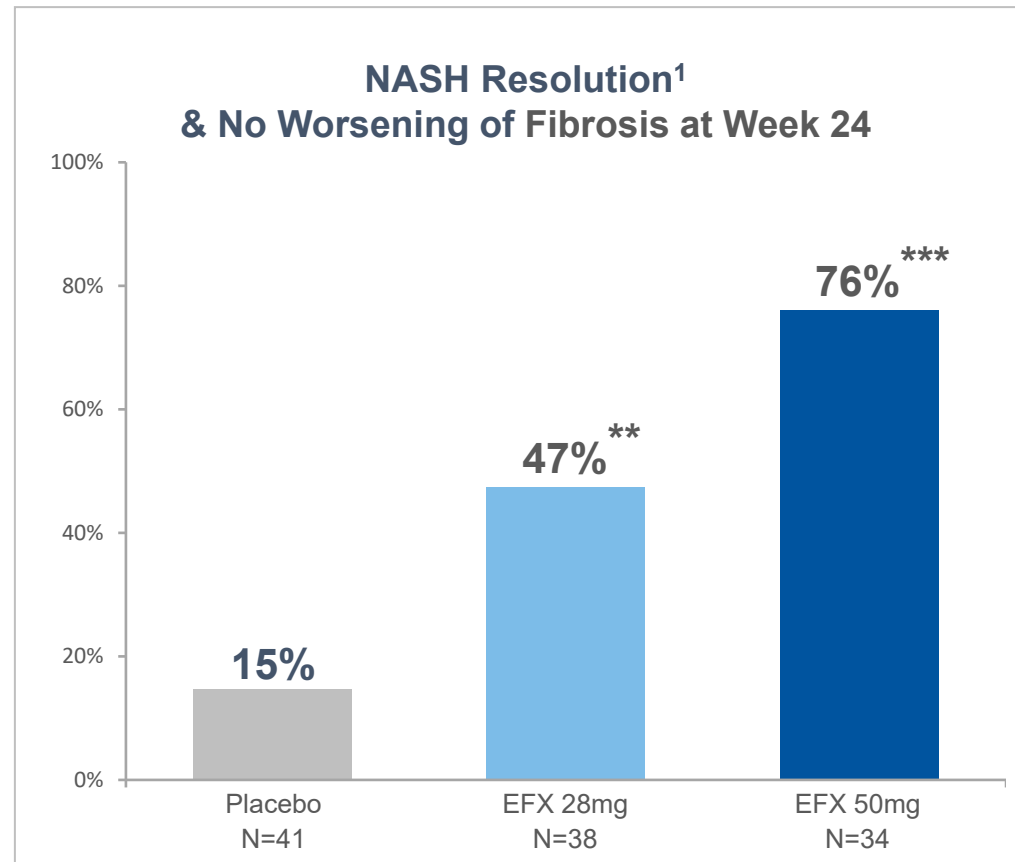
Note: These data are derived from different clinical trials at different points in time, with differences in trial design and patient populations. As a result, cross-trial comparisons cannot be made, and no head-to-head clinical trials have been conducted.

<sup>1</sup> Baseline and Week 24 biopsies available; <sup>2</sup> End-of-study biopsy available with no major protocol deviations; <sup>3</sup> Missing biopsies were imputed as non-responders; <sup>4</sup> End-of-study biopsy available.

Lanifibranor - Francque et al. (2021) New Engl J Med 385, 1547–1558; Obeticholic acid - Intercept (2022) July 7 Press Release; Semaglutide - Newsome et al. (2020) New Engl J Med 384, 1113-24; Resmetirom – Madrigal (2022) December 19 Press Release; Pegozafermin - 89Bio (2022) August 1 Corporate Presentation. All trademarks are the property of their respective owners.



# Both EFX Doses Achieved Statistical Significance on Key Secondary Endpoint (NASH Resolution)



<sup>1</sup> NAS score of 0 or 1 for lobular inflammation and a score of 0 for ballooning

\*\* p<0.01, \*\*\* p<0.001, versus placebo (CMH)

# EFX NASH Resolution in Context: Pre-Cirrhotic NASH (NASH Resolution and No Worsening of Fibrosis)



**Efruxifermin**  
Phase 2b (F2-F3)  
66% F3  
24 Wks / Completers<sup>1</sup>  
**Consensus Readers**



**Semaglutide**  
Phase 2b (F2-F3)  
69% F3  
72 Wks / ITT<sup>2</sup>  
**Consensus Readers**



**Lanifibranor**  
Phase 2b (F1-F3)  
% F3 Not Reported  
24 Wks / Completers<sup>3</sup>  
Single Reader



**Resmetirom**  
Phase 3 (F1-F3)  
62% F3  
52 Wks / ITT<sup>3</sup>  
**Two Readers**  
(Combined Statistically)

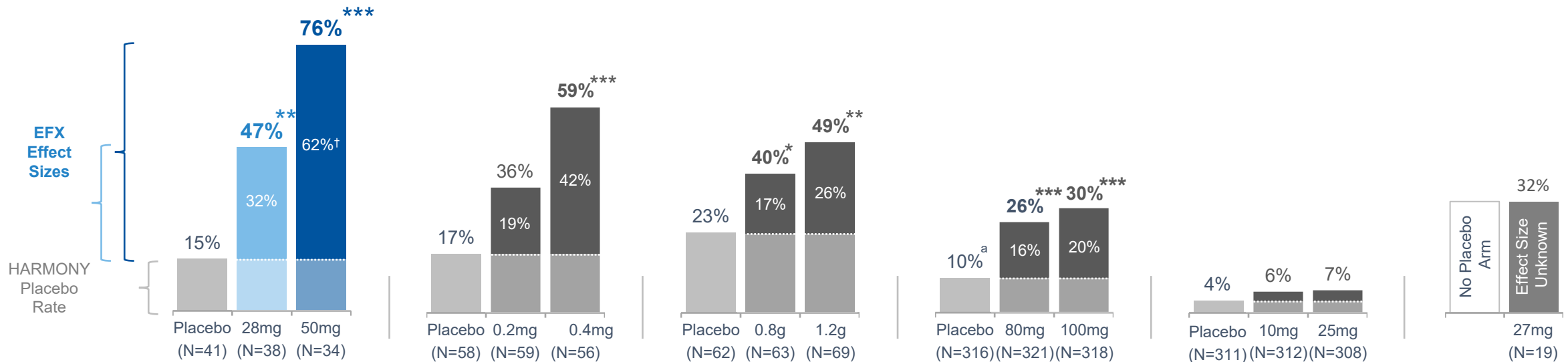


**Obeticholic Acid**  
Phase 3 (F2-F3)  
54% F3  
72 Wks / ITT<sup>2</sup>  
**Consensus Readers**



**Pegozafermin**  
Phase 1b/2a (F2-F3)  
65% F3  
20 Wks / Completers<sup>4</sup>  
Single Reader

By Reported Effect Size  
(Treatment Minus Placebo)



