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): May 13, 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	**94080**
(Address of principal executive offices)	**(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 2.02 Results of Operations and Financial Condition

On May 13, 2021, Akero Therapeutics, Inc. announced its financial results for the quarter ended March 31, 2020. A copy of the press release is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Current Report on Form 8-K and Exhibit 99.1 attached hereto is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (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 7.01 Regulation FD Disclosure

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 99.2 to this Current Report on Form 8-K. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.2.

The information under this Item 7.01, including Exhibit 99.2 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

Exhibit No.	Description
99.1	Press release issued by Akero Therapeutics, Inc. on May 13, 2021, furnished herewith.
99.2	Corporate slide presentation of Akero Therapeutics, Inc., furnished 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: May 13, 2021

AKERO THERAPEUTICS, INC.

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

Exhibit 99.1

Akero Therapeutics Reports First Quarter 2021 Financial Results and Provides Business Update

SOUTH SAN FRANCISCO, May 13, 2021 /GLOBE NEWSWIRE/ -- Akero Therapeutics, Inc. (Nasdaq: AKRO), a cardio-metabolic biotechnology company developing transformational treatments for non-alcoholic steatohepatitis (NASH), today reported first quarter financial results for the period ending March 31, 2021.

"We continued to build on the strong foundation provided by last year's reports from the Phase 2a BALANCED main study, with new data showing signs of reversing fibrosis in biopsy-confirmed F4 NASH patients with compensated cirrhosis after only 16 weeks of treatment," said Andrew Cheng, M.D., Ph.D., president and chief executive officer of Akero. "Our histology results, as well as non-invasive markers of fibrosis, indicate that efruxifermin (EFX) acts both directly and indirectly to rapidly reverse fibrosis. Consistent data across three placebo-controlled clinical trials increase our confidence that EFX will be efficacious as a treatment for all stages of NASH. This confidence is reflected in our initiation of two parallel, separate Phase 2b clinical trials in F2-F3 and F4 NASH this year, for which we expect to begin reporting data in the third quarter of 2022."

First Quarter Business Highlights & Company Updates

- During the first quarter, Akero reported positive, topline, preliminary results for its 16-week evaluation of EFX in the treatment of adult NASH patients with compensated cirrhosis (F4), Child-Pugh Class A (BALANCED study, Cohort C).
    - Among 12 EFX-treated patients who volunteered to have end-of-treatment biopsies, 7 of 12 (58%) achieved either a one-stage improvement in fibrosis without worsening of NASH or NASH resolution, compared with 0 of 5 (0%) for the placebo group.
    - 4 of 12 (33%) EFX-treated patients achieved a one-stage improvement of fibrosis without worsening of NASH, compared to 0% for placebo, indicating rapid reversal of fibrosis among cirrhotic NASH patients after only 16 weeks of treatment.
    - 3 of 12 (25%) EFX-treated patients achieved NASH resolution compared to 0% for placebo.
    - Improvements in histology were supported by improvements in noninvasive serum-based and imaging markers of fibrosis.
    - EFX-treated patients also experienced improvements in ALT, serum lipids and glycemic control, with a trend toward weight loss, consistent with the results previously observed for patients with F1-F3 fibrosis.
- During the first quarter, Akero initiated its HARMONY study, a Phase 2b, multicenter, randomized, double-blind, placebo-controlled, clinical trial in biopsy-confirmed NASH patients with fibrosis stage 2 or 3, with the first patient randomized in March.

Multiple Milestones Anticipated for 2021 and 2022

- Akero plans to report additional data from the BALANCED main study at the upcoming meeting of the European Association for the Study of the Liver (EASL) on June 23-26, 2021.
    - EASL Abstract No. 1314: "The role of reduction in liver fat content (MRI-PDFF) and ALT in predicting treatment response in NASH: A secondary analysis of the randomized, controlled BALANCED trial," presented by Rohit Loomba, M.D.
    - EASL Abstract No. 1762: "Correlation between changes in liver fat content and improvements in serum markers of liver injury, fibrosis, metabolism, and in histologic parameters following treatment with efruxifermin," presented by Stephen Harrison, M.D.

- Akero plans to present new data at the upcoming meeting of the American Diabetes Association on June 25-29, 2021, for which two abstracts have been accepted for presentation.

- Akero expects to initiate its planned SYMMETRY study, a Phase 2b, multicenter, randomized, double-blind, placebo-controlled, clinical trial in biopsy-confirmed NASH patients with compensated cirrhosis (F4), Child-Pugh Class A, in the second half of 2021.

- Akero expects to report topline, preliminary results for the HARMONY study in the third quarter of 2022, based on the primary histology endpoint after 24 weeks of treatment.

- Akero expects to complete manufacturing of its planned Phase 3 combination drug/device product in 2022, with release for clinical trials in the first half of 2023.

First Quarter 2021 Financial Results

- Akero's cash, cash equivalents and short-term marketable securities for the period ended March 31, 2021 were $250.0 million.

- Akero believes that its cash, cash equivalents and marketable securities will be sufficient to fund its current operating plan into the third quarter of 2023.

- Research and development expenses for the three-month period ended March 31, 2021 were $10.6 million, compared to $8.8 million for the comparable period in 2020. These increases are attributable to higher costs related to Akero's EFX program, including third-party contract manufacturing, contract research organization costs associated with the BALANCED and HARMONY studies and internal personnel costs.

- General and administrative expenses for the three-month period ended March 31, 2021 were $4.5 million, compared to $3.6 million for the comparable period in 2020. These increases are attributable to higher expenses for personnel, including non-cash stock-based compensation, and professional services and other costs associated with operating as a public company.

- Total operating expenses were $15.1 million for the three-month period ended March 31, 2021, compared to $12.4 million for the comparable period in 2020.

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 Cohort C

Cohort C was an expansion cohort of the Phase 2a BALANCED study, which evaluated EFX in patients with NASH who have compensated cirrhosis (F4), Child-Pugh Class A. Thirty cirrhotic NASH subjects with a biopsy-confirmed fibrosis score of F4 were randomized 2:1 to receive either 50mg of EFX or placebo for 16 weeks. The primary objective of the expansion cohort was to assess safety and tolerability of EFX in NASH patients at the greatest risk of progressing to end-stage liver disease, including liver failure and liver cancer. The trial design included various non-invasive measures of liver health, including markers of liver fibrosis such as Enhanced Liver Fibrosis (ELF) score and Pro-C3, as well as liver ultrasound imaging. The trial design also permitted patients to volunteer for end-of-treatment biopsies.

About the HARMONY Study

The Phase 2b HARMONY study is a multicenter, randomized, double-blind, placebo-controlled, clinical trial in biopsy-confirmed NASH patients with fibrosis stage 2 or 3. Patients are being randomized to receive once-weekly subcutaneous dosing of 28 or 50mg EFX or placebo. The primary endpoint for the trial is regression of fibrosis at 24 weeks. Patients will continue to receive EFX or placebo during long-term follow-up to provide additional safety data.

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, improve 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 Phase 2 clinical trials as a potential treatment for NASH. Akero is headquartered in South San Francisco. Visit us at 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 Akero'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; Akero’s Phase 2b HARMONY study and Phase 2b SYMMETRY study including expected timing to complete enrollment and report preliminary results; the availability of a new combination drug product-device to support Phase 3 clinical trials; expectations regarding Akero’s use of capital, expenses and other future financial results; 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 Akero's ongoing and future operations, including potential negative impacts on Akero’s employees, third-parties, manufacturers, supply chain and production as well as on global economies and financial markets; the success, cost, and timing of Akero's product candidate development activities and planned clinical trials; Akero'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; Akero's ability to fund operations; as well as those risks and uncertainties set forth more fully under the caption "Risk Factors" in Akero’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 Akero’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. Akero undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

Akero Therapeutics, Inc.
Condensed Consolidated Balance Sheets
(Unaudited)
(In thousands)

	March 31, 2021	December 31, 2020
Assets		
Cash, cash equivalents and short-term marketable securities	$ 249,984	$ 268,387
Other current assets	5,792	2,958
Non-current assets	1,847	1,994
Total assets	$ 257,623	$ 273,339
Liabilities and Stockholders' Equity		
Current liabilities	$ 10,136	$ 13,111
Non-current liabilities	1,467	1,516
Stockholders' equity	246,020	258,712
Total liabilities and stockholders' equity	$ 257,623	$ 273,339

Akero Therapeutics, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2021	2020
Operating expenses:		
Research and development	$ 10,602	$ 8,791
General and administrative	4,526	$ 3,588
Total operating expenses	15,128	12,379
Loss from operations	(15,128)	(12,379)
Other income	38	493
Net loss	$ (15,090)	$ (11,886)
Comprehensive loss	$ (15,089)	$ (11,835)
Net loss per common share, basic and diluted	$ (0.43)	$ (0.42)
Weighted-average number of shares used in computing net loss per common share, basic and diluted	34,744,275	28,499,475

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650.487.6488
media@akerotx.com

akero

A Global Disease,
A Pioneering Treatment

Corporate Presentation

May 2021

CORPORATE HIGHLIGHTS

Efruxifermin (EFX): Highly Differentiated, Potentially Best-in-Class NASH Medicine	• Human FGF21 analog addresses all core aspects of NASH pathology • Engineered for optimal activity and convenient once-weekly dosing • We believe Phase 2a BALANCED study results among strongest data in field for both F1-F3 and cirrhotic (F4) patients • Generally well-tolerated
Regulatory Status	• EFX designated as a Priority Medicine (PRIME) based on strength of Phase 2a data • Plan to pursue marketing approval in 2 distinct patient populations: F2/F3 & F4 NASH
2021 Milestones (Completed & Upcoming)	• Dosed first patient in Phase 2b HARMONY study in F2/F3 patients in March 2021 • Expect to present new clinical data at June 2021 meetings of the European Association for the Study of the Liver (EASL) and American Diabetes Association (ADA) • Expect to initiate Phase 2b SYMMETRY study in cirrhotic (F4) patients in 2H'21 • Expect to report preliminary results of Phase 2b HARMONY study in 3Q'22
Experienced Team	• Involved in 20+ FDA approvals • Extensive experience in drug discovery, development and commercialization

