

Restoring Balance. Renewing Life.

## **JP Morgan Presentation**

Andrew Cheng, MD, PhD President & CEO

January 11, 2022

#### » Safe Harbor

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#### » Key Take-Aways



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

- Substantial potential market
  opportunity
- Differentiated mechanism of action
- Strongest reported efficacy data among FGF21s

Building Momentum Toward Phase 3 Pivotal Trials

2



Experienced Team with Strong Cash Position

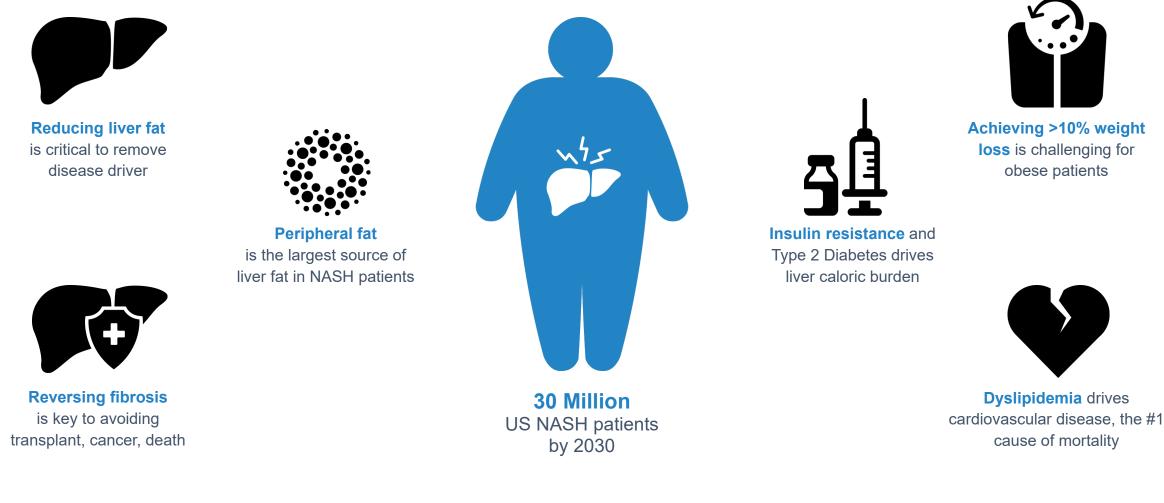
- Two parallel Phase 2b trials underway
  - HARMONY (F2-F3)
  - SYMMETRY (F4, compensated)
- Regulatory designations
  - Fast Track (US FDA)
  - PRIME (European EMA)
- Commercial drug product-device for Phase 3

Preliminary HARMONY results expected 3Q'22

- Involved in 20+ FDA approvals
- ~\$215M cash on hand as of 3Q'21
- Cash runway through 3Q'23

#### » Providing a Potentially Effective Treatment for NASH



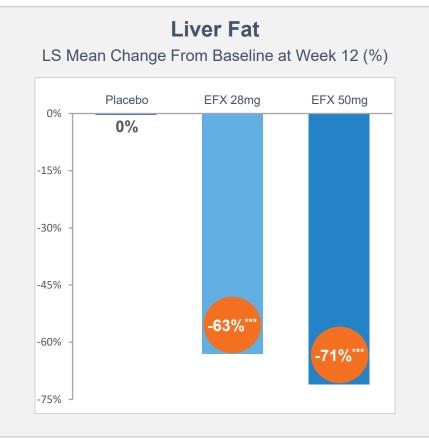


#### » Demonstrating EFX's Potential in Phase 2a BALANCED Study

	BALANCED <sup>1</sup> (N=80)	Cohort C <sup>2</sup> (Expansion of BALANCED) (N=30)
Patient Population	F1-F3 Biopsy-confirmed	F4 Biopsy-confirmed
Duration	16 Weeks	16 Weeks
EFX Arms	28, 50, 70mg	50mg
Placebo-Controlled	$\checkmark$	$\checkmark$