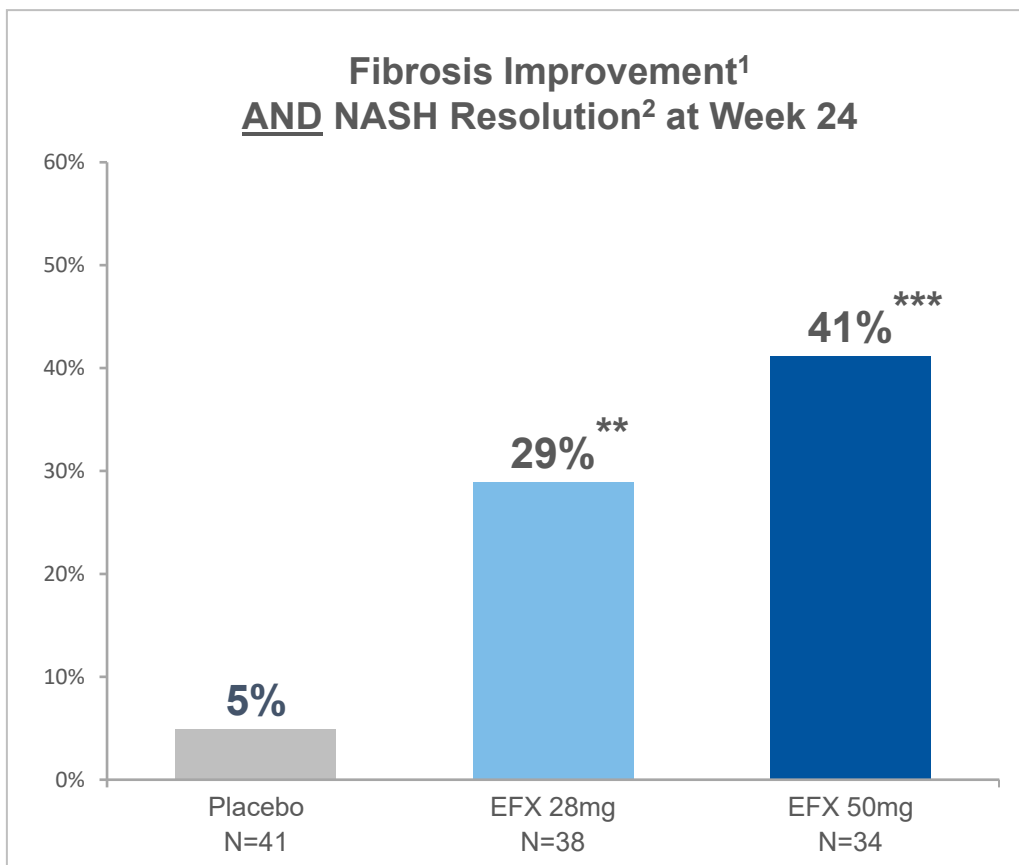
Note: These data are derived from different clinical trials at different points in time, with differences in trial design and patient populations. As a result, cross-trial comparisons cannot be made, and no head-to-head clinical trials have been conducted.

<sup>1</sup> Baseline and Week 24 biopsies available; <sup>2</sup> Missing biopsies were imputed as non-responders; <sup>3</sup> End-of-study biopsy available with no major protocol deviations; <sup>4</sup> End-of-study biopsy available.  
<sup>a</sup> Modified definition of NASH resolution (requiring ≥2 point reduction in NAS) might lead to lower placebo response rate

Semaglutide - Newsome et al. (2020) New Engl J Med 384, 1113–1124; Lanifibranor - Francque et al. (2021) New Engl J Med 385, 1547–1558; Resmetirom – Madrigal (2022) December 19 Press Release; Obeticholic acid - Intercept (2022) July 7 Press Release; Pegozafermin - 89Bio (2022) August 1 Corporate Presentation. All trademarks are the property of their respective owners.



# Both EFX Doses Achieved Statistical Significance on Composite Endpoint (Fibrosis Improvement and NASH Resolution)



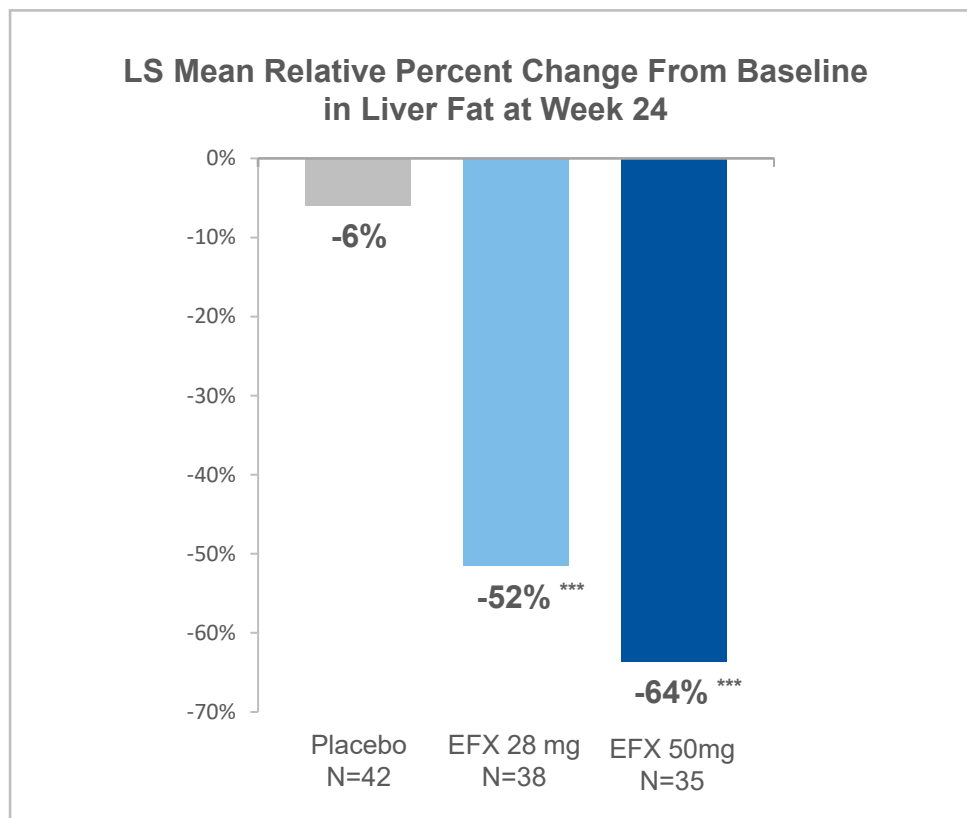
### Patients Achieving Fibrosis Improvement $\geq 2$ Stages and No Worsening of NASH at Week 24

Placebo (N=41)	EFX 28mg (N=38)	EFX 50mg (N=34)
5%	16%	15%

<sup>1</sup> Improvement in liver fibrosis greater than or equal to one stage  
<sup>2</sup> NAS score of 0 or 1 for lobular inflammation and a score of 0 for ballooning  
\*\* p<0.01, \*\*\* p<0.001, versus placebo (CMH)



# Magnitude of Reduction and Normalization of Liver Fat Comparable to Phase 2a BALANCED Study<sup>1</sup>



\*\*\* p<0.001, versus placebo (ANCOVA)

**Proportion of Patients Achieving Fat Reduction Thresholds at Week 24**

Endpoint	Placebo (N=42)	EFX 28mg (N=38)	EFX 50mg (N=35)
<b>Relative Reduction in Liver Fat</b>			
≥50%	2%	63% ***	77% ***
<b>Normalization of Liver Fat Content</b>			
≤5%	2%	34% ***	51% ***

\*\*\* p<0.001, versus placebo (CMH)

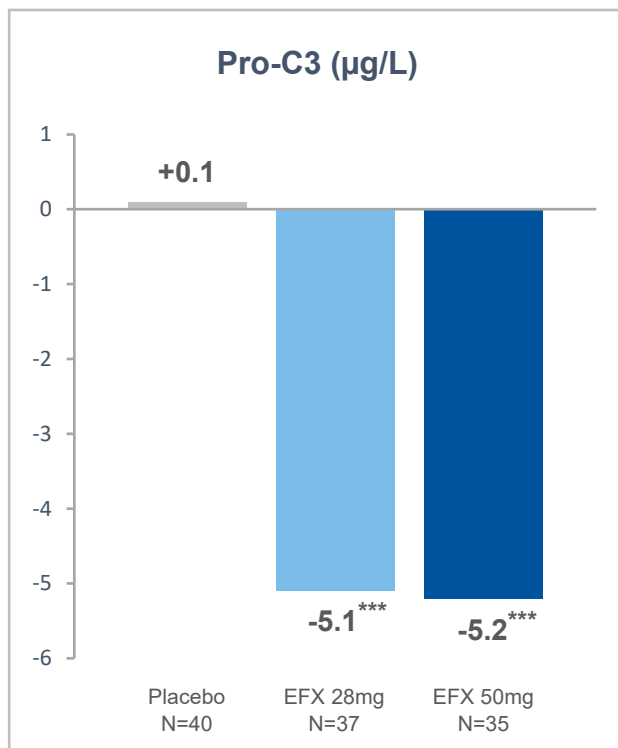
<sup>1</sup> The Phase 2a BALANCED study was a 12-week randomized clinical trial in patients with F1-F3 NASH