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

Tim Rolph, D.Phil | Founder & CSO

- 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 | Founder, EVP & COO

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

Kitty Yale | EVP & 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

William White | EVP, 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

akero

NASH: A SERIOUS AND DEBILITATING MULTI-SYSTEM DISEASE

NASH epidemic fueled by rise in obesity and diabetes
No treatments currently available

An estimated **17 million Americans** have NASH, with expectation that population will **grow >50% by 2030**

The number of NASH patients with advanced-stage fibrosis and cirrhosis is predicted to **grow to 8 million** in the US by 2030, **an increase of approximately 140% from 2015**

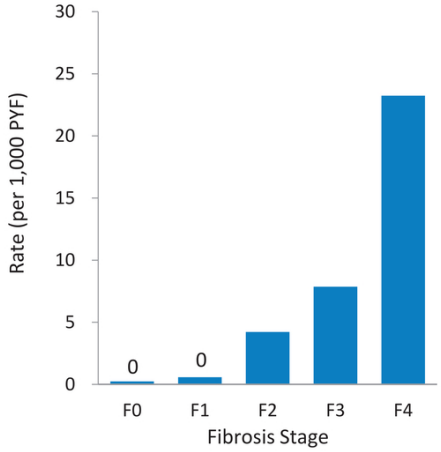
NASH is a **leading cause of liver transplantation** in the US and Europe

The **leading cause of death** for NASH patients is cardiovascular disease

CIRRHOTIC NASH PATIENTS HAVE POOR PROGNOSIS

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

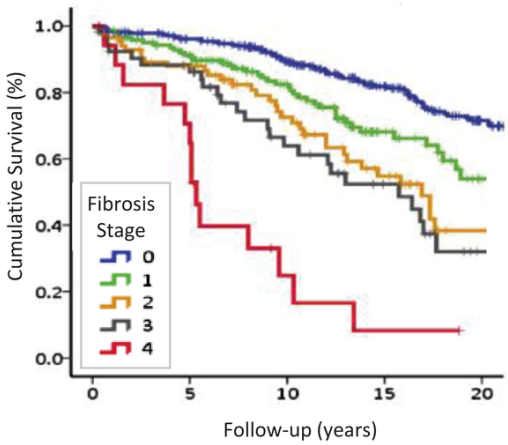
Liver-Related Mortality



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

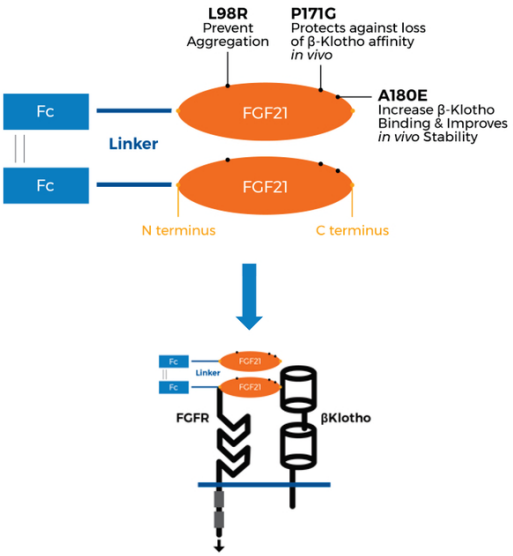
~60% 5-year mortality for F4 NASH patients absent transplant

Survival Free of Liver Transplantation



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

EFX ENGINEERING POTENTIALLY OPTIMAL FOR NASH EFFICACY, WITH CONVENIENT ONCE-WEEKLY DOSING



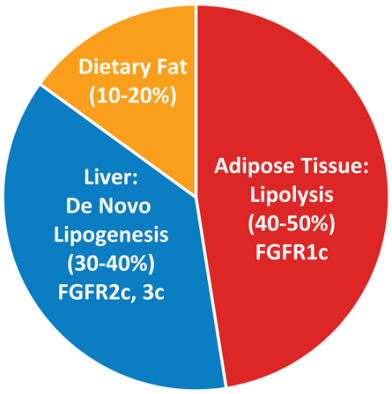
Key attributes

- 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; Kharitonenkov, 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 NASH Patients

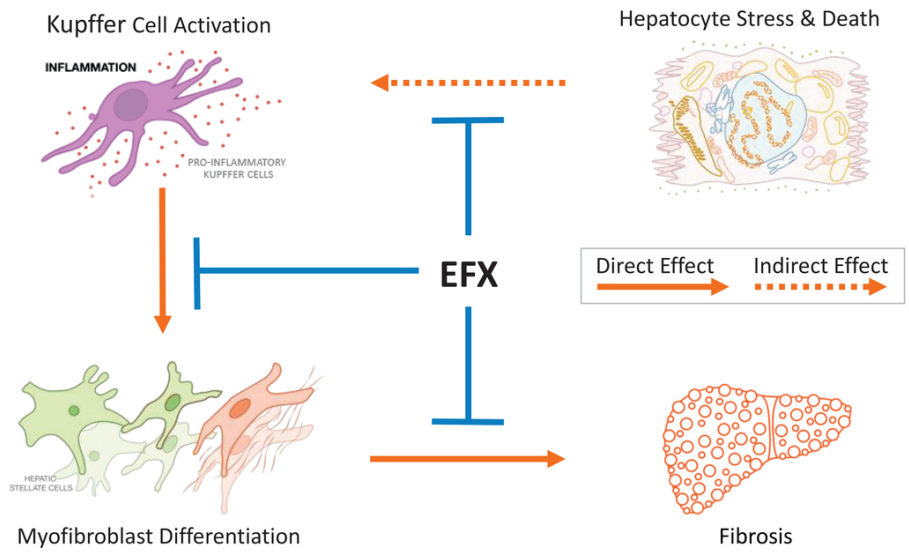


Lambert, JE *et al.* (2014) *Gastroenterology* 146(3): 726-35

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	✓

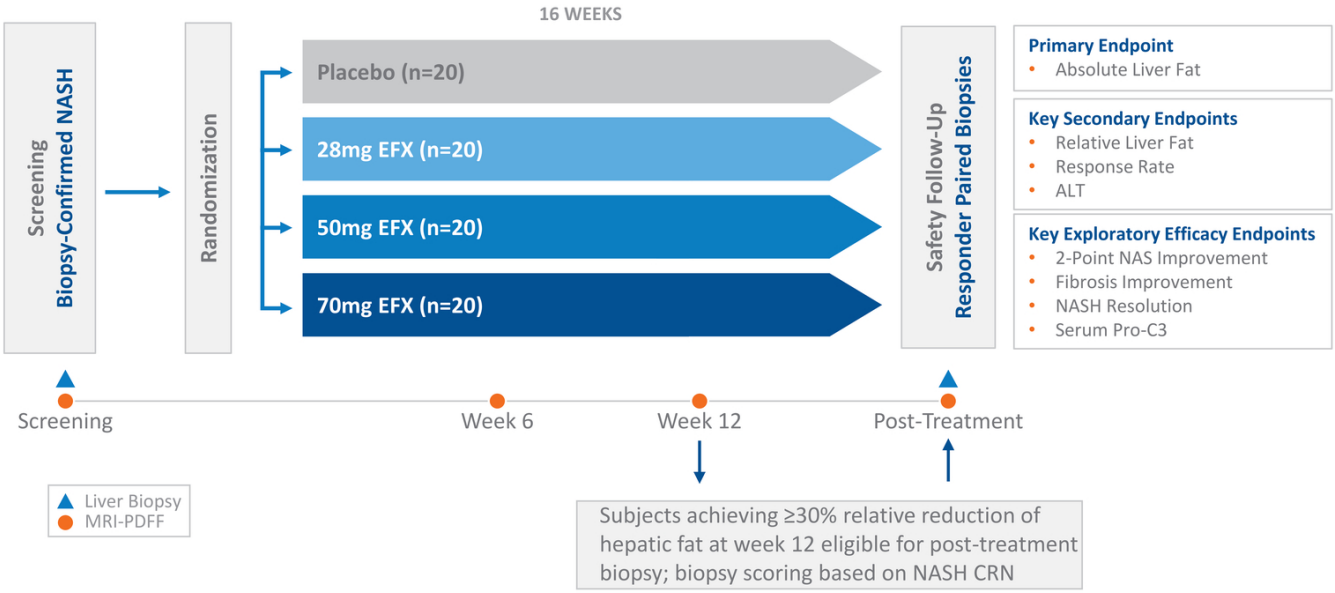
EFX DIRECT AND INDIRECT ANTI-FIBROTIC EFFECTS



