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 30, 2020

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

170 Harbor Way, 3rd Floor
South San Francisco, CA 94080
(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 June 30, 2020, Akero Therapeutics, Inc. (the “Company”) issued a press release titled “Akero Announces Strongly Positive Histological Data Across All Efruxifermin Dose Groups in 16-Week Phase 2a BALANCED Study in NASH Patients.” A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

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 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 June 30, 2020, the Company announced results of a 16-week analysis of secondary and exploratory endpoints in its Phase 2a BALANCED study of efruxifermin (“EFX”), formerly known as AKR-001, in patients with nonalcoholic steatohepatitis (“NASH”). Notably, of the 40 treatment responders who had end-of-treatment biopsies, we observed that 48% achieved at least a one-stage improvement in fibrosis without worsening of NAFLD activity score (“NAS”) and 28% achieved at least a two-stage improvement in fibrosis. In addition, 48% of responders achieved NASH resolution with no worsening of fibrosis. Improvements in glycemic control and dyslipidemia, as well as weight loss, were also observed across all dose groups. Treatment with EFX was generally reported to be well tolerated.

The BALANCED study underscored EFX’s potential to address multiple important NASH comorbidities. We observed that all dose groups had mean weight loss over the 16-week study, with the 70 mg dose group achieving a statistically significant 3.7kg (about 8 pounds) reduction in body weight at Week 16. Clinically meaningful improvements in glycemic control were observed, including significant reductions in HbA1c in the 50 and 70 mg dose groups of 0.4 and 0.5, respectively. EFX also improved dyslipidemia, including significant increases in HDL cholesterol and significant decreases in triglycerides observed across all EFX dose groups.

EFX was reported to be generally well tolerated. There were no deaths in the study and there were two Serious Adverse Events, one of which occurred prior to dosing. Across EFX groups, the most frequent AEs were grade 1 or 2 gastrointestinal events, which were transient in nature. There were no discontinuations due to treatment-emergent adverse events in the 50 mg dose group and no discontinuations due to the most common adverse event, diarrhea. There were no treatment-related effects on blood pressure, heart rate, or bone mineral density. The BALANCED study is an ongoing randomized, double-blind, placebo-controlled study in NASH patients. The company previously reported that each of the 28, 50 and 70 mg EFX dose groups met the primary endpoint compared to placebo, with absolute reductions of 12, 13 and 14 percent of liver fat, respectively, compared with 0.3 percent for placebo, and relative reductions of 63, 71 and 72 percent, compared to 0 percent for placebo. All of these results were highly statistically significant at $p<0.001$.

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: Akero'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; Akero's Phase 2a BALANCED clinical trial, including its initial primary efficacy results; 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 June 30, 2020
99.2	Slide presentation of Akero Therapeutics, Inc.

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 30, 2020

AKERO THERAPEUTICS, INC.

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

Exhibit 99.1

Akero Announces Strongly Positive Histological Data
Across All Efruxifermin Dose Groups in
16-Week Phase 2a BALANCED Study in NASH Patients

48% fibrosis improvement of at least one stage without worsening of NAS across all dose groups, with a 62% response rate for the 50mg dose group

28% fibrosis improvement of at least two stages across all dose groups, with a 38% response rate for the 50mg dose group

48% NASH resolution without worsening of fibrosis across all dose groups, with a 54% response rate for the 50mg dose group

SOUTH SAN FRANCISCO, CA – June 30, 2020 – Akero Therapeutics, Inc. (Nasdaq: AKRO) today announced results of a 16-week analysis of secondary and exploratory endpoints in its Phase 2a BALANCED study of efruxifermin (EFX), formerly known as AKR-001, in patients with nonalcoholic steatohepatitis (NASH). Notably, of the 40 treatment responders who had end-of-treatment biopsies, we observed that 48% achieved at least a one-stage improvement in fibrosis without worsening of NAFLD activity score (NAS) and 28% achieved at least a two-stage improvement in fibrosis. In addition, 48% of responders achieved NASH resolution with no worsening of fibrosis. Improvements in glycemic control and dyslipidemia, as well as weight loss, were also observed across all dose groups. Treatment with EFX was generally reported to be well tolerated.

“These substantial improvements observed in multiple measures of liver health, particularly the one- and two-stage improvements in fibrosis, are extremely encouraging and among the strongest biopsy results reported in NASH to date,” said Stephen Harrison, M.D., medical director of Pinnacle Clinical Research. “I believe Efruxifermin continues to set itself apart as one of the most promising drug candidates in NASH, with impressive histology results after just 16 weeks of treatment.”

Summary of Week 16 Biopsy Endpoints[1]

Measure (Mean)	Placebo (N=2)	All EFX (N=40)	28mg (N=13)	50mg (N=13)	70mg (N=14)
Improvement in at least one stage of fibrosis without worsening NAS (%)[2]	0	48	46	62	36
Improvement in at least two stages of fibrosis (%)[2]	0	28	31	38	14
Resolution of NASH without worsening of fibrosis (%)[2]	50*	48	46	54	43
Combination of improvement in at least one stage of fibrosis and NASH resolution (%)[2]	0	28	31	39	14
NAS Reduction ≥2 points without worsening of fibrosis (%)[2]	50*	78	77	77	79

[1] Secondary and exploratory histological endpoints were not powered for statistical significance

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

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

The BALANCED study underscored EFX's potential to address multiple important NASH comorbidities. We observed that all dose groups had mean weight loss over the 16-week study, with the 70 mg dose group achieving a statistically significant 3.7kg (about 8 pounds) reduction in body weight at Week 16. Clinically meaningful improvements in glycemic control were observed, including significant reductions in HbA1c in the 50 and 70 mg dose groups of 0.4 and 0.5, respectively. EFX also improved dyslipidemia, including significant increases in HDL cholesterol and significant decreases in triglycerides observed across all EFX dose groups.