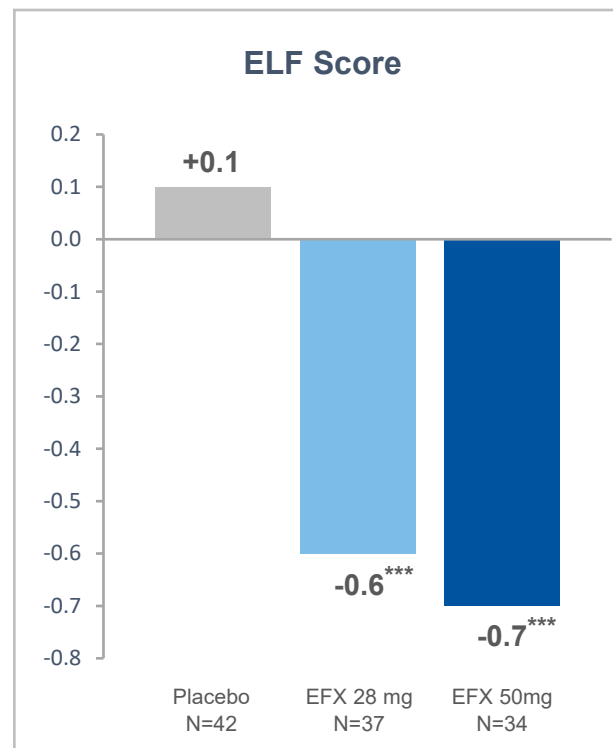


# Statistically Significant Reductions in Non-Invasive Markers Reflect Histological Improvement in Fibrosis

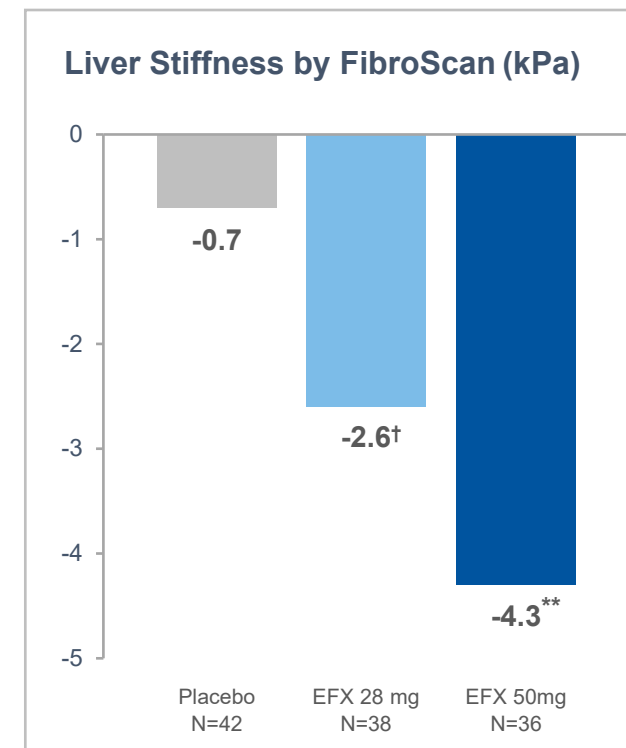
## LS Mean Change From Baseline to Week 24



\*\*\* p<0.001, versus placebo (MMRM<sup>1</sup>)



\*\*\* p<0.001, versus placebo (MMRM<sup>1</sup>)

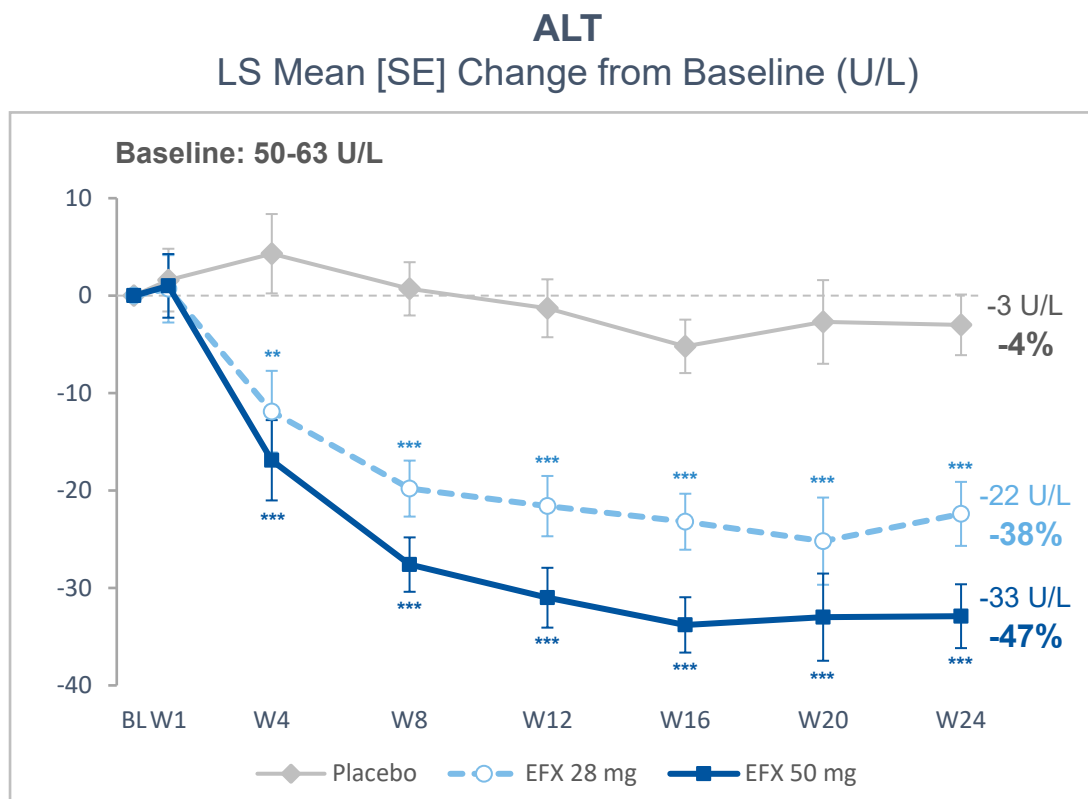


\*\* p<0.01, versus placebo (ANCOVA<sup>2</sup>)  
† p<0.01, versus baseline (ANCOVA<sup>2</sup>)