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

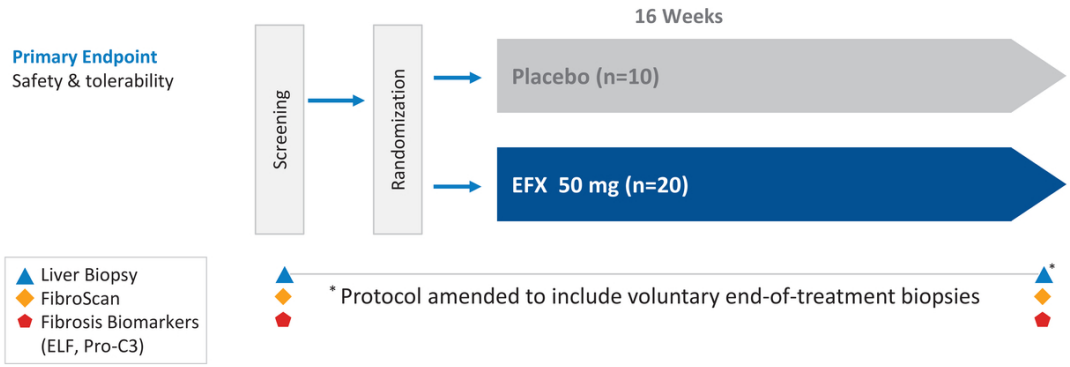
**Cited literature available on company website*

PHASE 2A TRIAL (BALANCED) DESIGN (F1-F3 NASH)



PHASE 2A EXPANSION COHORT C TRIAL DESIGN (F4 NASH)

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

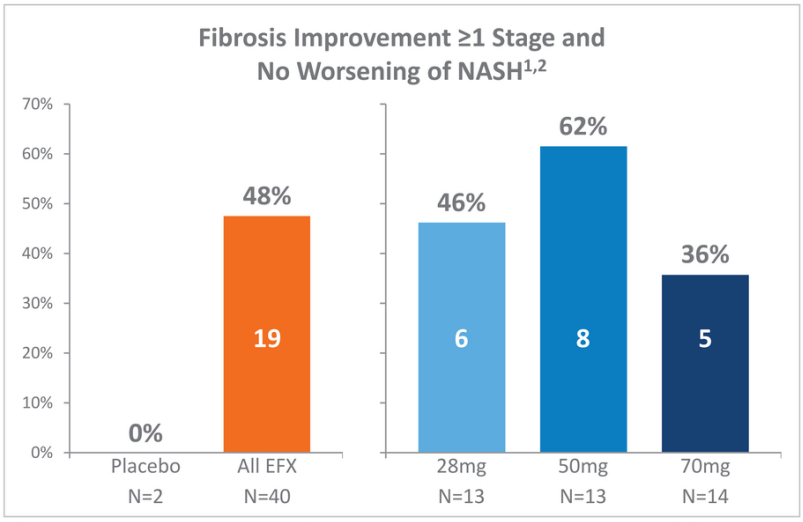


BASELINE DEMOGRAPHICS: MAIN STUDY & COHORT C

	BALANCED Main Study[a]				Cohort C[b]	
Parameter Mean	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)

HIGH RATES OF FIBROSIS IMPROVEMENT AFTER 16 WEEKS ACROSS ALL DOSE GROUPS (F1-F3 NASH)



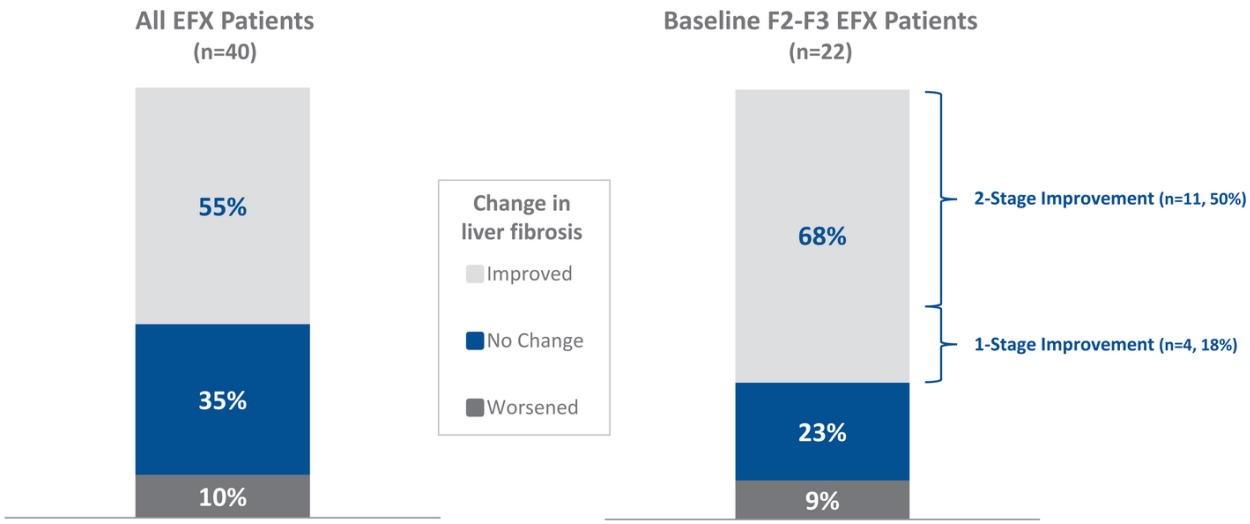
Biopsy Reading

- 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

[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

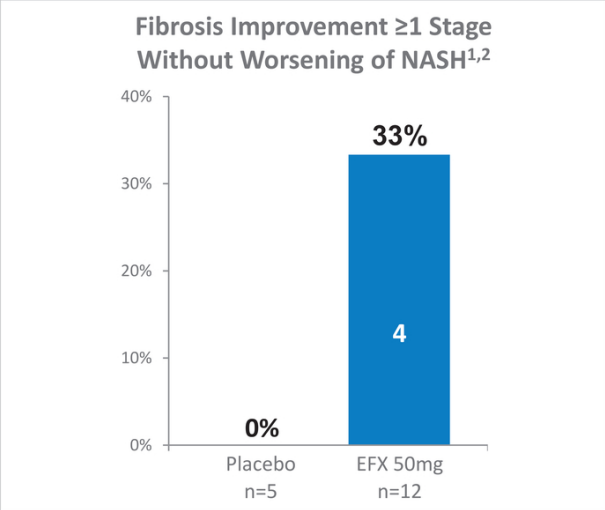
Source Data: Liver Biopsy Evaluable Analysis Set, F1-F3 (all BALANCED main study responders who had baseline and end-of-treatment liver biopsy results)

FIBROSIS IMPROVEMENT IN F2-F3 PATIENTS: HALF OF PATIENTS IMPROVED 2 STAGES



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

HIGH RATE OF FIBROSIS IMPROVEMENT AFTER ONLY 16 WEEKS AMONG CIRRHOTIC PATIENTS (F4 NASH)



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

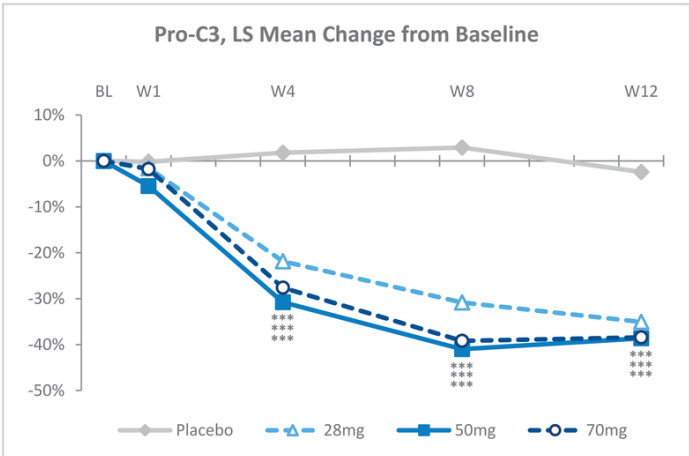
Baseline Biopsy Timing

- Mean time from historical biopsy to patient screening = 6 months

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

Source Data: Liver Biopsy Analysis Set, F4; *Topline preliminary data*

RAPID IMPROVEMENTS IN FIBROSIS BIOMARKERS CONSISTENT WITH HISTOLOGICAL IMPROVEMENTS (F1-F3 NASH)



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

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

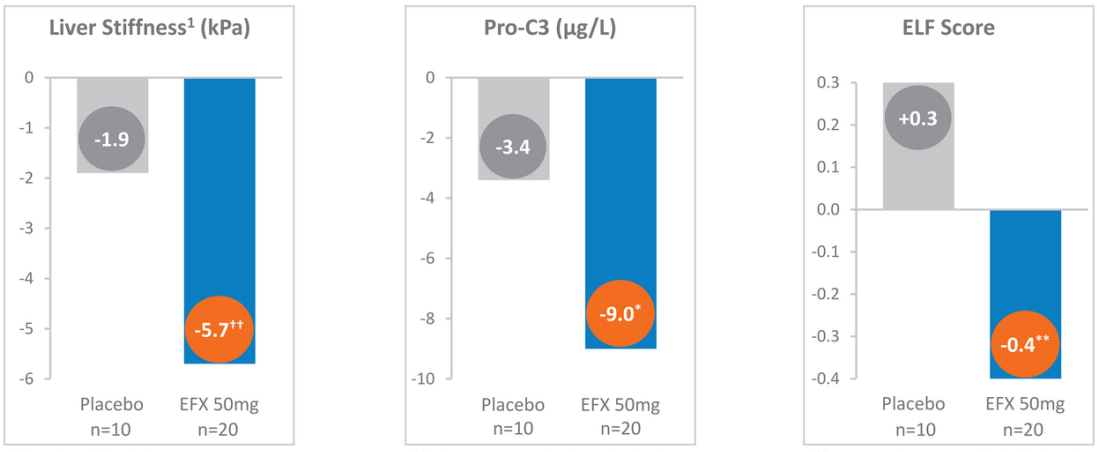
Dose Group	Baseline	Δ Week 12
Placebo	9.4	0.0
28mg	9.5	-0.7***
50mg	9.5	-0.8***
70mg	9.6	-0.4*