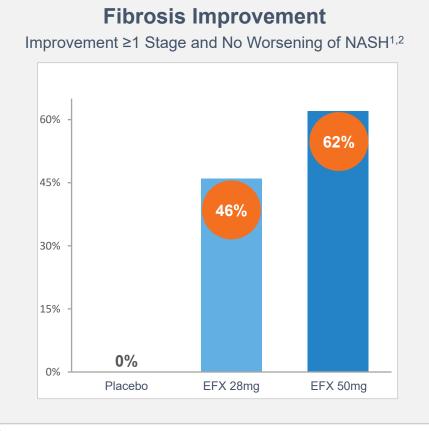
<sup>1</sup> Harrison, SA et al. (2021) Nat Med 27:1262–1271 <sup>2</sup> Harrison, SA et al. J. of Hepatology 2021; 75; S204

#### » Substantial Reductions in Liver Fat at Week 12 (F1-F3 NASH)



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

#### » High Rates of Fibrosis Improvement After 16 Weeks (F1-F3)

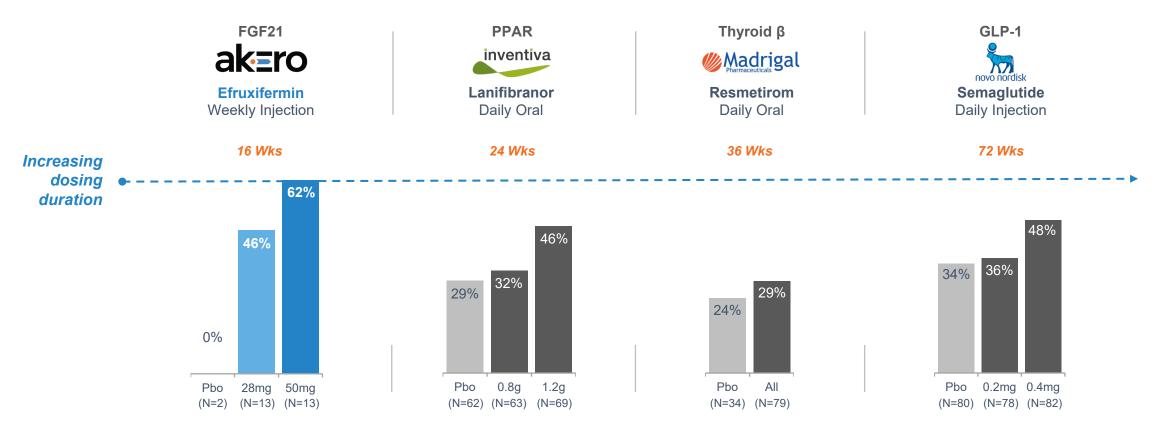


<sup>1</sup> Improvement in liver fibrosis greater than or equal to one stage and no worsening of NASH (defined as no increase in NAS for ballooning, inflammation, or steatosis) <sup>2</sup> Secondary and exploratory histological endpoints were not powered for statistical significance

#### » EFX F1-F3 Fibrosis Improvement in Context



Proportion of Subjects with ≥1 Stage Improvement in Fibrosis and No Worsening of NASH<sup>1</sup>



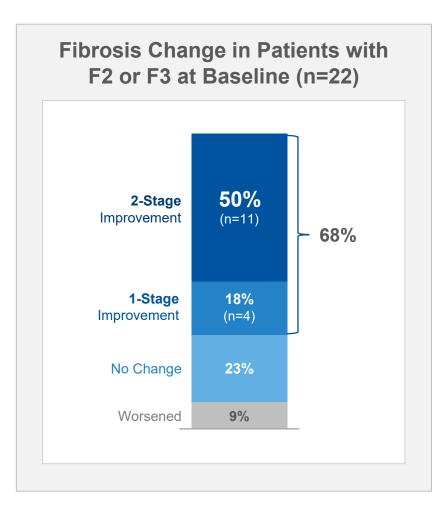
Note: These data are derived from different Phase 2 clinical trials at different points in time, with differences in trial design and patient populations. No head-to-head clinical trials have been conducted.

