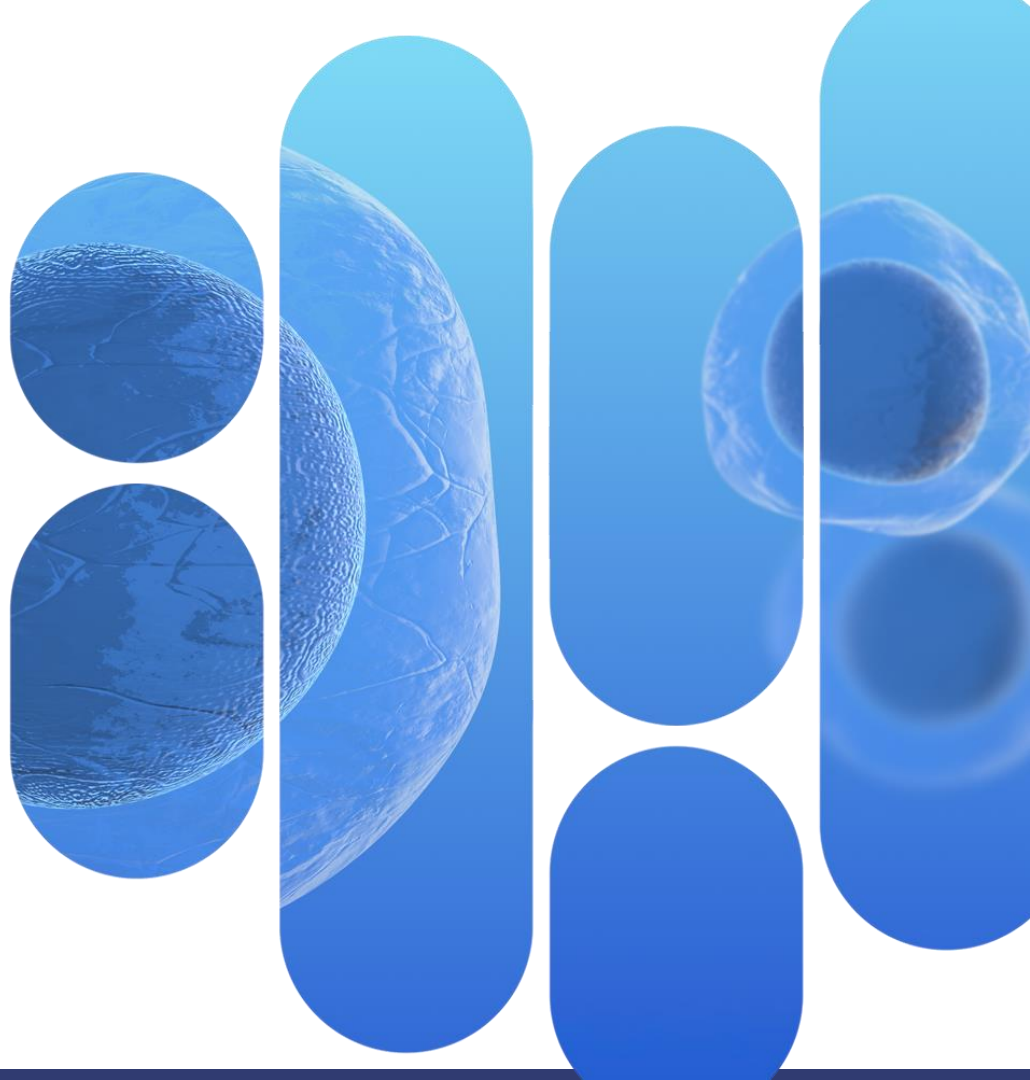
89bio

Developing a Differentiated FGF21 for Non-Alcoholic Steatohepatitis (NASH) and Severe Hypertriglyceridemia (SHTG)



Nasdaq: ETNB

August 2020

Disclaimer

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This presentation contains “forward-looking statements” within the meaning of the federal securities laws, which statements are subject to substantial risks and uncertainties and are based on estimates and assumptions. Other than statements of historical facts, all statements included in this presentation are forward-looking statements, including statements concerning our plans, objectives, goals, strategies, future events, future revenues or performance, financing needs, plans or intentions relating to product candidates, estimates of market size, business trends, the anticipated timing, costs, design and conduct of our planned clinical trials for BIO89-100, our only product candidate, the association of preclinical data with potential clinical benefit, the timing of anticipated milestones, the effect of the COVID-19 pandemic on our clinical trials and business operations, the timing and likelihood of regulatory filings and approvals for BIO89-100, our ability to commercialize BIO89-100, if approved, the pricing and reimbursement of BIO89-100, if approved, the potential to develop future product candidates, our ability to scale up manufacturing, the potential benefits of strategic collaborations and our intent to enter into any strategic arrangements, the timing and likelihood of success, plans and objectives of management for future operations and future results of anticipated product development efforts and our liquidity and capital resources. In some cases, you can identify forward-looking statements by terms such as “may,” “might,” “will,” “objective,” “intend,” “should,” “could,” “can,” “would,” “expect,” “believe,” “design,” “estimate,” “predict,” “potential,” “plan” or the negative of these terms, and similar expressions intended to identify forward-looking statements. These statements involve known and unknown risks, uncertainties and other factors that could cause our actual results to differ materially from the forward-looking statements expressed or implied in this presentation including those described more fully our most recent Form 10-K and Form 10-Q under the caption “Risk Factors” and elsewhere in such report and in other subsequent disclosure documents filed with the SEC.

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We obtained the industry, market and competitive position data used throughout this presentation from our own internal estimates and research, as well as from industry and general publications, and research, surveys and studies conducted by third parties. Internal estimates are derived from publicly available information released by industry analysts and third-party sources, our internal research and our industry experience, and are based on assumptions made by us based on such data and our knowledge of the industry and market, which we believe to be reasonable. In addition, while we believe the industry, market and competitive position data included in this presentation is reliable and based on reasonable assumptions, we have not independently verified any third-party information, and all such data involve risks and uncertainties and are subject to change based on various factors. These statements involve known and unknown risks, uncertainties and other factors that could cause our actual results to differ materially from the forward-looking statements expressed or implied in this presentation, including those described more fully in our most recent Form 10-K and Form 10-Q under the caption “Risk Factors” and elsewhere in such report and in other subsequent disclosure documents filed with the SEC.

Management Team

Rohan Palekar CEO		• CEO, CCO experience • Avanir, Medivation, J&J • Commercial, strategy, and R&D experience
Hank Mansbach, MD CMO		• 20+ years biopharma and R&D leadership in clinical development and medical affairs • Ultragenyx, Medivation, Valeant, GSK
Ram Waisbourd COO and CBO		• 20 years of operations, BD, and strategy experience • VP of strategy and transformation, Teva R&D • VP of business development, XTL bio
Ryan Martins CFO		• CFO, Strategy/IR, finance, sell-side experience • Revolution Medicines, Ultragenyx, Chiron, Jefferies, Lazard, Barclays/Lehman Brothers
Quoc Le-Nguyen CTO & Head of Quality		• 20+ years biopharma and leadership in technical operations, product supply, and quality • Aduro, Bayer, Novartis, Chiron, BioMarin

89bio - Investment Highlights

FGF21 IS A HIGHLY PROMISING VALIDATED MECHANISM OF ACTION

- Broad metabolic effects **plus** direct impact on liver

BIO89-100 IS A DIFFERENTIATED FGF21 ANALOG

- GlycoPEGyated molecule with robust biologic effects, favorable dosing, and tolerability
- Compelling pre-clinical and early clinical data

PURSUING TWO PROMISING LARGE INDICATIONS

- Non-Alcoholic Steatohepatitis (NASH): Potential to be a mainstay of therapy
- Severe Hypertriglyceridemia (SHTG): Quicker path to market with competitive differentiation

MAJOR ANTICIPATED MILESTONES

- NASH: Phase 1b/2a topline data late 3Q/early 4Q 2020; Expect Phase 2b/3 initiation in 1H21
- SHTG: Phase 2 initiation 3Q20, topline data 2H21

