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): March 22, 2021

Akero Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-38944**	**81-5266573**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(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

N/A
(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.

On March 22, 2021, Akero Therapeutics, Inc. (the “Company”) issued a press release titled “Akero Announces Positive Histological Improvements in Cirrhotic NASH (F4) Patients after 16 Weeks in Extension Cohort C.” A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information under this Item 7.01, including Exhibit 99.1 hereto, is being furnished herewith and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall such information be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 8.01. Other Events.

The Company from time to time presents and/or distributes to the investment community slide presentations to provide updates and summaries of its business. A copy of its Cohort C Expansion of the Phase 2a BALANCED Study slide presentation is being filed herewith as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.2.

On March 22, 2021, the Company announced results of an expansion cohort of a 16-week Phase 2a clinical trial, Cohort C, evaluating efruxifermin (“EFX”) in the treatment of adult patients with cirrhotic nonalcoholic steatohepatitis (“NASH”) (compensated stage 4 fibrosis, Child-Pugh Class A). Of the 17 confirmed compensated cirrhosis (F4) study subjects who volunteered to have end-of-treatment biopsies, 4 of 12 patients (33%) treated with EFX achieved a one-stage improvement in fibrosis without worsening of NASH. Another 3 of 12 EFX patients (25%) achieved NASH resolution. In total, 7 of 12 EFX patients (58%) showed histological improvements. None of the 5 placebo patients (0%) achieved either one-stage improvement in fibrosis without worsening of NASH, or resolution of NASH. In addition, statistically significant improvements in glycemic control and lipoprotein profile, and a trend toward weight loss, were also observed.

Cohort C is an expansion of the Phase 2a BALANCED study evaluating EFX in the treatment of F4 NASH patients, Child-Pugh Class A. Thirty cirrhotic NASH subjects with a historical biopsy-confirmed fibrosis score of F4 were randomized 2:1 to receive either 50mg of EFX or placebo for 16 weeks. A total of 27 subjects were subsequently confirmed by the central reader to have F4 fibrosis at baseline. The primary objective of Cohort C was to assess the safety and tolerability of EFX in NASH patients at greatest risk of progressing to end-stage liver disease, including liver failure and liver cancer. Secondary objectives included assessments of liver stiffness by Fibroscan and serum markers of liver fibrosis, such as the Enhanced Liver Fibrosis (ELF) score and Pro-C3. The trial design was amended to allow voluntary end-of-treatment biopsies.

Summary of Biopsy Results and Non-Invasive Fibrosis Measurements

Histology Endpoint (% responders)	**Placebo (n=5)**	**50mg (n=12)**
Improvement in at least one stage of fibrosis without worsening of NASH,%[1,2]	0	33
Resolution of NASH, %[1,2]	0	25
Non-invasive measurement (LS Mean)	**Placebo (n=10)**	**50mg (n=20)**
Liver Stiffness, kPa[3]	-1.9	-5.7††
Pro-C3, µg/L[4]	-3.4	-9.0*
ELF Score[4]	+0.3	-0.4*

[1] Study not powered to assess statistical significance of changes in histological endpoints

[2] Liver Biopsy Evaluable Analysis Set (all patients who had baseline and end-of-treatment liver biopsy results)

[3] Liver Stiffness Analysis Set (all subjects with a week 16 FibroScan)

[4] Biomarker Analysis Set (all subjects with a post baseline interpretable measure of ELF or pro-C3, respectively)

†† $p<0.01$, versus baseline (ANCOVA)

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

EFX was reported to be generally well-tolerated. The most common adverse event in the EFX group was mild or moderate diarrhea. There were two discontinuations, one in the placebo group and one in the EFX group. There was one serious adverse event in the placebo group and no deaths in either group.

Statements contained under this Item 8.01, including Exhibit 99.2, regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Such statements include, but are not limited to: the Company's guidance regarding its business plans and objectives for EFX, including the therapeutic potential and clinical benefits thereof, as well as the safety and tolerability of EFX and future clinical development plans; the Company's Phase 2a BALANCED study, including its results and analysis; and the potential impact of COVID-19 on patient retention, strategy, future operations and clinical trials.

Any forward-looking statements are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. Risks that contribute to the uncertain nature of the forward-looking statements include: risks related to the impact of public health epidemics affecting countries or regions in which we have operations or do business, such as COVID-19, which has been labelled a pandemic by the World Health Organization, including potential negative impacts on Akero’s employees, manufacturers, supply chain and production as well as on global economies and financial markets; the company's ability to execute on its strategy; positive results from a clinical study may not necessarily be predictive of the results of future or ongoing clinical studies; regulatory developments in the United States; and risks related to the competitive landscape. For a discussion of these and other risks and uncertainties, and other important factors, any of which could cause the Company’s actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in the Company’s annual report on Form 10-K filed, with the United States Securities and Exchange Commission (SEC) and quarterly reports on Form 10-Q filed with the SEC, as well as discussions of potential risks, uncertainties, and other important factors in the Company’s other filings with the SEC. All forward-looking statements contained in this presentation speak only as of the date on which they were made. The Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by Akero Therapeutics, Inc. on March 22, 2021, furnished herewith
99.2	Slide presentation of Akero Therapeutics, Inc., filed herewith

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: March 22, 2021

AKERO THERAPEUTICS, INC.