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

Source Data: Full Analysis Set, F1-F3

IMPROVEMENTS IN FIBROSIS BIOMARKERS IN CIRRHOTIC NASH PATIENTS SUPPORT HISTOLOGY RESULTS (F4 NASH)

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)

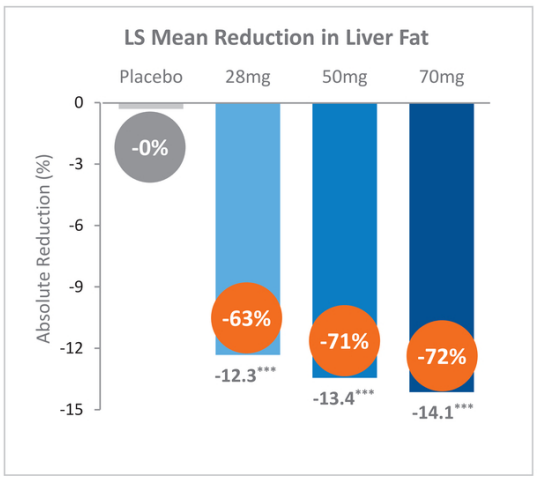
Source Data: Biomarker Analysis Set, F4 (all Cohort C subjects with baseline and interpretable on-study measure of ELF or pro-C3, respectively); Liver Stiffness Analysis Set, F4 (all Cohort C subjects with baseline and interpretable on-study measure of Liver Stiffness); *Topline preliminary data*

INTERPRETING THE RAPID REVERSAL OF FIBROSIS OBSERVED IN NASH PATIENTS TREATED WITH EFX

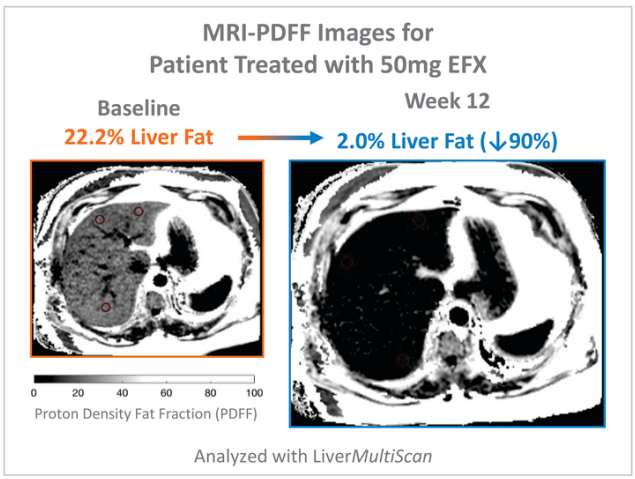
- Fibrosis reversal in cirrhotic patients (F4), two-stage improvement of fibrosis in F2/F3 patients, and corroborating non-invasive markers of fibrosis improvement likely reflects direct anti-fibrotic activity
- Fibrosis reversal is especially advantageous for cirrhotic patients who face high risk of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

SUBSTANTIAL REDUCTIONS IN LIVER FAT AT WEEK 12 ACROSS ALL DOSE GROUPS (F1-F3 NASH)

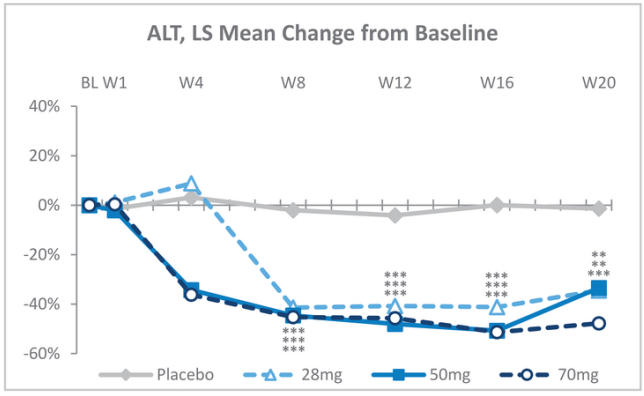


*** p<0.001, versus placebo (ANCOVA)

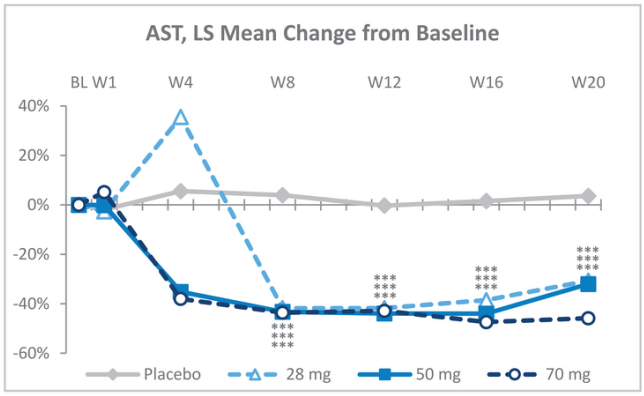


Source Data: Full Analysis Set, F1-F3

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

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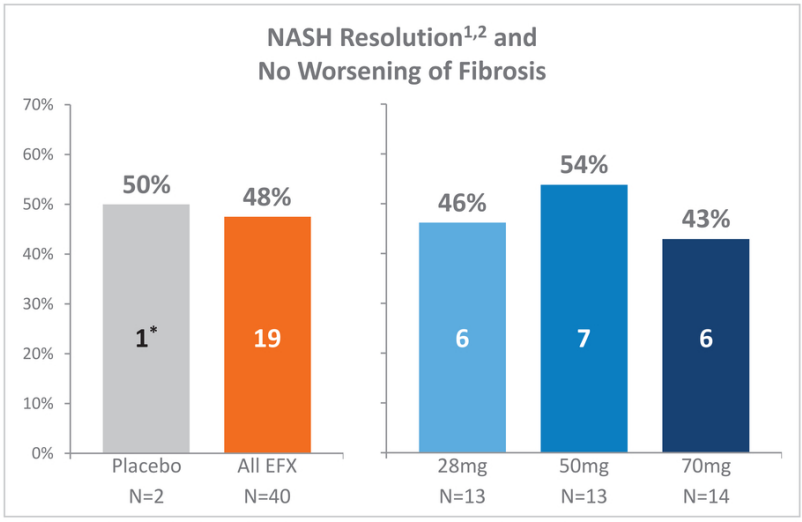
Source Data: Full Analysis Set, F1-F3

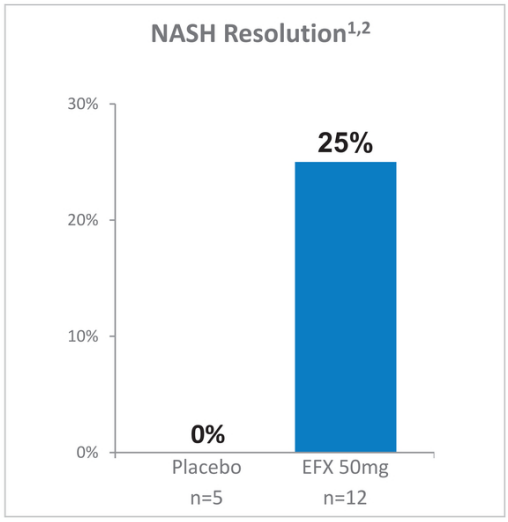
HIGH RESPONSE RATES ON NASH RESOLUTION AFTER 16 WEEKS ACROSS ALL DOSE GROUPS (F1-F3 NASH)



[1] NAS score of 0 or 1 for lobular inflammation and a score of 0 for ballooning
[2] Secondary 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

NASH RESOLUTION ALSO OBSERVED IN CIRRHOTIC PATIENTS (F4 NASH)



[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 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%)

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

DRUG-RELATED TREATMENT-EMERGENT ADVERSE EVENTS (TEAE) (F1-F3 NASH)

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*

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

TOLERABILITY OVERVIEW (F4 NASH)

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

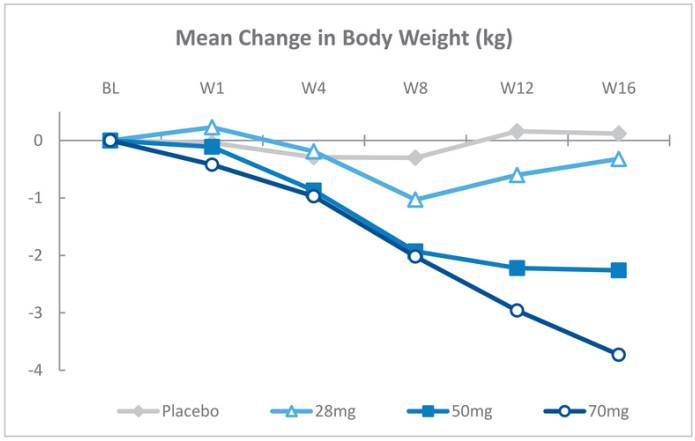
[a] *Withdrawal of consent*
[b] *abdominal distension, constipation, diarrhea, pruritus*
[c] *pulmonary embolism*

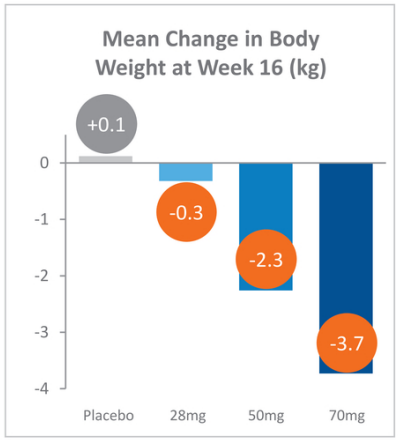
Key Observations

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

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); *Topline preliminary data*

