



akero

**A Global Disease,
A Pioneering Treatment**
Akero Therapeutics, Inc.

June 2020



SAFE HARBOR

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AKR-001'S POTENTIAL AS CORNERSTONE NASH THERAPY

Strong Emerging Clinical Profile with Potential to be Leading FGF Compound

- Fc-FGF21 fusion protein licensed from Amgen
- All AKR-001 dose groups met all Week 12 endpoints in ongoing 16-week Phase 2a BALANCED study in adult, biopsy-confirmed NASH patients
 - >70% relative reduction in liver fat in 50mg and 70mg groups at Week 12
- Robust improvements in lipoproteins and insulin sensitivity markers observed in Amgen-sponsored Phase 1b clinical trial in adult patients with Type 2 diabetes

Key Upcoming Milestones

Late June 2020

Ph2a data readout
including paired biopsies

1H 2021

Cohort C (F4) readout
Phase 2b/3 initiation

EXTENSIVE DEVELOPMENT, 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

NASH: A SERIOUS AND DEBILITATING MULTI-SYSTEM DISEASE

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

A GROWING HEALTH EPIDEMIC



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**



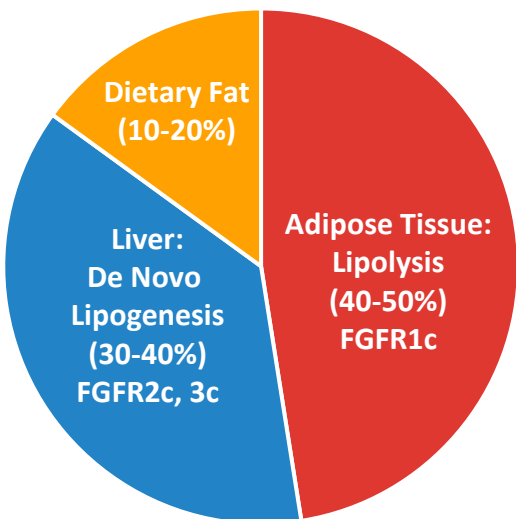
NASH is a **leading cause of liver transplantation** in the US and Europe



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

FGF21 ACTS ON TWO MAJOR SOURCES OF LIVER FAT WITH POTENTIAL FOR OPTIMAL REDUCTION

Sources of Fat Flowing into and Through Liver for NASH Patients

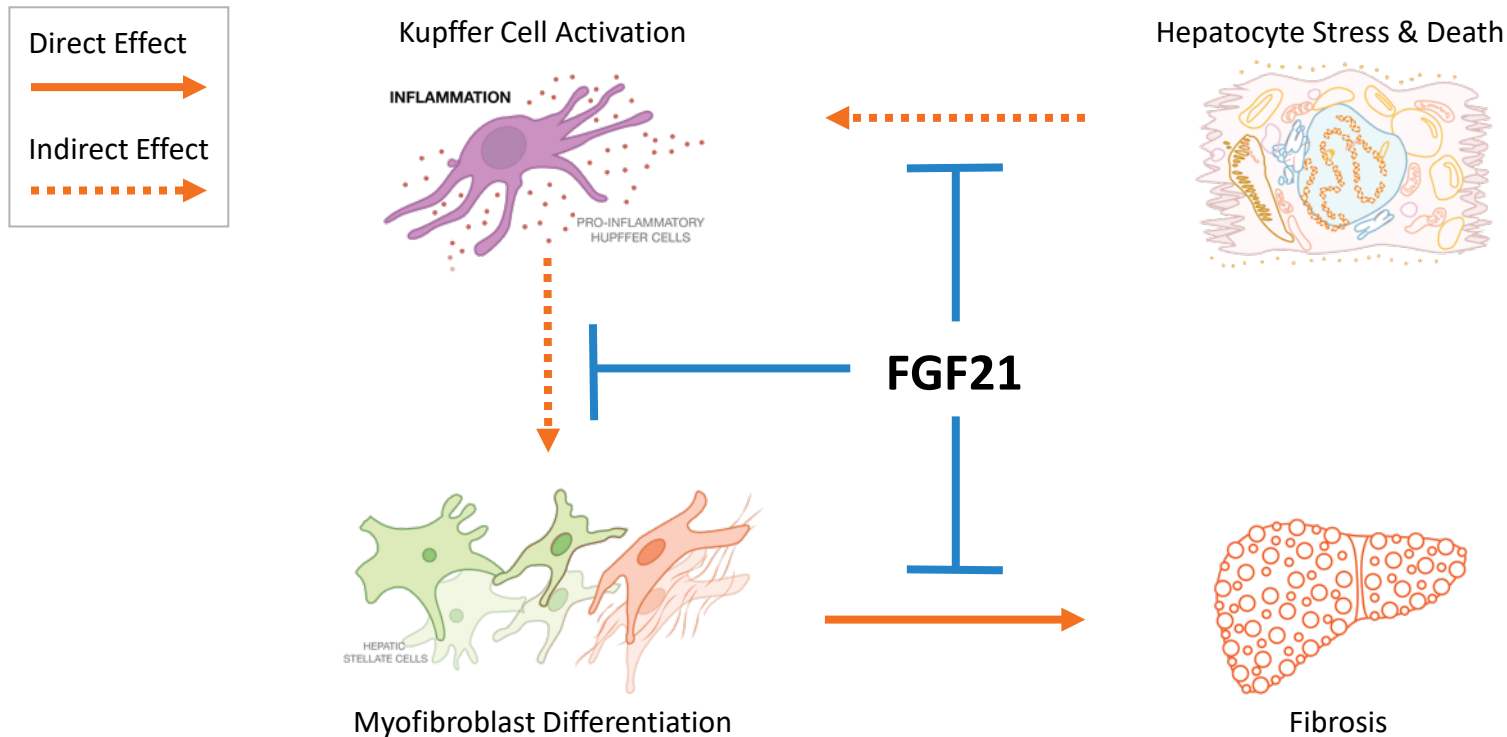


Lambert, JE et al. (2014) *Gastroenterology* 146(3): 726-35

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

Source of Liver Fat	FGF Receptor	FGF21 Activity
Lipolysis	FGFR1c	✓
De Novo Lipogenesis	FGFR2c FGFR3c	✓