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

Exhibit 99.1

Akero Announces Positive Histological Improvements in Cirrhotic NASH (F4) Patients after 16 Weeks in Extension Cohort C

-- 33% of patients treated with efruxifermin (EFX) (4 of 12) improved by one fibrosis stage without worsening of NASH --

-- 25% of EFX patients (3 of 12) showed NASH resolution --

-- Rapid fibrosis improvement in cirrhotic patients after only 16 weeks of EFX treatment, the highest rate reported publicly to date, suggests direct anti-fibrotic effects --

SOUTH SAN FRANCISCO, CA – March 22, 2021 / GLOBE NEWSWIRE / – Akero Therapeutics, Inc. (Nasdaq: AKRO), a cardio-metabolic biotechnology company developing transformational treatments for non-alcoholic steatohepatitis (NASH), today announced results of an expansion cohort of a 16-week Phase 2a clinical trial, Cohort C, evaluating efruxifermin (EFX) in the treatment of adult patients with cirrhotic nonalcoholic steatohepatitis (NASH) (compensated stage 4 fibrosis, Child-Pugh Class A). Of the 17 confirmed compensated cirrhosis (F4) study subjects who volunteered to have end-of-treatment biopsies, 4 of 12 patients (33%) treated with EFX achieved a one-stage improvement in fibrosis without worsening of NASH. Another 3 of 12 EFX patients (25%) achieved NASH resolution. In total, 7 of 12 EFX patients (58%) showed histological improvements. None of the 5 placebo patients (0%) achieved either one-stage improvement in fibrosis without worsening of NASH, or resolution of NASH. In addition, statistically significant improvements in glycemic control and lipoprotein profile, and a trend toward weight loss, were also observed.

“I believe these data are unprecedented,” said Stephen Harrison, M.D., medical director of Pinnacle Clinical Research. “Today’s data in cirrhotic patients, who have the highest unmet need, show clear signals of fibrosis improvement without worsening of NASH and NASH resolution, supported by compelling, statistically significant results for non-invasive fibrosis measures. These results set EFX apart.”

Cohort C is an expansion of the Phase 2a BALANCED study evaluating EFX in the treatment of F4 NASH patients, Child-Pugh Class A. Thirty cirrhotic NASH subjects with a historical biopsy-confirmed fibrosis score of F4 were randomized 2:1 to receive either 50mg of EFX or placebo for 16 weeks. A total of 27 subjects were subsequently confirmed by the central reader to have F4 fibrosis at baseline. The primary objective of Cohort C was to assess the safety and tolerability of EFX in NASH patients at greatest risk of progressing to end-stage liver disease, including liver failure and liver cancer. Secondary objectives included assessments of liver stiffness by Fibroscan and serum markers of liver fibrosis, such as the Enhanced Liver Fibrosis (ELF) score and Pro-C3. The trial design was amended to allow voluntary end-of-treatment biopsies.

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EFX was reported to be generally well-tolerated. The most common adverse event in the EFX group was mild or moderate diarrhea. There were two discontinuations, one in the placebo group and one in the EFX group. There was one serious adverse event in the placebo group and no deaths in either group.

“The promising results in cirrhotic NASH patients reported today build on the strong results previously reported for patients with F1-F3 fibrosis,” said Andrew Cheng, M.D., Ph.D., president and CEO of Akero. “We believe EFX has the potential to be a foundational NASH monotherapy for cirrhotic patients as well as patients with earlier-stages of fibrosis. We look forward to continuing the development of our Phase 2b HARMONY study in patients with F2-F3 fibrosis started in February 2021, and our planned Phase 2b SYMMETRY study in cirrhotic patients (F4 fibrosis), which we plan to initiate in the second half of this year. We remain extremely grateful to all of our study patients and investigators, particularly given that this study cohort was conducted during the COVID-19 pandemic.”

Conference Call / Webcast Details

The company will host a conference call and webcast with slide presentation at 4:30 p.m. ET (1:30 p.m. PT) today, March 22. The webcast will be made available on Akero’s website at www.akerotx.com under the Investors tab in the Events, Presentations & Webcasts section.

To access the call, please dial 1-877-282-0556 (U.S. toll free) or 1-270-215-9899 (international) five minutes prior to the start time, and provide Conference ID #1885464. Following the live audio webcast, a replay will be available on the company's website for 90 days.

About NASH

Non-alcoholic steatohepatitis (NASH) is a serious, life-threatening disease that has rapidly emerged as a leading cause of liver failure in the world and is the leading indication for liver transplant among women. An estimated 17.3 million Americans had NASH in 2016, a number that is expected to increase to 27.0 million by 2030. NASH is a severe form of nonalcoholic fatty liver disease (NAFLD) characterized by hepatocyte injury, liver inflammation, and fibrosis that can progress to scarring (cirrhosis), liver failure, cancer and death. There are currently no approved therapies for the disease.

About Efruxifermin

Efruxifermin (EFX) is an Fc-FGF21 fusion protein that has been engineered to mimic the balanced biological activity profile of native FGF21, an endogenous hormone that alleviates cellular stress and regulates metabolism throughout the body. Previous clinical trials show that EFX has the potential to reverse fibrosis, resolve NASH, reduce liver fat, improve glycemic control and lipoprotein profile, and reduce body weight. EFX is designed to offer convenient once-weekly subcutaneous dosing.