Summary of Cardio-Metabolic Biomarkers

Measure (Mean Change From Baseline)	Placebo (N=21)	28 mg (N=19)	50 mg (N=20)	70 mg (N=20)
Body Weight (kg)[1]	+0.1	-0.3	-2.3	-3.7*
HbA1C (%, absolute)[1]	+0.1	-0.1	-0.4*	-0.5**
Triglycerides (%)[1]	+8	-37***	-45***	-43***
HDL Cholesterol (%)[1]	0	+32***	+40***	+40***
Non-HDL Cholesterol (%)[1]	0	-20***	-13*	-15**
LDL Cholesterol (%)[1]	+1	-14*	0	-3

[1] Full Analyses Set (all patients randomized into the study)
*p<0.05, **p<0.01, ***p<0.001, versus placebo

EFX was reported to be generally well tolerated. There were no deaths in the study, and there were two Serious Adverse Events, one of which occurred prior to dosing. Across EFX groups, the most frequent AEs were grade 1 or 2 gastrointestinal events, which were transient in nature. There were no discontinuations due to treatment-emergent adverse events in the 50 mg dose group and no discontinuations due to the most common adverse event, diarrhea. There were no treatment-related effects on blood pressure, heart rate or bone mineral density.

"We believe the BALANCED study data, which exceeded our expectations, demonstrate the strong potential of efruxifermin to be a foundational monotherapy for the treatment of NASH," said Andrew Cheng, M.D., Ph.D., president and CEO of Akero. "We look forward to the continued development of efruxifermin and are working diligently to deliver this potentially leading treatment to patients. We are extremely grateful to all of our investigators and study patients, particularly given that this study cohort was completed amidst the COVID-19 pandemic."

The BALANCED study is an ongoing randomized, double-blind, placebo-controlled study in NASH patients. The company previously reported that each of the 28, 50 and 70 mg EFX dose groups met the primary endpoint compared to placebo, with absolute reductions of 12, 13 and 14 percent of liver fat, respectively, compared with 0.3 percent for placebo, and relative reductions of 63, 71 and 72 percent, compared to 0 percent for placebo. All of these results were highly statistically significant at $p<0.001$.

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, June 30. The webcast of the conference call will be made available on the company's website at www.akerotx.com under the Investors tab in the Events, Presentations & Webcasts section. To access the call via dial-in, please dial 1-866-652-5200 (U.S. toll free) or 1-412-317-6060 (international) five minutes prior to the start time. Following the live audio webcast, a replay will be available on the company's website for 90 days.

About NASH
NASH (non-alcoholic steatohepatitis) is a serious form of NAFLD (non-alcoholic fatty liver disease) and is estimated to affect 17 million Americans. NASH is closely linked to the obesity and diabetes epidemics seen around the world. NASH is characterized by an excessive accumulation of fat in the liver that causes stress and injury to liver cells, leading to inflammation and fibrosis, which can progress to cirrhosis, liver failure, cancer and eventually death. NASH is a leading cause of liver transplants in the US and Europe.

About the BALANCED Study
The Phase 2a BALANCED study is a multicenter, randomized, double-blind, placebo-controlled, dose-ranging trial in biopsy-confirmed adult patients with NASH. The main study enrolled a total of 80 patients. Participants were randomized to receive weekly subcutaneous doses of efruxifermin (EFX), formerly known as AKR-001, or placebo for up to 16 weeks, with safety and tolerability followed through week 20. The primary efficacy endpoint for the study is absolute change from baseline in hepatic fat fraction measured by magnetic resonance imaging – proton density fat fraction (MRI-PDFF) at week 12. Secondary measures include change from baseline in ALT at 12 weeks, the number of patients who had a decrease of ≥2 points in the NAFLD activity score (NAS) at 24 weeks and safety and tolerability measures.

About Efruxifermin
Efruxifermin (EFX), formerly known as AKR-001, is Akero’s lead product candidate for NASH, currently being evaluated in the ongoing Phase 2a BALANCED study. EFX is designed to reduce liver fat and inflammation, reverse fibrosis, increase insulin sensitivity and improve lipoproteins. This holistic approach offers the potential to address the complex, multi-system disease state of NASH, including improvements in lipoprotein risk factors linked to cardiovascular disease – the leading cause of death in NASH patients. Engineered to mimic the biological activity profile of native FGF21, EFX offers convenient once-weekly dosing and has been generally well-tolerated in clinical trials to date.

About Akero Therapeutics
Akero is a cardio-metabolic NASH company dedicated to reversing the escalating NASH epidemic by developing pioneering medicines designed to restore metabolic balance to improve overall health. The company's lead product candidate, Efruxifermin (EFX), formerly known as AKR-001, is currently being evaluated in an ongoing Phase 2a clinical trial. Akero Therapeutics is headquartered in South San Francisco, CA. For more information, please visit www.akerotx.com.

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. Such statements include, but are not limited to, statements regarding: Akero'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; Akero's Phase 2a BALANCED clinical trial, including its initial primary efficacy results; and the potential impact of COVID-19 on patient retention, strategy, future operations and clinical trials.

Any forward-looking statements in this statement 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, 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 Akero's actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in the company's 2019 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 Akero's other filings 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.

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Exhibit 99.2

akero

A Global Disease, A Pioneering Treatment

Akero Therapeutics, Inc.