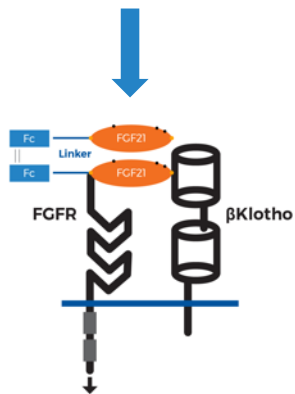
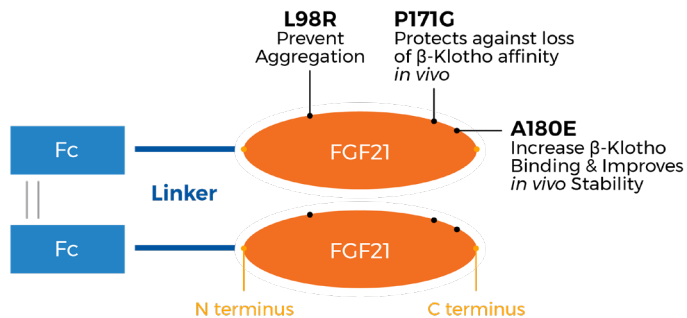
AKR-001 EXPECTED TO EXERT DIRECT AND INDIRECT ANTI-FIBROTIC EFFECTS



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

AKR-001 ENGINEERING POTENTIALLY OPTIMAL FOR NASH EFFICACY, WITH CONVENIENT ONCE-WEEKLY DOSING



Key attributes



Akero proprietary Fc-FGF21, Point mutations



Increases half-life from < 2 hours to 3-4 days



High affinity for β -Klotho



Better translation to human pharmacology



Balanced potency at FGFR1c, 2c, 3c

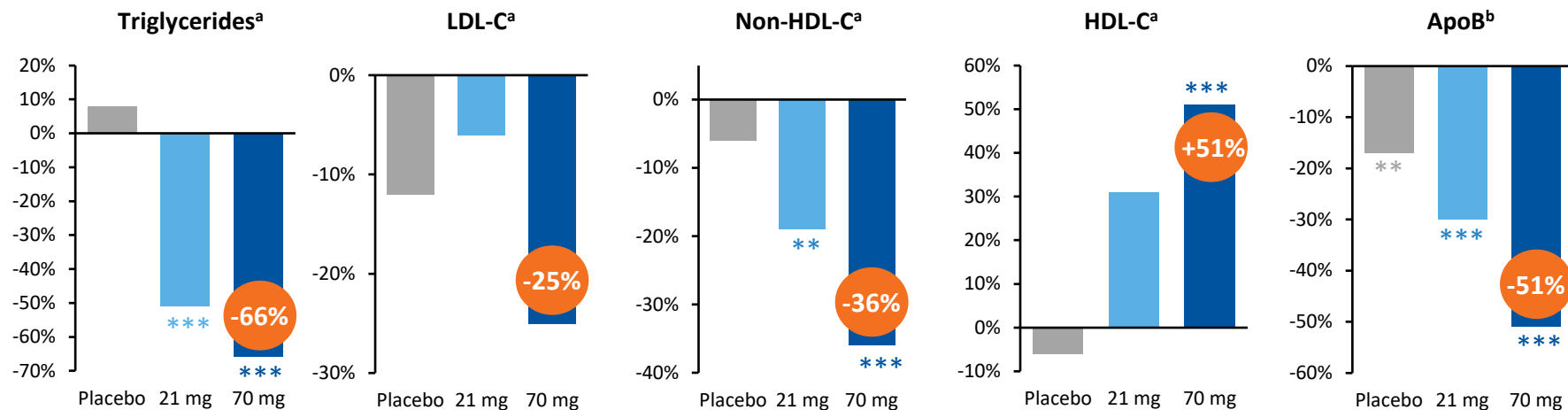


Inactive at FGFR4

Stanislaus, S *et al.* (2017) *Endocrinology* 158(5): 1314-27; Lee, S *et al.* (2018) *Nature* 553: 501-505; Kharitonov, A *et al.* (2007) *Endocrinology* 148(2)774-781

AKR-001 IMPROVED LIPOPROTEIN PROFILE In Phase 1b Trial in Type 2 Diabetic Patients

AKR-001's significant improvements in lipoproteins and reduction in adipose lipolysis are consistent with effective agonism of FGFR2c and 3c in the liver and FGFR1c in adipose tissue