About Akero Therapeutics

Akero Therapeutics is a clinical-stage cardio-metabolic company developing transformational treatments for non-alcoholic steatohepatitis (NASH), a disease without any approved therapies. Akero's lead product candidate, EFX, an engineered Fc-FGF21 fusion protein, is currently being evaluated in a Phase 2b clinical trial as a potential treatment for NASH. Akero is headquartered in South San Francisco. Visit www.akerotx.com for more information.

Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements, including, but not limited to, statements regarding the Company's business plans and objectives, including future plans or expectations for EFX, upcoming milestones, and therapeutic effects of EFX, as well as the dosing, safety and tolerability of EFX; the Company's Phase 2b HARMONY study including expected timing to complete enrollment and report preliminary results; the Company's Phase 2b SYMMETRY study, including expected timing for initiation and enrollment of the study; the availability of a new drug product formulation to support Phase 3 clinical trials; expectations regarding the Company's use of capital, expenses and other future financial results; statements regarding a potential meeting with the FDA and timing thereof and the potential impact of COVID-19 on strategy, future operations, enrollment and clinical trials. Any forward-looking statements in this press release are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. Risks that contribute to the uncertain nature of the forward-looking statements include: risks related to the impact of COVID-19 on the Company's ongoing and future operations, including potential negative impacts on the Company's employees, third-parties, manufacturers, supply chain and production as well as on global economies and financial markets; the success, cost, and timing of the Company's product candidate development activities and planned clinical trials; the Company's ability to execute on its strategy; positive results from a clinical study may not necessarily be predictive of the results of future or ongoing clinical studies; regulatory developments in the United States and foreign countries; the Company's ability to fund operations; as well as those risks and uncertainties set forth more fully under the caption "Risk Factors" in the Company's most recent Annual Report on Form 10-K, as filed with the Securities and Exchange Commission (SEC) as well as discussions of potential risks, uncertainties and other important factors in the Company's other filings and reports with the SEC. All forward-looking statements contained in this press release speak only as of the date on which they were made. The Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

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Media Contact:
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612.716.0556
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Exhibit 99.2

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A Global Disease,
A Pioneering Treatment

Cohort C Readout: 16-Week Study of EFX in Cirrhotic NASH Patients (F4)

March 22, 2021

SAFE HARBOR

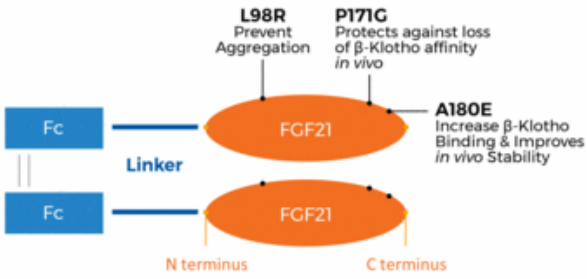
This presentation may contain "forward-looking statements" of Akero Therapeutics, Inc. ("we," "us," "our," "Akero" or the "Company") within the meaning of the Private Securities Litigation Reform Act of 1995 relating to our business, operations, and financial conditions, including but not limited to 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; our development plans for Efruxifermin, including our belief in the unique potential of Efruxifermin as a foundational NASH therapy; our preclinical and clinical results, including our top-line safety/tolerability, laboratory measures and paired biopsy data from our Phase 2a BALANCED study; the potential benefits resulting from the PRIME designation of EFX; plans to report preliminary results for Cohort C of the Phase 2a BALANCED study; the Phase 2b HARMONY study including expected timing to complete enrollment and report preliminary results; statements regarding a potential meeting with the FDA and timing thereof; 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 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

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.

EFRUXIFERMIN (EFX): BUILDING ON A STRONG FOUNDATION

EFX Engineering (ex-Amgen)

- Human FGF21 with 3 mutations fused to IgG1 Fc domain
- Half-life of 3-4 days: once-weekly dosing
- Balanced receptor potency comparable to native FGF21



BALANCED Study (F1-F3): Improvements from Baseline

- ✓ Fibrosis Reversal
- ✓ NASH Resolution
- ✓ Liver Fat
- ✓ ELF and Pro-C3
- ✓ ALT, AST
- ✓ Lipoproteins
- ✓ HbA1c
- ✓ Weight Loss

EXPANDING EFX TO CIRRHOTIC PATIENT POPULATION (F4)

Developing Treatments for Cirrhotic (F4) NASH

- FDA draft guidance specific for F4 patients
- Projected ~3.5M US F4 patients in 2030
- FDA: *The goals of treatment for compensated NASH cirrhosis are to halt or slow progression of fibrosis, prevent clinical decompensation, reduce the need for liver transplantation, and improve survival*

Nonalcoholic Steatohepatitis with Compensated Cirrhosis: Developing Drugs for Treatment

Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact Frank Anania at 240-402-9725.