BALANCED Study Readout

June 30, 2020

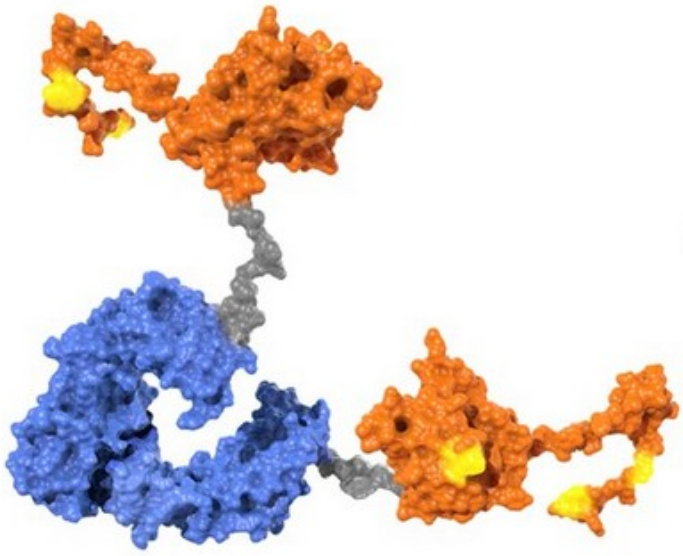
SAFE HARBOR

This presentation has been prepared by Akero Therapeutics, Inc. ("we," "us," "our," "Akero" or the "Company") and is made for informational purposes only and does not constitute an offer to sell or a solicitation of an offer to buy securities, nor shall there be any sale of any securities in any state or jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction. The information set forth herein does not purport to be complete or to contain all of the information you may desire. Statements contained herein are made as of the date of this presentation unless stated otherwise, and neither this presentation, nor any sale of securities, shall under any circumstances create an implication that the information contained herein is correct as of any time after such date or that information will be updated or revised to reflect information that subsequently becomes available or changes occurring after the date hereof.

This presentation may contain "forward-looking statements" 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; risks related to the competitive landscape; 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 applicable law, we do not plan to publicly update or revise any forward- looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. Although we believe the expectations reflected in such forward-looking statements are reasonable, we can give no assurance that such expectations will prove to be correct. Accordingly, readers are cautioned not to place undue reliance on these forward-looking statements. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements.

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.

INTRODUCING EFRUXIFERMIN



Efruxifermin
(EFX)

ē-FRUX-i-FER-min

(Formerly AKR-001)

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SUBSTANTIAL HISTOLOGIC IMPROVEMENTS AFTER ONLY 16 WEEKS

Histological Improvements

- Response rates for all EFX treated subjects who achieved at least a 30% liver fat reduction and had end-of-treatment biopsies (N=40):
  - **48%** NASH resolution without worsening of fibrosis
  - **48%** fibrosis improvement ≥1 stage without worsening of NAS
  - **28%** fibrosis improvement ≥2 stage
  - **28%** for combination of fibrosis improvement ≥1 stage and NASH resolution

Safety & Tolerability

- EFX was generally well tolerated (N=79) with no discontinuations due to treatment-emergent adverse events (TEAEs) in 50mg dose group
- Most frequent TEAEs were transient mild/moderate gastrointestinal events
- No treatment- or dose-related effects on blood pressure, heart rate, or bone mineral density