ESTABLISHED MANUFACTURING EXPERTISE AND IP PROTECTION BEYOND 2038

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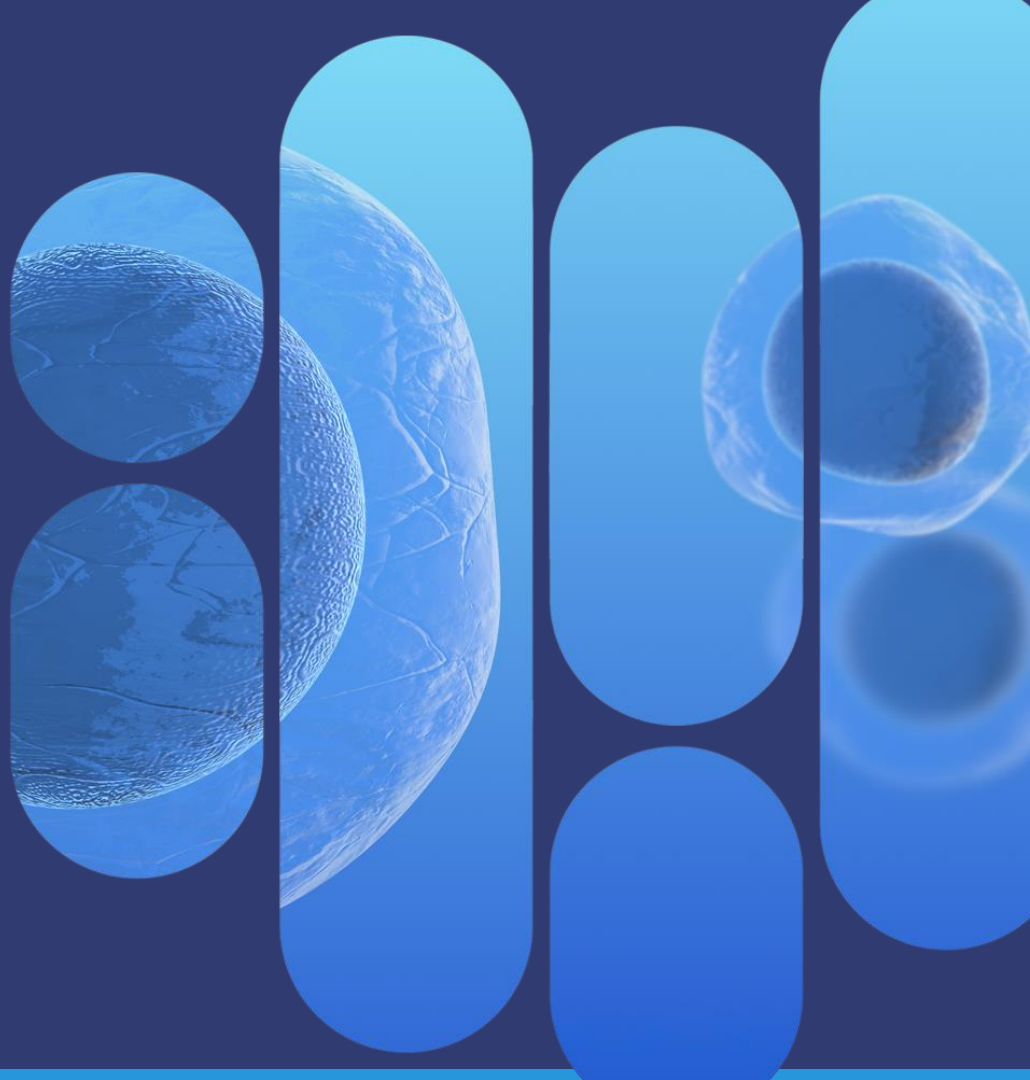
OPPORTUNITY IN NASH



BIO89-100: A Compelling Drug Candidate for NASH

FGF21 – A HIGHLY PROMISING VALIDATED MECHANISM OF ACTION

- Addresses liver pathology (steatosis, inflammation and fibrosis)
- Addresses systemic metabolic dysregulation

BIO89-100 – POTENTIAL TO BE A DIFFERENTIATED FGF21

- GlycoPEGylation technology from Teva
- Longer dosing interval (up to 2 weeks), robust biologic effects, favorable tolerability

BIO89-100 – STRONG EMERGING PROFILE

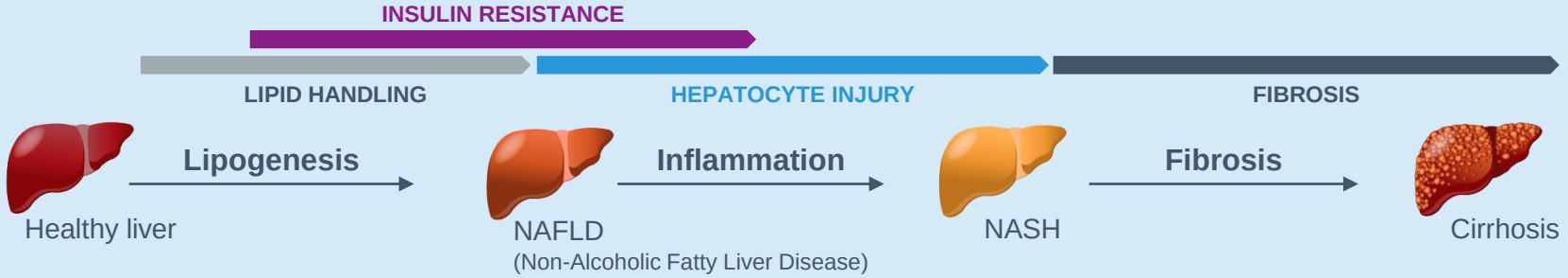
- Significant improvement in lipid markers in Phase 1a study
- Strong preclinical package: favorable PD effects and safety, target engagement of key receptors

BIO89-100 – KEY UPCOMING MILESTONES

- Phase 1b/2a study topline data: late 3Q/early 4Q 2020
- Phase 2b/3 study initiation: 1H21

NASH is A Serious Liver Condition With Significant Co-Morbidities

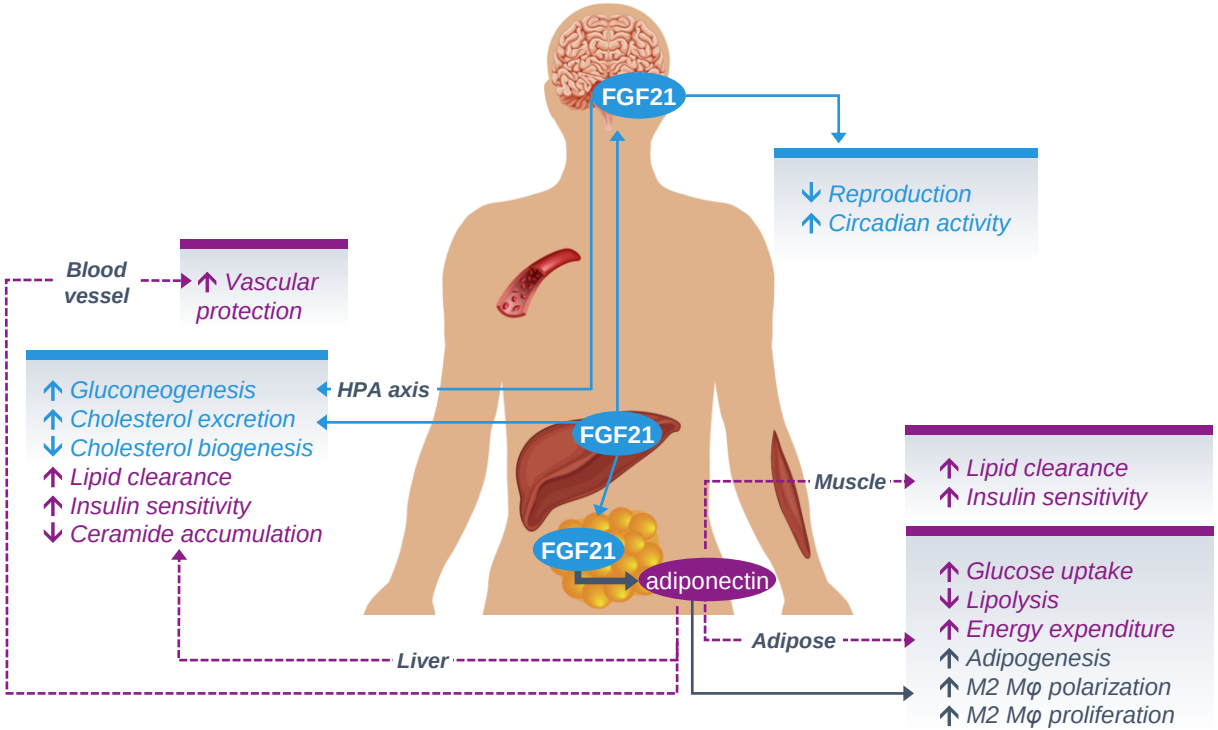
Metabolic Dysregulation → Excess Liver Fat Accumulation → Progressive Disease