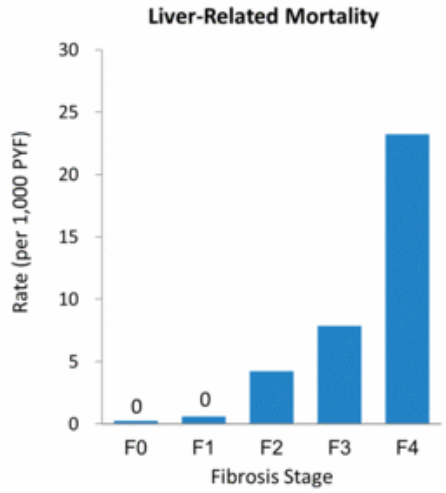
U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

June 2019
Clinical/Medical

247852844fl.docx
3/6/2019

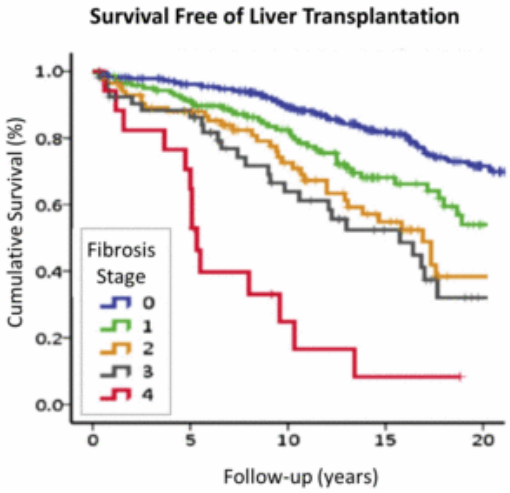
F4 NASH PATIENTS HAVE POOR PROGNOSIS

Liver-related mortality rate increases substantially from F3 to F4 fibrosis



Dulai, PS et al. (2017) Hepatology 65:1557-65

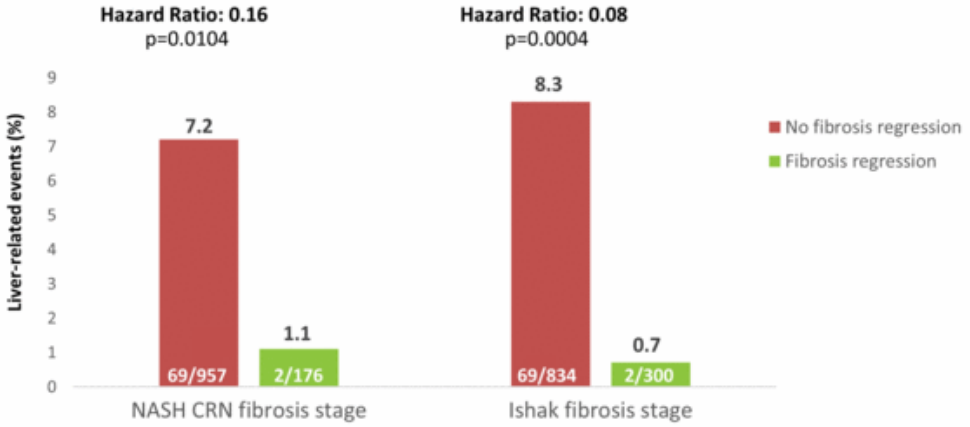
~60% 5-year mortality for F4 NASH patients absent transplant



Angulo, P et al. (2015) Gastroenterology 149:389-397

CIRRHOSIS REGRESSION IS ASSOCIATED WITH IMPROVED CLINICAL OUTCOMES

Pooled treatment groups from STELLAR 4 and simtuzumab cirrhosis study



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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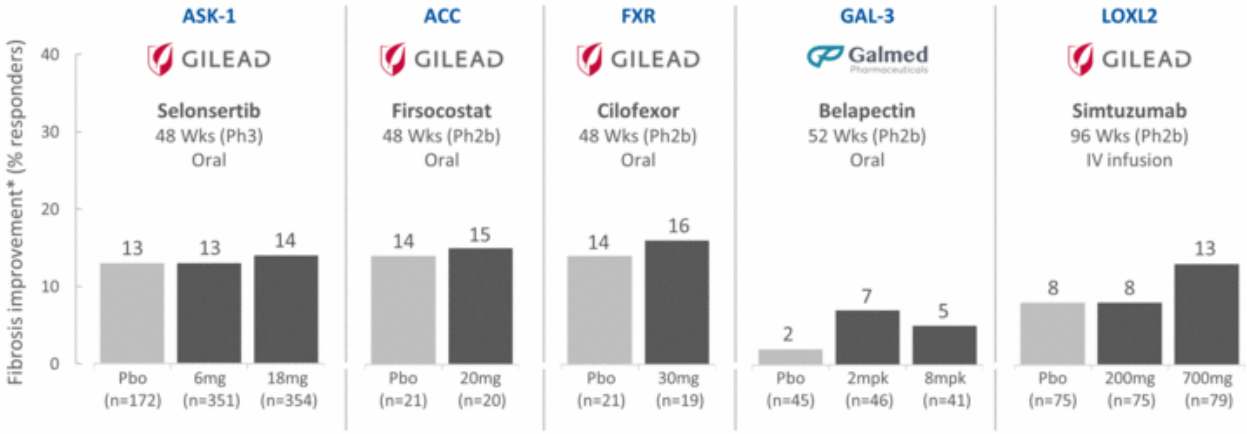
SINGLE AGENT FIBROSIS IMPROVEMENT IN CIRRHOTIC NASH*

No investigational product has been successful in cirrhotic F4 NASH patients



** Results from all publicly reported NASH studies for single agents in F4 patients that reported either ≥ 1-stage fibrosis improvement (belapectin and simtuzumab) or ≥ 1-stage fibrosis improvement and no worsening of NASH (selonsertib, firsocostat and cilofexor)*

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.