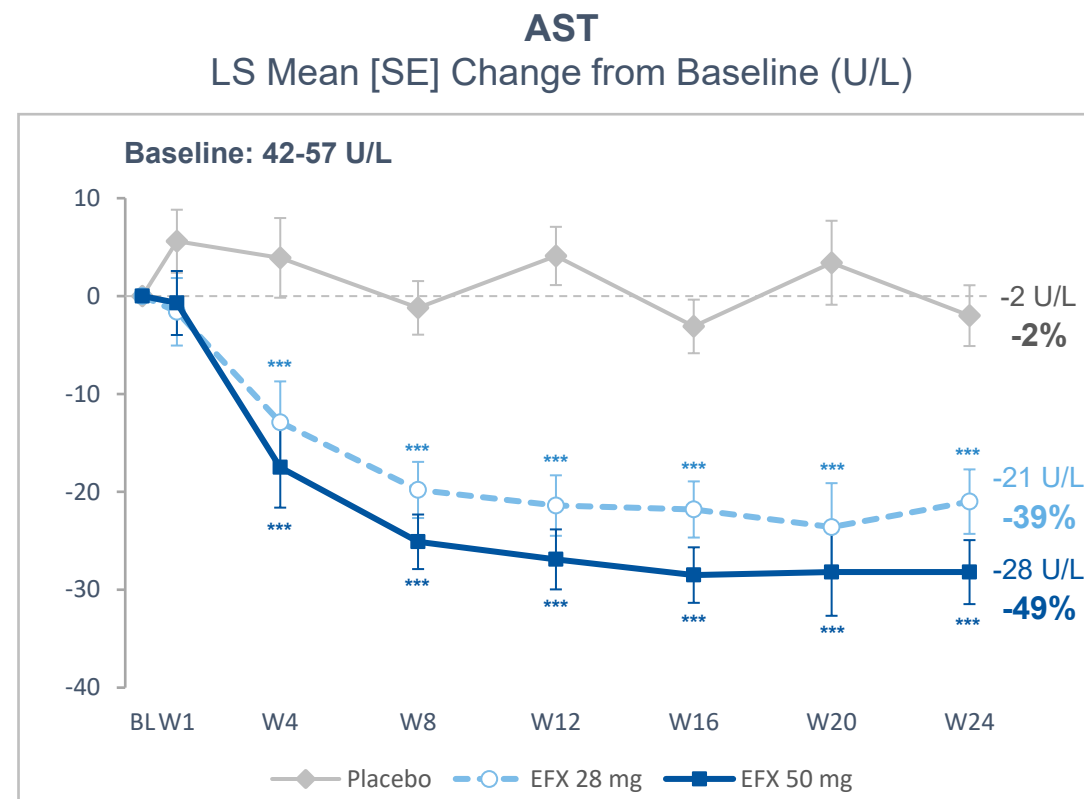
<sup>1</sup> Mixed Model Repeated Measures; <sup>2</sup> Analysis of Covariance



# Rapid and Sustained Statistically Significant Improvements in Markers of Liver Injury



\*\* p<0.01, \*\*\* p<0.001, versus placebo (MMRM<sup>1</sup>)



\*\*\* p<0.001, versus placebo (MMRM<sup>1</sup>)

Statistically significant improvements also observed for GGT & ALP

<sup>1</sup> Mixed Model Repeated Measures

## » Treatment-Emergent Adverse Events (TEAE)

<b>TEAE Overview</b>	<b>Placebo (N=43)</b>	<b>EFX 28mg (N=40)</b>	<b>EFX 50mg (N=43)</b>
TEAE Leading to Death	0 (0%)	0 (0%)	0 (0%)
Drug-Related Serious Adverse Event (SAE)	0 (0%)	0 (0%)	1 (2%) <sup>a,b</sup>
Drug-Related TEAE Leading to Discontinuation	0 (0%)	2 (5%) <sup>c</sup>	2 (5%) <sup>d,e</sup>
<b>Most Frequent (≥15%) Drug-Related TEAEs</b>	<b>Placebo</b>	<b>EFX 28mg</b>	<b>EFX 50mg</b>
Diarrhea	6 (14%)	14 (35%)	14 (33%)
Nausea	5 (12%)	10 (25%)	14 (33%)
Increased Appetite	2 (5%)	7 (18%)	10 (23%)
Frequent Bowel Movements	1 (2%)	8 (20%)	0 (0%)
Injection Site Erythema	5 (12%)	6 (15%)	7 (16%)
Injection Site Bruising	1 (2%)	6 (15%)	3 (7%)

<sup>a</sup> (1) Esophagitis

<sup>b</sup> There were three additional non-drug-related SAEs: (1) Edema; (2) Covid-19; (3) Pancreatitis

<sup>c</sup> (1) Increased appetite & weight gain; (2) diarrhea

<sup>d</sup> (1) Esophagitis & vomiting; (2) Nausea

<sup>e</sup> There was one additional non-drug-related SAE: Lymphadenopathy (not drug-related)

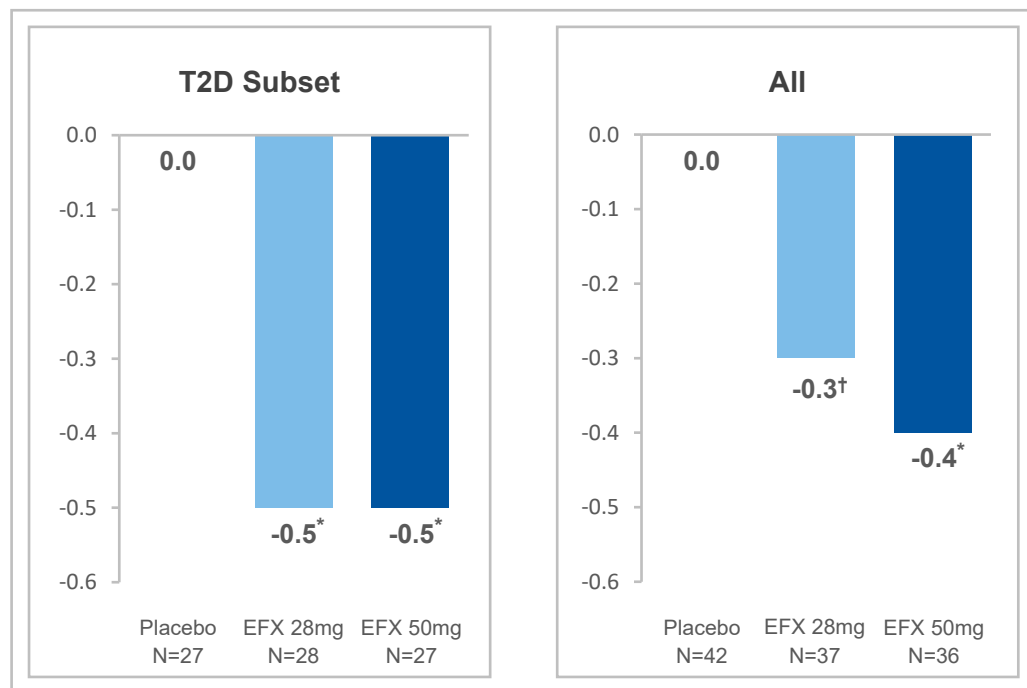


# Clinically Meaningful Improvements Observed in Glycemic Control and Insulin Sensitivity, Particularly in Patients with T2D



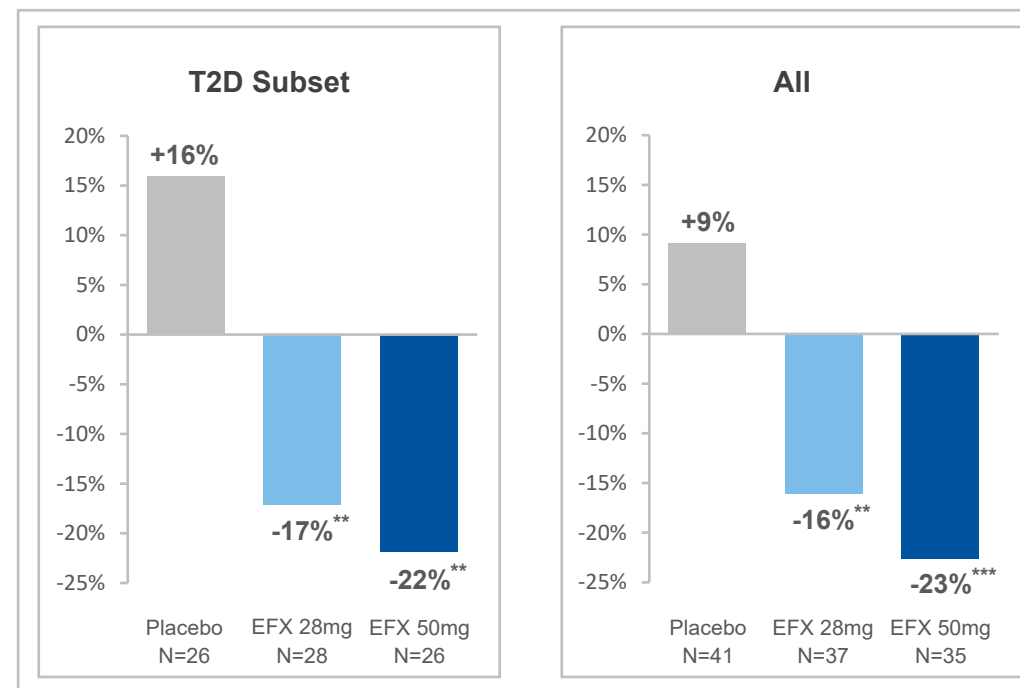
## LS Mean Change From Baseline to Week 24<sup>2</sup>