- 16.5 million cases projected to grow to 27 million cases by 2030
- Expected to become the leading cause of liver transplant

Co-morbidity	Prevalence in NASH population
Hypertriglyceridemia	83%
Obesity	82%
Hyperlipidemia / Dyslipidemia	72%
Metabolic syndrome	71%
Type 2 diabetes	44%

FGF21 Has Potential To Be Mainstay of Therapy in NASH



- Endogenous metabolic hormone that regulates energy expenditure and glucose and lipid metabolism
- Reduces liver fat by action within liver and from periphery
- Impacts liver fibrosis via metabolic pathway and upregulation of adiponectin
- Native FGF21 has a short half-life of < 2 hrs

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FGF21 – Validated and Highly Differentiated Mechanism for NASH

		FGF21	FGF19	FXR	PPAR*	THR-β	GLP-1
Robust efficacy with respect to liver pathologies	Liver fat reduction	✓	✓	✓		✓	✓
	Fibrosis improvement	✓	✓	✓	✓	?	
Ability to address underlying co-morbidities	Triglyceride reduction	✓	✓		✓	✓	
	LDL-C improvement	✓	Worsens LDL	Worsens LDL		✓	
	HDL-C improvement	✓			✓		
	Glucose reduction	✓			✓		✓
Well tolerated at effective dose	Limited Side Effects	✓	LDL ↑	Pruritis LDL ↑	Weight Gain Edema	Drug-drug interaction	✓ GI effect
	Dosing frequency	Injectable QD/QW/Q2W	Injectable QD	Oral	Oral	Oral	Injectable QD

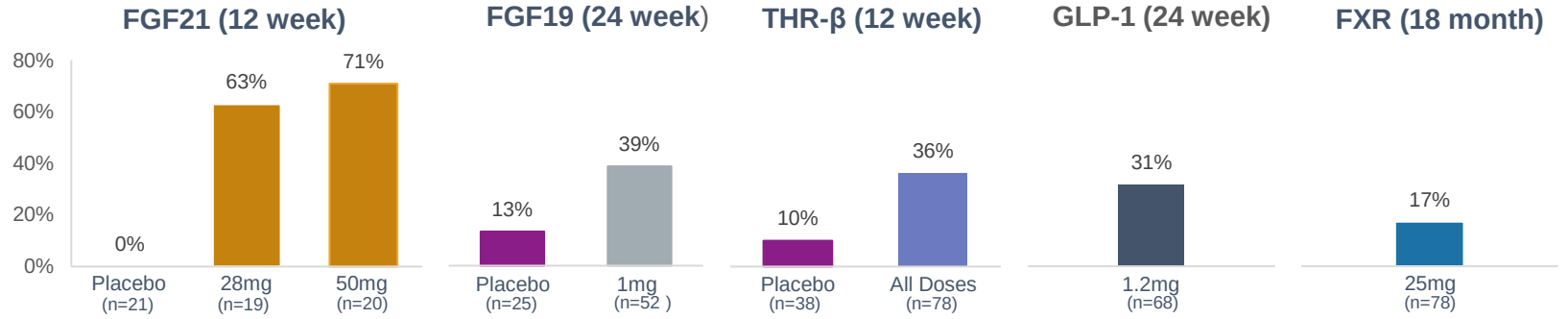
✓ Effective ? Indeterminate ✓ Modest Effect Unknown or Unchanged

* Based on pan-PPAR

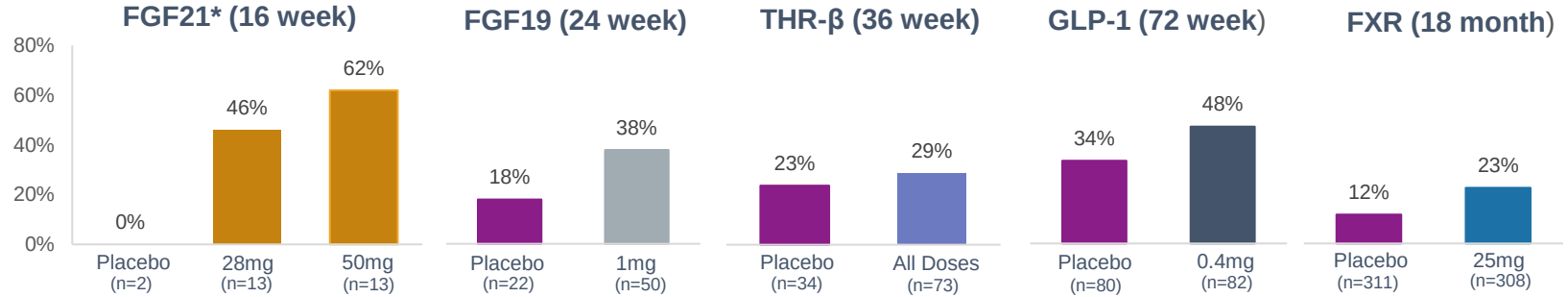
Note: Table representative of data published and/or presented on the mid/late stage clinical programs targeting these mechanisms. Third party company data taken from publications/publicly available presentations.

FGF21 – Highly Differentiated Mechanism for NASH

CHANGE IN LIVER FAT FROM BASELINE (% REDUCTION)



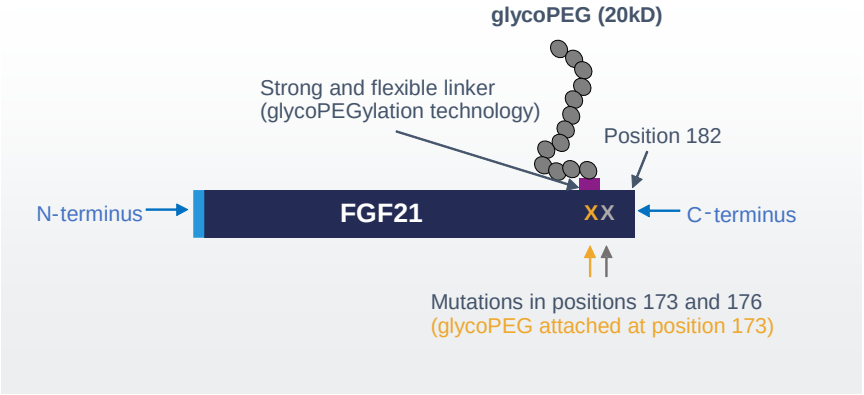
PROPORTION OF SUBJECTS WITH ≥ 1 STAGE IMPROVEMENT IN FIBROSIS WITH NO WORSENING OF NASH