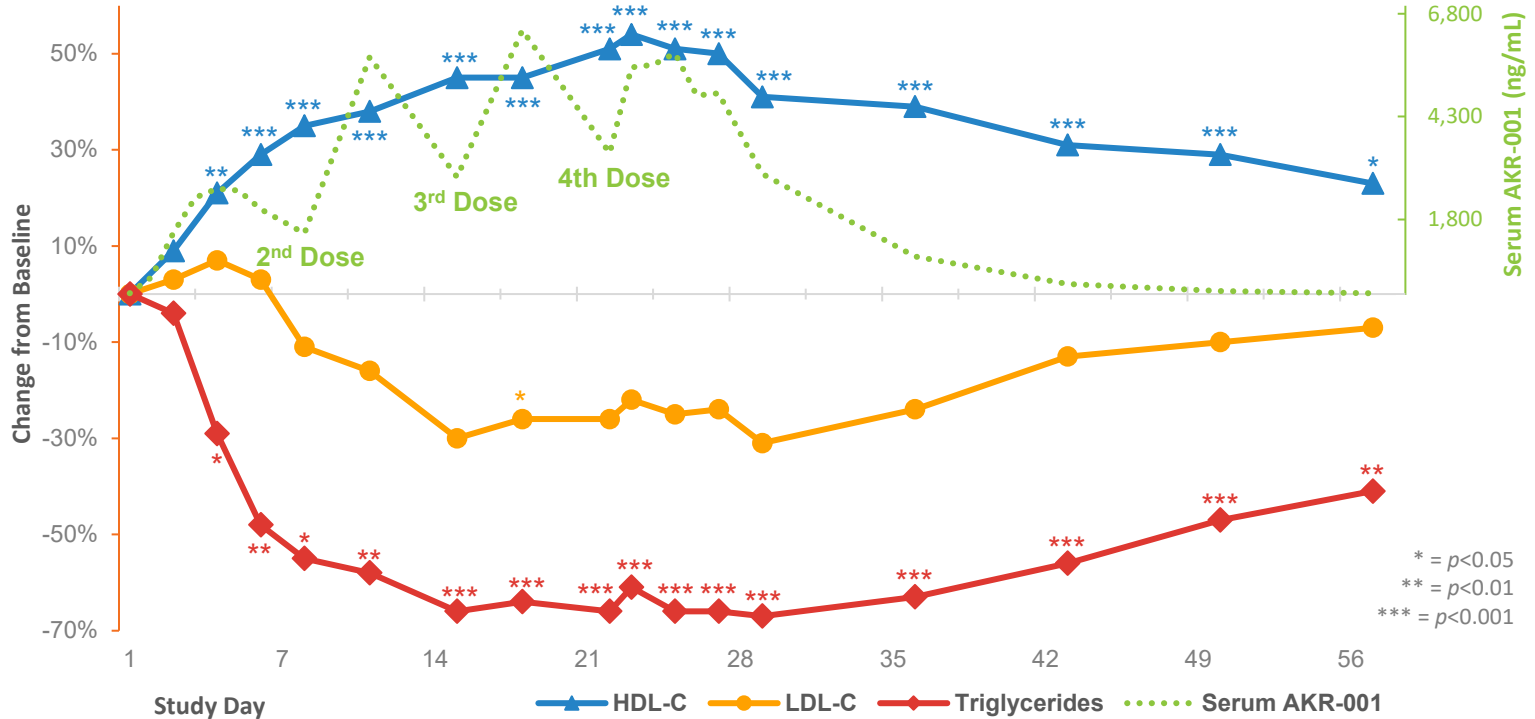


Percent Change From Baseline, Placebo, 21 mg QW and 70 mg QW; ^a Day 25; ^b Day 29; ** = $p < 0.01$; *** = $p < 0.001$



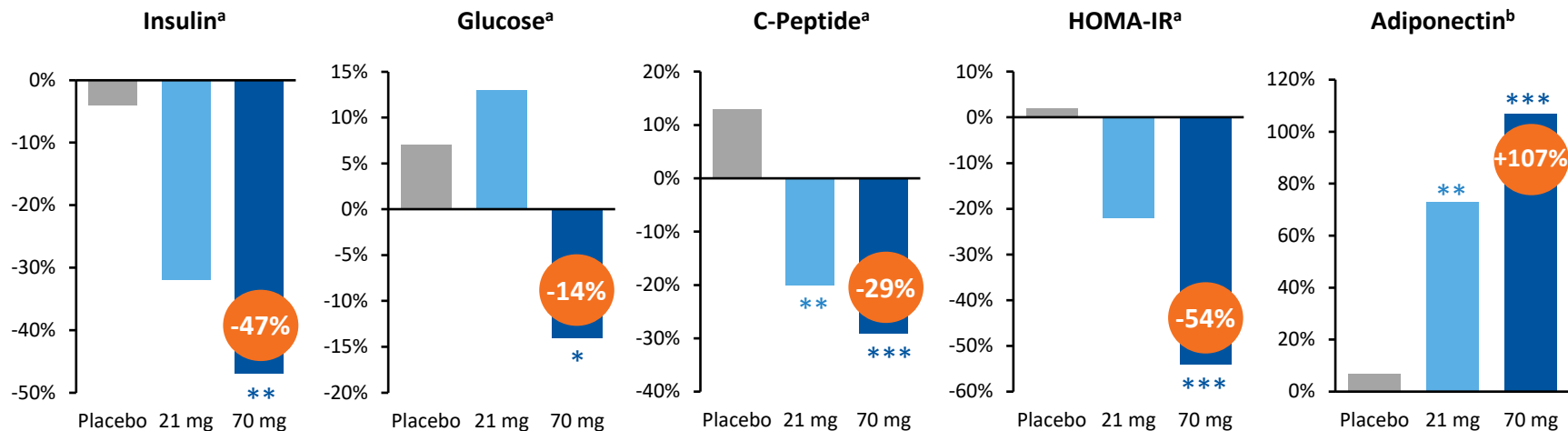
AKR-001 IMPROVED LIPOPROTEINS RAPIDLY AND DURABLY

AKR-001 70 mg QW effects on lipoproteins in Phase 1b clinical trial



AKR-001 IMPROVED MARKERS OF INSULIN SENSITIVITY In Phase 1b Trial in Type 2 Diabetic Patients

AKR-001's improvement in markers of insulin sensitivity
is consistent with effective FGFR1c agonism



Percent Change From Baseline, Placebo, 21 mg QW and 70 mg QW; ^a Day 25; ^b Day 29; * = $p < 0.05$; ** = $p < 0.01$; *** = $p < 0.001$