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

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

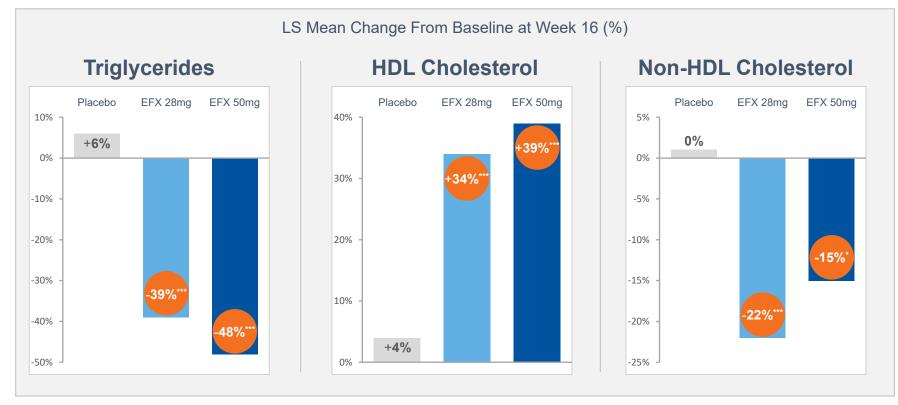
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#### » Half of F2-F3 Patients Achieved 2-Stage Fibrosis Improvement



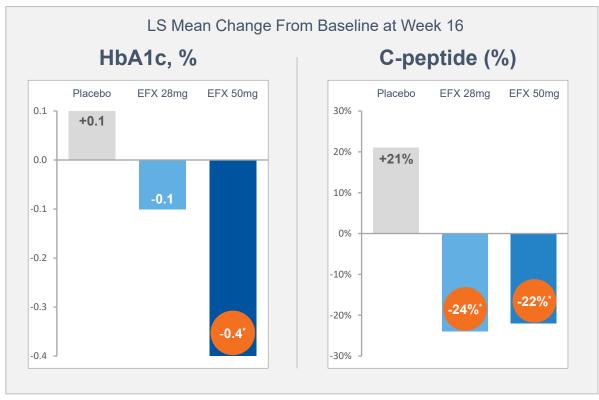
### » Improved Lipoprotein Profile (F1-F3)