WEIGHT LOSS OBSERVED FOR ALL DOSE GROUPS (F1-F3 NASH)

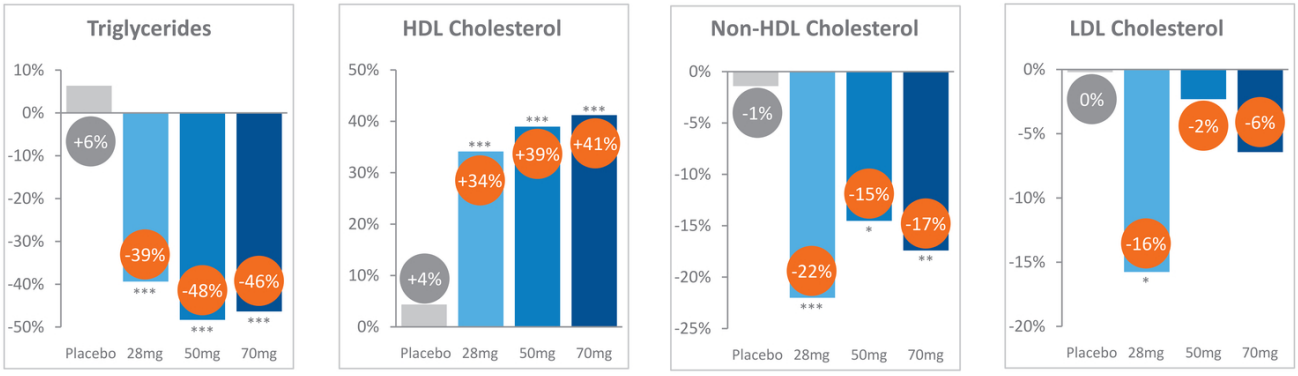




Source Data: Full Analysis Set, F1-F3

IMPROVED LIPOPROTEIN PROFILE (F1-F3 NASH)

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)

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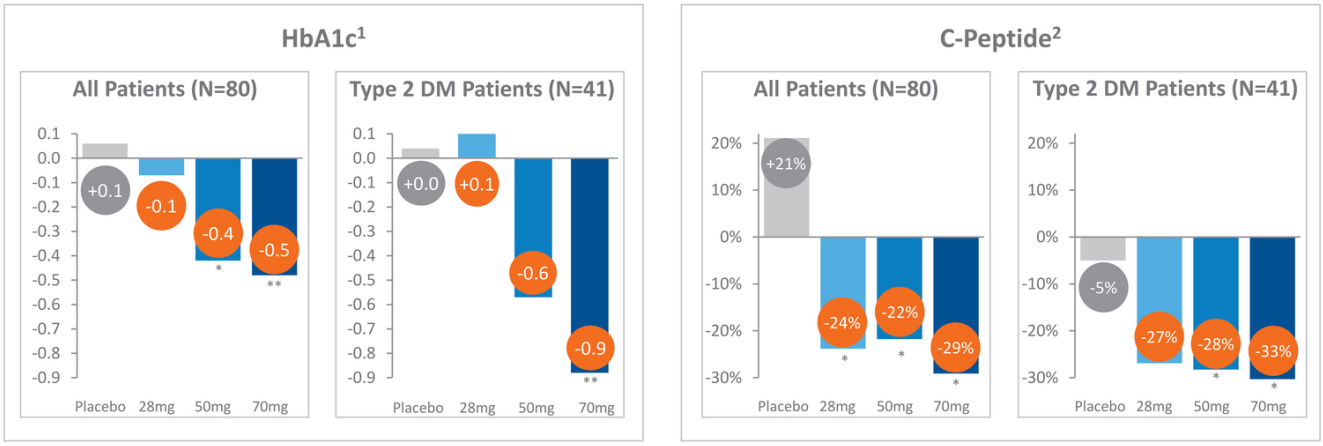
Source Data: Full Analysis Set, F1-F3

CLINICALLY MEANINGFUL IMPROVEMENTS IN GLYCEMIC CONTROL AFTER 16 WEEKS (F1-F3 NASH)

LS Mean Change From Baseline to Week 16 (%)



[1] Absolute change from baseline, %

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

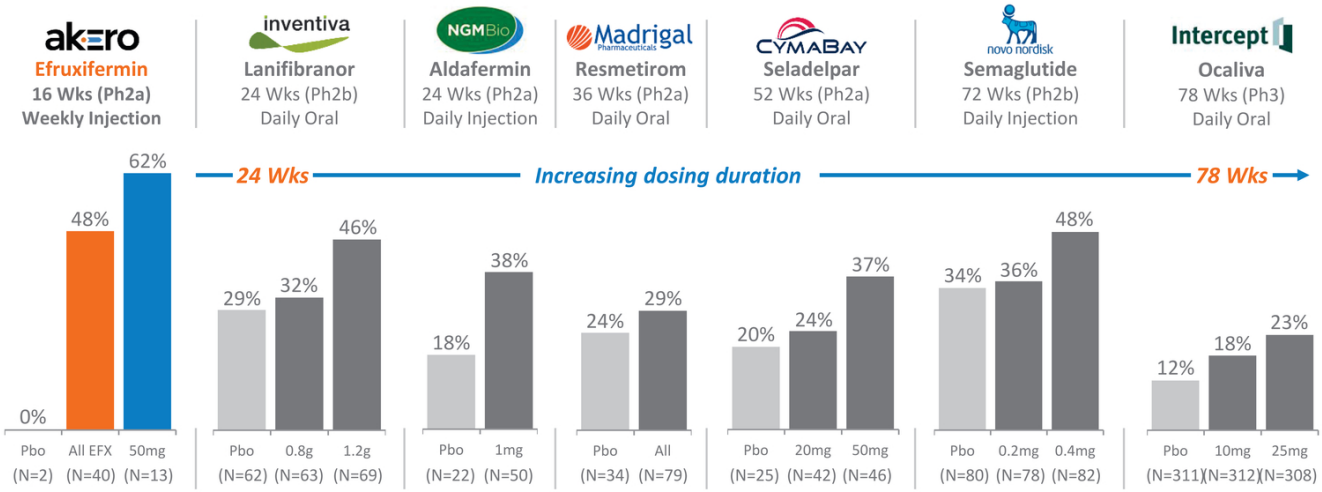
[2] Relative percent change from baseline

* p<0.05, versus placebo (ANCOVA)

Source Data: Full Analysis Set, F1-F3

NASH DEVELOPMENT LANDSCAPE: FIBROSIS IMPROVEMENT (F1-F3)

Proportion of Subjects with ≥1 Stage Improvement in Fibrosis and No Worsening of NAS[1]

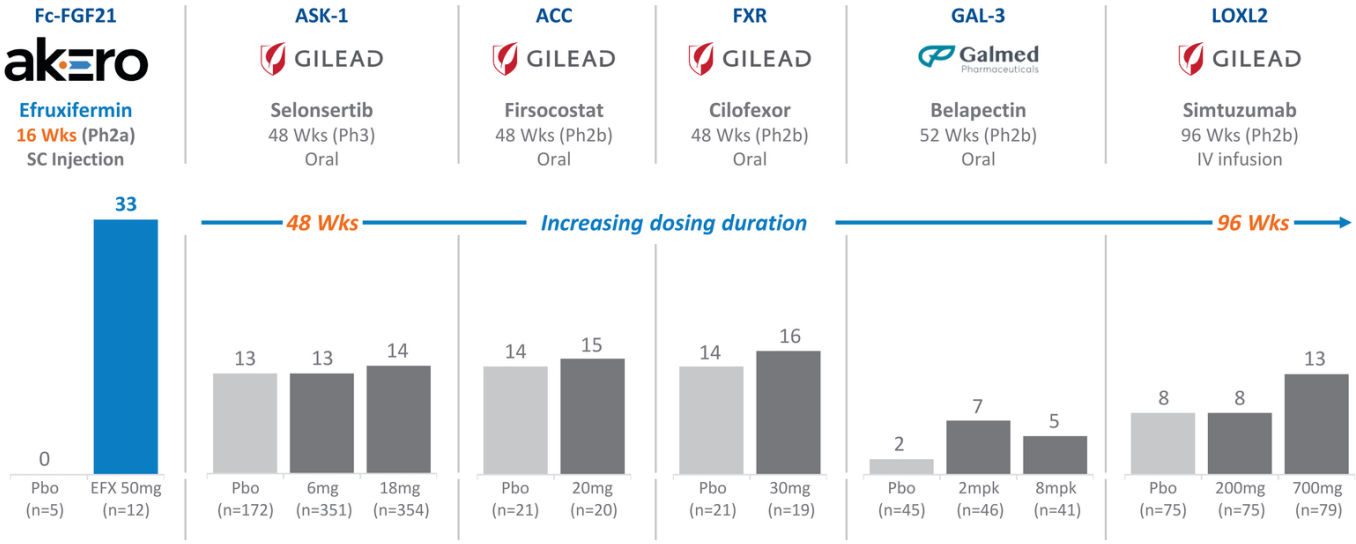


Note: These data are derived from different clinical trials at different points in time, with differences in trial design and patient populations. No head-to-head clinical trials have been conducted.