Harrison, SH et al. (2020) J Hepatol 73(1):26-39; Loomba, R et al. (2020) Hepatol 73(2):625-43; Chalasani, N et al. (2020), Gastro 158:1334–45; Harrison, SH et al. (2018) Gastro 155:1140-53

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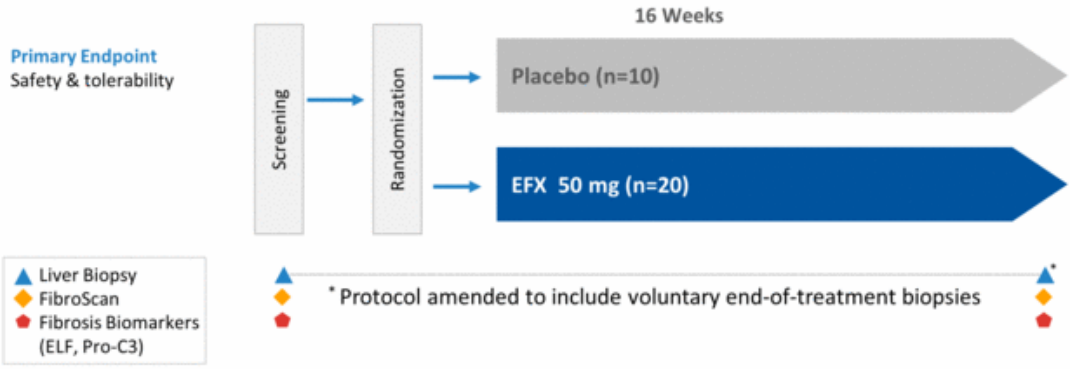
PHASE 2A EXPANSION COHORT C (F4) TRIAL DESIGN

BALANCED study included an expansion cohort, Cohort C, of patients with compensated cirrhosis (F4), Child-Pugh Class A; results to inform subsequent development in cirrhotic patients

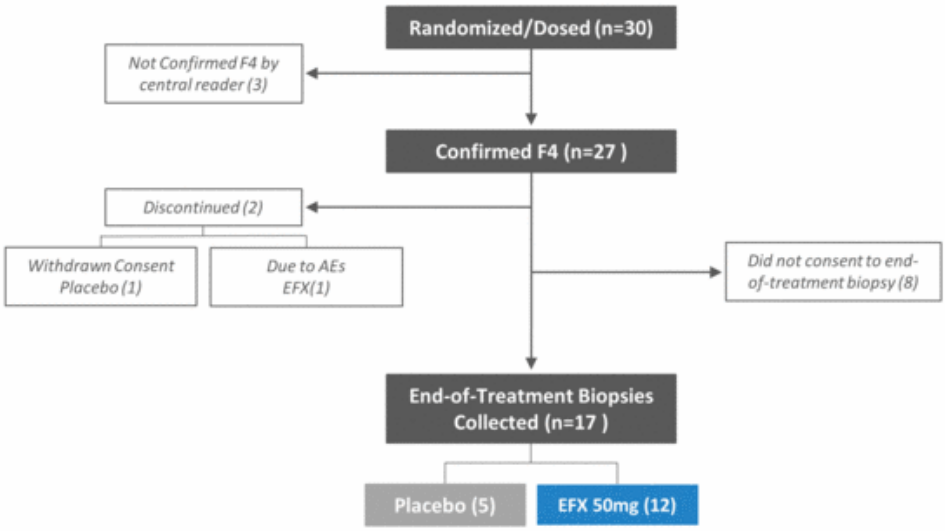


BASELINE DEMOGRAPHICS

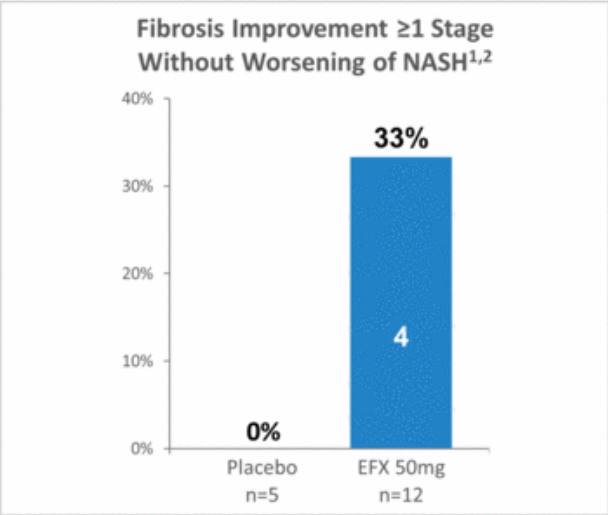
Parameter Mean	Placebo (n=10)	EFX 50mg (n=20)
Age (Years)	57.1	61.1
Sex (Male/Female)	7/3	4/16
Weight (kg)	119.1	97.9
Alanine Aminotransferase (ALT) (U/L)	32.7	31.7
Aspartate Aminotransferase (AST) (U/L)	28.9	31.4
HbA1c (%)	6.5	6.1
% Type 2 Diabetes	50	50
Triglycerides (mg/dL)	121.7	134.6
Liver Stiffness (kPA)	25.8	22.1
ELF Score	9.7	10.4
Pro-C3 (µg/L)	22.6	25.6