### HbA1c(%)<sup>1</sup>



\* p<0.05, versus placebo (MMRM); † p<0.05, versus baseline (MMRM)

### C-Peptide<sup>3</sup>



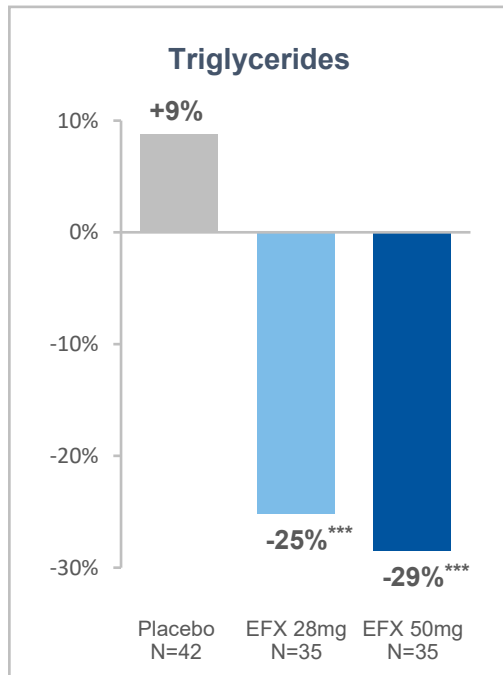
\*\* p<0.01, \*\*\* p<0.001, versus placebo (MMRM)

<sup>1</sup> Absolute change from baseline, %; <sup>2</sup> Patients remained on diabetic medications; <sup>3</sup> Relative percent change from baseline

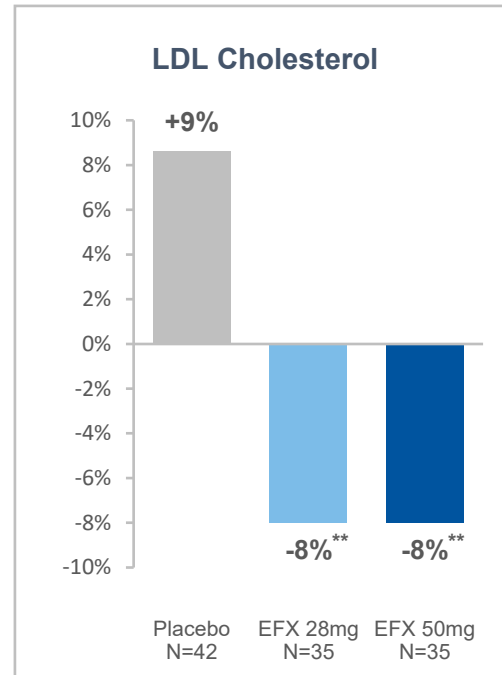
# » Statistically Significant Improvements Observed in Lipoprotein Profile



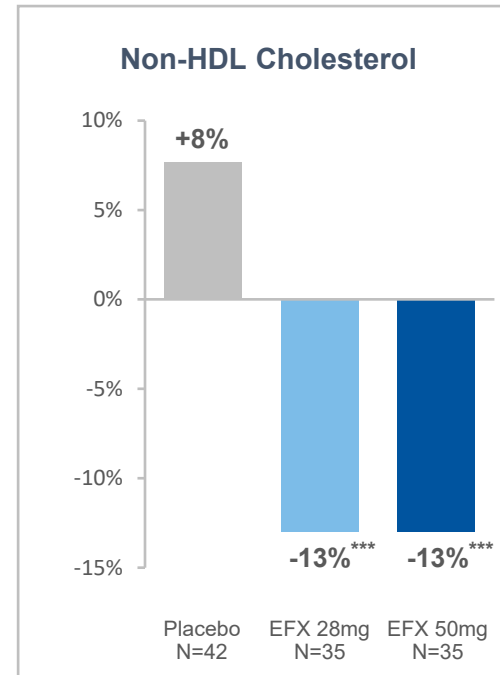
LS Mean Change From Baseline to Week 24 (%)



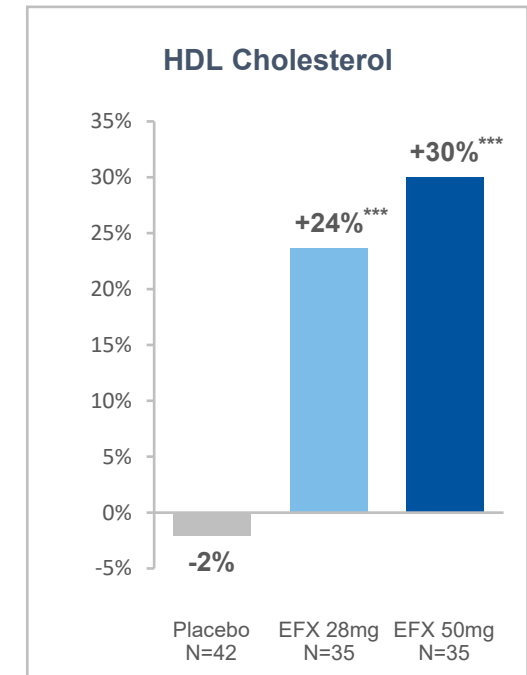
\*\*\* p<0.001, versus placebo (MMRM)



\*\* p<0.01, versus placebo (MMRM)

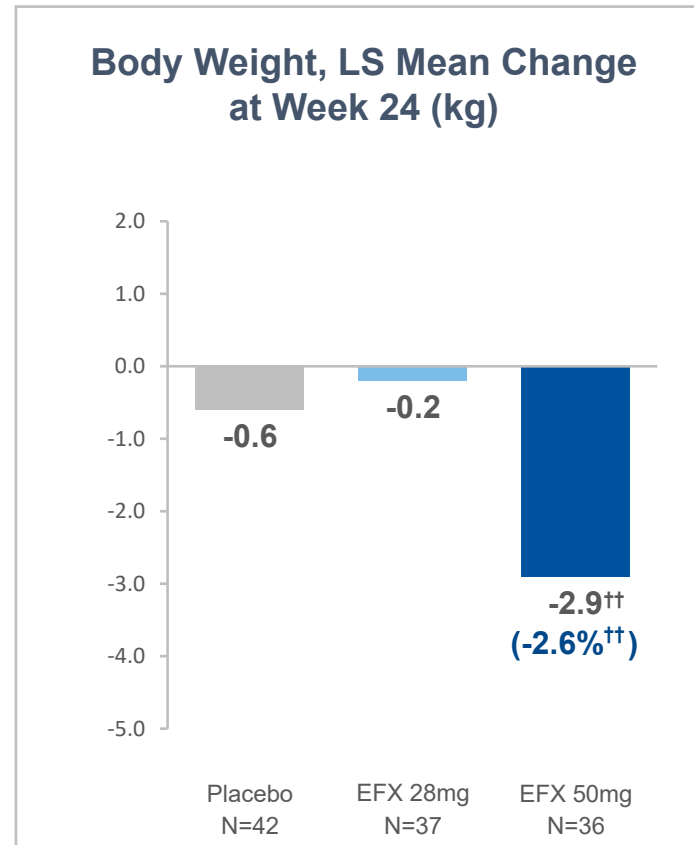


\*\*\* p<0.001, versus placebo (MMRM)