Inventiva (2020) June 16 Corporate Presentation; NGM Bio (2020) June 3 Corporate Presentation; Harrison, S et al. (2019) Lancet 394(10213):2012-24; CymaBay (2020) March 12 Press Release; Novo Nordisk (2020) June 19 R&D Investor Presentation; Younossi Z et al. (2019) Lancet 394(10215):2184-96. 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)

COHORT C RESULTS IN CONTEXT: FIBROSIS IMPROVEMENT* (F4)



** Results from all publicly reported NASH studies for single agents in F4 patients reporting either ≥ 1-stage fibrosis improvement (belapectin and simtuzumab) or ≥ 1-stage fibrosis improvement and no worsening of NASH (EFX, selonsertib, firsocostat and cilofexor); numerical values represent percent responders*

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

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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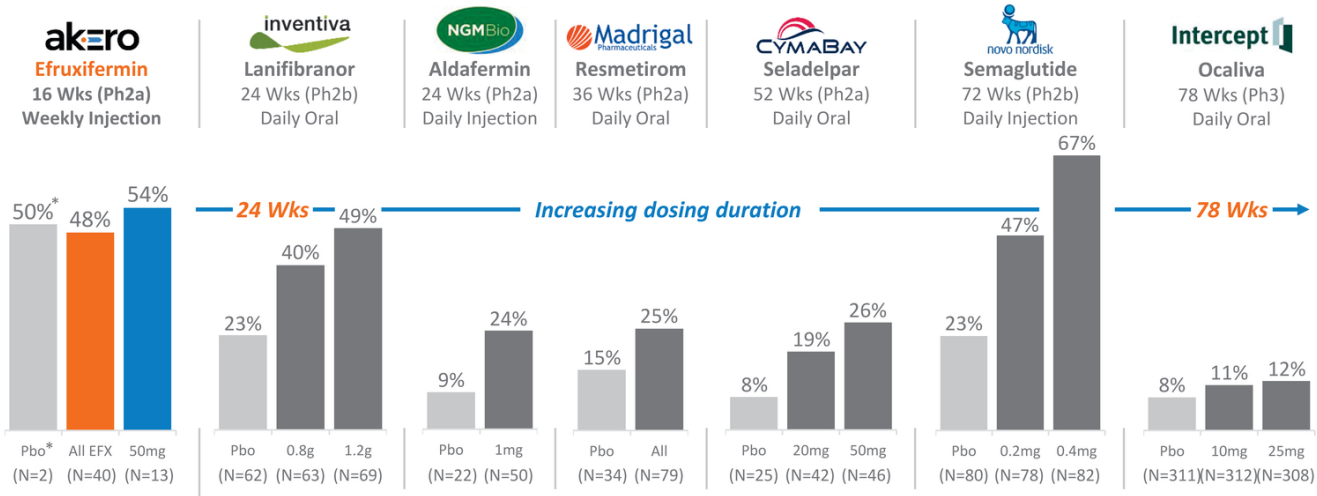
NASH DEVELOPMENT LANDSCAPE: NASH RESOLUTION (F1-F3)

Proportion of Subjects with Resolution of NASH and No Worsening of Fibrosis[1]



** A single placebo responder lost 25 pounds over 16 weeks (11% weight reduction)*

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.

Inventiva (2020) June 16 Corporate Presentation; NGM Bio (2020) June 3 Corporate Presentation; Harrison, S et al. (2019) Lancet 394(10213):2012-24; CymaBay (2020) March 12 Press Release; Novo Nordisk (2020) June 19 R&D Investor Presentation; Younossi Z et al. (2019) Lancet 394(10215):2184-96. All trademarks are the property of their respective owners.

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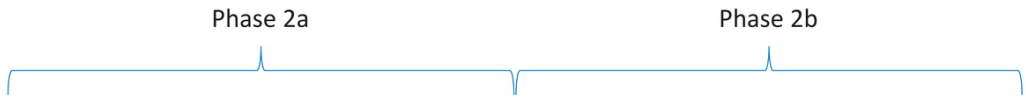
[1] FDA Guidance for Industry: Noncirrhotic Nonalcoholic Steatohepatitis With Liver Fibrosis: Developing Drugs for Treatment (2018)

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



Biopsy-Confirmed: F1-F3 | F4 | F2/F3 | F4

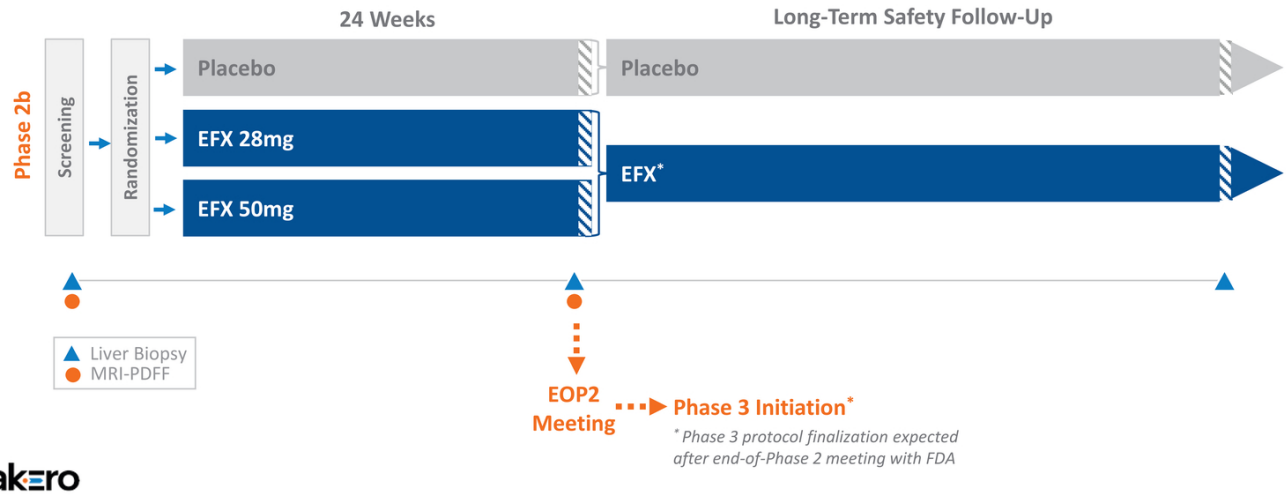
	BALANCED	Cohort C (Expansion of BALANCED)	HARMONY	SYMMETRY
Status	**Completed** (Readout Jun'20)	**Completed** (Readout Mar'21)	**Readout expected in 3Q'22**	**Initiation expected in 2H'21**
Duration	16 Weeks	16 Weeks	24 Weeks	Under review
EFX Arms	28, 50, 70mg	50mg	28, 50mg	Under review
Placebo-Controlled	✓	✓	✓	✓

PHASE 2B (F2/F3) TRIAL DESIGN (HARMONY)

Key Inclusion Criteria
- F2-3 NASH
- NAS ≥4
- Liver fat ≥8%

Phase 2b Primary Endpoint
- Fibrosis Improvement

Key Secondary Efficacy Endpoints
- NASH Resolution
- Fibrosis Markers
- Lipoproteins
- Glycemic Control
- Weight Change
- MRI-PDFF
- Liver Injury Markers



*Phase 3 protocol finalization expected after end-of-Phase 2 meeting with FDA

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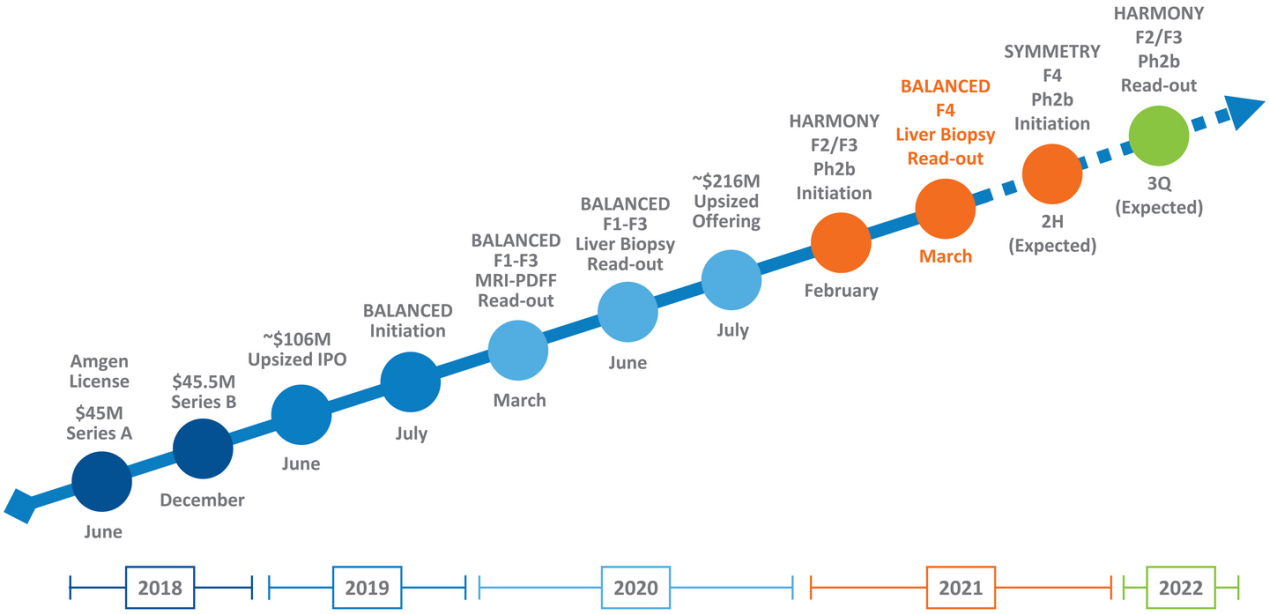
STRONG FINANCIAL POSITION

