

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d)
of The Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): June 8, 2022

Akero Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-38944
(Commission
File Number)

81-5266573
(I.R.S. Employer
Identification No.)

601 Gateway Boulevard, Suite 350
South San Francisco, CA
(Address of principal executive offices)

94080
(Zip Code)

Registrant's telephone number, including area code (650) 487-6488

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	AKRO	The Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 7.01 Regulation FD Disclosure

Akero Therapeutics, Inc. (the "Company") from time to time presents and/or distributes to the investment community at various industry and other conferences slide presentations to provide updates and summaries of its business. A copy of its current corporate slide presentation is being furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.1.

The information under this Item 7.01, including Exhibit 99.1 attached hereto is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Corporate slide presentation of Akero Therapeutics, Inc., furnished herewith
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: June 8, 2022

AKERO THERAPEUTICS, INC.

By: /s/ Andrew Cheng
Name: Andrew Cheng, M.D., Ph.D.
Title: President and Chief Executive Officer



Restoring Balance. Renewing Life.

Corporate Presentation



June 2022



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 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 paired biopsy data from our Phase 2a BALANCED study; the potential benefits resulting from the PRIME and Fast Track designations of EFX; the Phase 2b HARMONY and SYMMETRY studies, including expected timing to complete enrollment, 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; expectations regarding the Company's 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

2

Building Momentum Toward Phase 3 Pivotal Trials

- Two parallel Phase 2b trials underway
 - HARMONY (F2-F3)
 - SYMMETRY (F4, compensated)
- Regulatory designations
 - Fast Track (US FDA)
 - PRIME (European EMA)
- Commercial drug product-device for Phase 3

3

Experienced Team with Strong Cash Position

- Involved in 20+ FDA approvals
- ~\$165M cash on hand as of 1Q'22
- Cash runway into 3Q'23

HARMONY results expected 3Q'22

» Extensive Development and Commercialization Experience
Involved in 20+ Medicine Approvals



Andrew Cheng, MD, PhD | President & CEO

- 19 years at Gilead
- Chief Medical Officer & HIV Division Head
- Major role in 11 NDA/MAA approvals



Kitty Yale | Chief Development Officer

- Over 25 years at Gilead, Roche, Pfizer
- VP, Gilead Worldwide Clinical Operations
- Major role in 8 global approvals NDA, MAA, JNDA and CFDA



Tim Rolph, D.Phil | Co-Founder & Chief Scientific Officer

- Over 30 years at Pfizer & Glaxo
- CSO of Pfizer's cardiovascular and metabolic disease unit
- Head of Groton & UK Discovery Research, Pfizer
- Major role in discovery and early clinical evaluation of two medicines: Selzentry (HIV) and Steglatro (Diabetes)



Jonathan Young, PhD, JD | Co-Founder & COO

- Over 15 years in biotechnology product development, law and regulatory policy
- General Counsel and VP Policy, Braeburn
- Partner and General Counsel, FoxKiser



William White | CFO & Head of Corporate Development

- 18 years in life sciences investment banking at Goldman Sachs, Citigroup and Deutsche Bank
- Most recently, Head of US Life Sciences Investment Banking at Deutsche Bank
- Advised on more than \$70bn in M&A and \$25bn in financing transactions



Reducing liver fat
is critical to remove
disease driver



Peripheral fat
is the largest source of
liver fat in patients with
NASH



30 Million
US patients with NASH
by 2030



Insulin resistance and
Type 2 Diabetes drives
liver caloric burden



**Achieving >10% weight
loss** is challenging for
patients who are obese

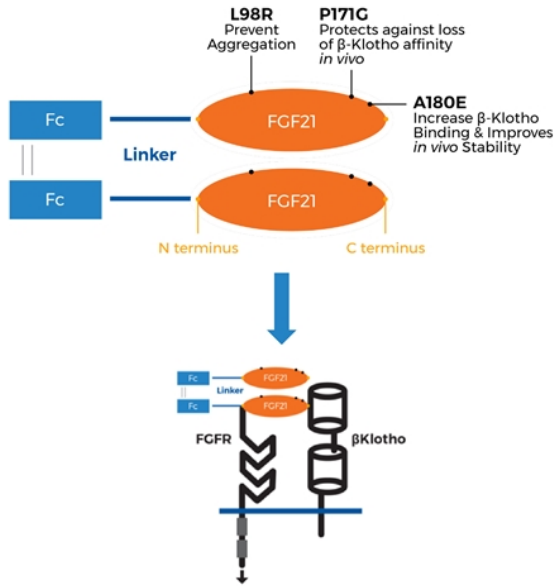


Reversing fibrosis
is key to avoiding
transplant, cancer, death





Dyslipidemia drives
cardiovascular disease, the #1
cause of mortality


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 β -Klotho
- 

Better translation to human pharmacology
- 

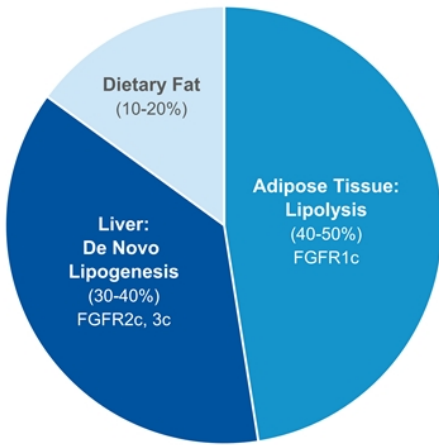
Balanced potency at FGFR1c, 2c, 3c
- 

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

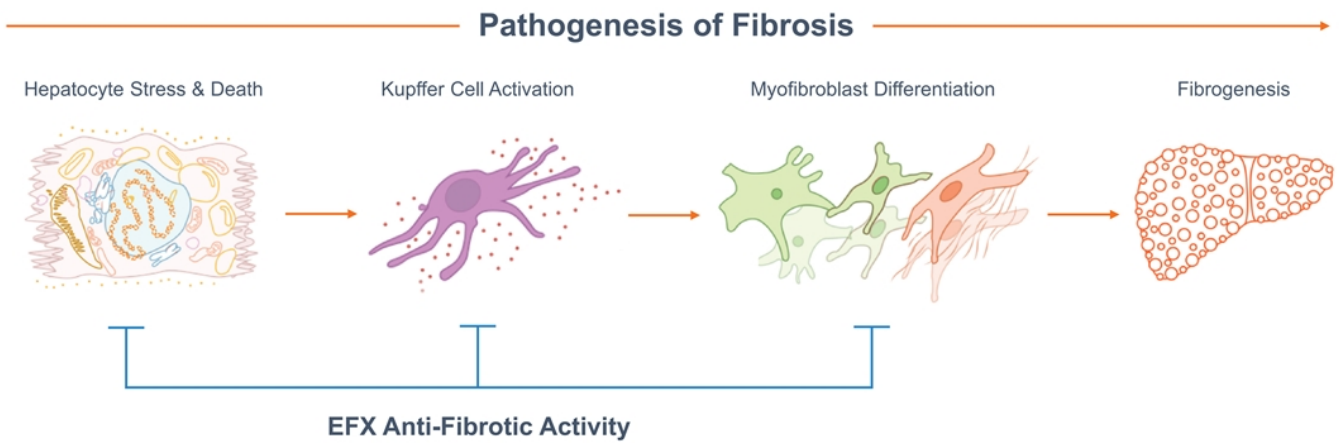
» EFX Acts on Two Major Sources of Liver Fat With Potential for Optimal Reduction