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

### » Clinically Meaningful Improvements in Glycemic Control (F1-F3)

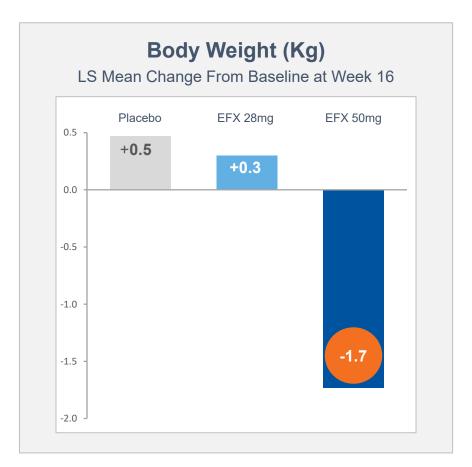


Absolute change from baseline, %

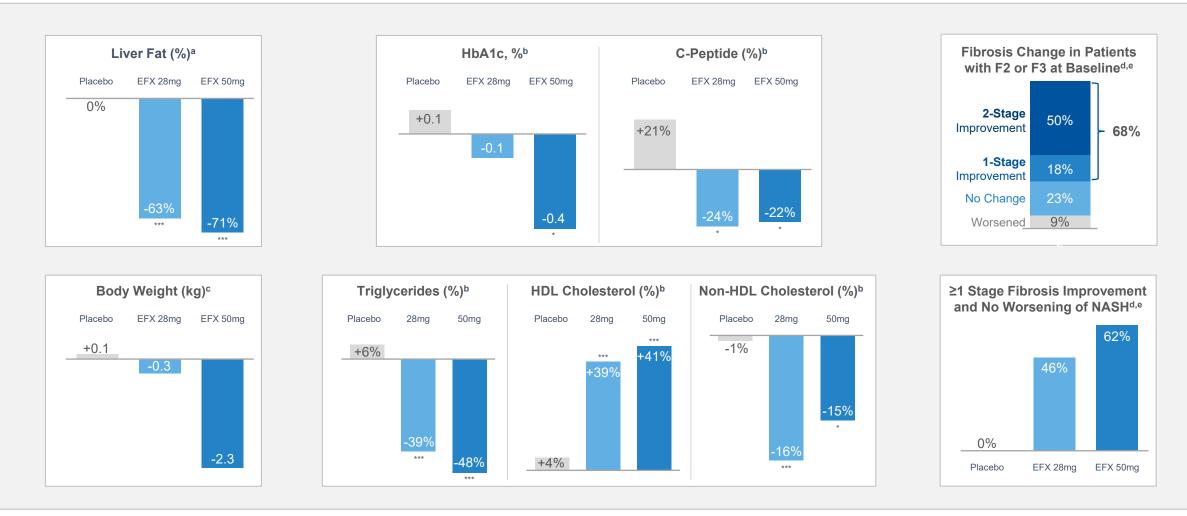
Relative percent change from baseline

\* p<0.05, versus placebo (ANCOVA)

#### » Weight Loss Observed After 16 Weeks (F1-F3)



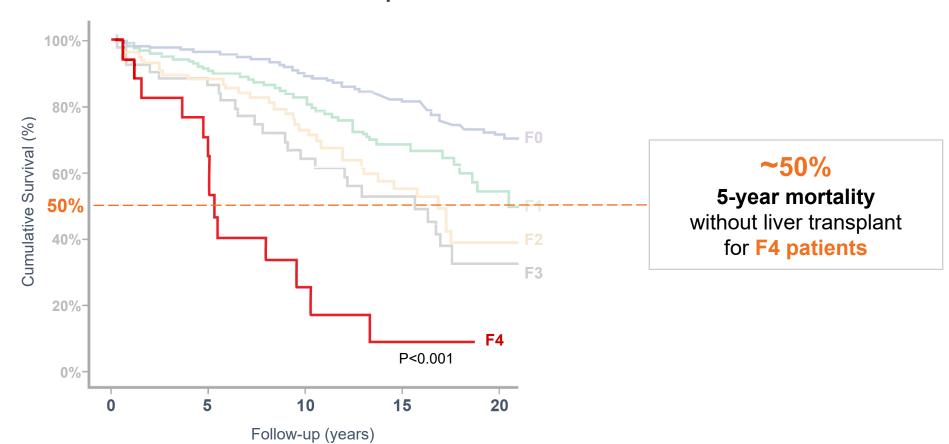
#### » Consistent Results Observed for Relevant Endpoints (F1-F3)



<sup>a</sup> LS Mean Change from Baseline to Week 12; <sup>b</sup> LS Mean Change from Baseline to Week 16; <sup>c</sup> Mean Change from Baseline to Week 16; <sup>d</sup> Proportion of subjects; <sup>e</sup> not powered for statistical significance \* *p*<0.05, \*\*\* *p*<0.001, versus placebo (ANCOVA)

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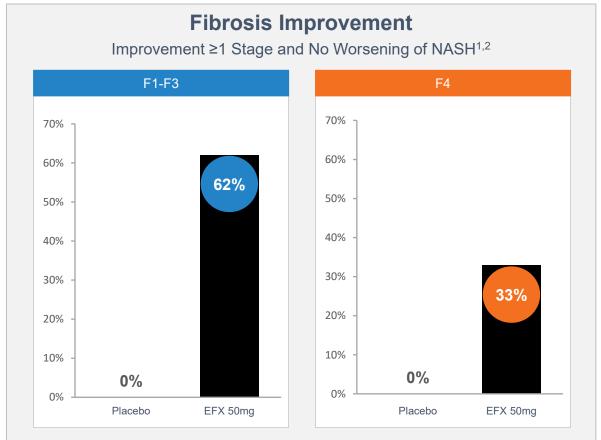
#### » Value of Preventing Progression to & Reversing From Cirrhosis