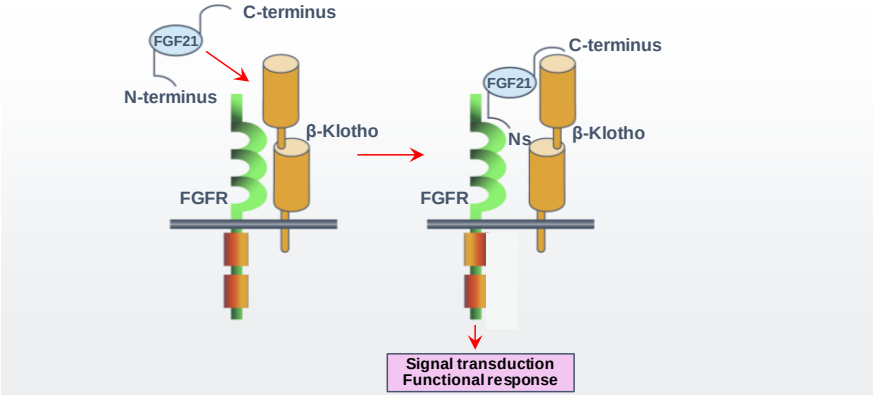


* No worsening of NAS (NAFLD Activity Score)

Note: All data on this slide are based on third-party studies and not our own. Conclusions on this slide are not based on head to head results; Graphs are representative of data published and/or presented on the mid/late stage clinical programs targeting these mechanisms

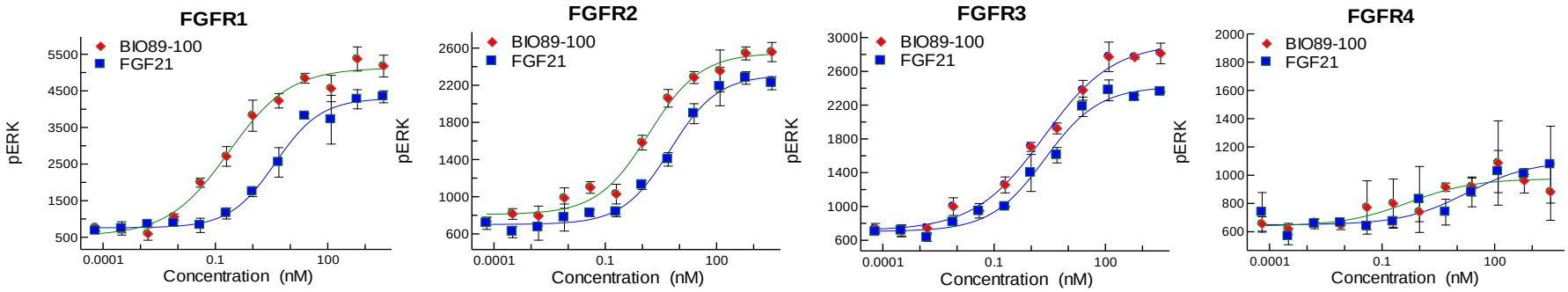
BIO89-100 Is An FGF21 Optimally Engineered To Balance Efficacy and Long Dosing Interval





- Proprietary glycoPEGylation technology with site-specific mutations
- Long half-life of 55-100 hours vs. native FGF21 half-life of < 2 hours
- Low nanomolar potency against FGF receptors 1c, 2c, 3c, similar to native FGF21; no activity against receptor 4 (leads to increased LDL)

BIO89-100 Exhibits Highly Potent FGF Receptor Agonism



- BIO89-100 has the potential to reproduce the beneficial metabolic effects of native FGF21

RECEPTOR	FGF21 EC_{50} (nM) Mean ± S.D.	BIO89-100 EC_{50} (nM) Mean ± S.D.
KLB	nd	nd
KLB/FGFR1	4.5 ± 1.0	0.3 ± 0.07
KLB/FGFR2	4.5 ± 0.9	1.1 ± 0.4
KLB/FGFR3	1.8 ± 0.3	1.2 ± 0.4
KLB/FGFR4	nd	nd

nd – not determined; rhFGF19 EC_{50} at FGFR4 = 1.7 ± 0.4

* Receptor agonism measured in L6 cells expressing β-klotho and either FGF Receptor 1c, 2c, 3c, or 4 via pERK functional assay

** Figures represent data from a single experiment. Table represents mean data from multiple experiments

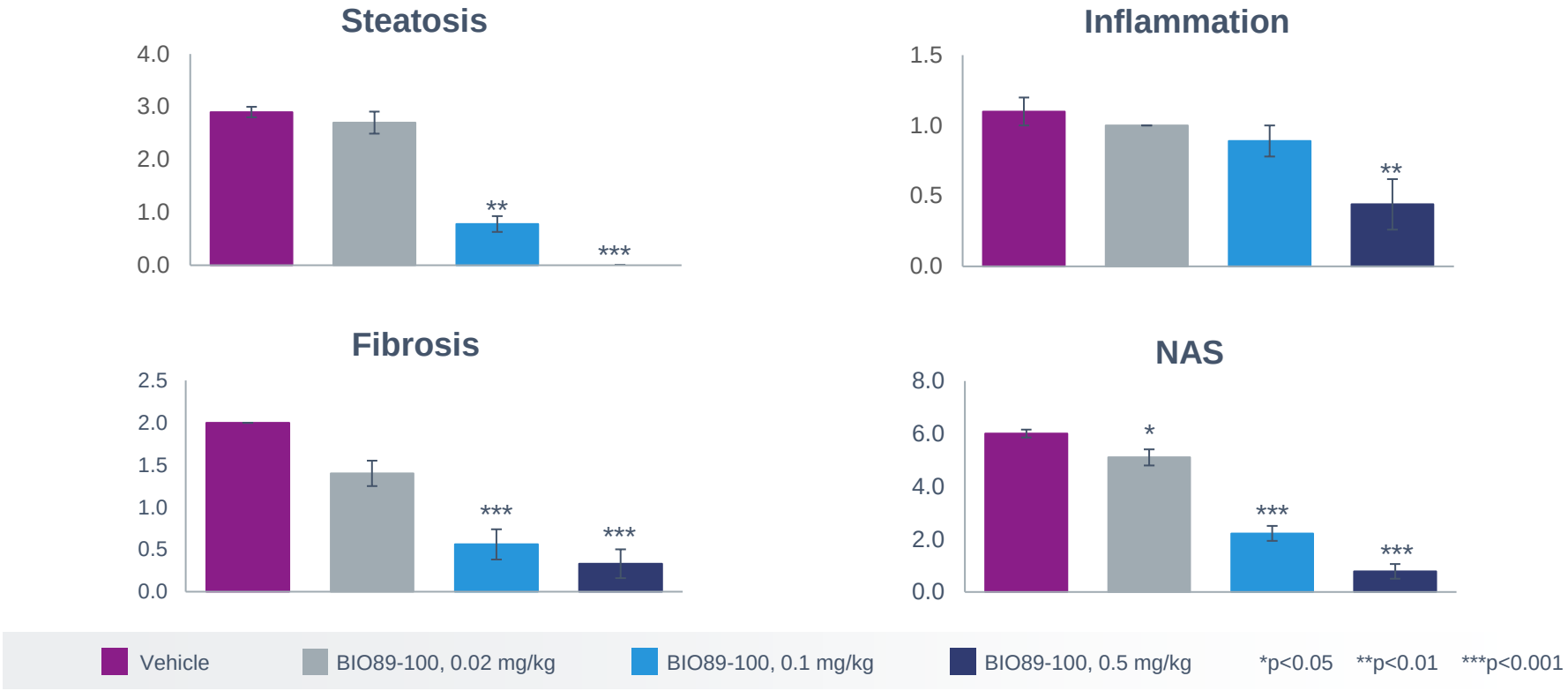
Strong Pre-clinical Data with BIO89-100

Pre-clinical Pharmacology Study with BIO89-100	Reduced Hepatocyte Injury	Reduced Liver Steatosis, Inflammation & Fibrosis	Improved Lipid Handling*	Improved Insulin Sensitivity	Body Weight Reduction
DIN mouse model (10 weeks)	✔	✔	✔	✔	✔
DIN mouse model (19 weeks)	✔	✔	✔	✔	✔
Diabetic obese cynomolgus monkey study (8 weeks; weekly dosing)	✔	Not evaluated	✔	✔	✔
Diabetic obese cynomolgus monkey study (4 weeks; weekly & 2-week dosing)	✔	Not evaluated	✔	✔	✔