THE PHASE 2a BALANCED STUDY TRIAL DESIGN

KEY INCLUSION CRITERIA

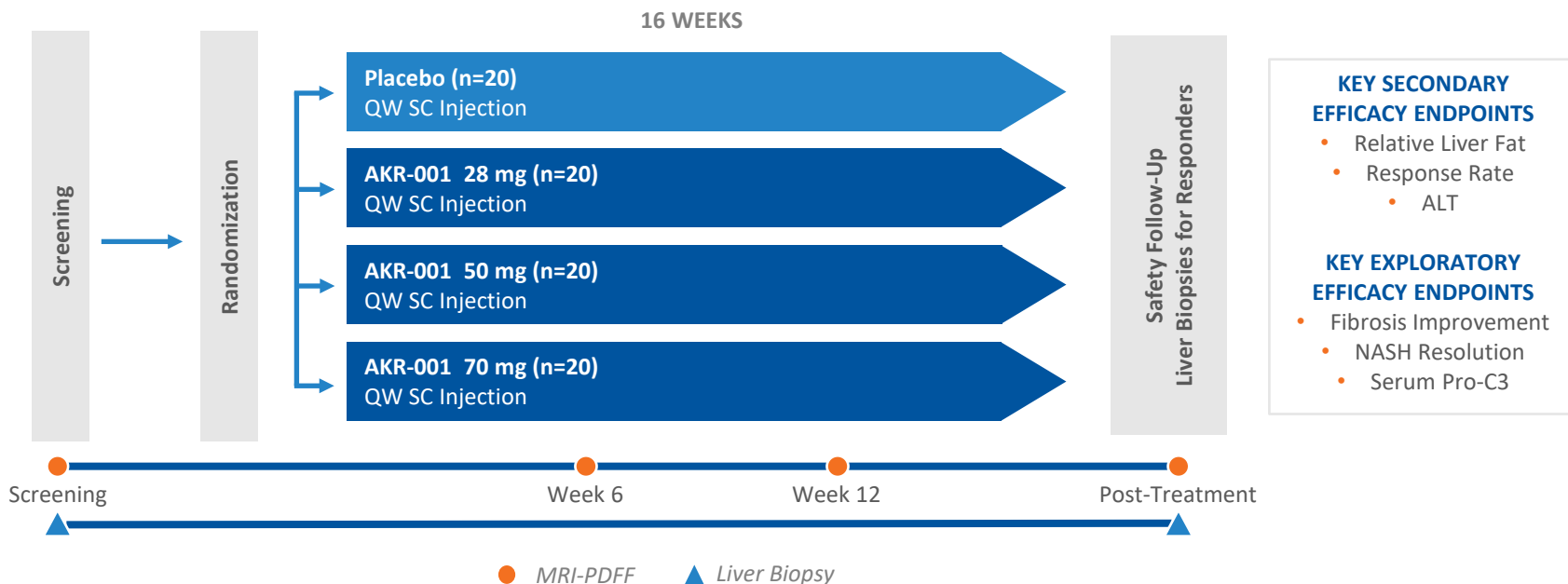
- F1-F3 NASH
 - NAS ≥ 4
- Liver fat $\geq 10\%$

PRIMARY ENDPOINT

Absolute change from baseline in hepatic fat fraction (MRI-PDFF) at Week 12

PAIRED BIOPSIES

Subjects achieving $\geq 30\%$ relative reduction of hepatic fat at week 12 are eligible for post-treatment biopsy



AKR-001 MET ALL WEEK 12 EFFICACY ENDPOINTS

In Phase 2a Study in Biopsy-Confirmed Adult NASH Patients

Efficacy Measures

- All AKR-001 dose groups (n=59) met the primary endpoint, with statistically significant absolute reductions in liver fat of **12-14%**
- Statistically significant relative reductions in liver fat for all AKR-001 dose groups were observed, with **>70%** reductions for the 50 mg and 70 mg dose groups
- Readout of paired biopsy data is expected in 2Q 2020, with **50 subjects** eligible for end-of-study biopsies based on achieving **≥30%** relative reductions in liver fat at week 12

Blinded Safety & Tolerability

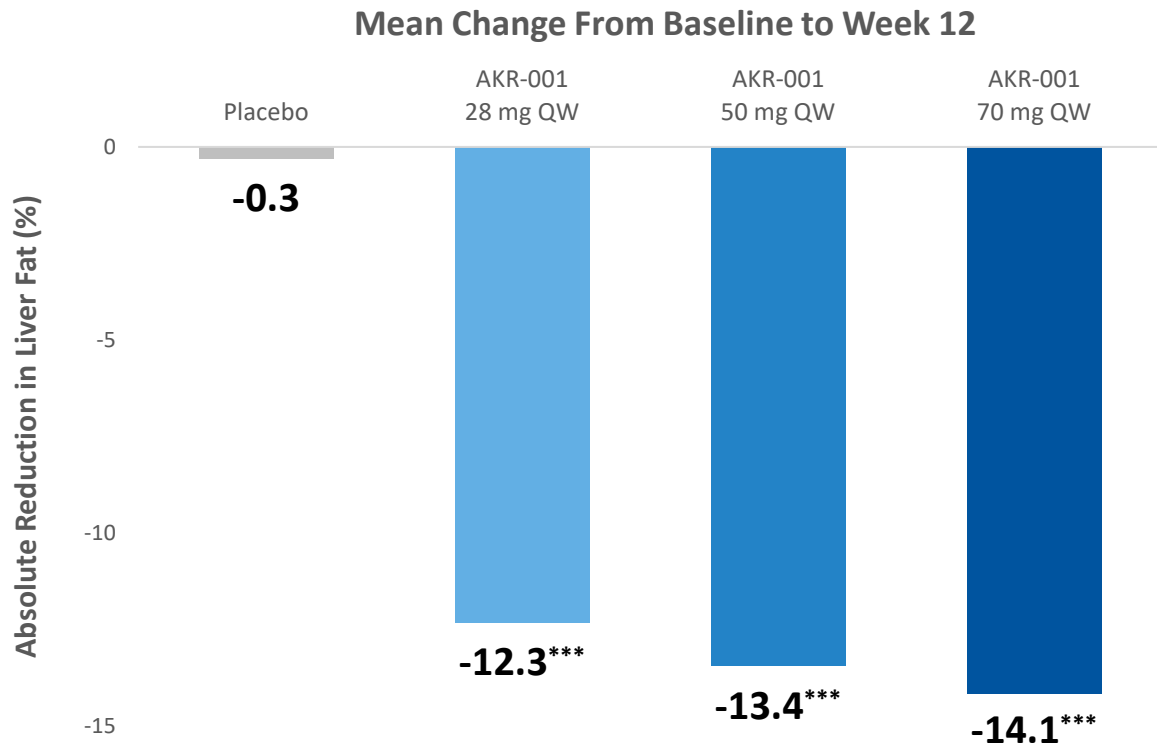
- Study is ongoing and remains blinded through completion of the study
- Blinded tolerability profile appears generally consistent with results from prior AKR-001 clinical trials
 - Adverse events observed most frequently in prior trials were mild/moderate gastrointestinal events and injection site reactions
- Data Monitoring Committee reviewed unblinded safety data and recommended an expansion cohort proceed without protocol amendment