COMPLETED UPSIZED IPO *June 20, 2019*	COMPLETED UPSIZED FOLLOW-ON OFFERING *July 10, 2020*	CASH[1] ON HAND *As of March 31, 2021*
~$106M Raised in aggregate gross proceeds	~$216M Raised in aggregate gross proceeds	~$250M
$16/share Priced upsized IPO at top of marketing range	$36/share Priced upsized follow-on offering at top of marketing range	[1] Cash, cash equivalents and short-term marketable securities

Current cash, cash equivalents and marketable securities are expected to be sufficient to fund current operating plan into the third quarter of 2023

CONSISTENT RECORD OF MILESTONE DELIVERY



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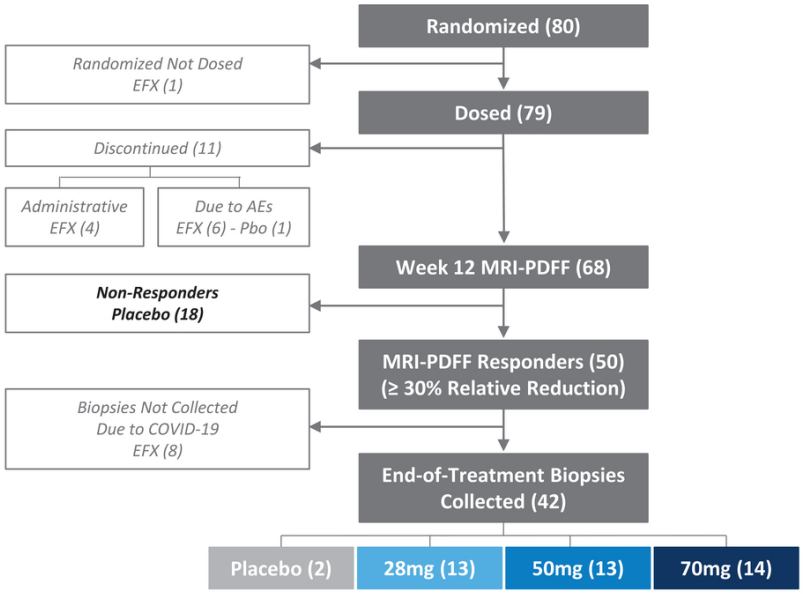
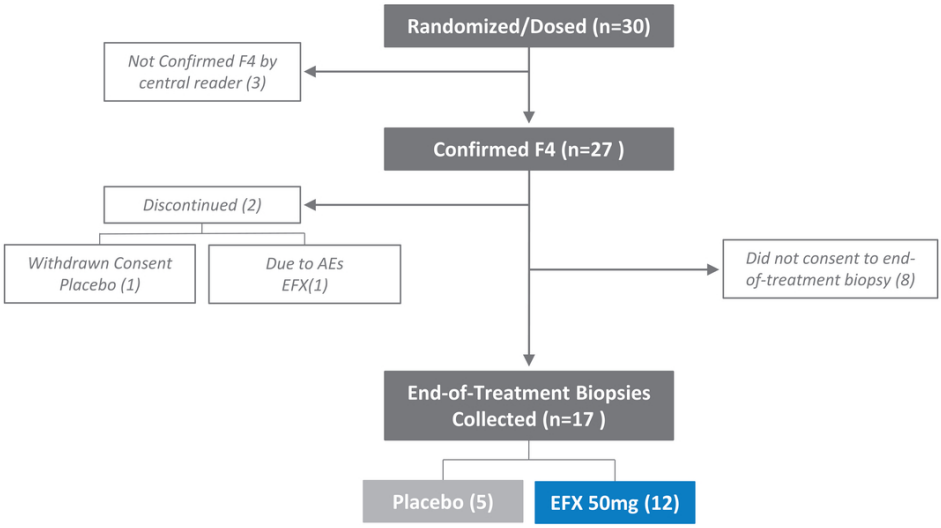
Backup Slides

PATIENT DISPOSITION (BALANCED MAIN STUDY)



PATIENT DISPOSITION (BALANCED COHORT C)



MAGNITUDE OF LIVER FAT REDUCTION (F1-F3 NASH)

Proportion of Patients Achieving Fat Reduction Thresholds at Week 12

Endpoint	Placebo[1] (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%***

[1] A single placebo responder lost 25 pounds over 16 weeks (11% weight reduction)

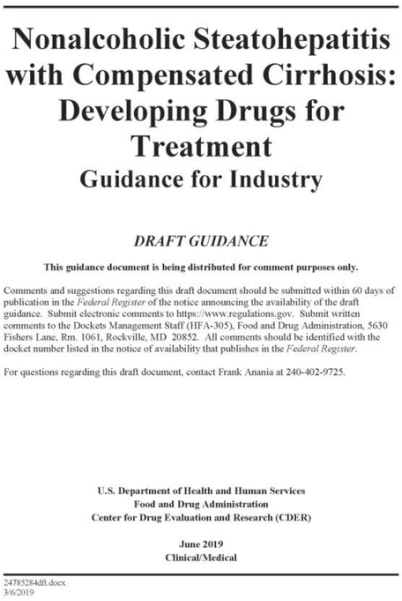
* p<0.05, ** p<0.01, *** p<0.001 versus placebo (ANCOVA)

Source Data: MRI-PDFF Evaluable Analysis Set (all BALANCED main study subjects who had baseline and Week 12 MRI-PDFF

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.

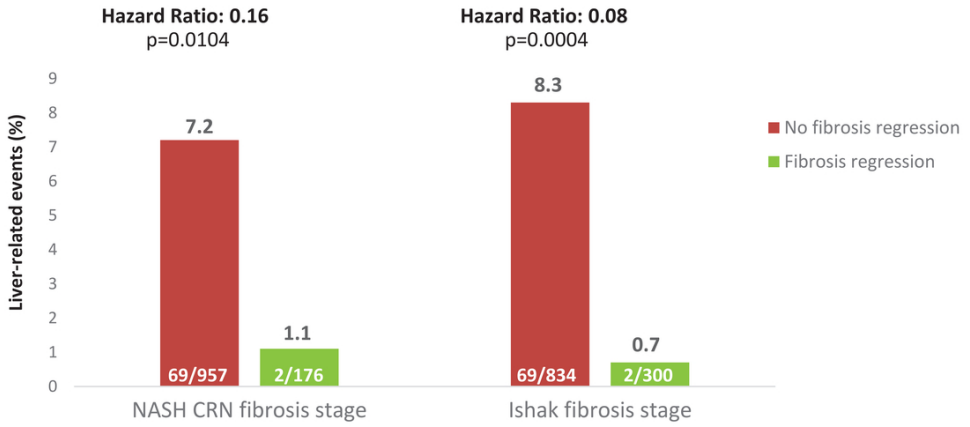
U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

June 2019
Clinical/Medical

24785284dft.docx
3/6/2019

CIRRHOSIS REGRESSION IS ASSOCIATED WITH IMPROVED CLINICAL OUTCOMES

Pooled treatment groups from STELLAR 4 and simtuzumab cirrhosis study



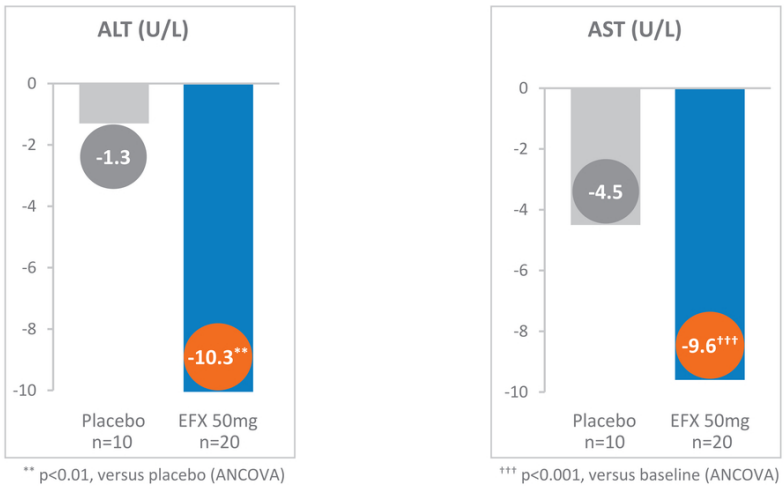
Cirrhosis regression observed in 16% of patients (treatment and placebo groups) over 48 weeks

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.