✔ Statistically significant benefit observed

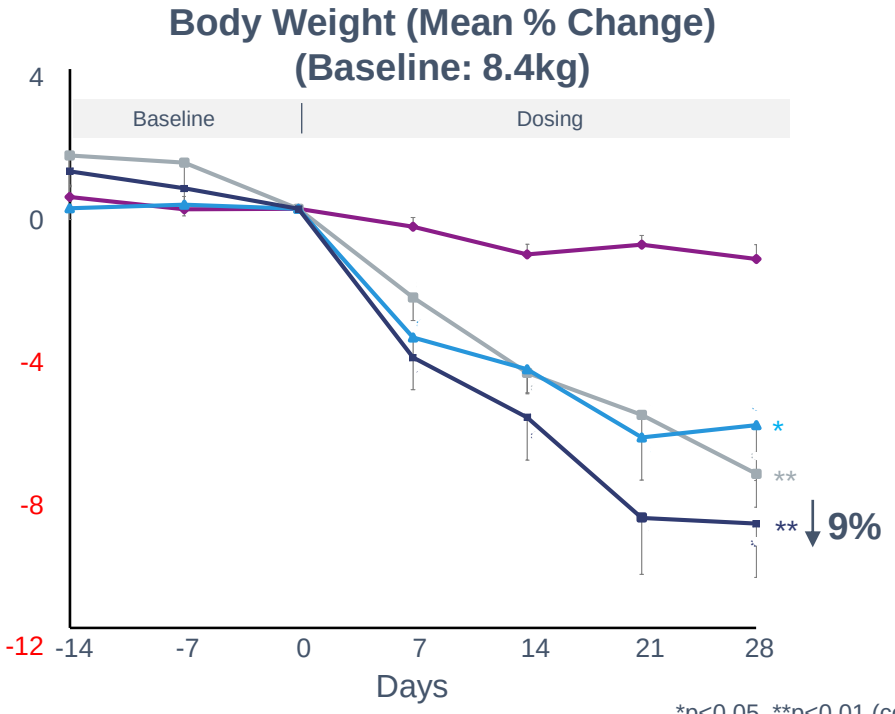
* Improved TG and cholesterol

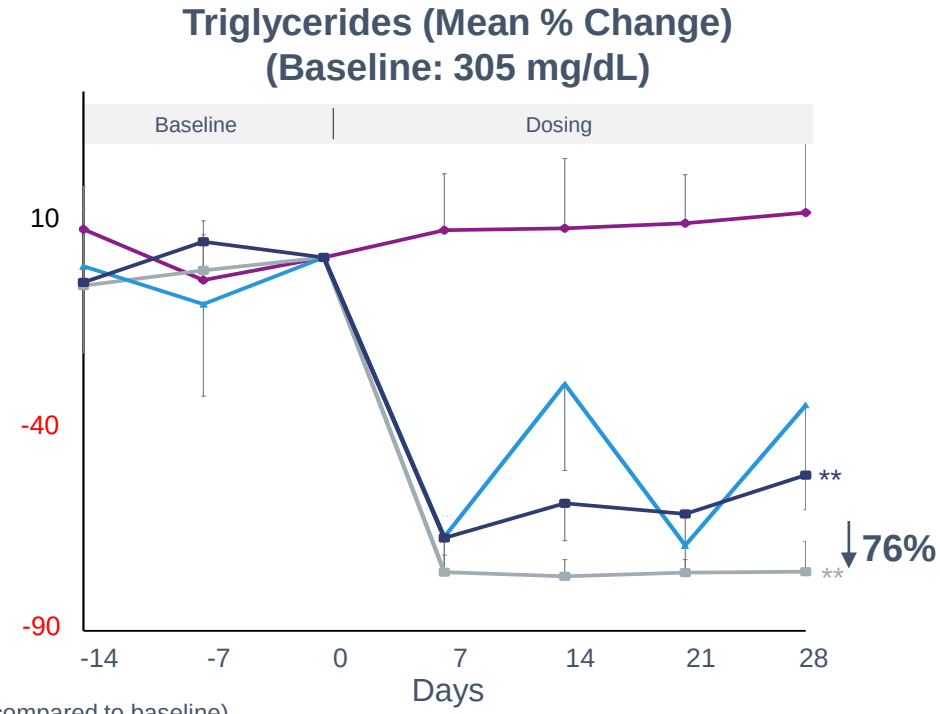
Reduction in Steatosis, Inflammation, Fibrosis and NAFLD Activity Score with BIO89-100 in DIN Model



Note : Obeticholic acid, 25 mg/kg tested as active control – did not separate from control in this study
Scoring system: Steatosis (0-3), Inflammation (0-3), Fibrosis (0-4), NAS (0-13) - all were assessed at week 19; mean scores

Significant Reduction in Body Weight and Triglycerides in Diabetic Obese Monkeys With Once Every 2 Weeks Dosing





*p<0.05, **p<0.01 (compared to baseline)

Vehicle weekly
BIO89-100, 1.0 mg/kg, weekly
BIO89-100, 1.0 mg/kg once every 2 weeks
BIO89-100, 2.0 mg/kg once every 2 weeks

BIO89-100 Demonstrated a Favorable Clinical Profile in Phase 1a Study

- Double-blind, placebo-controlled single ascending dose (SAD) study in 58 healthy volunteers (43 on drug)
- Significant improvements in key lipid parameters at 8 and 15 days after single dose (baseline values were in normal range)*
  - Triglycerides reduction up to 51%
  - LDL-C reduction up to 37%
  - HDL-C increase up to 36%
- BIO89-100 was well tolerated
  - Most commonly observed treatment related AEs (in ≥ 2 subjects) were injection site reaction and headache, all of which were reported as mild; no treatment related GI specific AEs (in ≥ 2 subjects) were observed
- Half-life of 55-100 hours with dose proportional PK
  - Supports weekly and once every 2-week dosing regimen

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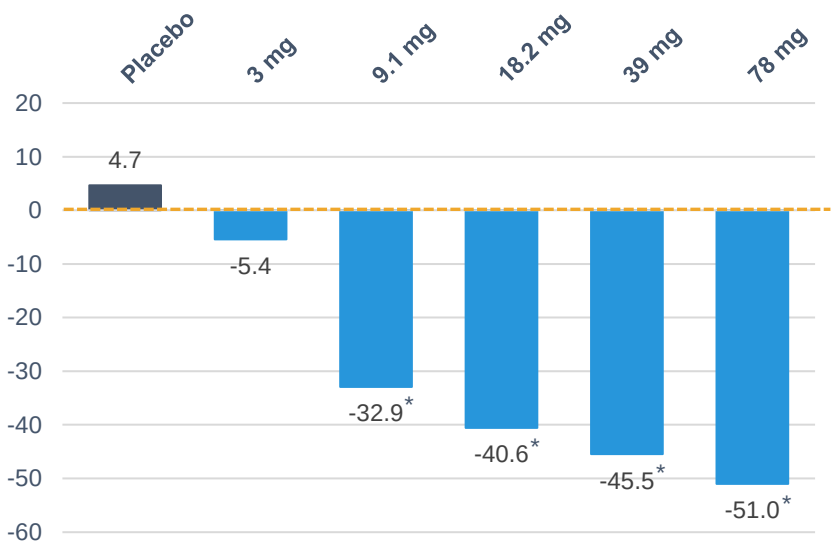
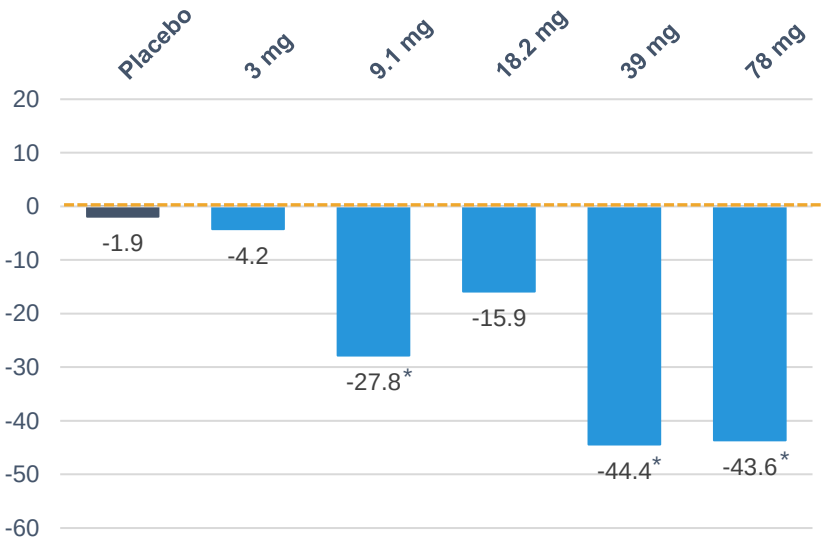
* Mean changes versus baseline