Improved Glycemic Control

- Significant improvements in HbA1c, HOMA-IR, C-Peptide, and Adiponectin

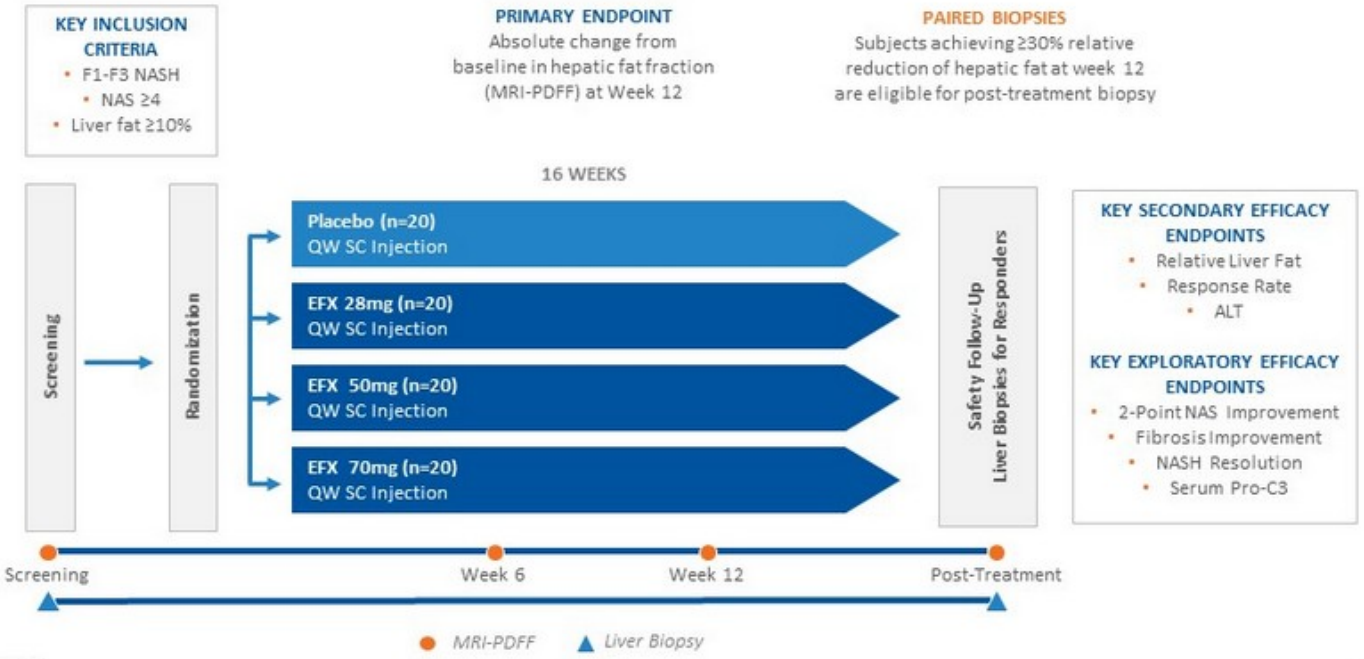
Weight Loss

- Reductions seen across all groups

Improved Dyslipidemia

- Significant improvements in triglycerides, HDL, and non-HDL cholesterol across all dose groups

BALANCED STUDY TRIAL DESIGN



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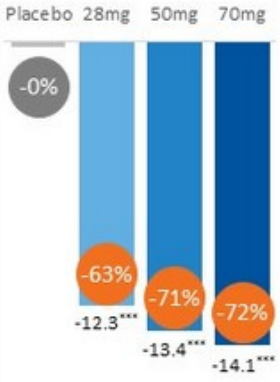
BASELINE DEMOGRAPHICS

Parameter Mean	Placebo (N=21)	EFX 28mg (N=19)	EFX 50mg (N=20)	EFX 70mg (N=20)
Age (Years)	52	50	53	53
Sex (Male/Female)	6/15	9/10	10/10	9/11
Weight (kg)	99.6	108.2	103.6	103.1
BMI (kg/m^2)	37.6	38.8	36.7	37.2
Liver Fat Content (% by MRI-PDFF)	19.3	21.4	18.3	19.4
NAFLD Activity Score (NAS)	5.1	5.6	5.1	5.6
Fibrosis Stage (% F2-F3)	62	63	65	65
Alanine Aminotransferase (ALT) (U/L)	50.7	62.5	53.4	56.8
Aspartate Aminotransferase (AST) (U/L)	38.6	41.1	35.4	44.6
% Type 2 Diabetes	67	37	50	50

Analysis Set	N	Definition
Full Analysis Set (FAS)	N=80	All subjects who were randomized into the study
Safety Set (SS)	N=79	All subjects who received at least one dose of study drug.
MRI-PDFF Evaluable Analysis Set (MAS)	N=68	All FAS subjects who have Baseline and Week 12 hepatic fat fraction assessed by MRI-PDFF
Liver Biopsy Evaluable Analysis Set (BAS)	N=42	All responders who have Baseline and end-of-treatment liver biopsy results

SUBSTANTIAL REDUCTIONS IN LIVER FAT AT WEEK 12 ACROSS ALL DOSE GROUPS

Mean Absolute Reduction in Liver Fat[1]

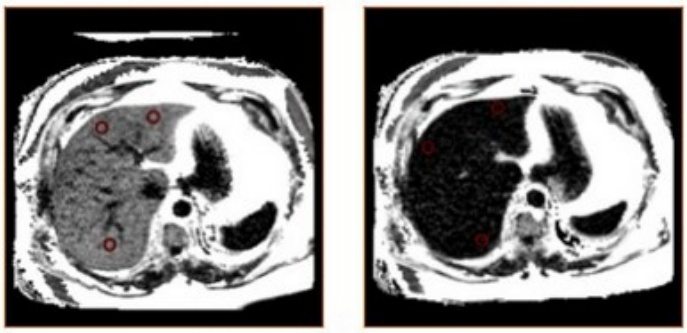


*** p<0.001, versus placebo

MRI-PDFF Images for Subject 207-012 (50mg EFX)

Baseline
22.2% Liver Fat

Week 12
2.0% Liver Fat



Analyzed with Liver*MultiScan*

Response Rate[2]

Proportion of subjects who had a Week 12 MRI-PDFF showing ≥30% relative reduction

Placebo	10%
28mg	100%
50mg	100%
70mg	100%

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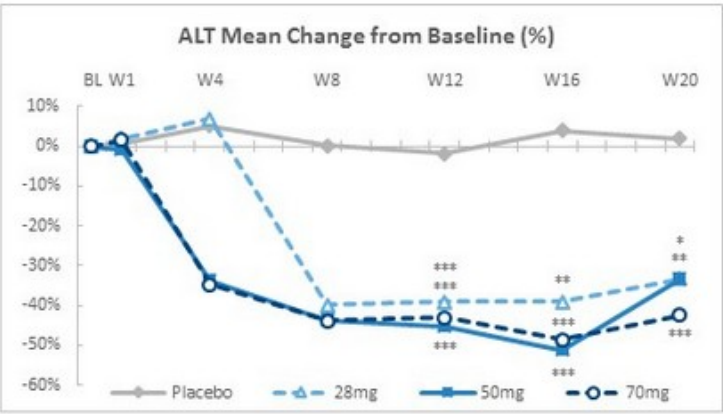
[1] Source Data: FAS; [2] Source Data: MAS

REDUCTION IN HEPATOCYTE STRESS AND COLLAGEN SYNTHESIS ACROSS ALL DOSE GROUPS



Similar dose-related improvements observed for AST, GGT, ALP

* p<0.05, ** p<0.01, *** p<0.001, versus placebo
(statistical significance tested only at Weeks 12, 16 and 20)