Sources of Fat Flowing into and Through Liver for Patients with NASH



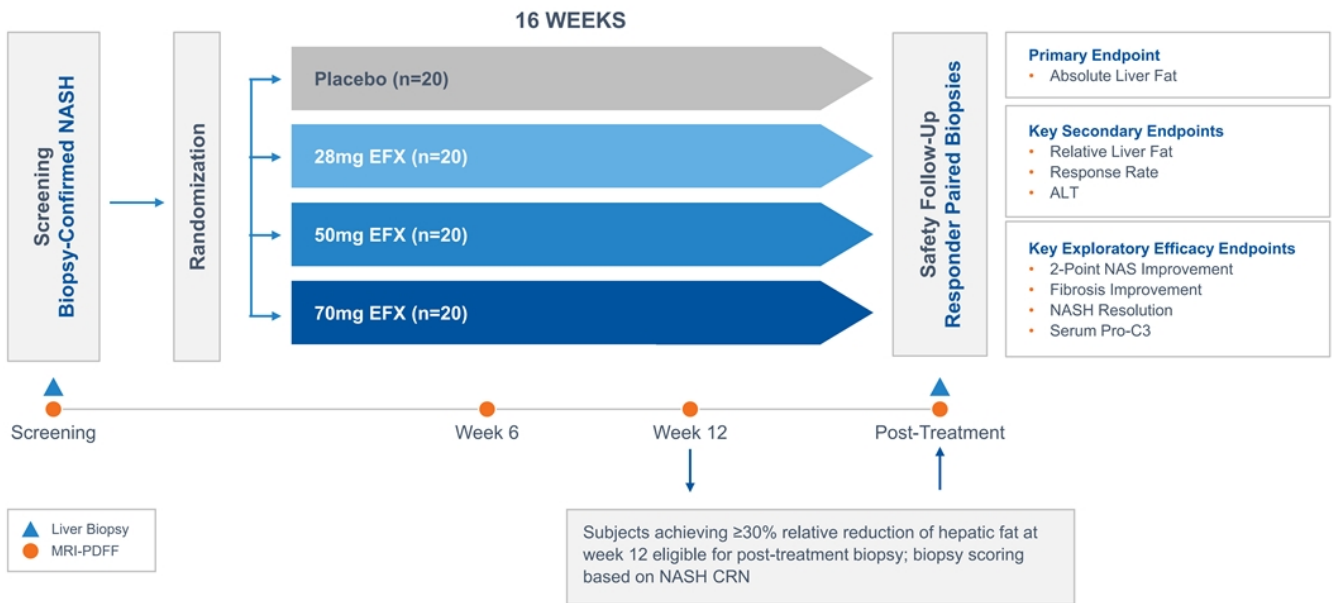
Acting on both hepatic and peripheral sources of liver fat is key to optimizing liver fat reduction

Source of Liver Fat	FGF Receptor	EFX Activity
Lipolysis	FGFR1c	✓
De Novo Lipogenesis	FGFR2c FGFR3c	✓

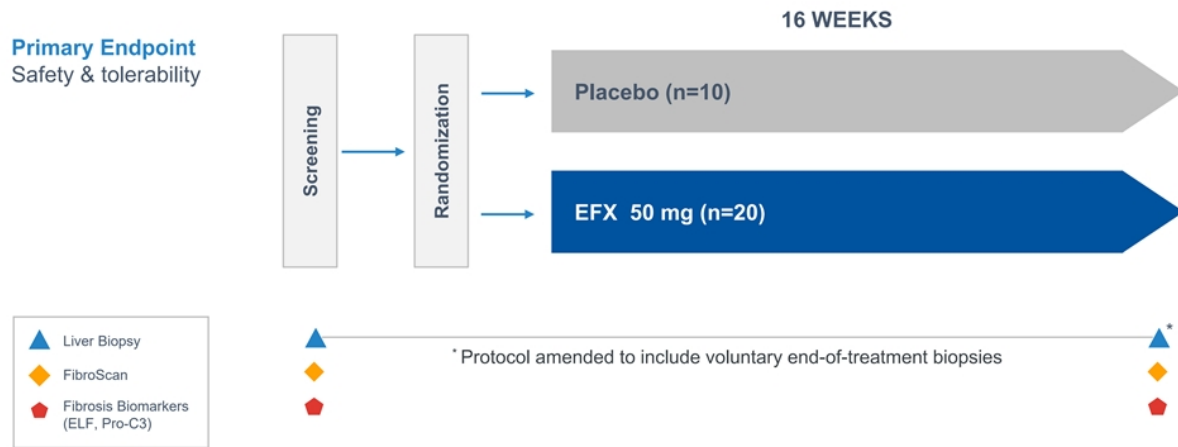


Bao, L et al. (2018) *Br J Pharmacol* 175:3379-3393; Fisher, FM et al. (2014) *Gastroenterology* 147:1073-1083.e6; Jimenez, V et al. (2018) *EMBO Mol Med* 10:e8791; Lee, JH et al. (2016) *Am J Transl Res* 8:4750-4763; Sanyal, A et al. (2018) *Lancet* 392:2705-2717; Le, CT et al. (2018) *PLOS one* 13:e0192146; Xu, P et al. (2016) *Toxicol Appl Pharmacol* 290:43-53; Yu, Y et al. (2016) *Int Immunopharmacol* 38:144-152

*Cited literature available on company website



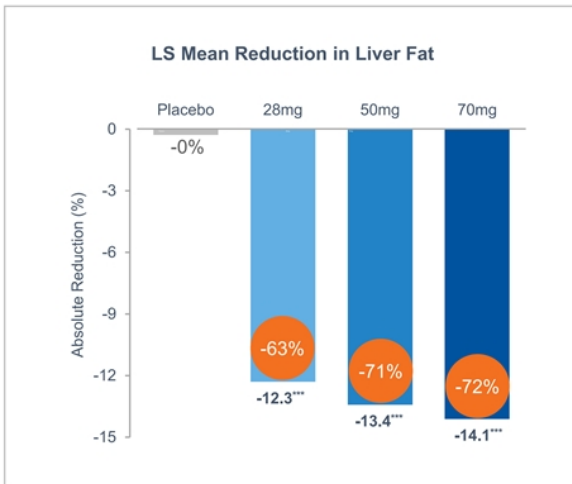
BALANCED study included an expansion cohort, Cohort C, of patients with compensated cirrhosis (F4), Child-Pugh Class A



Parameter Mean	BALANCED Main Study ^a				Cohort C ^b	
	Placebo (N=21)	EFX 28mg (N=19)	EFX 50mg (N=20)	EFX 70mg (N=20)	Placebo (N=10)	EFX 50mg (N=20)
Age (Years)	52	50	53	53	57.1	61.1
Sex (Male/Female)	6/15	9/10	10/10	9/11	7/3	4/16
Weight (kg)	99.6	108.2	103.6	103.1	119.1	97.9
NAFLD Activity Score (NAS) (range)	5.1 (4 to 7)	5.6 (4 to 7)	5.1 (3 to 7)	5.6 (5 to 7)	3.4 ^c (1 to 6)	4.2 ^c (1 to 7)
Alanine Aminotransferase (ALT) (U/L)	50.7	62.5	53.4	56.8	32.7	31.7
Aspartate Aminotransferase (AST) (U/L)	38.6	41.1	35.4	44.6	28.9	31.4
% Type 2 Diabetes	67	37	50	50	50	50
HbA1c (%)	6.5	6.2	6.4	6.2	6.5	6.1
Triglycerides (mg/dL)	208	176	177	180	122	135
ELF Score	9.4	9.5	9.5	9.6	9.7	10.4
Pro-C3 (µg/L)	16.1	19.2	16.2	17.2	22.6	25.6
Liver Stiffness (kPA)	11.9	12.5	11.3	12.4	25.8	22.1

^a Full Analysis Set, F1-F3 (all subjects randomized into the BALANCED main study); ^b Full Analysis Set, F4 (all subjects randomized into BALANCED Cohort C [except where otherwise noted]); ^c Liver Biopsy Analysis Set, F4 (all Cohort C subjects confirmed by central reader as F4 at baseline with Week 16 liver biopsy results)

Substantial Reductions in Liver Fat at Week 12 Across All Dose Groups (F1-F3 NASH)



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

Proportion of Patients Achieving Fat Reduction Thresholds

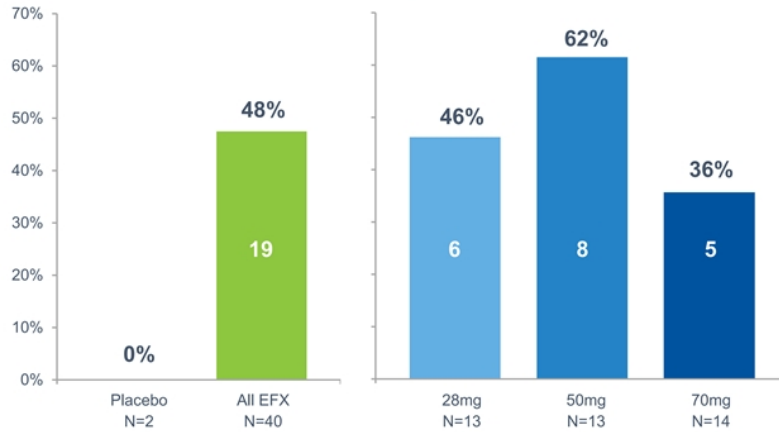
Endpoint	Placebo (N=20)	28mg (N=16)	50mg (N=17)	70mg (N=15)
Relative Reduction in Liver Fat				
≥30%	10%	100%**	100%***	100%***
≥50%	5%	69%**	100%***	93%***
≥70%	5%	50%*	53%**	80%***
Normalization of Liver Fat Content				
≤5%	5%	25%*	53%**	67%***