Robust and Durable Improvement in Triglycerides Following a Single Dose of BIO89-100

Mean Percentage Change at Day 8 from Baseline (%)



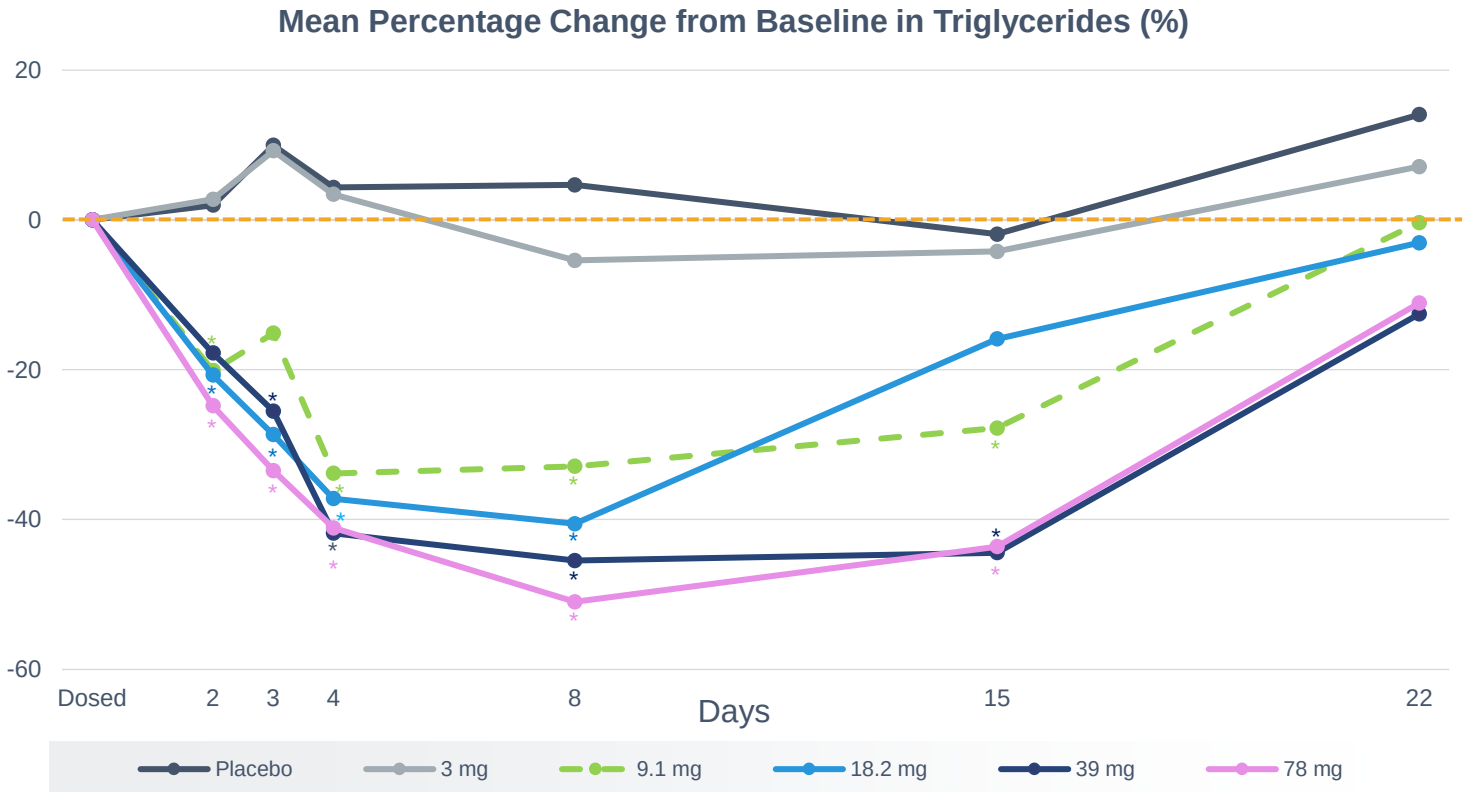
Mean Percentage Change at Day 15 from Baseline (%)



Dose (mg)	Placebo	3 mg	9.1 mg	18.2 mg	39 mg	78 mg
N	15	6	7	6	6	6
Baseline	99.3	78.2	95.9	84.5	124.5	101.5

* 95% CI exclude 0% change from baseline

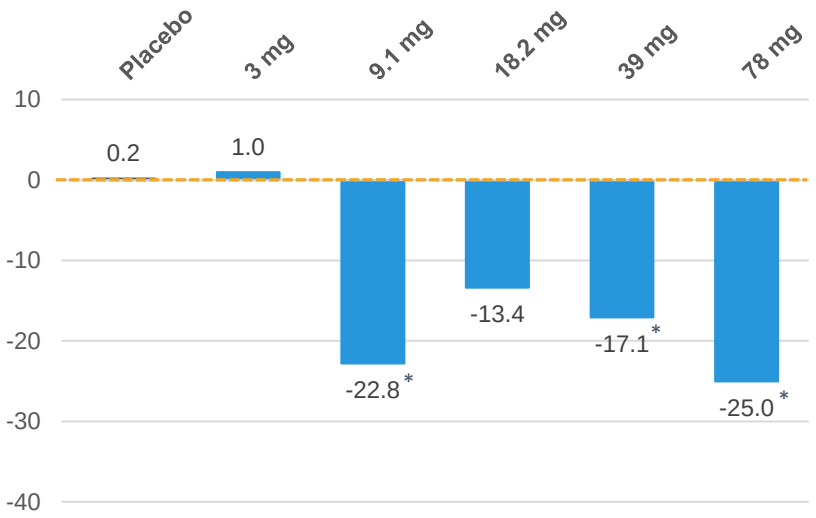
Rapid and Durable Improvement in Triglycerides Following a Single Dose of BIO89-100



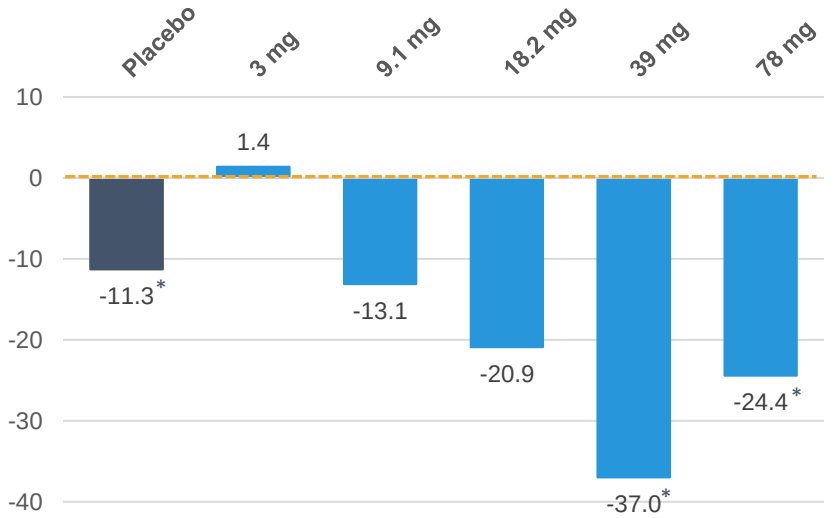
* 95% CI exclude 0% change from baseline