REDUCTIONS IN MARKERS OF LIVER INJURY (F4 NASH)

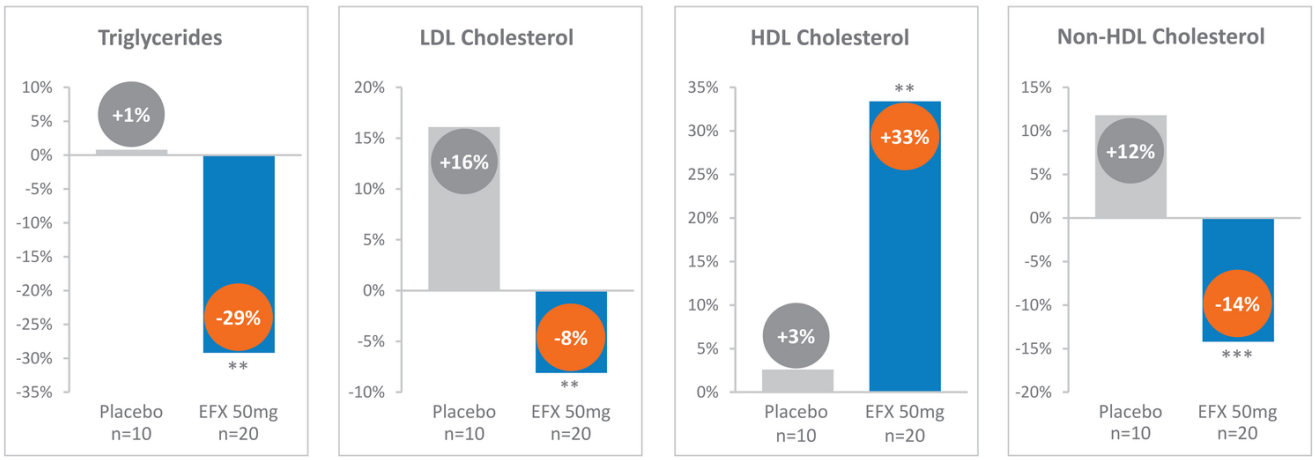
LS Mean Change from Baseline to Week 16



Source Data: Full Analysis Set, F4; *Topline preliminary data*

IMPROVED LIPOPROTEIN PROFILE (F4 NASH)

LS Mean Change From Baseline to Week 16 (%)



** p<0.01, versus placebo (ANCOVA)

** p<0.01, versus placebo (ANCOVA)

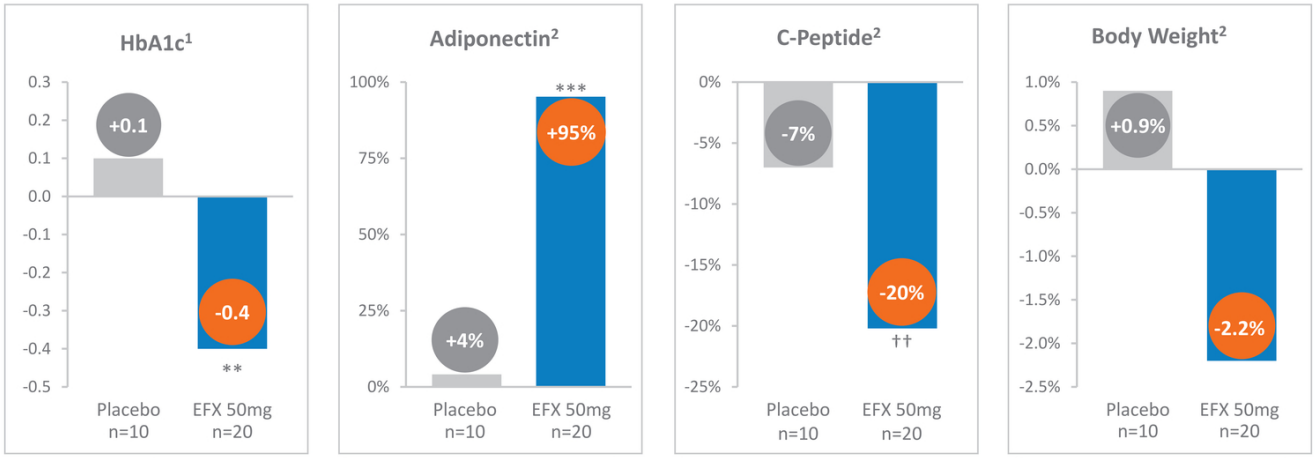
** p<0.01, versus placebo (ANCOVA)

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

Source Data: Full Analysis Set, F4; *Topline preliminary data*

IMPROVED GLYCEMIC CONTROL; TREND TOWARD WEIGHT LOSS (F4 NASH)

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

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

FGF21 DEVELOPMENT LANDSCAPE

Noninvasive Measures: Percent Change From Baseline to End of Study	Akero (EFX) 16 weeks			BMS (Pegbelfermin) 16 weeks			89Bio (BIO89-100) 12 weeks			
Dose	pbo	28 QW	50 QW	pbo	20 QW	10 QD	pbo	18 QW	27 QW	36 Q2W
Patient Population	Biopsy-confirmed NASH			Biopsy-confirmed NASH			80% NAFLD; 20% biopsy-confirmed NASH*			
≥1 Stage Fibrosis Improvement and No Worsening of NASH, % of Subjects	0%	46%	62%	No end-of-study biopsy			No end-of-study biopsy			
MRI-PDFF, % relative reduction	0	-63	-71	-6	-26	-38	+10	-36	-60	-50
ALT	0	-41	-51	-5	-22	-33	-4	-27	-44	-40
Triglycerides	+6	-39	-48	0	-5	-5	-2	-18	-28	-21
HDL-C	+4	+34	+39	-2	+12	+13	+2	+9	+3	+10
LDL-C	0	-16	-2	+1	+1	-11	+1	+3	-16	-4
Adiponectin	-8	+65	+80	-4	+16	+15	-4	+29	+61	+24
% HbA1c, absolute change	+0.1	-0.1	-0.4	NR			0	+0.1	-0.3	+0.5

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.

NR, not reported

Sanyal et al (2019) Lancet;
89Bio October 5 Corporate Presentation

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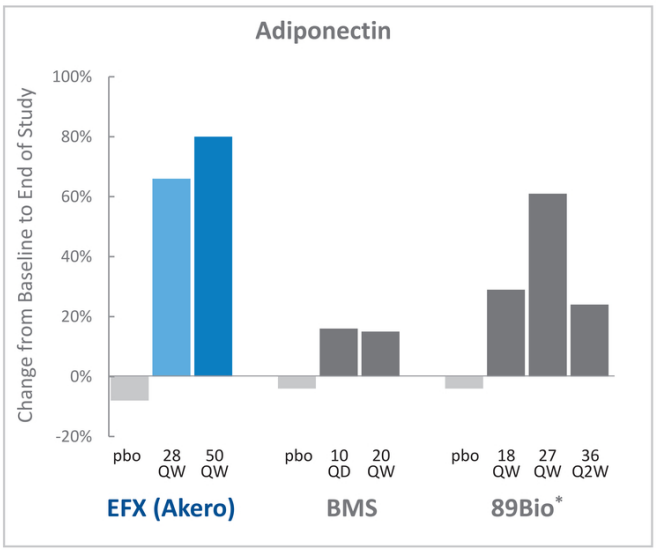
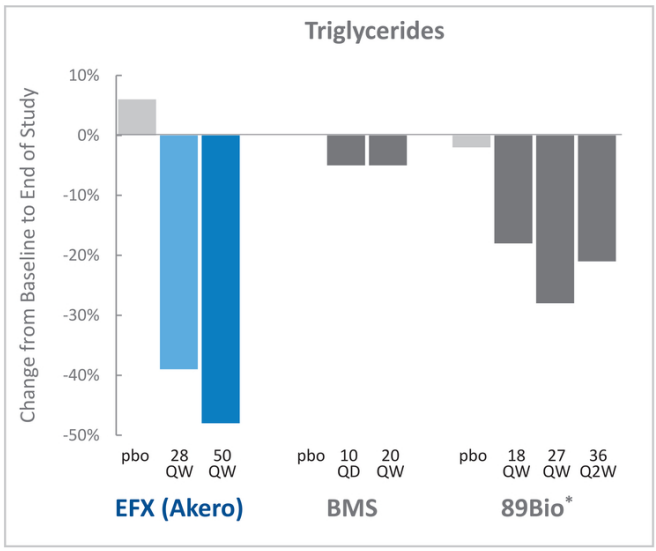
** Subjects with biopsy-confirmed NASH were present only in the 18mg QW & 18 Q2W cohorts (Loomba et al., 2020 AASLD Poster #LP34)*

PERIPHERAL FGFR1c ACTIVATION





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.

Sanyal et al (2019) Lancet;
89Bio October 5 Corporate Presentation

** Subjects with biopsy-confirmed NASH were present only in the 18mg QW & 18 Q2W cohorts (Loomba et al., 2020 AASLD Poster #LP34)*

FGF21 DEVELOPMENT LANDSCAPE: SUMMARY

Consideration	Fc-FGF21 Fusion Protein (Akero)	Pegylated FGF21 (BMS or 89Bio)
Patient Population: NASH diagnosed only by biopsy; NASH patients have more advanced disease and worse comorbidities	Biopsy-confirmed NASH	BMS: biopsy-confirmed NASH; 89Bio: ~20% biopsy-confirmed NASH*
Histology: Fibrosis only histological endpoint correlated with liver outcomes	Demonstrated fibrosis improvement by histology	BMS: histology data pending 89Bio: no histology data
Liver Fat Reduction: Max reduction requires inhibition of both hepatic fat synthesis and adipose tissue lipolysis	71% (50mg QW)	BMS: 38% (10mg QD) 89Bio: 60% (27mg QW*)
Liver Enzymes (LFTs): Reductions indicate improved liver health	Large reductions in LFTs; Consistent dose response	BMS/89Bio: Smaller effects on LFTs
Lipids: Cardiovascular risk #1 cause of mortality for NASH patients. Reflects liver and adipose effects	Robust and consistent TG and HDL-C effects	BMS/89Bio: Smaller effects on TG and HDL-C
Glycemic Control: Improvement in HbA1c mediated by peripheral insulin sensitization; 50% NASH patients diabetic	Significant decrease in HbA1c	BMS: HbA1c not reported 89Bio: no significant change in HbA1c
Safety & Tolerability: Baseline patient population influences profile; Mild GI events common for FGF21 in NASH patients	In line with FGF21 class	BMS: In line with FGF21 class 89Bio: ~80% NAFLD*

***EFX** delivered numerically largest effects, a clear dose response, with maximal or near-maximal effect at 50mg QW*

akero

** Subjects with biopsy-confirmed NASH were present only in the 18mg QW & 18 Q2W cohorts (Loomba et al., 2020 AASLD Poster #LP34)*

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A Global Disease,
A Pioneering Treatment

NASDAQ: AKRO