Source Data: Full Analysis Set (all subjects who were randomized into the study);
Topline preliminary data

PATIENT DISPOSITION



HIGHEST REPORTED RATE OF FIBROSIS IMPROVEMENT IN CIRRHOTIC NASH PATIENTS, AFTER ONLY 16 WEEKS



[1] No increase in NAS for ballooning, inflammation, or steatosis
[2] Study not powered to assess statistical significance of changes in histological endpoints

Biopsy Reading

- All baseline and end-of-treatment biopsies were read by a single NASH-CRN pathologist
- All biopsies were read blinded to both treatment assignment and patient
- Baseline biopsies were read independently of end-of-treatment biopsies, in random fashion and not paired

Source Data: Liver Biopsy Analysis Set (all subjects confirmed by central reader as F4 at baseline with Week 16 liver biopsy results); *Topline preliminary data*

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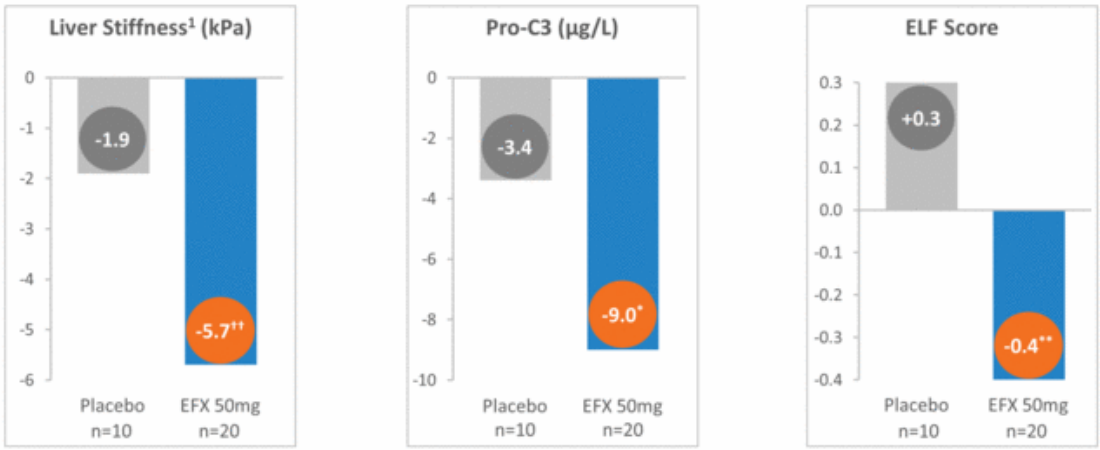
NON-INVASIVE MARKERS OF FIBROSIS PROVIDE SUPPORT FOR HISTOLOGY RESULTS

LS Mean Change From Baseline to Week 16



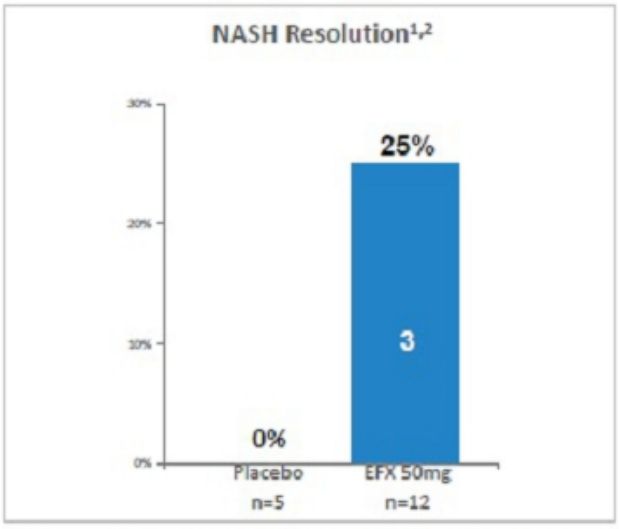
[1] Measured by FibroScan
†† p<0.01, versus baseline (ANCOVA)

* p<0.05, versus placebo (ANCOVA)

** p<0.01, versus placebo (ANCOVA)

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

HIGH RATE OF NASH RESOLUTION, AFTER ONLY 16 WEEKS



7 of 12 (58%) EFX patients achieved fibrosis improvement* or NASH resolution, compared to 0 of 5 (0%) placebo patients

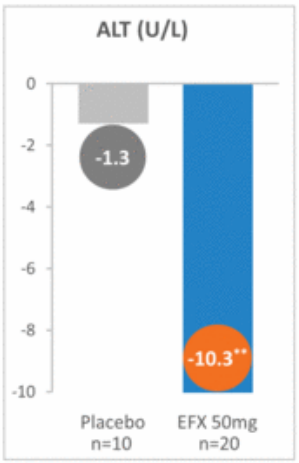
*Improvement of one-stage fibrosis and no worsening of NASH (there was no overlap among patients who achieved fibrosis improvement without worsening of NASH (n=4) and other patients who achieved NASH resolution (n=3))