BASILINE DEMOGRAPHICS

Parameter Mean	Placebo (N=21)	AKR-001 28mg (N=19)	AKR-001 50mg (N=20)	AKR-001 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	103.5	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

ABSOLUTE REDUCTION IN LIVER FAT: All AKR-001 Dose Groups Met Primary Endpoint



Normalization of Liver Fat

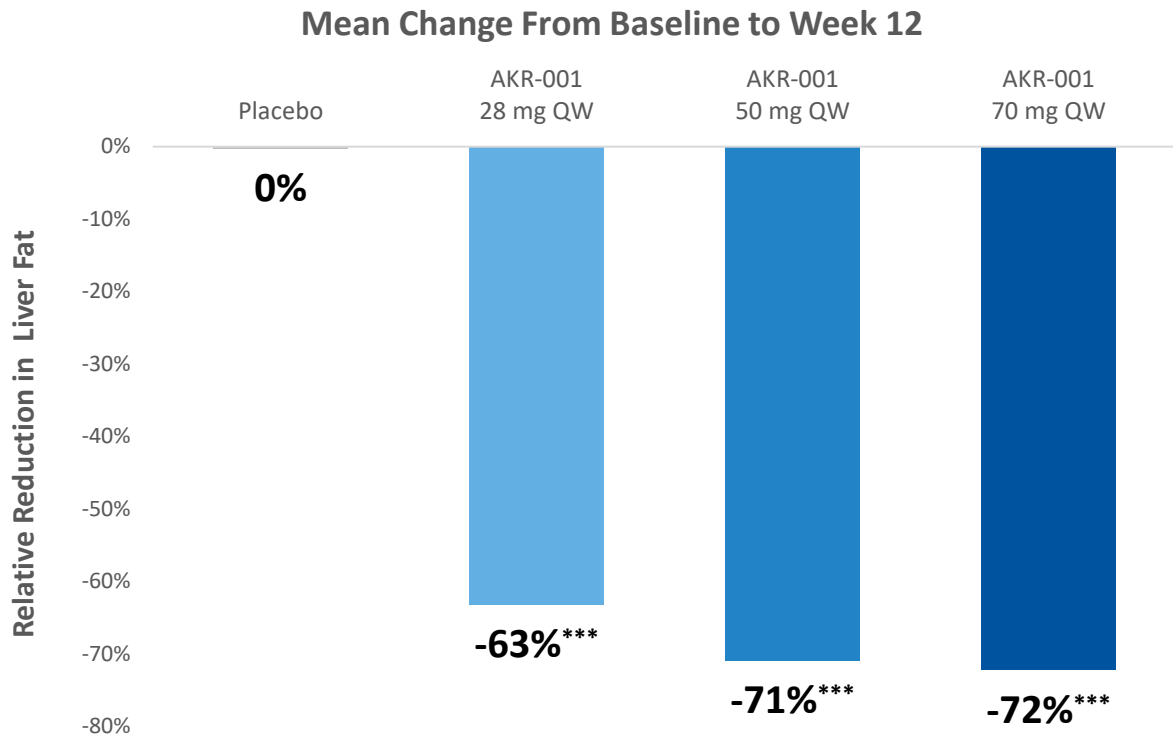
Proportion of subjects with $\leq 5.0\%$ absolute liver fat at Week 12