Survival Free of Liver Transplantation

#### Fibrosis Improvement Observed in both Pre-cirrhotic (F1-F3) and Compensated Cirrhotic (F4) Patients

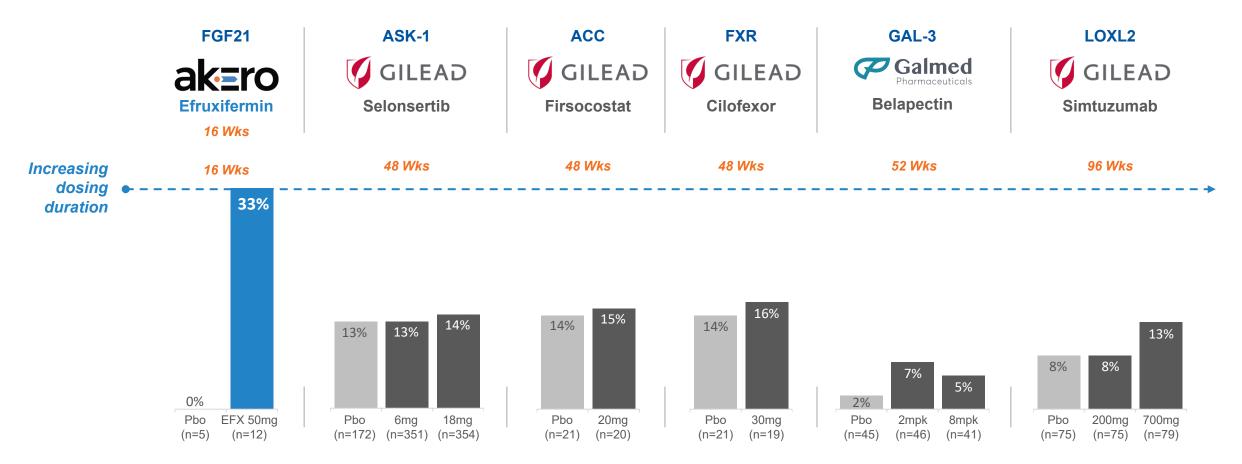




<sup>1</sup> Improvement in liver fibrosis greater than or equal to one stage and no worsening of NASH (defined as no increase in NAS for ballooning, inflammation, or steatosis) <sup>2</sup> Secondary and exploratory histological endpoints were not powered for statistical significance

#### » EFX F4 Fibrosis Improvement in Context

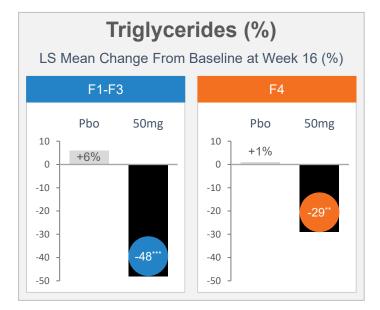


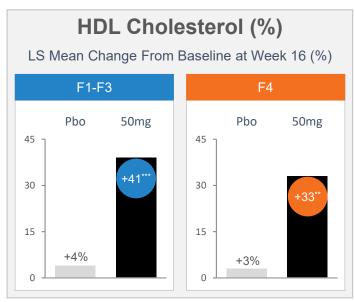


\* Results from all publicly reported NASH Phase 2 clinical trials in F4 patients reporting either  $\geq$  1-stage fibrosis improvement (belapectin and simtuzumab) or  $\geq$  1-stage fibrosis improvement and no worsening of NASH (selonsertib, firsocostat and cilofexor); numerical values represent percent responders

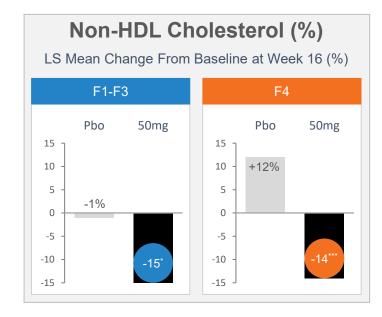
Note: These data are derived from different clinical trials at different points in time, with differences in trial design and patient populations. No head-tohead clinical trials have been conducted. Improvement in Lipid Profile Observed in both Pre-cirrhotic (F1-F3) and Compensated Cirrhotic (F4) Patients





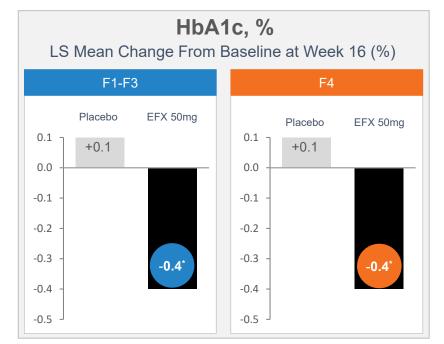


\* p<0.05, \*\* p<0.01, \*\*\* p<0.001, versus placebo (ANCOVA)