* p<0.05, ** p<0.01, *** p<0.001, versus placebo (ANCOVA)

Source Data: Full Analysis Set, F1-F3

High Rates of Fibrosis Improvement After 16 Weeks Across All Dose Groups (F1-F3 NASH)

Fibrosis Improvement ≥ 1 Stage and No Worsening of NASH^{1,2}



¹ 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)

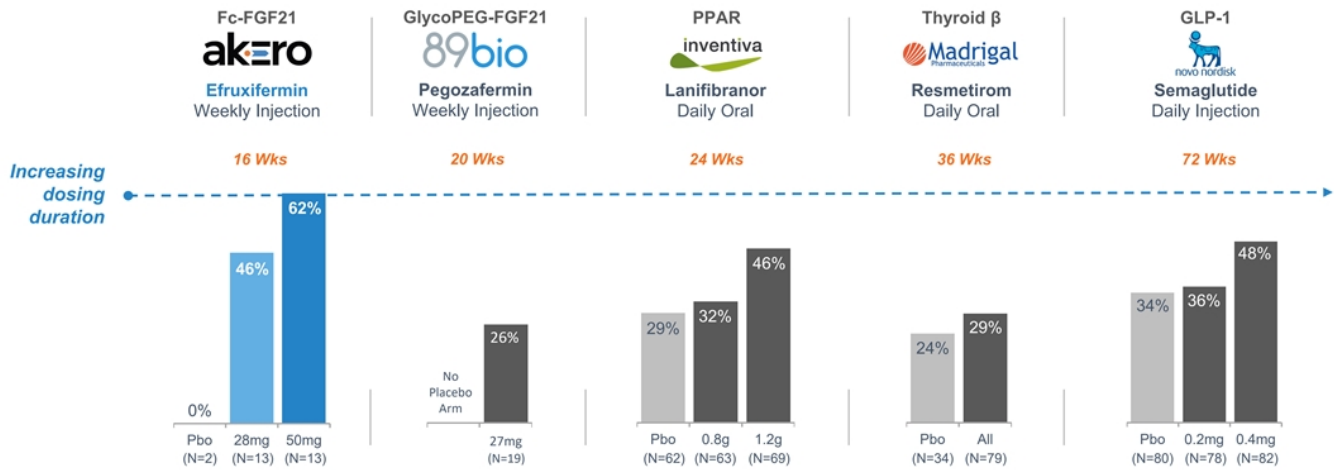
² Secondary and exploratory histological endpoints were not powered for statistical significance

Biopsy Reading

- All baseline and end-of-treatment biopsies were centrally read by a single NASH-CRN pathologist
- Baseline biopsies were not re-read with end-of-treatment biopsies
- All biopsies were read blinded to both treatment assignment and patient

Source Data: Liver Biopsy Evaluable Analysis Set, F1-F3 (all BALANCED main study responders who had baseline and end-of-treatment liver biopsy results)

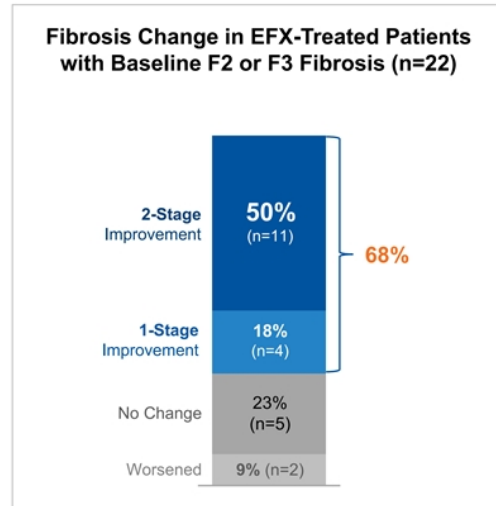
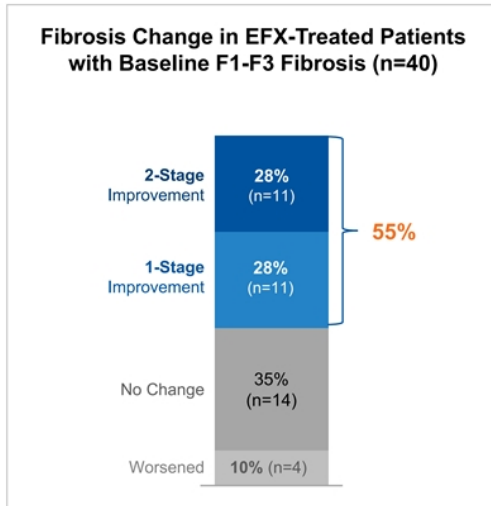
Proportion of Patients with ≥1 Stage Improvement in Fibrosis and No Worsening of NASH¹



Note: These data are derived from different Phase 2 clinical trials at different points in time, with differences in trial design and patient populations. No head-to-head clinical trials have been conducted.

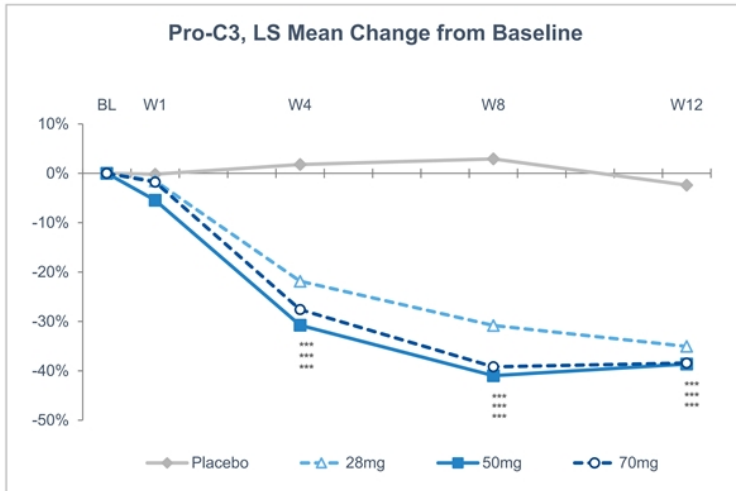
89Bio (2022) January 24 Corporate Presentation; Inventiva (2020) June 16 Corporate Presentation; Harrison, S et al. (2019) Lancet 394(10213):2012-24; Novo Nordisk (2020) June 19 R&D Investor Presentation. All trademarks are the property of their respective owners.

¹ FDA Guidance for Industry: Noncirrhotic Nonalcoholic Steatohepatitis With Liver Fibrosis: Developing Drugs for Treatment (2018)



Source Data: Liver Biopsy Evaluable Analysis Set, F1-F3

Rapid Improvements in Fibrosis Biomarkers Consistent with Histological Improvements (F1-F3 NASH)



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

Source Data: Full Analysis Set, F1-F3

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Pro-C3, LS Mean (ug/L)

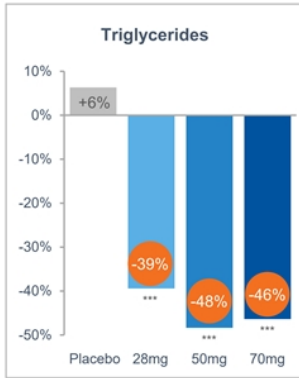
Dose Group	Baseline	Δ Week 12
Placebo	16.1	-1.5
28mg	19.2	-6.1***
50mg	16.2	-5.9***
70mg	17.2	-6.7***

Enhanced Liver Fibrosis (ELF) Score, LS Mean

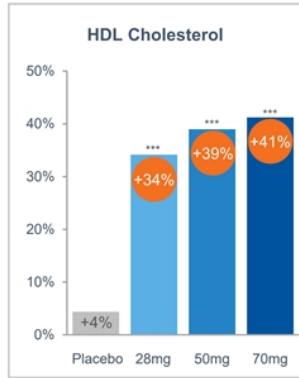
Dose Group	Baseline	Δ Week 12
Placebo	9.4	0.0
28mg	9.5	-0.7***
50mg	9.5	-0.8***
70mg	9.6	-0.4*

* p<0.05, *** p<0.001 versus placebo (ANCOVA)