Serum Pro-C3

Mean Change from Baseline to Week 16

Placebo	+4%
28mg	-34%***
50mg	-27%**
70mg	-32%***

** p<0.01 *** p<0.001, versus placebo

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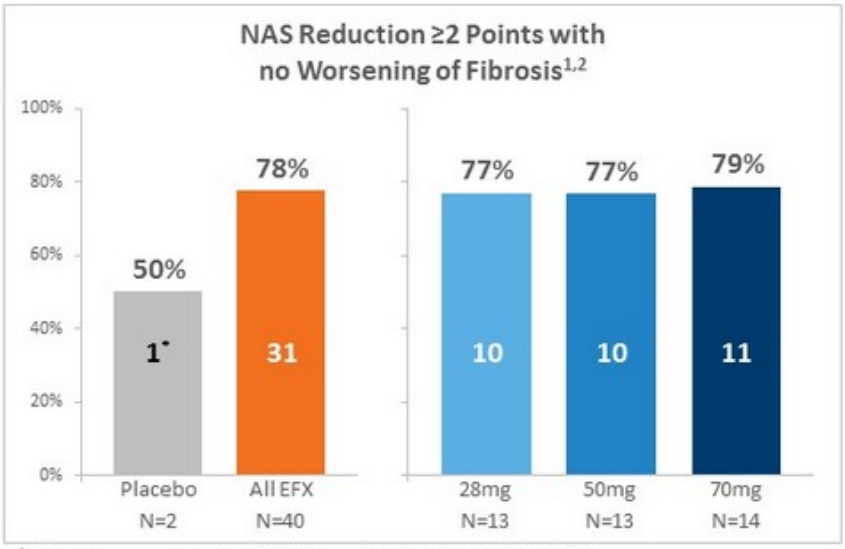
Source Data: FAS; ANCOVA LS Mean

CONSISTENT IMPROVEMENT IN STEATOHEPATITIS



[1] Endpoint recommended by FDA for Phase 2 clinical trials in NASH (F1-F3)
[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)

Mean NAS Reduction

Change in NAS from Baseline after 16 weeks of dosing

Placebo	-2.5
28mg	-2.9
50mg	-3.1
70mg	-3.6

The placebo arm was enriched for NAS endpoints because only 10% of placebo patients met the MRI-PDFF responder definition and had an end-of-treatment biopsy

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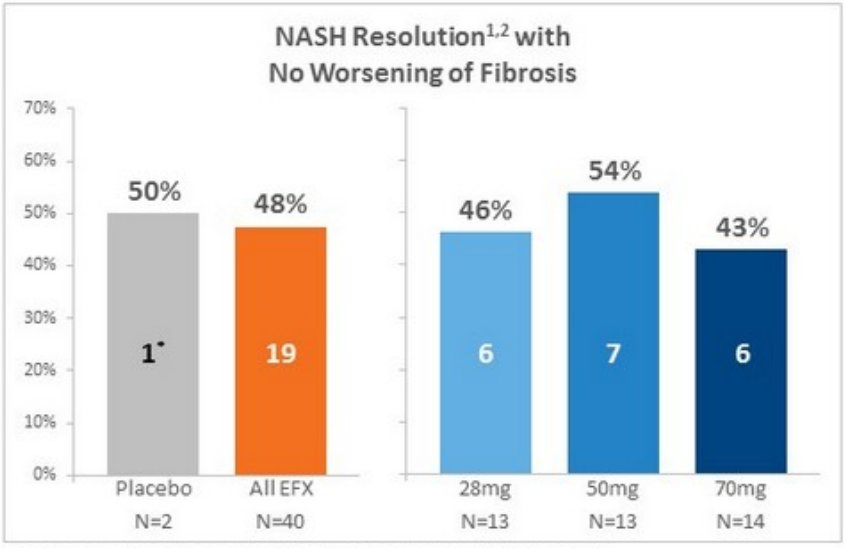
Source Data: BAS

HIGH RESPONSE RATES ON NASH RESOLUTION AFTER 16 WEEKS ACROSS ALL DOSES



Biopsy Reading

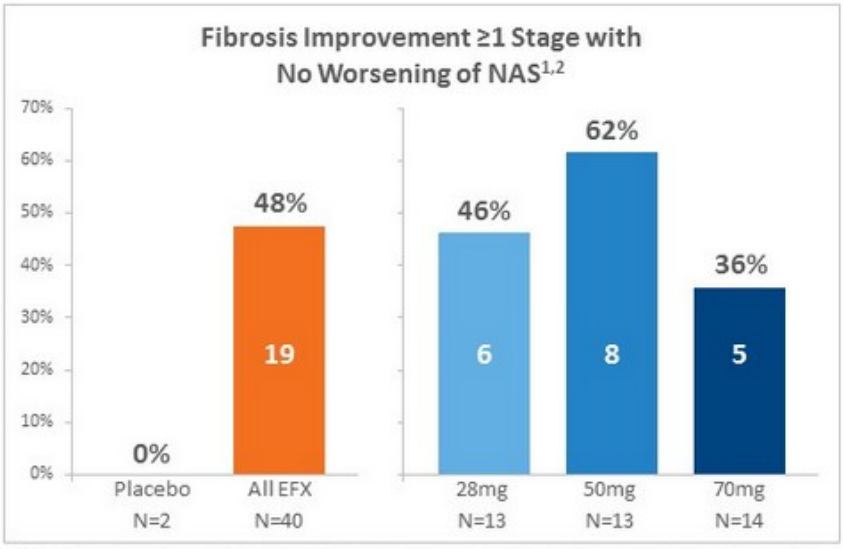
- All baseline and end-of-treatment biopsies were centrally read by a single NASH-CRN pathologist
- Baseline biopsies were not re-read with end-of-treatment biopsies
- All biopsies were read blinded to both treatment assignment and patient