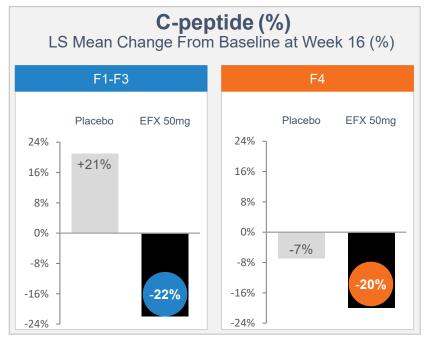


# Improved Glycemic Control Observed in both Pre-cirrhotic (F1-F3) and Compensated Cirrhotic (F4) Patients





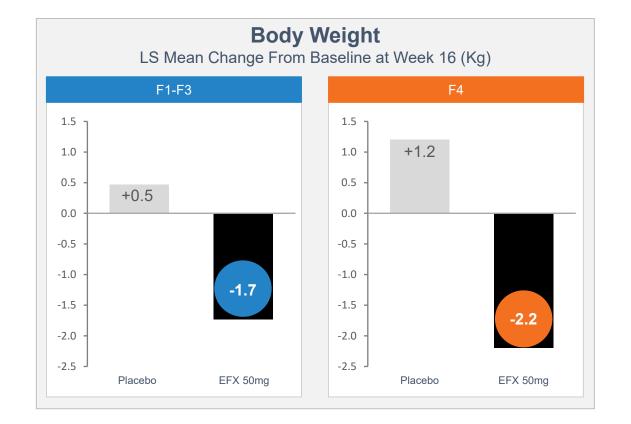
Absolute change from baseline, % \* p<0.05, versus placebo (ANCOVA)