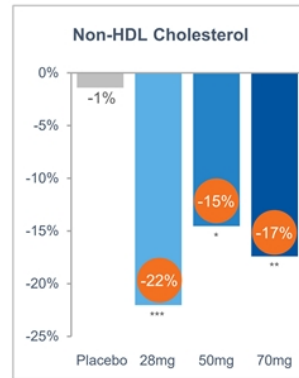
LS Mean Change From Baseline to Week 16 (%)



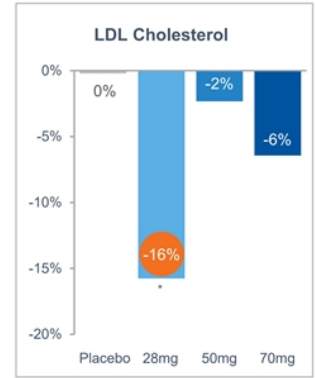
*** p<0.001, versus placebo (ANCOVA)



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



* p<0.05, ** p<0.01, *** p<0.001, versus placebo (ANCOVA)

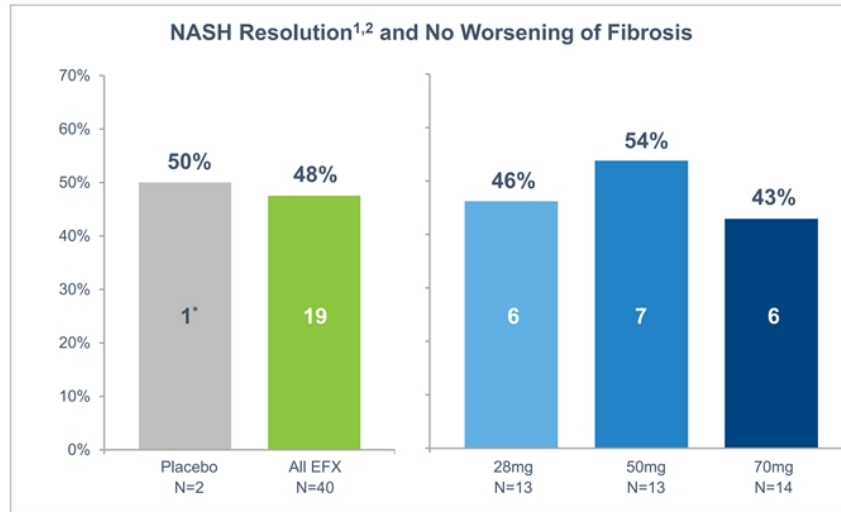


* p<0.05, versus placebo (ANCOVA)

Source Data: Full Analysis Set, F1-F3

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» High Response Rates on NASH Resolution After 16 Weeks Across All Dose Groups (F1-F3 NASH)

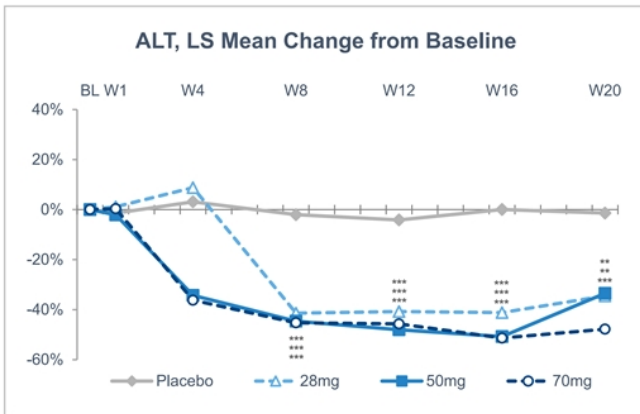


¹NAS score of 0 or 1 for lobular inflammation and a score of 0 for ballooning; ²Secondary and exploratory histological endpoints were not powered for statistical significance; * A single placebo responder lost 25 pounds over 16 weeks (11% weight reduction)

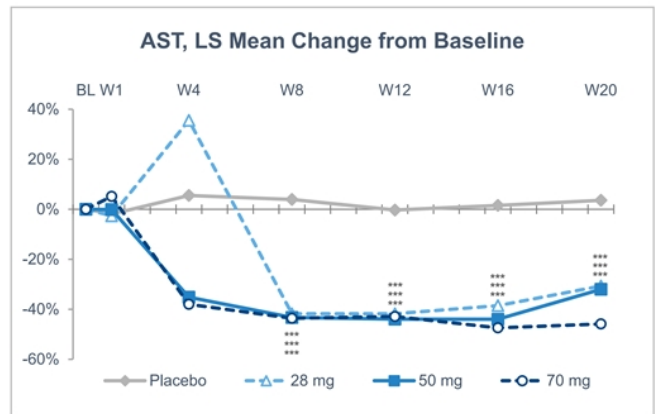
Source Data: Liver Biopsy Evaluable Analysis Set, F1-F3

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» Substantial Reductions in Markers of Liver Injury After 16 Weeks of Treatment (F1-F3 NASH)



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



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

Similar dose-related improvements observed for GGT & ALP

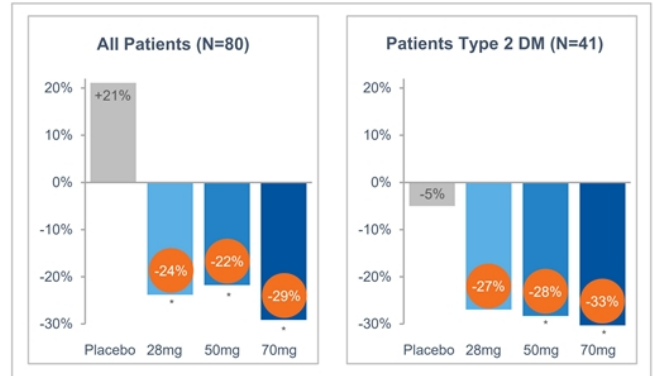
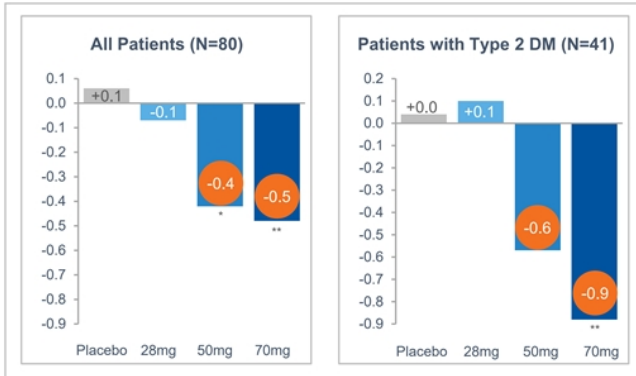
Source Data: Full Analysis Set, F1-F3

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LS Mean Change From Baseline to Week 16 (%)

HbA1c¹

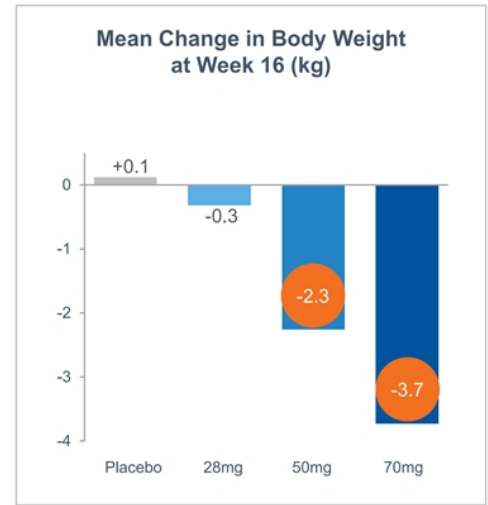
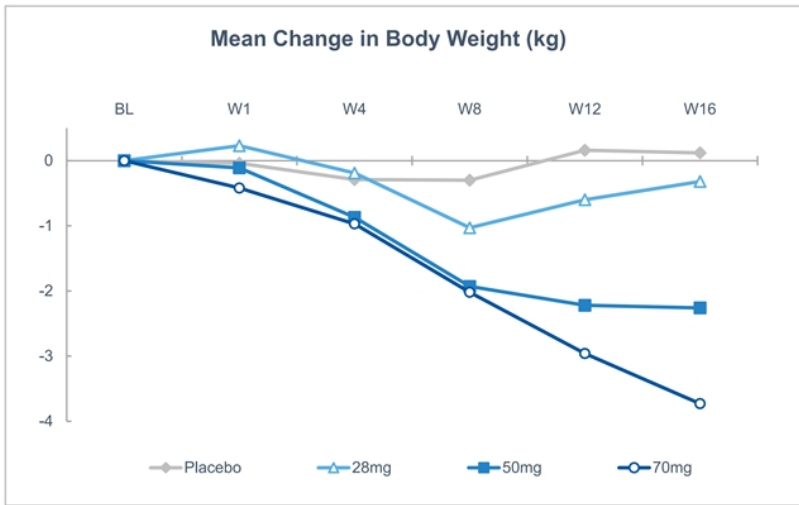
C-Peptide²