Placebo	5%
28 mg	21%
50 mg	45%
70 mg	50%**

** p=0.004, versus placebo

*** p<0.001, versus placebo

RELATIVE REDUCTION IN LIVER FAT: All AKR-001 Dose Groups Met Secondary Endpoint



Response Rate

Proportion of subjects with $\geq 30\%$ relative reduction at Week 12

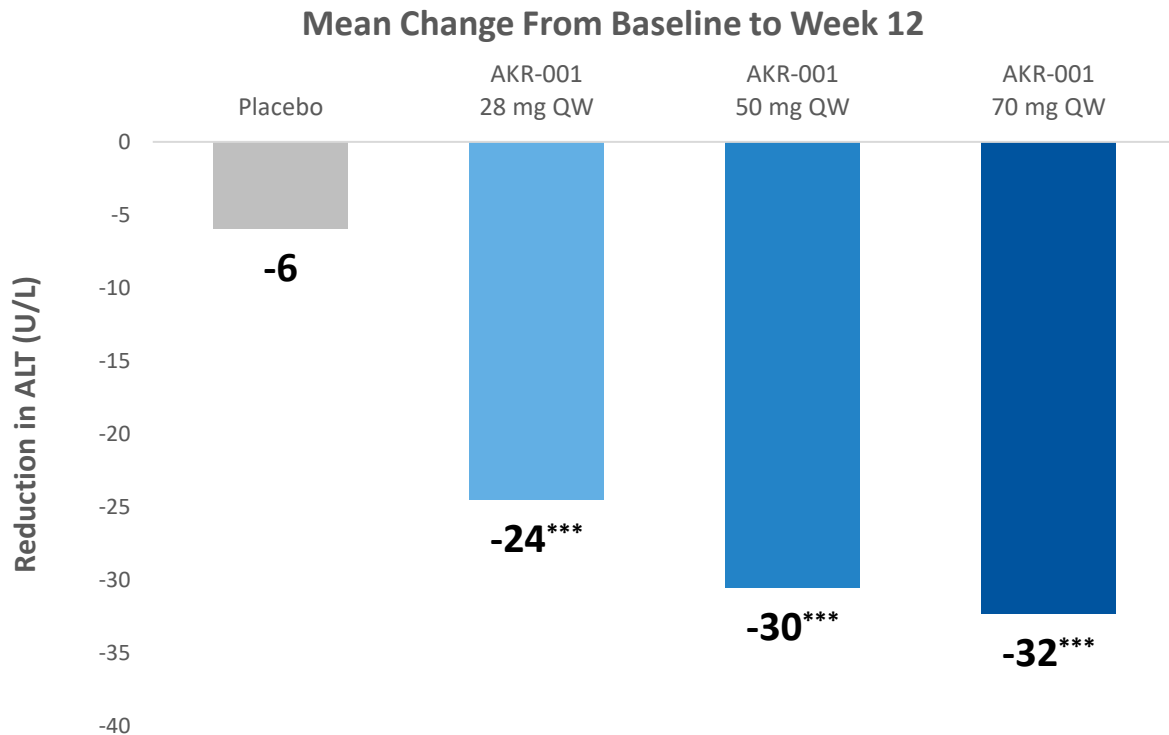
Placebo	10%
28 mg	84%***
50 mg	85%***
70 mg	75%***

End-of-Study Biopsies

50 subjects eligible
42 (84%) biopsies collected

*** $p < 0.001$, versus placebo

REDUCTION IN ALT: All AKR-001 Dose Groups Met Secondary Endpoint



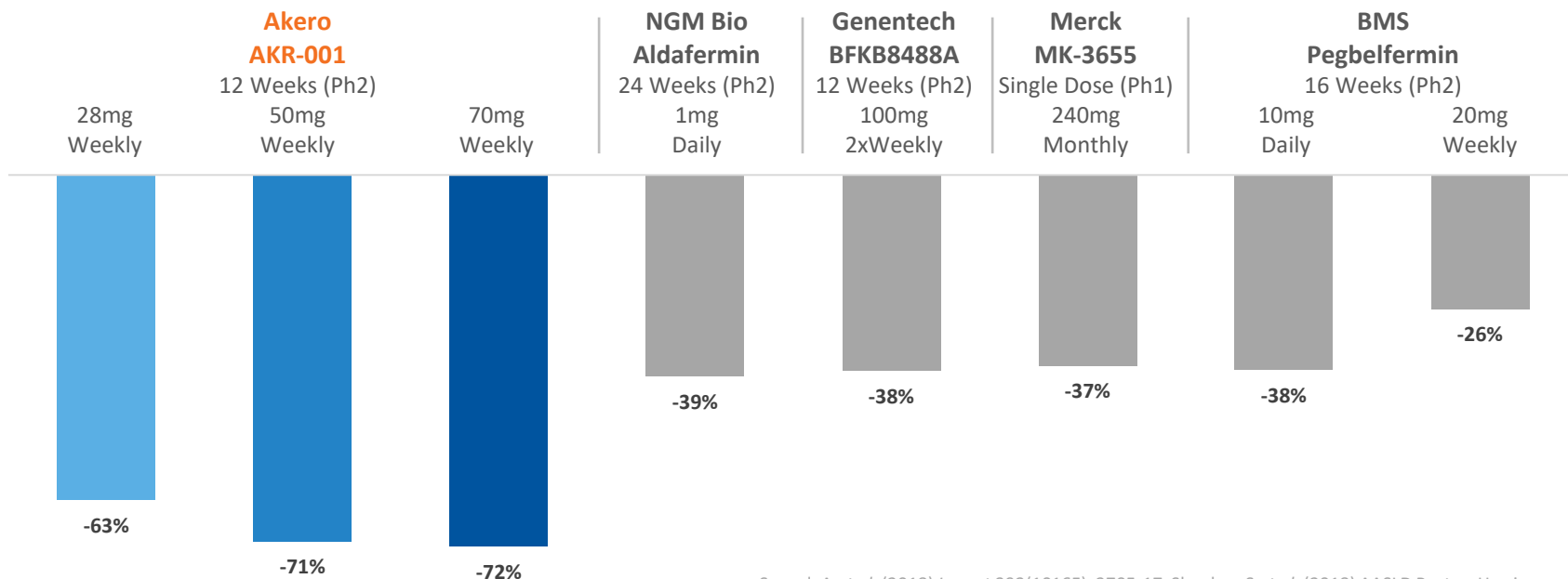
An ALT unit decrease of ≥ 17 U/L may correlate with histologic response

Loomba, R (2019) Gastroenterology

*** $p < 0.001$, versus placebo

DEVELOPMENT LANDSCAPE FOR RELATIVE REDUCTION IN LIVER FAT

Relative Fat Reduction (MRI-PDFF) of FGFs



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, A et al. (2018) *Lancet* 392(10165): 2705-17; Shankar, S et al. (2018) AASLD Poster; Harrison, S et al. (2018) EASL Presentation; Ge, H et al. (2014) *J Biol Chem* 289(44): 30470-80; Yu, X et al. (2013) *PLOS ONE* 8(7): e66923; Wu, X et al. (2013) *J Lipid Res* 54(2): 325-32; Wu, A-L et al. (2013) *PLOS ONE* 6(3): e17868; Wu, X et al. (2009) *Proc Natl Acad Sci* 106(34): 14379-84; Huang, X et al. (2007) *Diabetes* 56(10): 2501-10; Kunder et al. (2019) AASLD Poster; NGM (2019) October 7 Corporate Presentation.