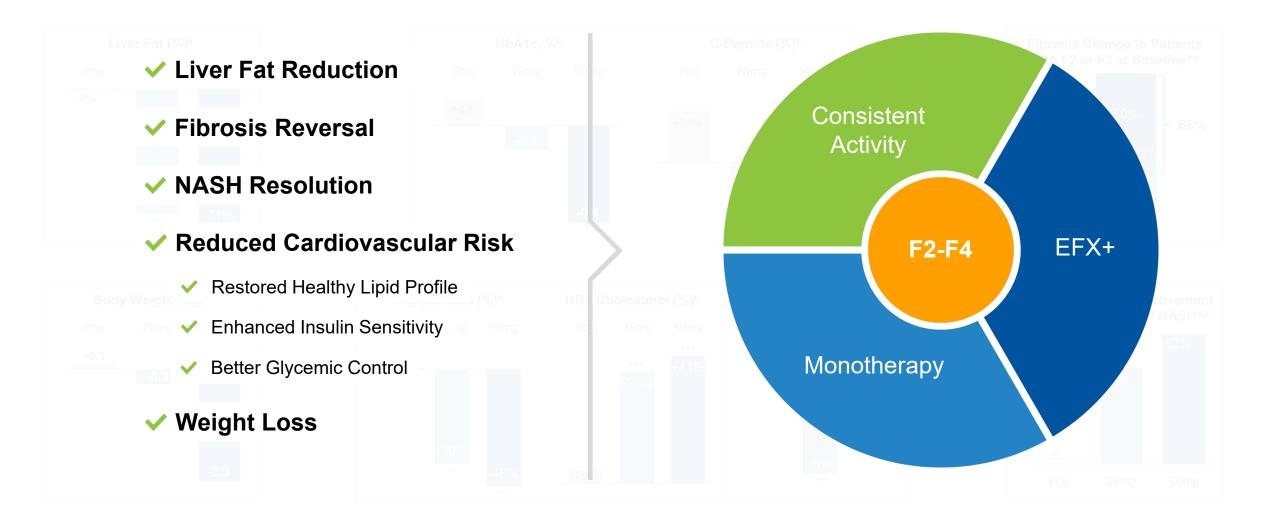
Relative percent change from baseline

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

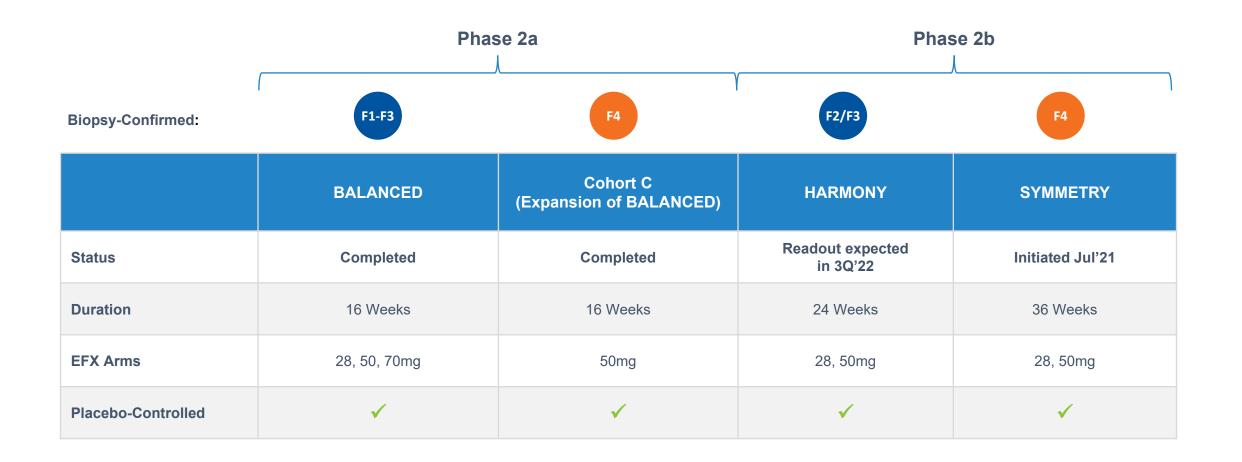




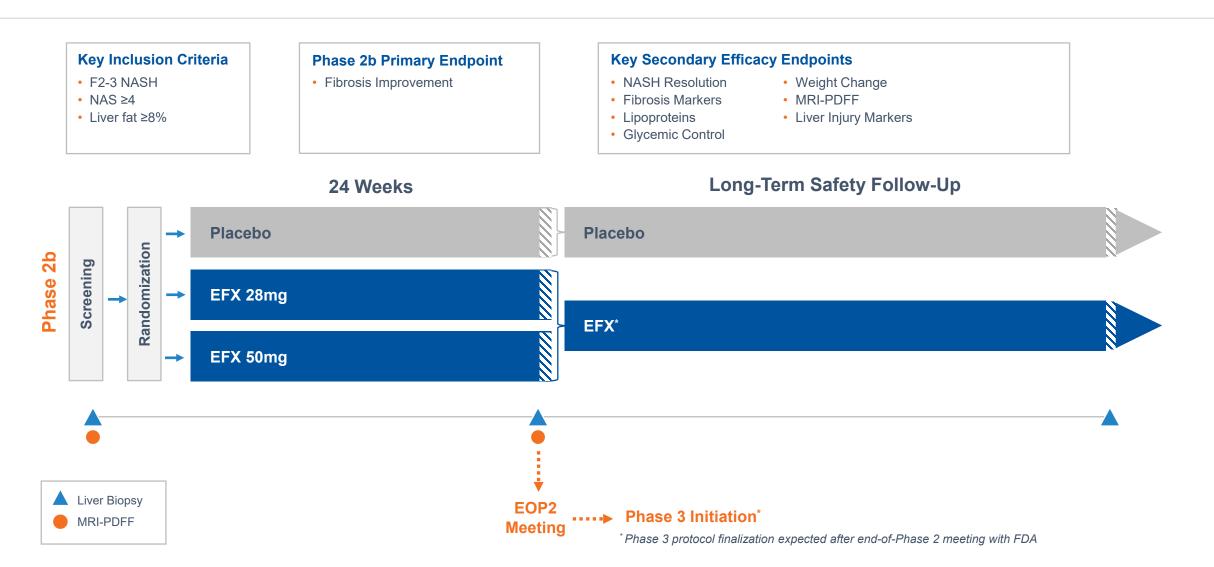
### » EFX Positioning as Potential Best-in-Class NASH Therapy