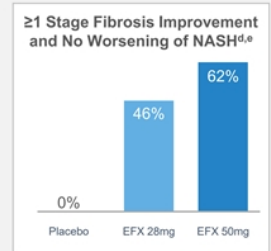
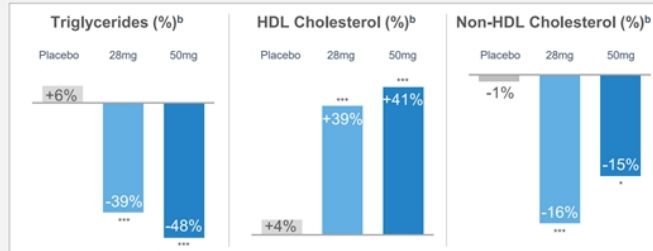
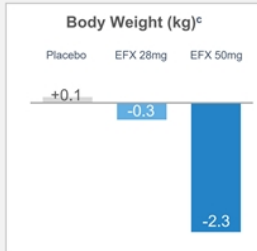
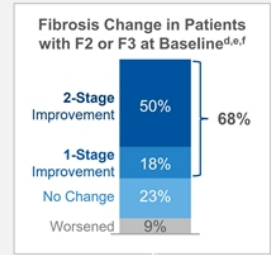
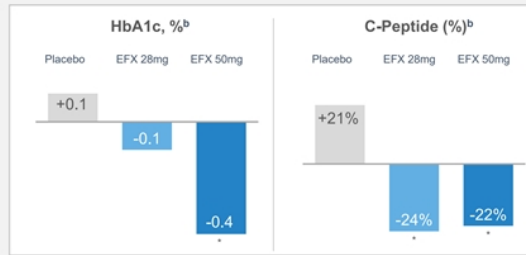
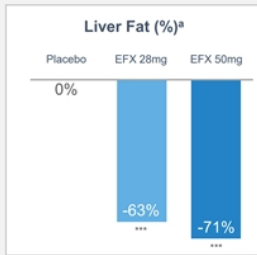
¹ Absolute change from baseline, %
* p<0.05, ** p<0.01, versus placebo (ANCOVA)

² Relative percent change from baseline
* p<0.05, versus placebo (ANCOVA)

Source Data: Full Analysis Set, F1-F3



Source Data: Full Analysis Set, F1-F3



^a LS Mean Change from Baseline to Week 12; ^b LS Mean Change from Baseline to Week 16; ^c Mean Change from Baseline to Week 16; ^d Proportion of subjects; * not powered for statistical significance; ^e Includes all EFX-treated patients, including 70mg dose

* p<0.05, *** p<0.001, versus placebo (ANCOVA)

Drug-related Treatment-Emergent Adverse Events (TEAE) (F1-F3)

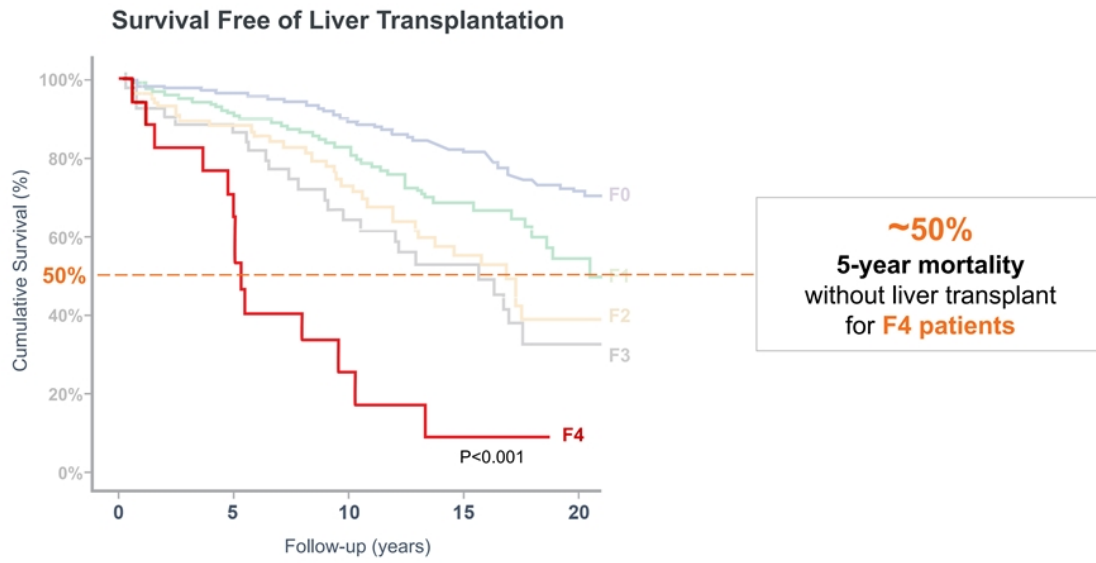
Most Frequent (>10%) Drug-Related AEs*	Placebo (N=21)	All EFX (N=58)	EFX 28mg (N=19)	EFX 50mg (N=19)	EFX 70mg (N=20)
Diarrhea	2 (10%)	21 (36%)	5 (26%)	10 (53%)	6 (30%)
Nausea	0 (0%)	20 (34%)	6 (32%)	4 (21%)	9 (45%)
Increased appetite	1 (5%)	13 (22%)	4 (21%)	4 (21%)	5 (25%)
Vomiting	0 (0%)	9 (16%)	5 (26%)	2 (11%)	2 (10%)
Frequent bowel movements	0 (0%)	8 (14%)	3 (16%)	2 (11%)	3 (15%)
Abdominal pain	0 (0%)	7 (12%)	1 (5%)	3 (16%)	3 (15%)
Injection site erythema	0 (0%)	7 (12%)	2 (11%)	0 (0%)	5 (25%)
Injection site reaction	0 (0%)	6 (10%)	2 (11%)	1 (5%)	3 (15%)
Fatigue	2 (10%)	6 (10%)	0 (0%)	1 (5%)	5 (25%)
TEAE/SAE Disposition	Placebo	All EFX	28mg	50mg	70mg
TEAE Leading to Death	0	0	0	0	0
TEAE Leading to Discontinuation	1 ^a	6	2 ^b	0	4 ^c
Serious Adverse Event (SAE)	0	2	1 ^d	0	1

* Across EFX dose groups

^a Muscular Weakness & Myalgia; ^b Nausea, Vomiting & Dysgeusia; Panic Attack and Anxiety-Linked Tremor;

^c Dysphagia (Not Drug Related); Acute Pancreatitis (also an SAE); Vomiting; Fatigue & Nausea; ^d Related to pre-dosing liver biopsy

Source Data: Safety Set, F1-F3 (all BALANCED main study subjects who received at least one dose of study drug)



»

Cirrhosis Regression is Associated with Improved Clinical Outcomes

Pooled treatment groups from STELLAR 4 and simtuzumab cirrhosis study

The bar chart displays the percentage of liver-related events for two fibrosis staging systems: NASH CRN and Ishak. For each system, two groups are compared: 'No fibrosis regression' (red bars) and 'Fibrosis regression' (green bars). The y-axis represents the percentage of liver-related events, ranging from 0 to 9. The x-axis shows the fibrosis stage. Hazard ratios and p-values are provided for each comparison.