[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

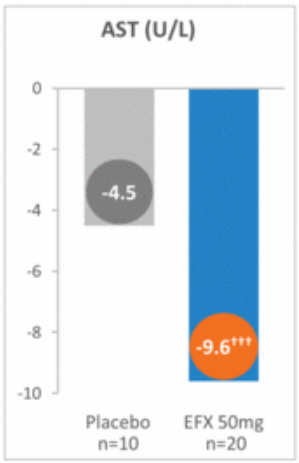
Source Data: Liver Biopsy Analysis Set; *Topline preliminary data*

REDUCTIONS IN MARKERS OF LIVER INJURY

LS Mean Change from Baseline to Week 16



** p<0.01, versus placebo (ANCOVA)



††† p<0.001, versus baseline (ANCOVA)

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Source Data: Full Analysis Set; *Topline preliminary data*

SAFETY OVERVIEW

	Placebo (N=10)	EFX 50mg (N=20)
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

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Source Data: F4 Safety Set (all subjects confirmed by central reader as F4 at baseline who received at least one dose of study drug); *Topline preliminary data*

TOLERABILITY OVERVIEW

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%)

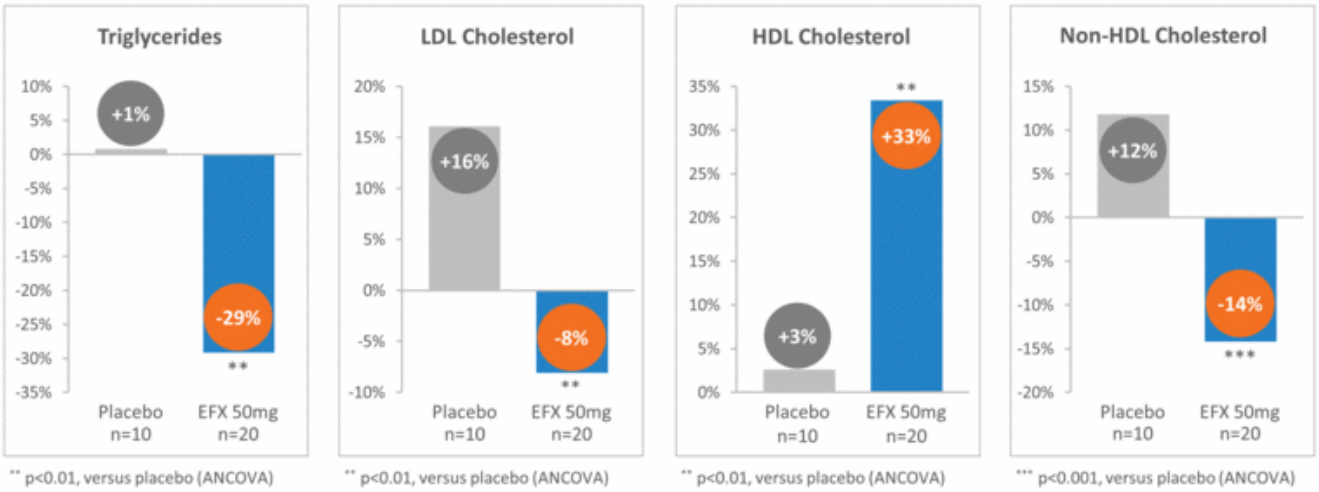
Key Observations

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

Source Data: F4 Safety Set; *Topline preliminary data*

IMPROVED LIPOPROTEIN PROFILE

LS Mean Change From Baseline to Week 16 (%)



** p<0.01, versus placebo (ANCOVA)

** p<0.01, versus placebo (ANCOVA)

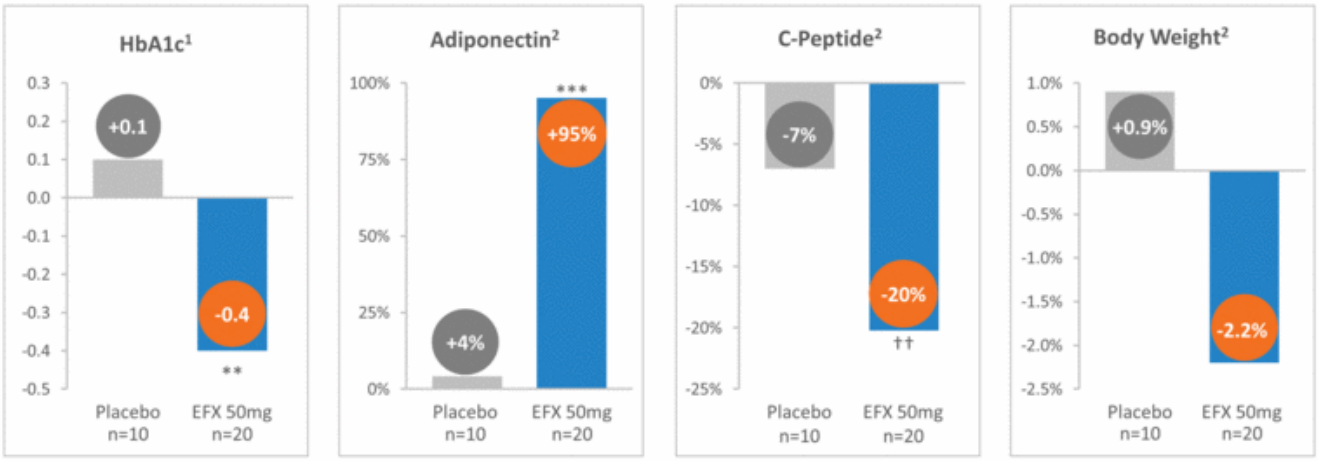
** p<0.01, versus placebo (ANCOVA)