#### » Building Foundation for Phase 3: Parallel Phase 2b Trials

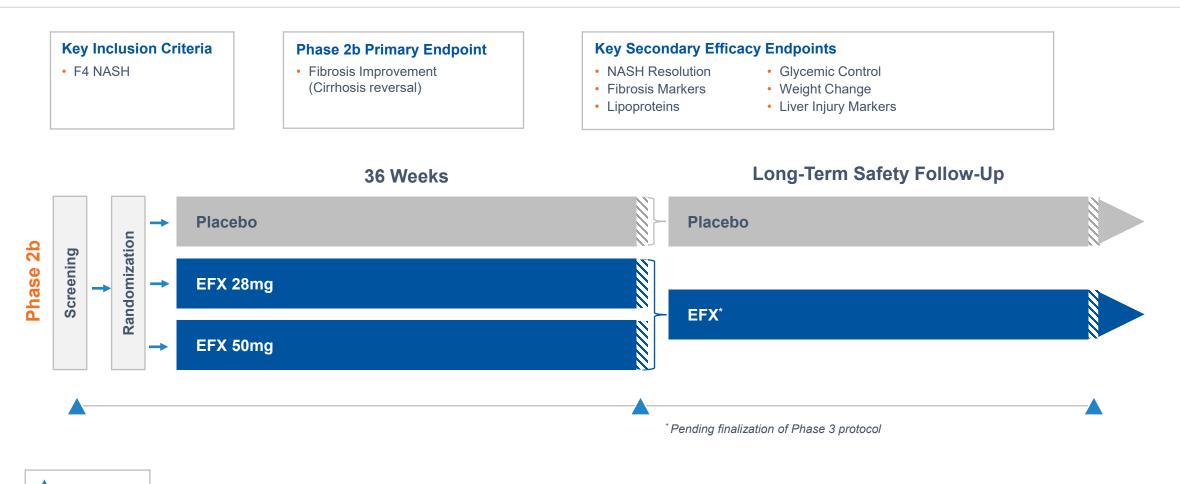


### » HARMONY Trial Design: Non-Cirrhotic NASH (F2/F3)



#### » SYMMETRY Trial Design: Cirrhotic NASH (F4)





Liver Biopsy

» Supplying API and Drug Product/Device for Phase 3



#### **Drug Substance (API)**



- Commercial scale
- Released for Phase 3
- Comparability demonstrated

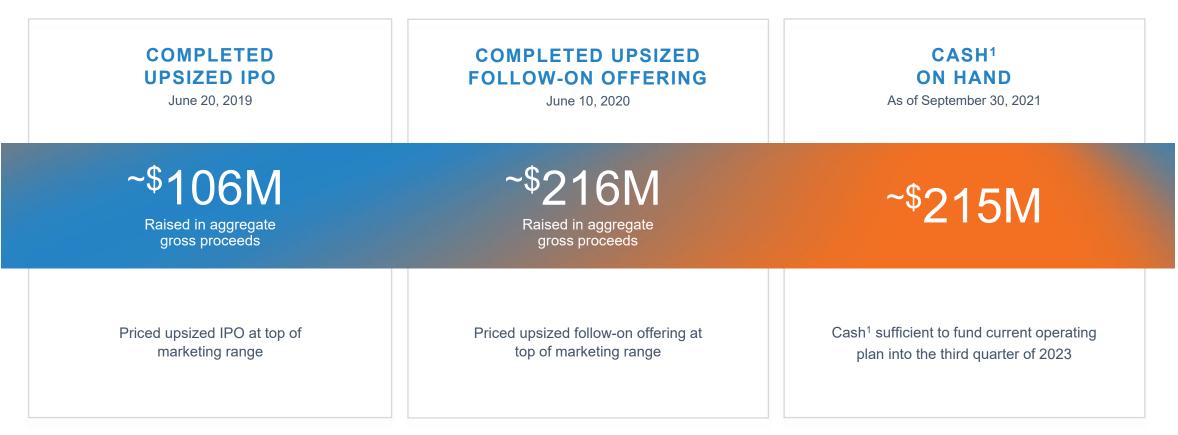
#### **Drug Product/Device Combination**



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

## » Strong Financial Position





<sup>1</sup> Cash, cash equivalents and short-term marketable securities



NASDAQ: AKRO

#### AKERO THERAPEUTICS

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