Fibrosis Stage	Group	Percentage (%)	Count (n/N)
NASH CRN fibrosis stage	No fibrosis regression	7.2	69/957
	Fibrosis regression	1.1	2/176
Ishak fibrosis stage	No fibrosis regression	8.3	69/834
	Fibrosis regression	0.7	2/300

Hazard Ratio: 0.16, p=0.0104 (for NASH CRN)
Hazard Ratio: 0.08, p=0.0004 (for Ishak)

Cirrhosis regression observed in 16% of patients (treatment and placebo groups) over 48 weeks

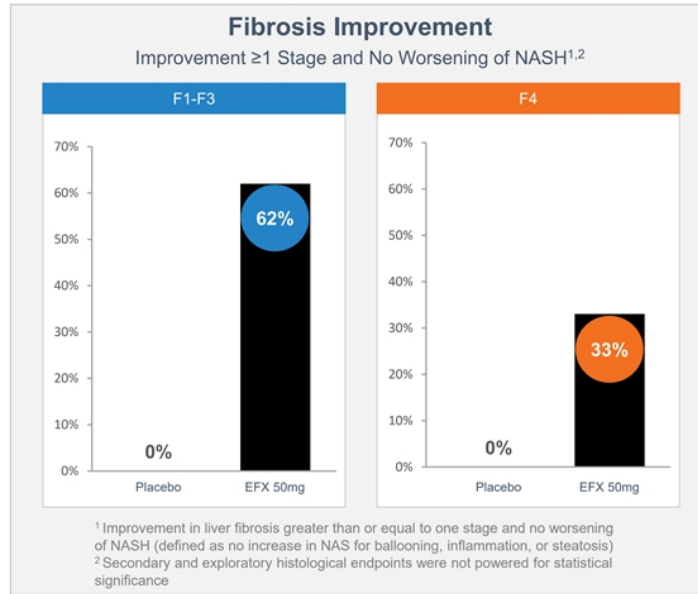
Sanyal A, et al. AASLD TLMdX2020. #90

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.

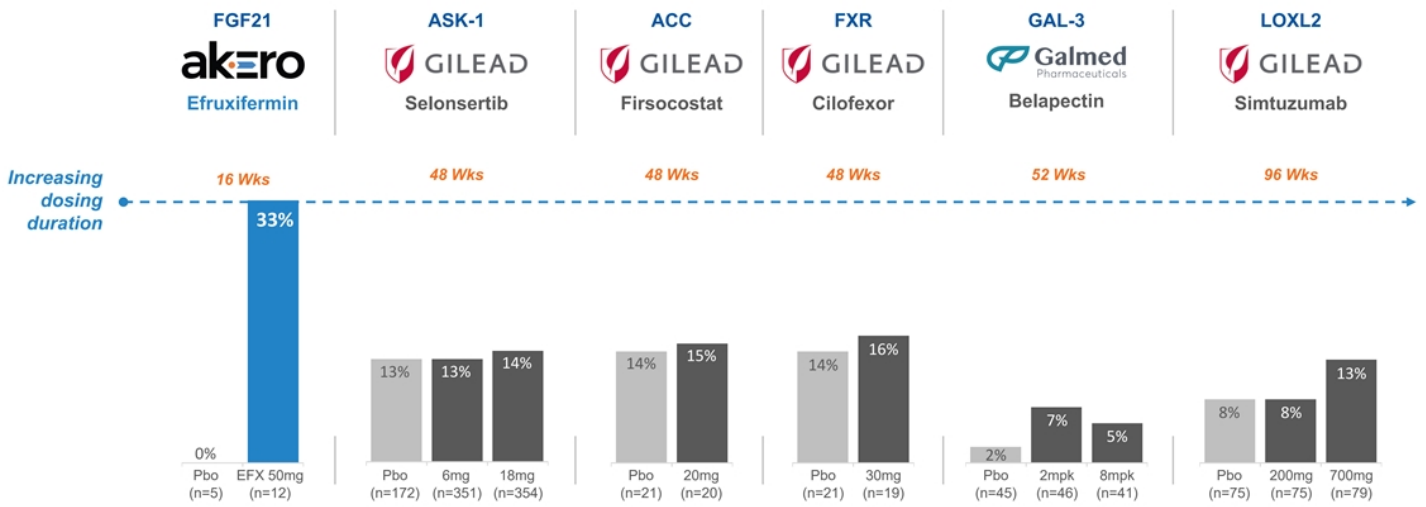
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» Fibrosis Improvement Observed in Patients with Pre-cirrhotic (F1-F3) and Compensated Cirrhotic (F4) NASH



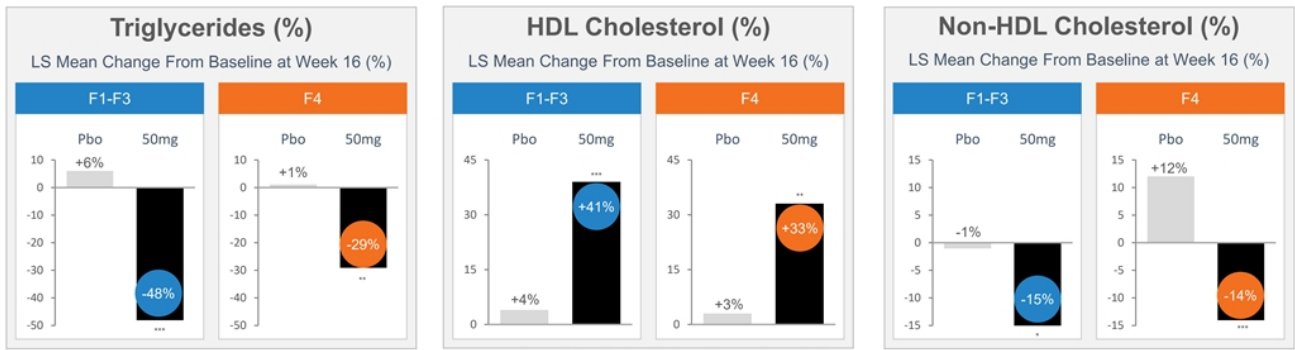
Source Data: Liver Biopsy Analysis Set, F4; Liver Biopsy Analysis Set, F4



* Results from all publicly reported NASH Phase 2 clinical trials in patients with compensated cirrhosis due to NASH reporting either ≥ 1-stage fibrosis improvement (belaepectin and simtuzumab) or ≥ 1-stage fibrosis improvement and no worsening of NASH (selonsertib, firsocostat and cilofexor); numerical values represent percent responders

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.

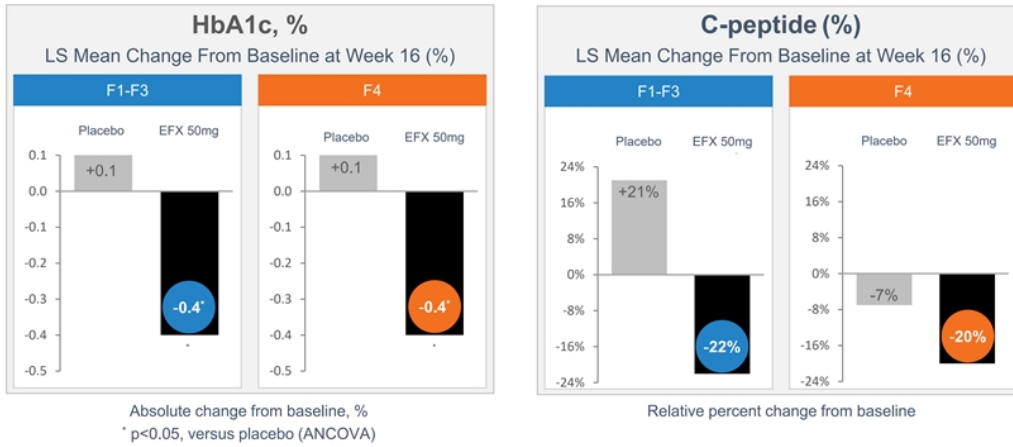
» Improvement in Lipid Profile Observed in Patients with both Pre-cirrhotic (F1-F3) and Compensated Cirrhotic (F4) NASH



* p<0.05, ** p<0.01, *** p<0.001, versus placebo (ANCOVA)

Source Data: Full Analysis Set, F1-F3; Full Analysis Set, F4

» Improved Glycemic Control Observed in Patients with both Pre-cirrhotic (F1-F3) and Compensated Cirrhotic (F4) NASH



Source Data: Full Analysis Set, F1-F3; Full Analysis Set, F4

» Weight Loss Observed in Patients with both Pre-cirrhotic (F1-F3) and Compensated Cirrhotic (F4) NASH