DEVELOPMENT LANDSCAPE FOR PHASE 3 HISTOLOGY ENDPOINTS

Inventiva
Lanifibranor
24 Weeks (Ph2b)
Daily Oral

NGM Bio
Aldafermin
24 Weeks (Ph2)
Daily Injection

Madrigal
Resmetirom
36 Weeks (Ph2)
Daily Oral

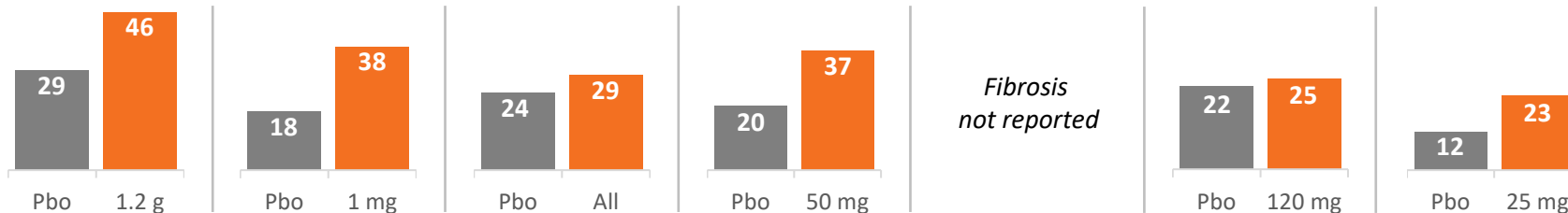
Cymabay
Seladelpar
52 Weeks (Ph2)
Daily Oral

Novo Nordisk
Semaglutide
72 Weeks (Ph2)
Daily Injection

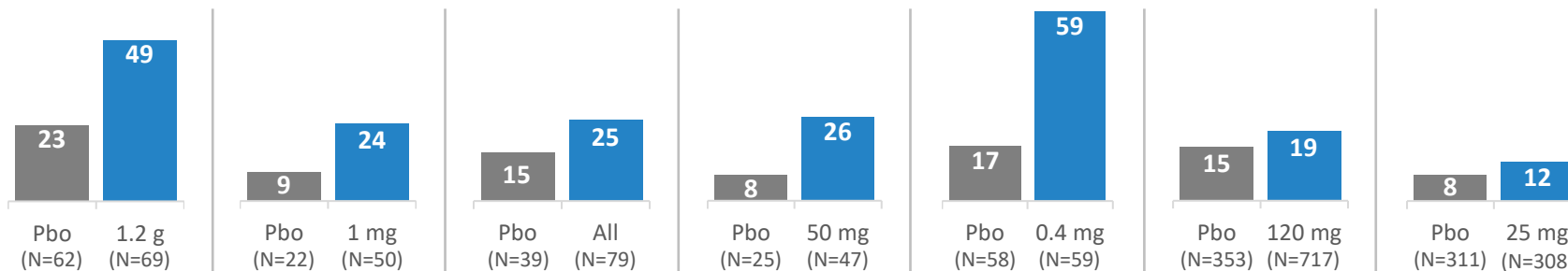
Genfit
Elafibranor
72 Weeks (Ph3)
Daily Oral

Intercept
Ocaliva
78 Weeks (Ph3)
Daily Oral

Percent of Subjects with ≥ 1 Stage Improvement in Fibrosis without Worsening of NASH

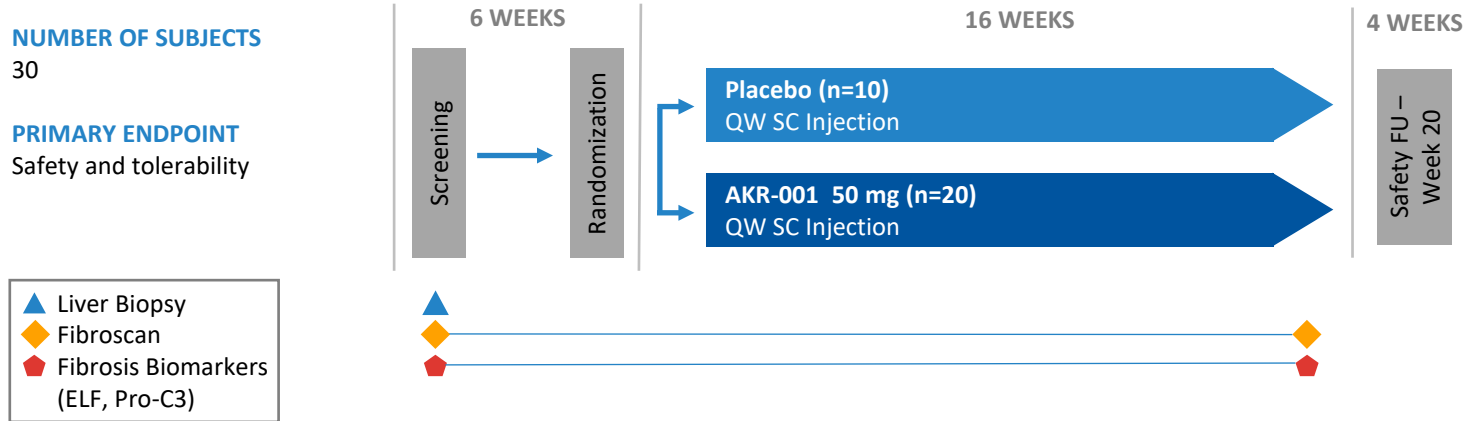


Percent of Subjects with Resolution of NASH without Worsening of Fibrosis



F4 COHORT EXPANSION (COHORT C)