\*\*\* p<0.001, versus placebo (MMRM)

## » Weight Loss Observed for 50mg EFX Dose Group



<sup>††</sup> p<0.01, versus baseline (MMRM)

# symmetry

FOR CIRRHOTIC NASH

Building on Encouraging 16-Week Data in Patients with F4 Fibrosis

**58%**<sup>a</sup>  
Achieved

FIBROSIS  
IMPROVEMENT

or

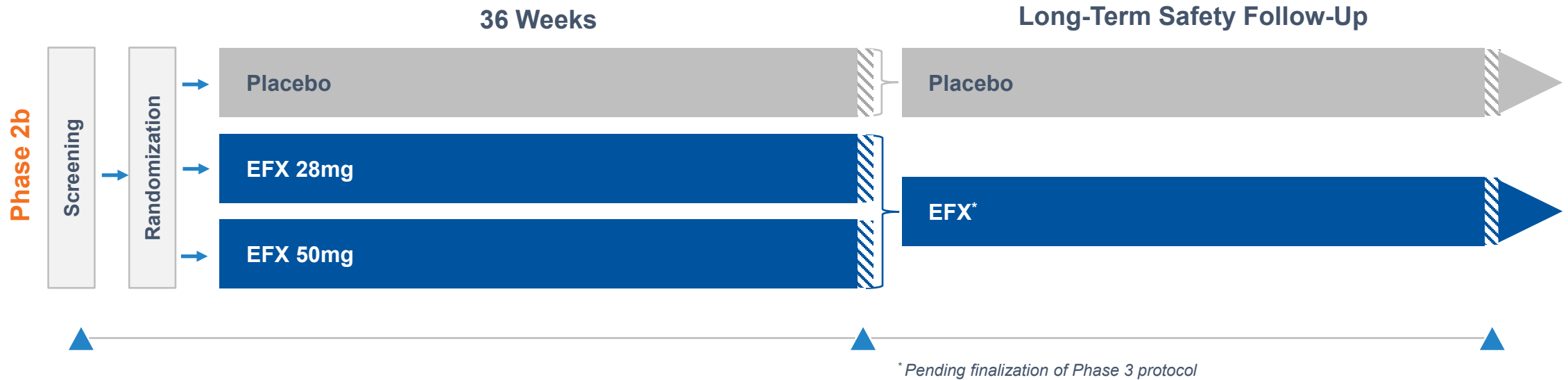
NASH  
RESOLUTION

in Phase 2a

<sup>a</sup> 7 of 12 (58%) patients treated with EFX 50mg in a 16-week expansion cohort (Cohort C) of the Phase 2a BALANCED study achieved either a one-stage improvement in fibrosis without worsening of NASH or NASH resolution without worsening of fibrosis, compared to 0% of placebo patients

# » SYMMETRY Trial Design: Cirrhosis Due to NASH (F4)

- |   |  |   |
|---|--|---|
| <b>Key Inclusion Criteria</b> <ul style="list-style-type: none"><li>• F4 NASH</li></ul> | <b>Phase 2b Primary Endpoint</b> <ul style="list-style-type: none"><li>• Fibrosis Improvement (Cirrhosis reversal)</li></ul> | <b>Key Secondary Efficacy Endpoints</b> <ul style="list-style-type: none"><li>• NASH Resolution</li><li>• Fibrosis Markers</li><li>• Lipoproteins</li><li>• Glycemic Control</li><li>• Weight Change</li><li>• Liver Injury Markers</li></ul> |
|---|--|---|