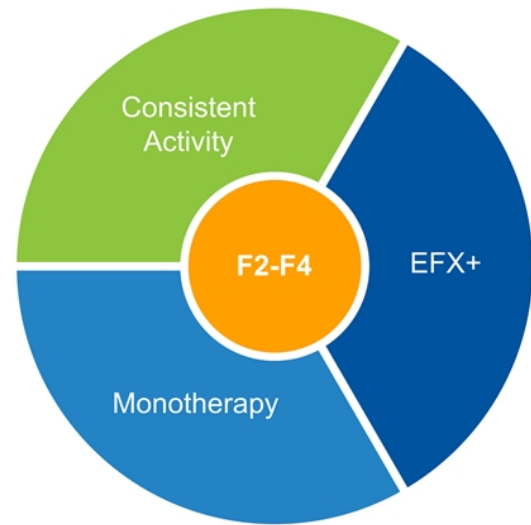


Source Data: Full Analysis Set, F1-F3; Full Analysis Set, F4

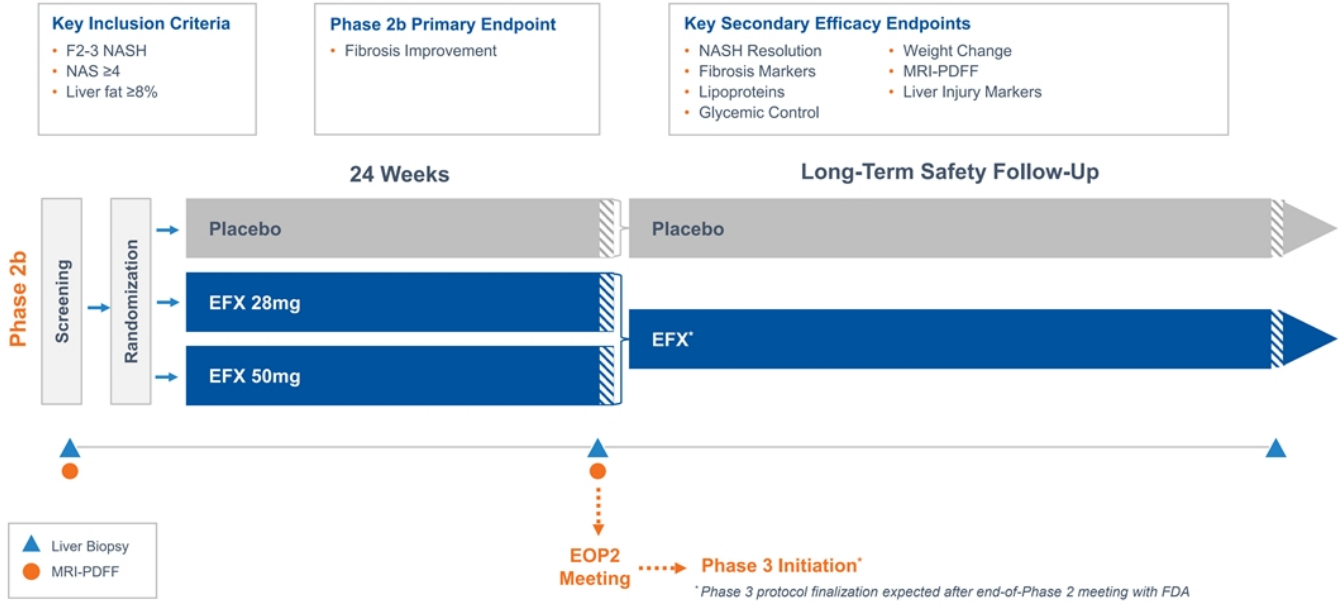


- Fibrosis reversal in patients with compensated cirrhosis (F4), two-stage improvement of fibrosis in patients with F2/F3 NASH, and corroborating non-invasive markers of fibrosis improvement in only 16 weeks likely reflects direct anti-fibrotic activity
- Fibrosis reversal is especially advantageous for patients with cirrhotic NASH who face high risk of mortality and severe morbidity
- Addressing underlying NASH disease drivers may indirectly contribute to fibrosis reversal for patients with F1-F3 NASH with adequate time for the liver to regenerate
- Redress of the underlying NASH disease drivers is necessary to sustain fibrosis reversal across all fibrosis stages
- Supports broader metabolic improvements

- ✓ **Liver Fat Reduction**
- ✓ **Fibrosis Reversal**
- ✓ **NASH Resolution**
- ✓ **Reduced Cardiovascular Risk**
 - ✓ Restored Healthy Lipid Profile
 - ✓ Enhanced Insulin Sensitivity
 - ✓ Better Glycemic Control
- ✓ **Weight Loss**



	Phase 2a		Phase 2b	
Biopsy-Confirmed:	F1-F3	F4	F2/F3	F4
	BALANCED	Cohort C (Expansion of BALANCED)	HARMONY	SYMMETRY
Status	Completed	Completed	Enrollment complete; Readout expected in 3Q'22	Initiated Jul'21
Duration	16 Weeks	16 Weeks	24 Weeks	36 Weeks
EFX Doses	28, 50, 70mg	50mg	28, 50mg	28, 50mg
Placebo-Controlled	✓	✓	✓	✓



Key Inclusion Criteria

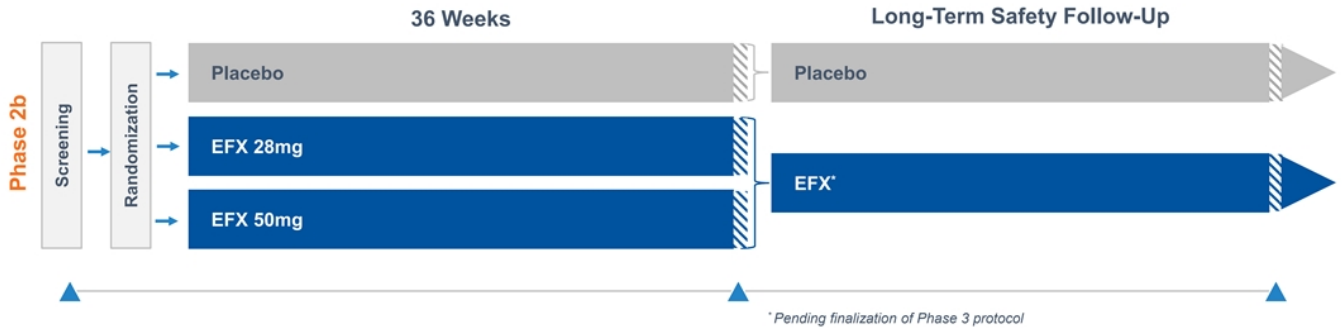
- F4 NASH

Phase 2b Primary Endpoint

- Fibrosis Improvement (Cirrhosis reversal)

Key Secondary Efficacy Endpoints

- NASH Resolution
- Fibrosis Markers
- Lipoproteins
- Glycemic Control
- Weight Change
- Liver Injury Markers

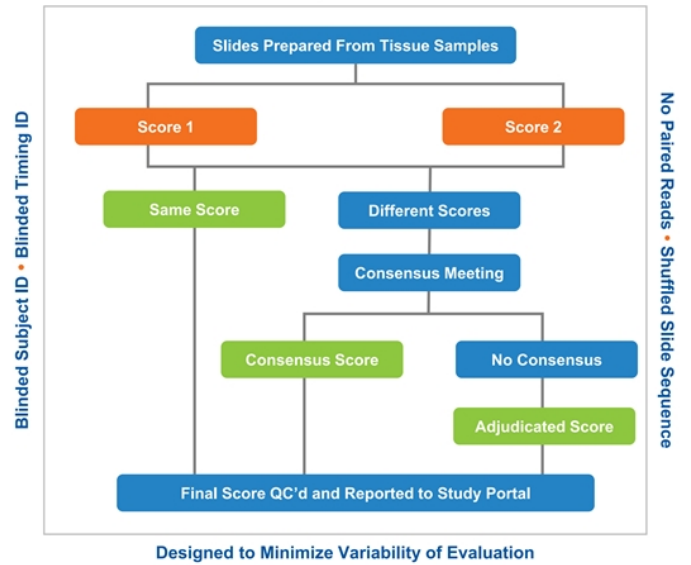


▲ Liver Biopsy

Key Features of EFX Biopsy Analysis Plan

- Incorporates FDA input on EFX Phase 2b trial designs, reflecting efforts to increase liver biopsy reliability
- All biopsies read by two, experienced pathologists well-versed in NASH-Clinical Research Network (CRN) scoring system
- Pathologists undergo training to align on interpretation of histology
- Each screening and on-treatment biopsy scored in parallel by same two pathologists
 - Both blinded to subject ID and visit ID
 - Screening and end-of-treatment biopsies for a single patient are not read simultaneously as paired samples
 - Randomized shuffling of screening biopsy slides and on-treatment biopsy slides to minimize temporal bias
 - Consensus meeting to resolve any scoring discrepancies
 - In absence of consensus, a third, equally qualified and trained pathologist adjudicates to finalize score

Biopsy Analysis Flow Chart



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

Drug Substance (API)