[1] 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)

akero

Source Data: BAS

HIGH RATES OF FIBROSIS IMPROVEMENT AFTER 16 WEEKS ACROSS ALL TREATED PATIENTS



≥2-Stage Improvement in Fibrosis

11 of 40 EFX patients (28%) had a ≥2-stage improvement

[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

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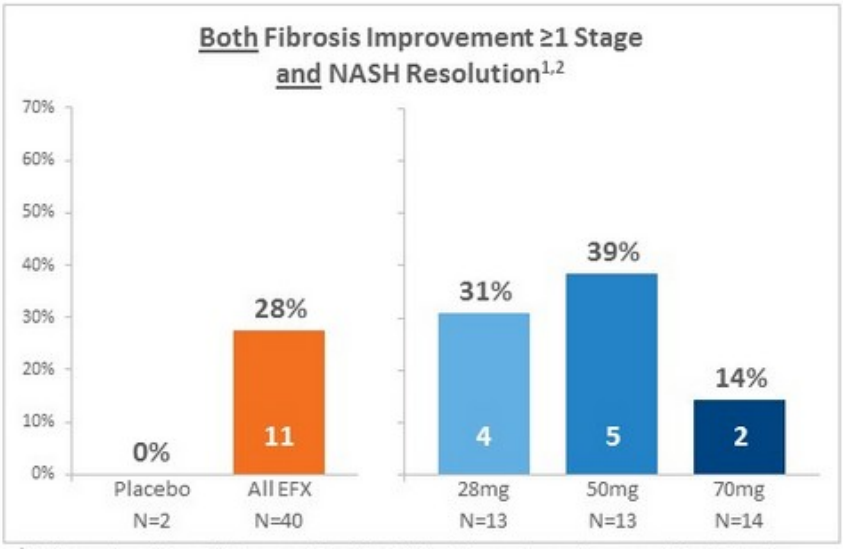
Source Data: BAS

ENCOURAGING RESPONSE RATES FOR BOTH FIBROSIS IMPROVEMENT AND NASH RESOLUTION AFTER 16 WEEKS



[1] Subjects who achieve a NAS score of 0 or 1 for lobular inflammation and a score of 0 for ballooning AND improvement in liver fibrosis greater than or equal to one stage

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

Source Data: BAS

SAFETY OVERVIEW

Treatment-Emergent Adverse Event (TEAE) Classification	Placebo (N=21)	EFX 28mg (N=19)	EFX 50mg (N=19)	EFX 70mg (N=20)
TEAE Leading to Death	0	0	0	0
TEAE Leading to Discontinuation	1[a]	2[b]	0	4[c]
Serious Adverse Event (SAE)	0	1[d]	0	1

[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

DRUG-RELATED TREATMENT-EMERGENT ADVERSE EVENTS (TEAEs)

Most Common (>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%)	19 (33%)	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%)

*Across EFX dose groups

Gastrointestinal Adverse Events:

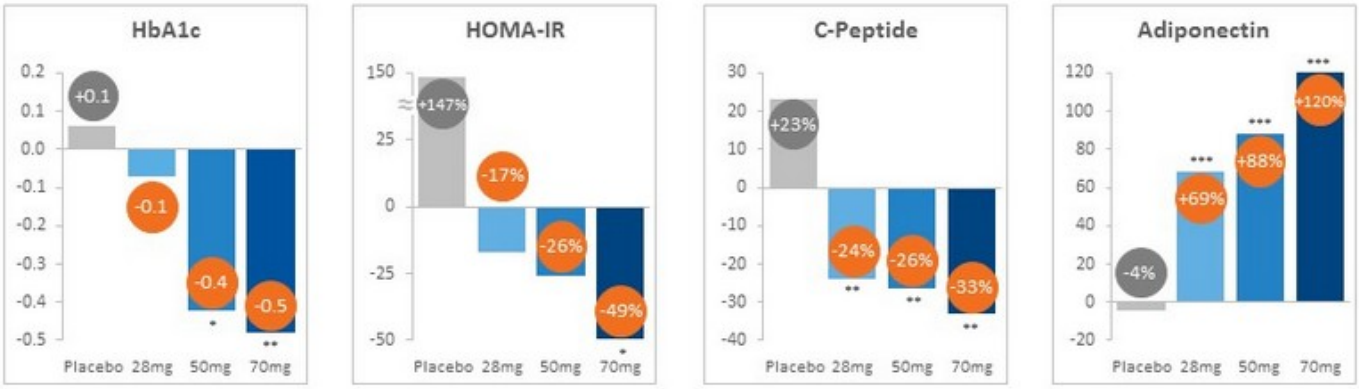
- Majority transient, Grade 1, with on-drug resolution
- Often single episodes
- Overall frequency decreased over treatment period
- No study discontinuations due to diarrhea

No Treatment-Related Effects On:

- Heart Rate
- Systolic Blood Pressure
- Diastolic Blood Pressure
- Bone mineral density