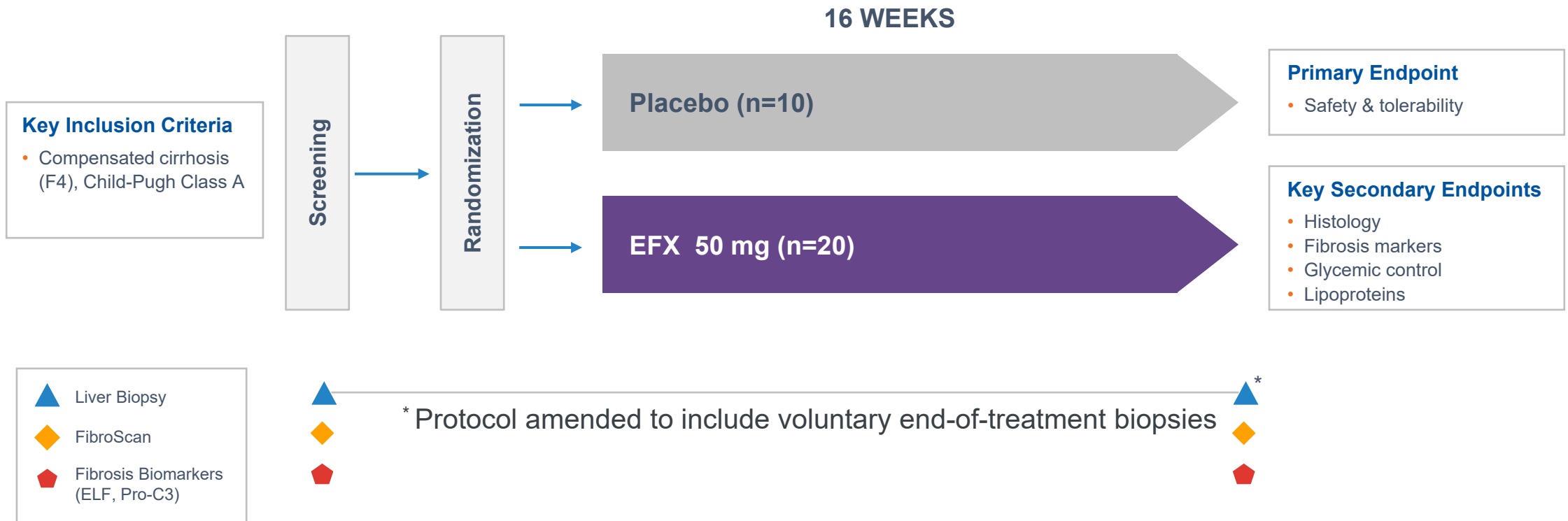


▲ Liver Biopsy

Enrollment completed in December 2022  
Readout expected in Q4'23

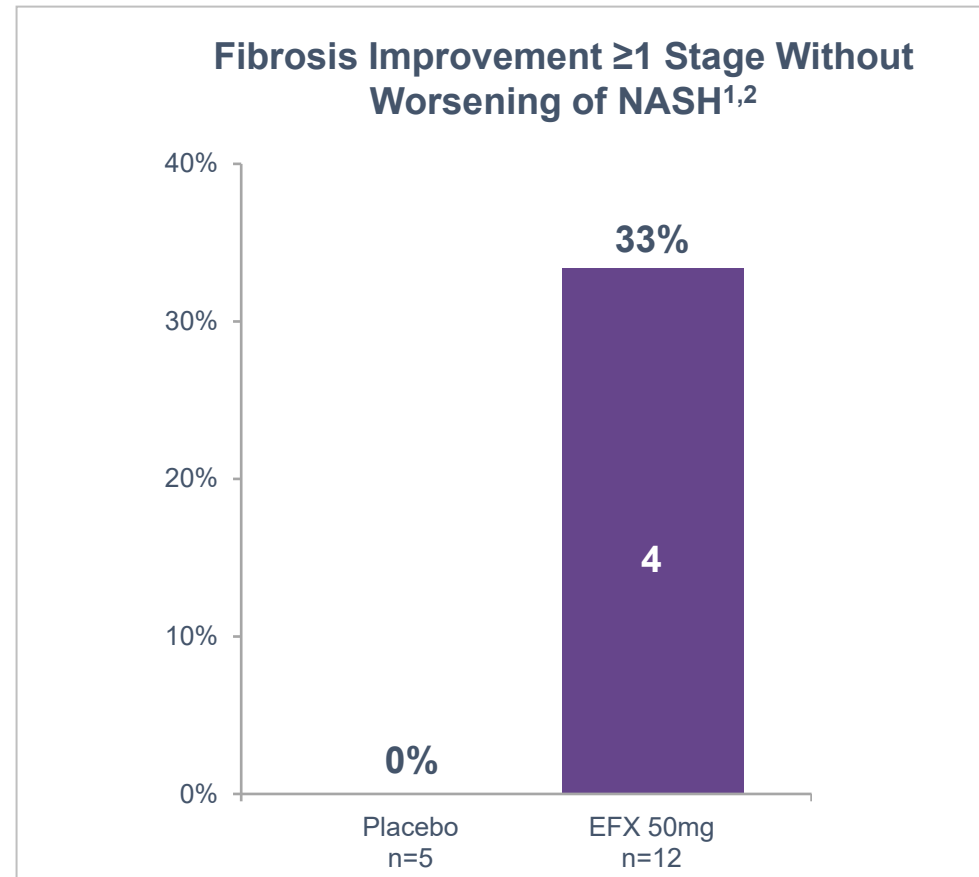


# » Design of Phase 2a Proof-of-Concept Trial for Cirrhotic NASH (F4)



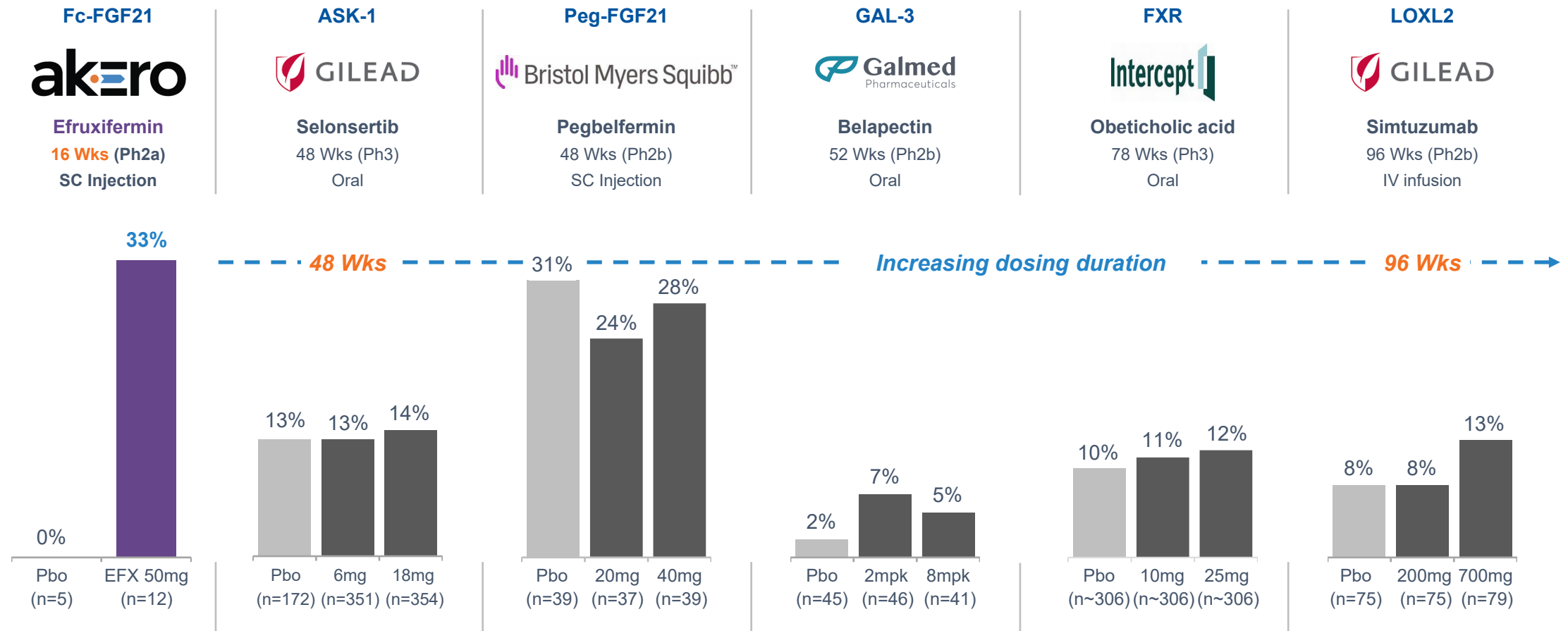


# High Rate of Fibrosis Improvement After Only 16 Weeks Among Patients with Cirrhosis (F4 NASH)



<sup>1</sup> No increase in NAS for ballooning, inflammation, or steatosis; <sup>2</sup> Study not powered to assess statistical significance of changes in histological endpoints

# » EFX Results In Context: Fibrosis Improvement\* (F4)



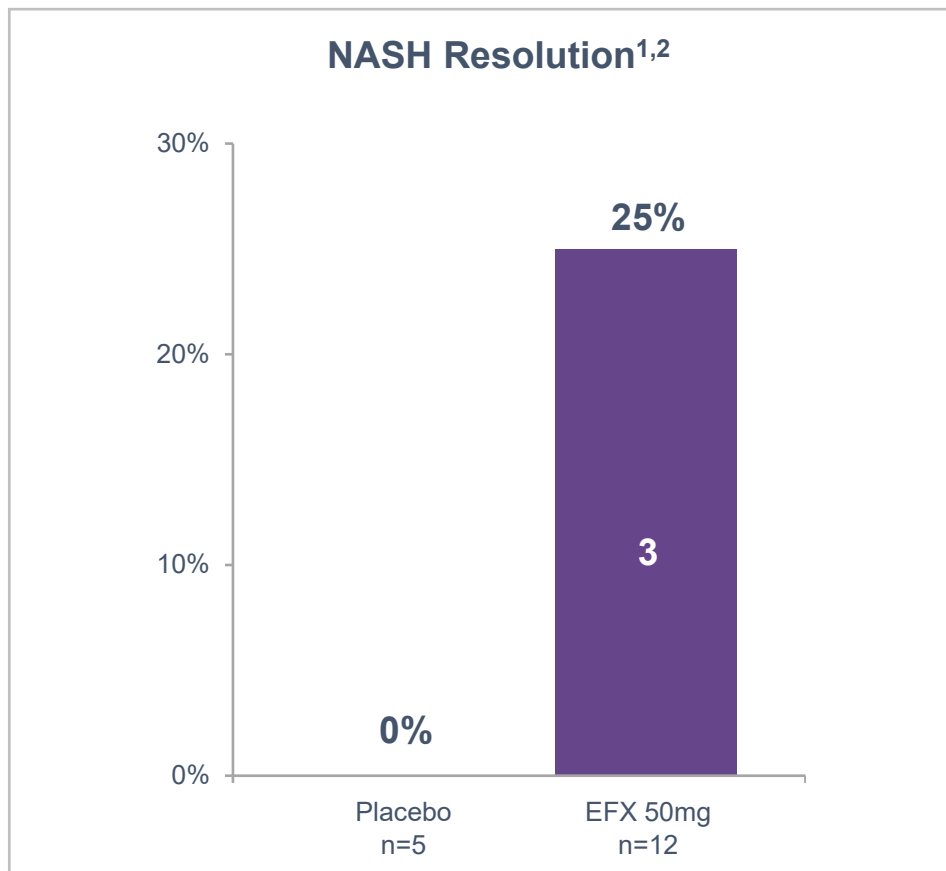
\* Includes results from publicly reported NASH studies for single agents in F4 patients reporting either ≥ 1-stage fibrosis improvement (belaepectin and simtuzumab) or ≥ 1-stage fibrosis improvement and no worsening of NASH (EFX, selonsertib, Pegbelfermin and obeticholic acid); numerical values represent percent responders