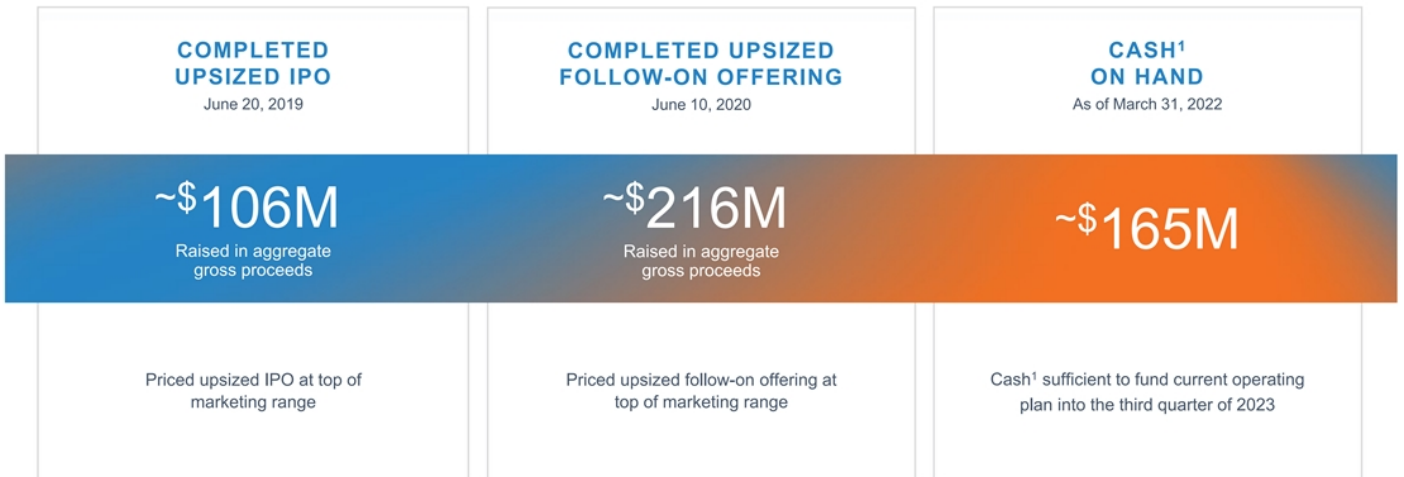


- ✓ Commercial scale
- ✓ Released for Phase 3
- ✓ Comparability demonstrated

Drug Product/Device Combination

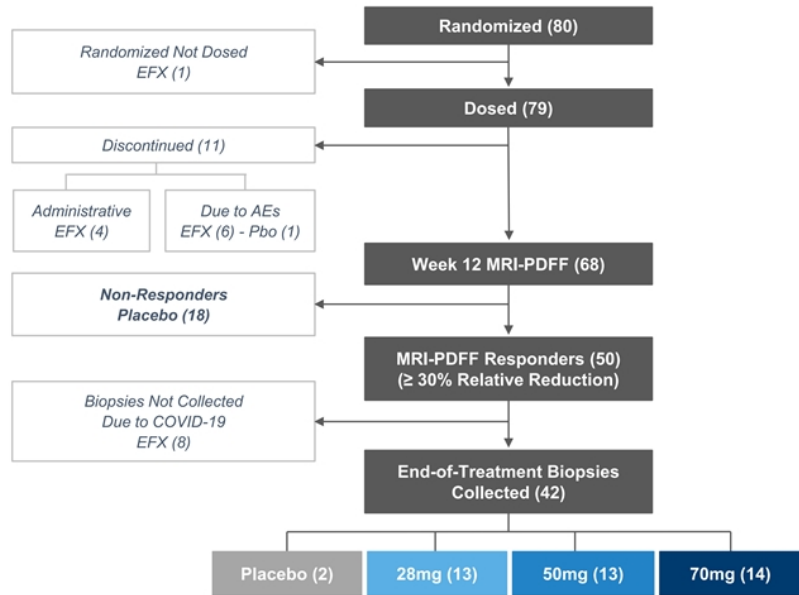


- ✓ Commercially precedented
- ✓ 1 mL SC weekly injection
- ✓ Self-administered, stable at 2-8°C



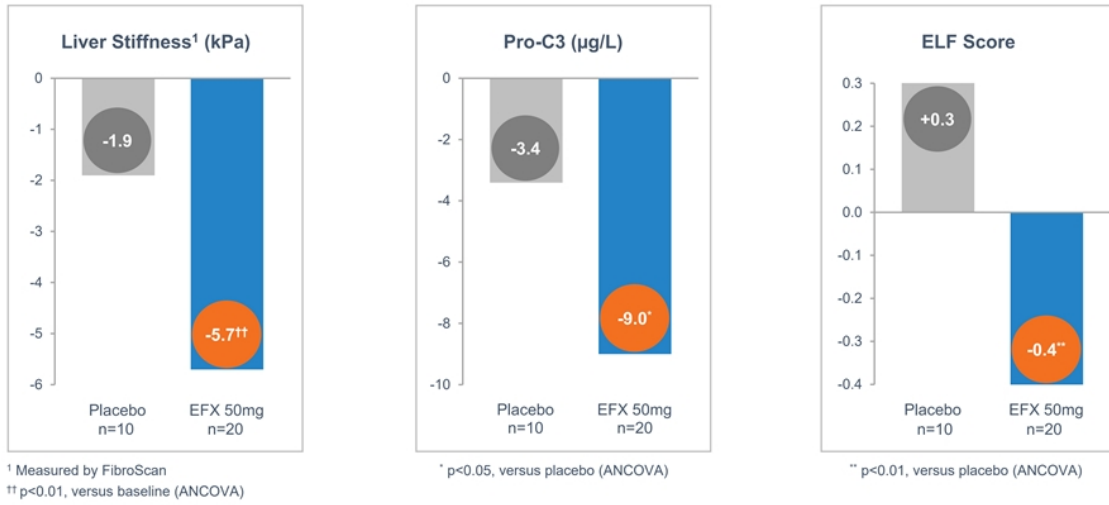
¹ Cash, cash equivalents and short-term marketable securities

Backup Slides



» Improvements in Fibrosis Biomarkers in Patients with Cirrhotic NASH Support Histology Results (F4)

LS Mean Change From Baseline to Week 16



Source Data: Biomarker Analysis Set, F4 (all Cohort C subjects with baseline and interpretable on-study measure of ELF or pro-C3, respectively); Liver Stiffness Analysis Set, F4 (all Cohort C subjects with baseline and interpretable on-study measure of Liver Stiffness)

Most Frequent (>15%) Drug-Related AEs	Placebo (N=10)	EFX 50mg (N=17)
Diarrhea	1 (10%)	7 (41%)
Nausea	1 (10%)	5 (29%)
Injection site reaction	0	5 (29%)
Injection site erythema	0	4 (24%)
Headache	0	3 (18%)
TEAE/SAE Disposition	Placebo	EFX 50mg
Study Discontinuations	1 ^a	1 ^b
Serious Adverse Events (SAE)	1 ^c	0
Deaths	0	0

^a Withdrawal of consent

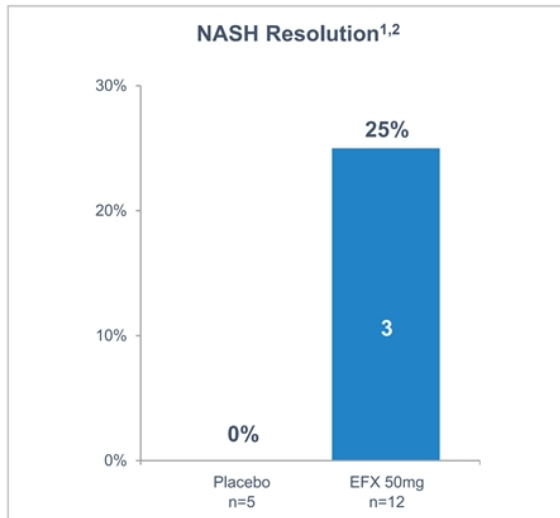
^b abdominal distension, constipation, diarrhea, pruritus

^c pulmonary embolism

Source Data: Safety Set, F4 (all Cohort C subjects confirmed by central reader as F4 at baseline who received at least one dose of study drug)

Key Observations

- Encouraging tolerability given population with more advanced disease
- All injection site AEs Grade 1
- No reports of tremor



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

Change in NAS among Patients Achieving NASH Resolution

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

Proportion of Patients with ≥2 Point NAS Reduction

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

Source Data: Liver Biopsy Analysis Set, F4



NASDAQ: AKRO

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