Screening of an additional cohort of patients with compensated cirrhosis (F4), Child-Pugh Class A, began on May 7, 2020; the first patient was dosed on June 17, 2020



Selection of 50 mg dose based on PK-PD modeling of Phase 1b data, results of BALANCED main study, and availability of drug product



STRONG FINANCIAL POSITION

COMPLETED UPSIZED IPO

June 20, 2019

~\$106M

Raised in aggregate
gross proceeds

\$16

Price upsized IPO at top
of marketing range

Q1 EARNINGS UPDATE

March 31, 2020

~\$125M

Cash and cash
equivalents

~\$12M

Q1 operating
expenses

SIGNIFICANT NEAR TERM MILESTONES

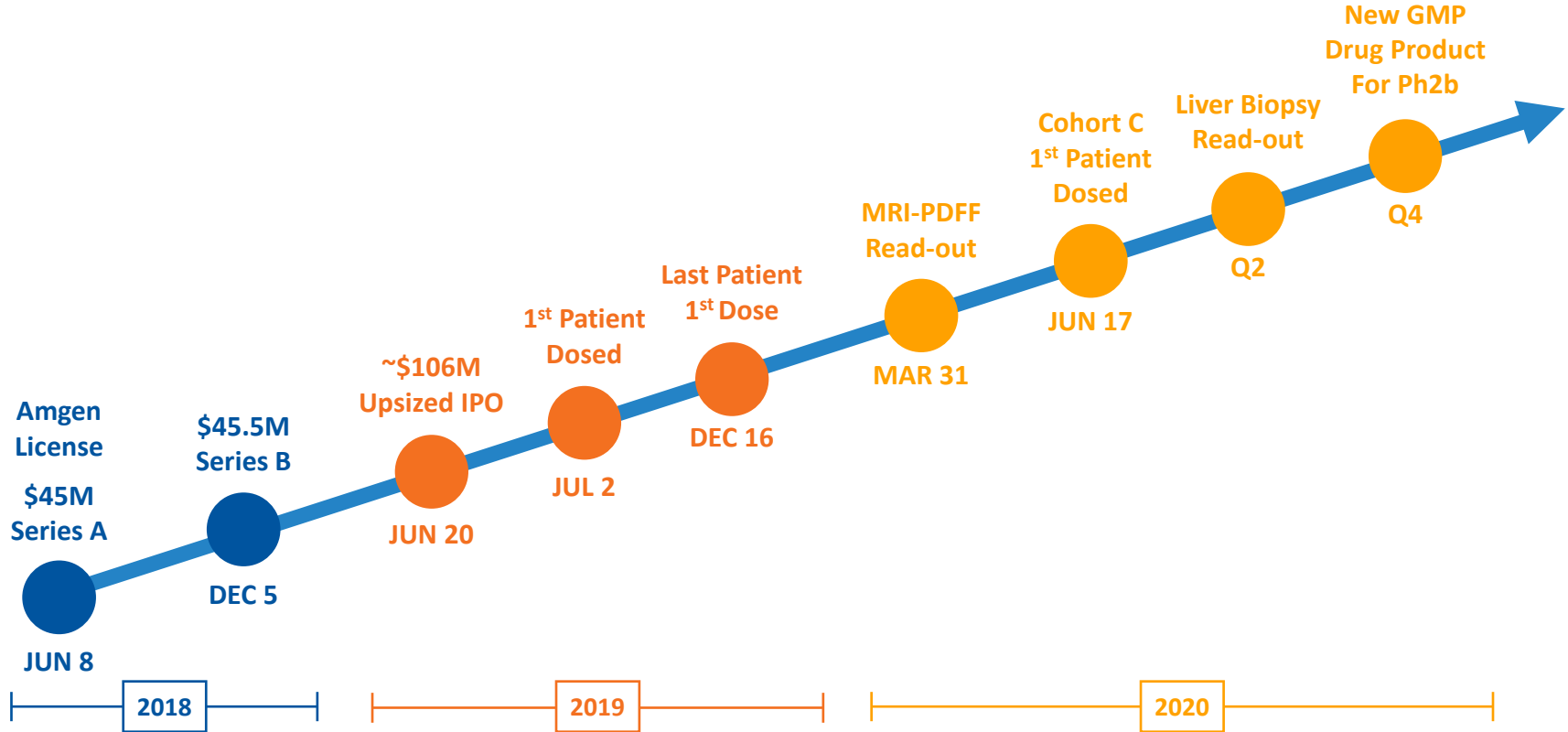
Biopsy Data

Readout late Q2 2020

Phase 2b/3

Anticipated initiation
1H 2021

MILESTONES PROJECTED MILESTONES DELIVERED



AKR-001 POTENTIAL AS A CORNERSTONE NASH THERAPY

- ✓ All AKR-001 dose groups met the primary endpoint for absolute reduction in liver fat
- ✓ All AKR-001 dose groups met secondary endpoints for relative reduction in liver fat and ALT reduction
- ✓ Data readout expected toward end of 2Q'20
 - Paired biopsy data for 42 subjects (84% of eligible subjects)
 - Biomarkers of liver injury and fibrosis and other relevant measures
 - Safety and tolerability
- ✓ GMP Drug Product expected in Q4'20 ahead of anticipated 1H'21 Ph2b/3 Start



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**A Global Disease,
A Pioneering Treatment**

NASDAQ: AKRO