CLINICALLY MEANINGFUL IMPROVEMENTS IN GLYCEMIC CONTROL AFTER 16 WEEKS

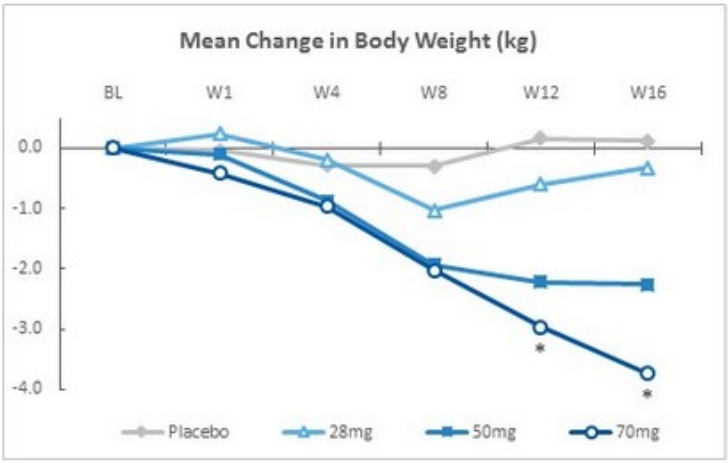
Mean Change From Baseline to Week 16 (%)[1]



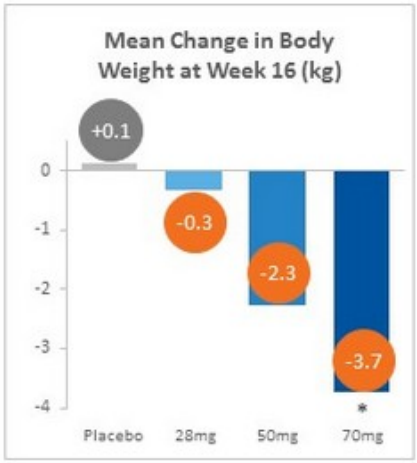
[1] HbA1c is presented in absolute percent change from baseline, whereas HOMA-IR, C-Peptide, and Adiponectin are presented in relative percent change from baseline

Source Data: FAS; ANCOVA LS Mean

WEIGHT LOSSES OBSERVED FOR ALL DOSE GROUPS: FIRST REPORT OF SIGNIFICANT WEIGHT LOSS FOR FGF21 CLASS



* p<0.05, versus placebo
(statistical significance tested only at Weeks 12 and 16)

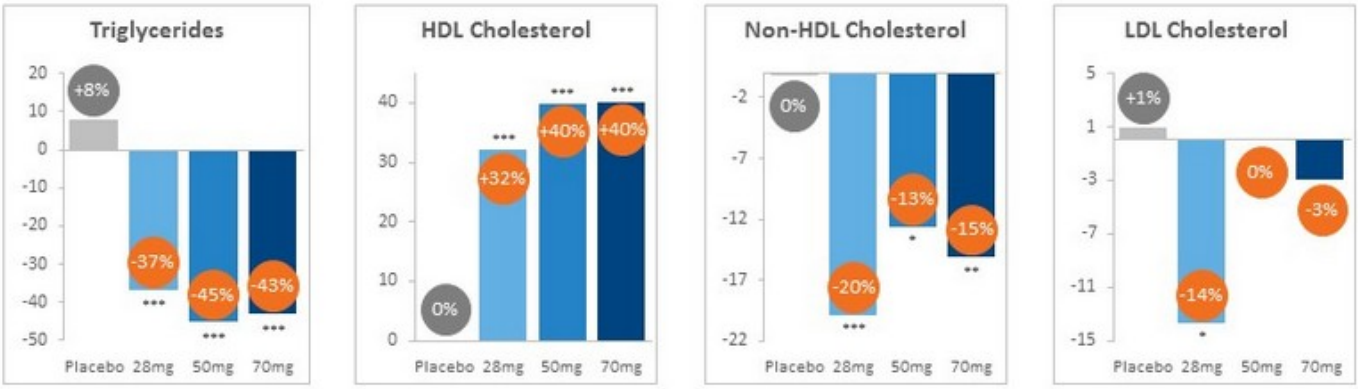


* p<0.05, versus placebo

Source Data: FAS; ANCOVA LS Mean

IMPROVED LIPOPROTEIN PROFILE FOR CARDIOVASCULAR HEALTH

Mean Change From Baseline to Week 16 (%)



*** p<0.001, versus placebo

*** p<0.001, versus placebo

* p<0.05, ** p<0.01, *** p<0.001, versus placebo

* p<0.05, versus placebo

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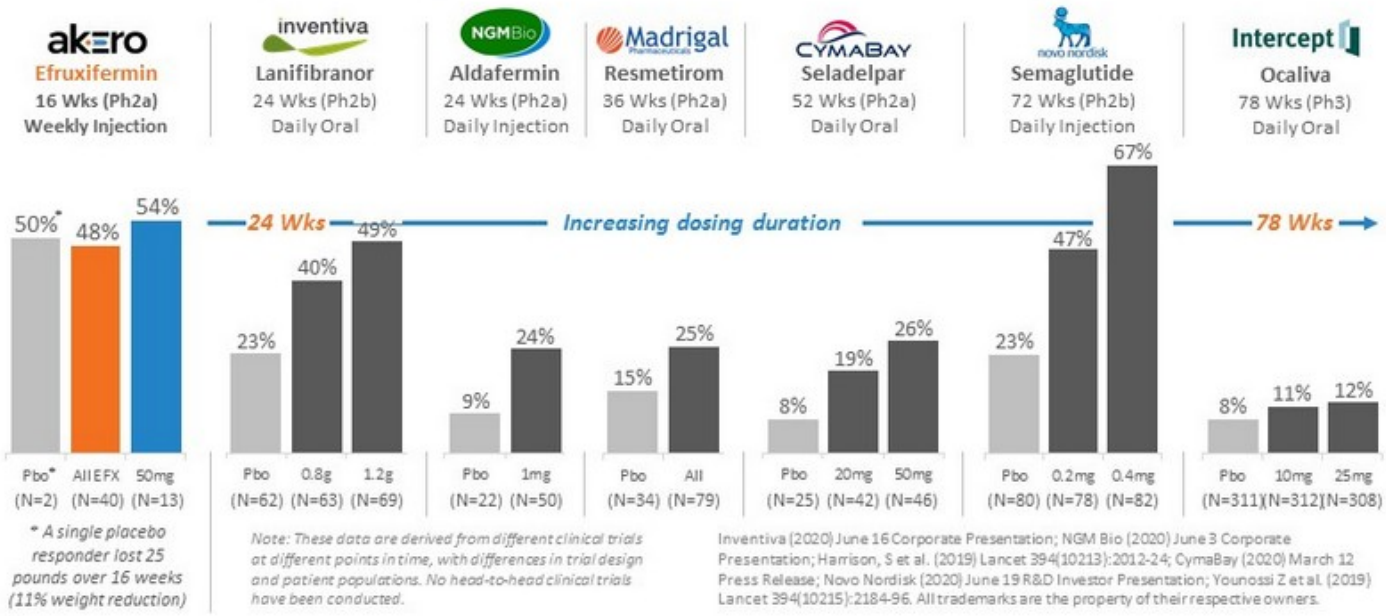
Source Data: FAS; ANCOVA LS Mean