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

Source Data: Full Analysis Set; *Topline preliminary data*

IMPROVED GLYCEMIC CONTROL; TREND TOWARD WEIGHT LOSS

LS Mean Change From Baseline to Week 16 (%)



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

² Relative percent change from baseline
*** p<0.001, versus placebo (ANCOVA)

² Relative percent change from baseline
†† p<0.01, versus baseline (ANCOVA)

² Relative percent change from baseline

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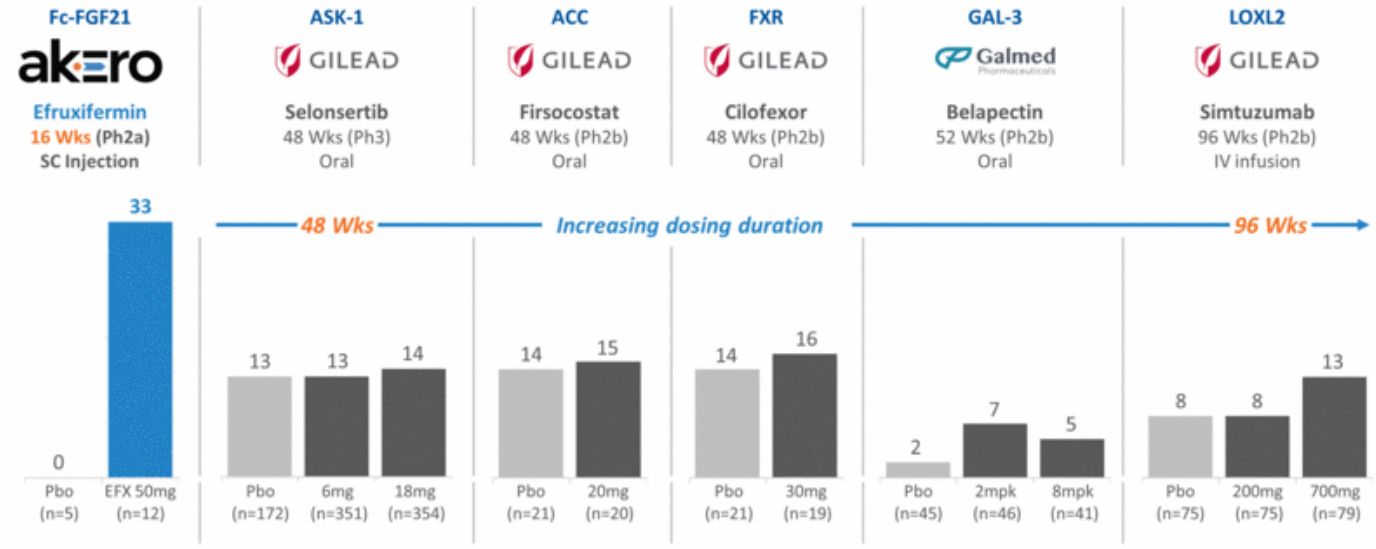
Source Data: Full Analysis Set; *Topline preliminary data*

EFX F4 RESULTS IN CONTEXT: FIBROSIS IMPROVEMENT*



** Results from all publicly reported NASH studies in F4 patients reporting either ≥ 1-stage fibrosis improvement (belapectin 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.

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INTERPRETING THE RAPID REVERSAL OF FIBROSIS OBSERVED IN CIRRHOTIC NASH PATIENTS (F4) TREATED WITH EFX

- Fibrosis reversal in cirrhotic patients (F4), two-stage improvement of fibrosis in F2/F3 patients, and corroborating non-invasive markers of fibrosis improvement likely reflects direct anti-fibrotic activity
- Fibrosis reversal is especially advantageous for cirrhotic patients who face high risk of mortality and severe morbidity

- Addressing underlying NASH disease drivers may indirectly contribute to fibrosis reversal for F1-F3 patients with adequate time for the liver to regenerate
- Redress of the underlying NASH disease drivers is necessary to sustain fibrosis reversal in F1-F4
- Supports broader metabolic improvements

NEXT STEPS FOR EFX: PARALLEL 2B TRIALS IN F2/F3 & F4

	BALANCED	Cohort C (Expansion of BALANCED)	HARMONY	SYMMETRY
Status	**Completed** (Readout Jun'20)	**Completed** (Readout Mar'21)	**Ongoing** (Initiated Feb'21)	**Expected to be initiated 2H'21**
Duration	16 Weeks	16 Weeks	24 Weeks	Under review
EFX Arms	28, 50, 70mg	50mg	28, 50mg	Under review
Placebo-Controlled	✓	✓	✓	✓

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