Robust and Durable Improvement in LDL Cholesterol Following a Single Dose of BIO89-100

Mean Percentage Change at Day 8 from Baseline (%)



Mean Percentage Change at Day 15 from Baseline (%)

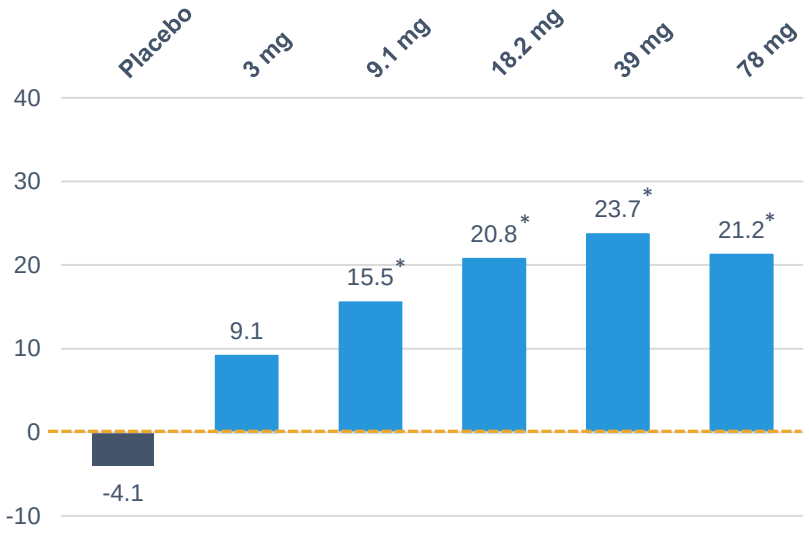


Dose (mg)	Placebo	3 mg	9.1 mg	18.2 mg	39 mg	78 mg
N	15	6	7	6	6	6
Baseline	129.6	123.3	120.3	122.8	138.8	130.3

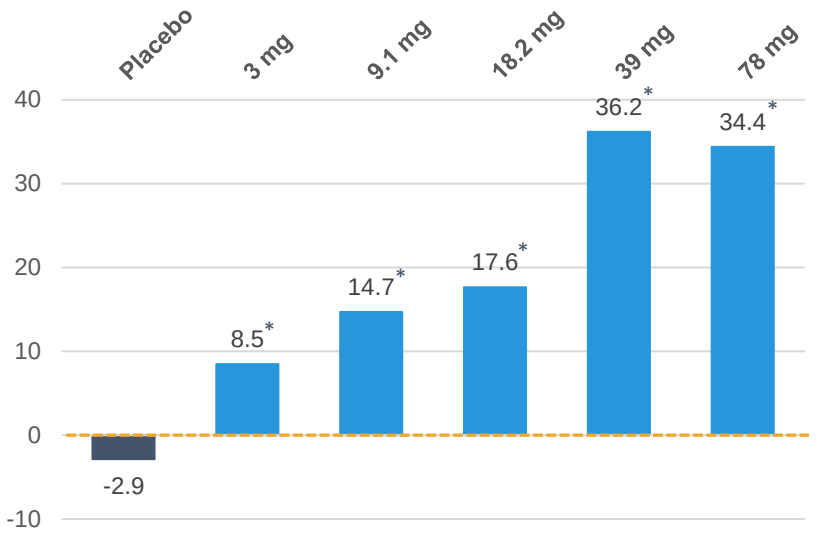
* 95% CI exclude 0% change from baseline

Robust and Durable Improvement in HDL Cholesterol Following a Single Dose of BIO89-100

Mean Percentage Change at Day 8 from Baseline (%)



Mean Percentage Change at Day 15 from Baseline (%)



Dose (mg)	Placebo	3 mg	9.1 mg	18.2 mg	39 mg	78 mg
N	15	6	7	6	6	6
Baseline	50.8	48.5	51	44.8	44.2	42.7

* 95% CI exclude 0% change from baseline

BIO89-100: Phase 1b/2a NASH Study

- Design: Randomized, double-blind, placebo-controlled
- Population: NASH or NAFLD patients with high risk of NASH*
- Dosing: Weekly or every 2 weeks; six cohorts:
  QW - 3mg/9mg/18mg/27mg; Q2W - 18mg/36mg
- Treatment Duration: 12 weeks
- Size/Power: n=81 patients enrolled; powered to show statistical difference on MRI-PDFF
- Topline results expected in late 3Q/early 4Q 2020

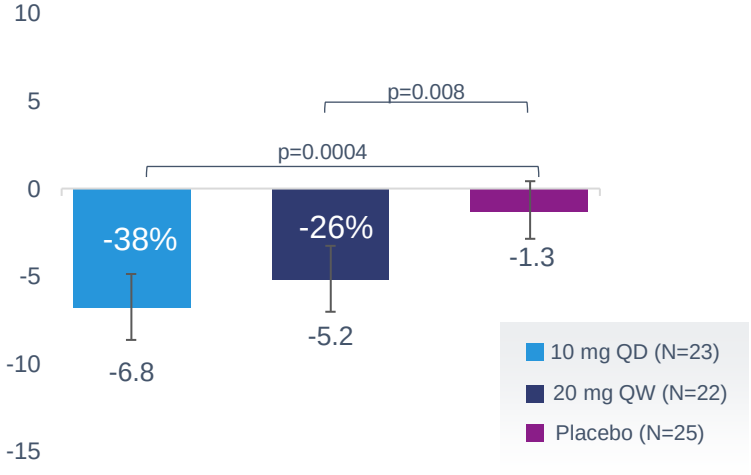
Trial Endpoints:

- Safety, PK
- MRI-PDFF (Week 7 and Week 13)
- Serum Lipids
- Key NASH biomarkers including:
  - ALT
  - Pro-C3
  - ELF
  - Inflammatory markers

* Central obesity plus T2DM or evidence of liver injury

FGF21 – Pegbelfermin (BMS-986036)

Pegbelfermin Absolute Change in % Liver Fat Fraction (Week 16)



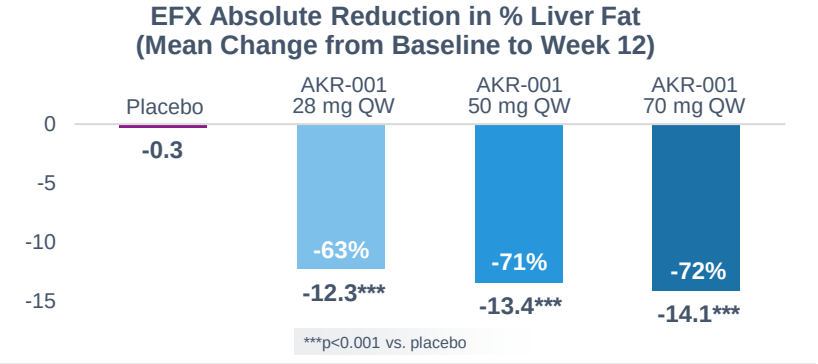
- Reduction in serum Pro-C3; effect also demonstrated on MRE
- Well tolerated; most common AEs were GI AEs
- Pegylated molecule with half-life of 19–24 hours