Selonsertib – Harrison, SH et al. (2020) J Hepatol 73(1):26-39;  
 Pegbelfermin – Abdelmalek, MF et al. (2021) AASLD Poster LP-8;  
 Belaepectin – Chalasani, N et al. (2020), Gastro 158:1334–45;  
 Obeticholic acid - Intercept (2022) September 30 Press Release;  
 Simtuzumab – Harrison, SH et al. (2018) Gastro 155:1140-53

*Note: These data are derived from different clinical trials at different points in time, with differences in trial design and patient populations. No head-to-head clinical trials have been conducted.*



# NASH Resolution Also Observed in Patients with Cirrhosis (F4 NASH)



<sup>1</sup> NAS score of 0 or 1 for lobular inflammation and a score of 0 for ballooning  
<sup>2</sup> Study not powered to assess statistical significance of histological endpoints

### Change in NAS among Subjects Achieving NASH Resolution

EFX Subject	Baseline NAS	Week 16 NAS
A	7	1
B	3	1
C	6	1

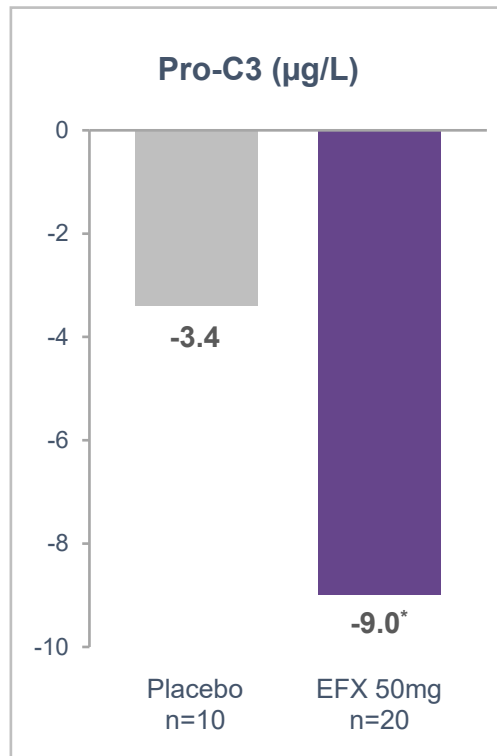
### Proportion of Subjects with ≥2 Point NAS Reduction

Placebo	EFX 50mg
1 (20%)	7 (58%)



# Improvements in Fibrosis Biomarkers in Patients with Cirrhosis Support Histology Results (F4 NASH)

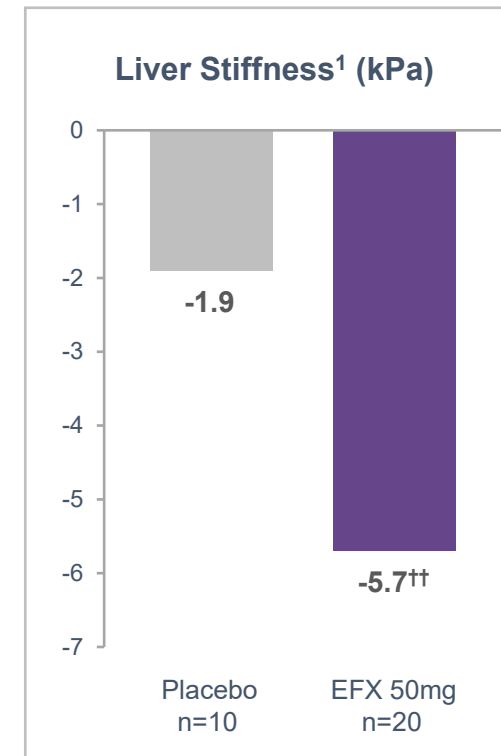
LS Mean Change From Baseline to Week 16



\* p<0.05, versus placebo (ANCOVA)  
†† p<0.01, versus baseline (ANCOVA)



\*\* p<0.01, versus placebo (ANCOVA)



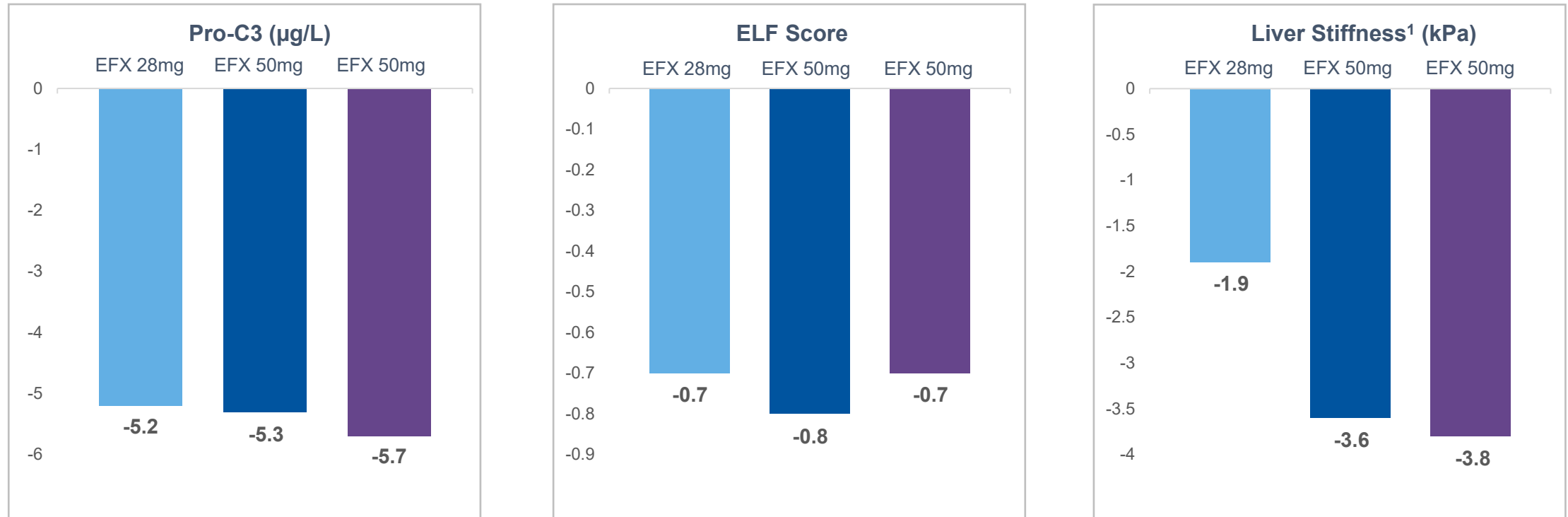
¹ Measured by FibroScan



# Placebo-Corrected Reductions in Cohort C (F4) Fibrosis Markers Consistent with Magnitude Observed for HARMONY (F2-F3)



LS Mean Placebo-Corrected Change From Baseline to Week 24<sup>a</sup> or Week 16<sup>b</sup>



- HARMONY / EFX 50mg
- HARMONY / EFX 50mg
- Cohort C / EFX 50mg

<sup>a</sup> HARMONY study (F2-F3); <sup>b</sup> BALANCED Cohort C (F4)

**Cohort D Design: Non-Cirrhotic NASH (F1-F3)**



FGF21 and GLP-1 have complementary mechanisms of action, respectively as an insulin sensitizer and an insulin secretagogue

Enrollment completed in December 2022; Readout expected in Q2'23

# » Strong Financial Position

## UPSIZED IPO

June 20, 2019

~\$106M

Priced upsized IPO at top of marketing range

## UPSIZED FOLLOW-ON

July 10, 2020

~\$216M

Priced upsized follow-on offering at top of marketing range

## PFIZER INVESTMENT & TERM LOAN

June 16, 2022

~\$125M

\$25M Pfizer investment at a premium & \$100M Hercules term loan facility

## UPSIZED FOLLOW-ON

September 19, 2022

~\$230M

Financial resources<sup>1</sup> sufficient to fund current operating plan into 2025

<sup>1</sup> Financial resources consists of cash, cash equivalents and short-term marketable securities on hand & Hercules term loan, if fully drawn





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