DEVELOPMENT LANDSCAPE: NASH RESOLUTION

Proportion of Subjects with Resolution of NASH without 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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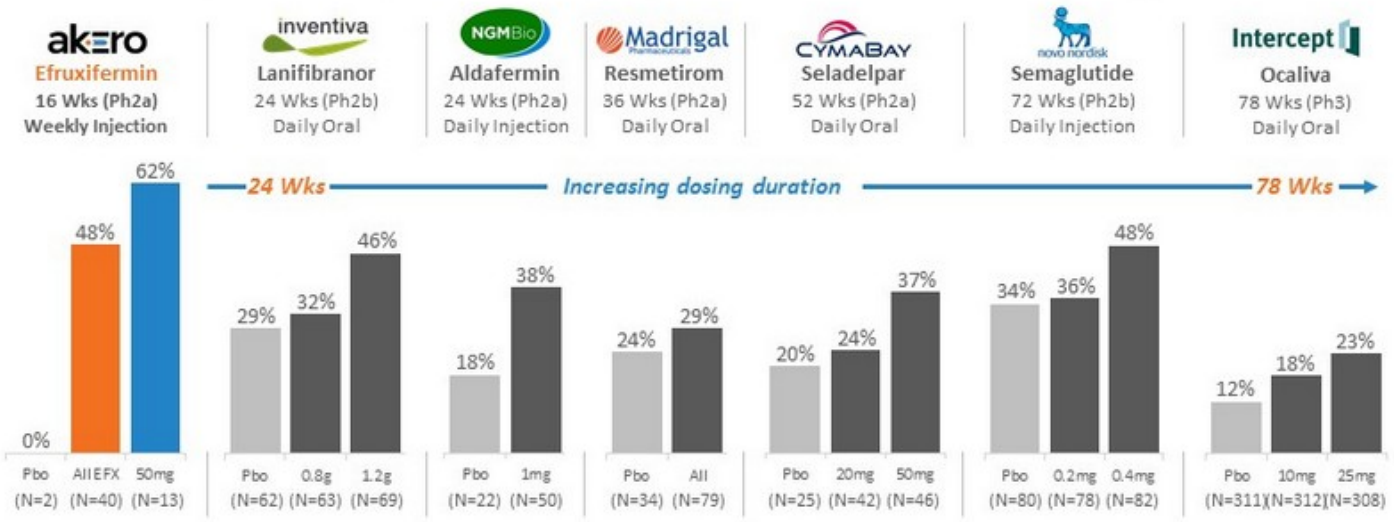
[1] FDA Guidance for Industry: Noncirrhotic Nonalcoholic Steatohepatitis With Liver Fibrosis: Developing Drugs for Treatment (2018)

DEVELOPMENT LANDSCAPE: FIBROSIS IMPROVEMENT

Proportion of Subjects with ≥1 Stage Improvement in Fibrosis without 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.

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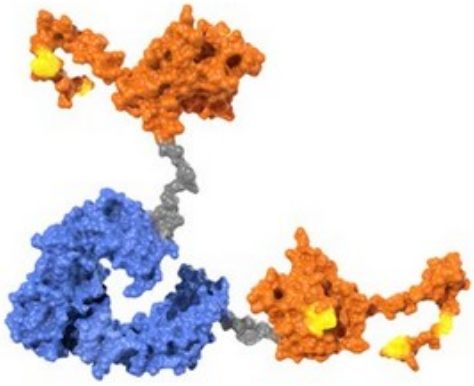
[1] FDA Guidance for Industry: Noncirrhotic Nonalcoholic Steatohepatitis With Liver Fibrosis: Developing Drugs for Treatment (2018)

EFRUXIFERMIN: UNIQUE POTENTIAL AS A FOUNDATIONAL NASH MONOTHERAPY

- ✓ Unprecedented fibrosis improvement
- ✓ Unprecedented reductions in liver fat
  - Confirmed by NASH resolution
- ✓ Ameliorated dyslipidemia
  - No LDL cholesterol increase
- ✓ Improved glycemic control
- ✓ Weight loss at all doses
- ✓ Large, sustained reductions in ALT
- ✓ Few discontinuations due to AEs



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A Global Disease, A Pioneering Treatment

NASDAQ: AKRO