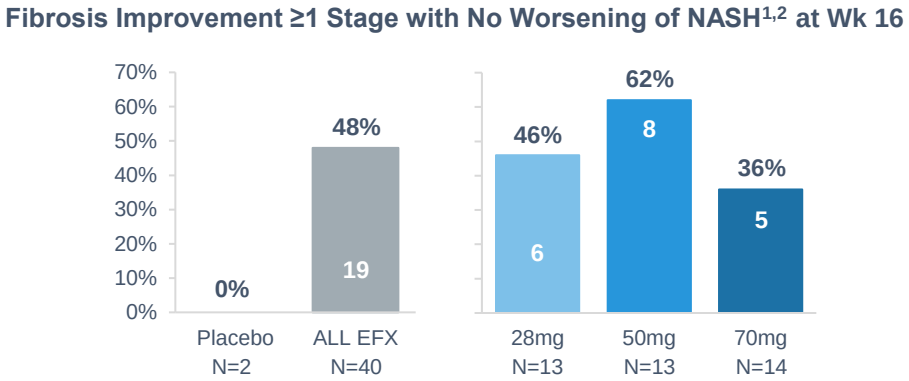
- Dosing: Pegbelfermin is dosed QD and QW
  - Pegylated molecule with non-native amino acid substitutions
  - QW dose not as effective as QD dose
- Efficacy: Lower lipid changes (vs. BIO89-100) in Phase 1 trial

*% Change vs. baseline (Day 15)**	Phase 1b study	
	10mg QD	21mg QW
TRIG	-35%	-25%
LDL-C	-25%	-20%
HDL-C	-8%	-9%

- Changes in TG and LDL-C in Phase 2a study in QW dosing arm were 5% and 1% respectively

FGF21 – Efruxifermin (AKR-001)*



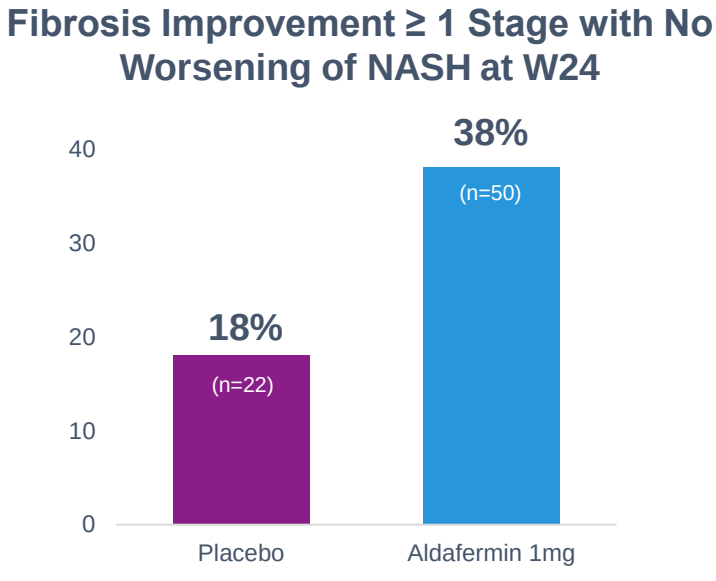


- Similarities with BIO89-100:
  - Low nanomolar potency with balanced activity against FGF21 receptors
  - Comparable effect on TG and HDL in Phase 1
  - Similar half-life (different technology)
- Efficacy across multiple liver and metabolic markers in Phase 2a study
- Dosing and tolerability profile of molecules could be different
  - EFX dosed QW; research shows strong preference for Q2W dosing
  - GI and tremor observed consistent with prior studies
- EFX and BIO89-100 expected to enter Phase 2b/3 in 1H21

[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

* As publicly reported by Akero on June 30, 2020

FGF19 – Aldafermin (NGM282)



- 39% reduction in liver fat (vs. 13% for placebo) at Week 24

- FGF19 and FGF21 belong to the same family of non-heparin binding FGF hormones
  - Both are believed to regulate energy and lipid metabolism in similar manner
  - FGF19 activates FGFR4, FGF21 does not
- Aldafermin results in significant increases in LDL (up 50%) vs. LDL decreases seen with some FGF21 analogs
- Aldafermin is a once-daily subcutaneous injection

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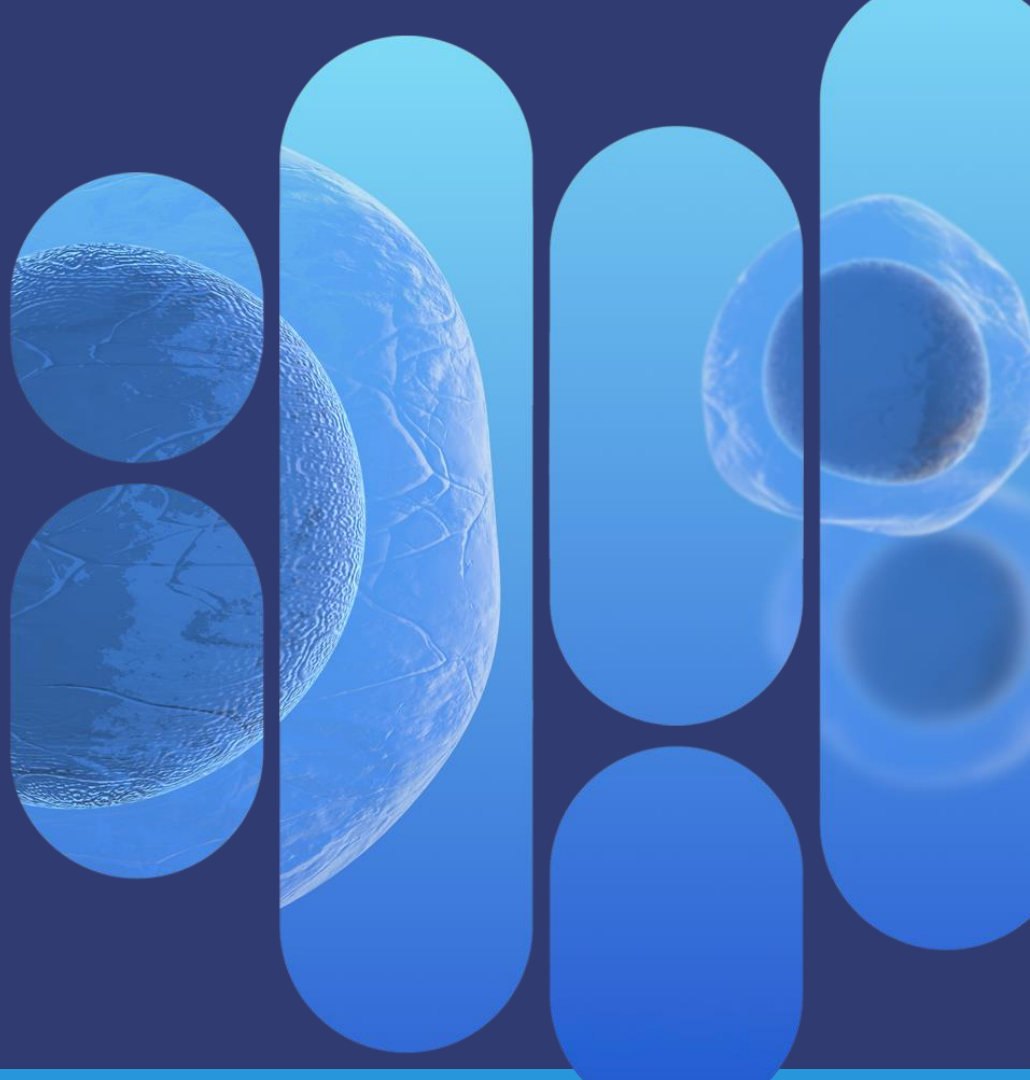
OPPORTUNITY IN SHTG



BIO89-100: A Compelling Drug Candidate for SHTG

SIGNIFICANT MARKET OPPORTUNITY

- Estimated up to 4M patients (~50% refractory to current standard of care)
- 56% of SHTG patients have hepatic fat, increasing CV risk

BIO89-100 IS A HIGHLY DIFFERENTIATED MOLECULE

- FGF21 is a promising mechanism of action for treatment of SHTG
- Significant triglyceride reduction **plus** potential improvement on hepatic fat and other metabolic parameters

QUICKER TO MARKET OPPORTUNITY

- Established regulatory path for approval
- Smaller, quicker registrational trials

KEY UPCOMING MILESTONES

- Phase 2 study initiation: 3Q20
- Phase 2 study topline data: 2H21

SHTG Market Opportunity

Large patient population

Estimated **up to 4 million** patients

With large unmet need

- **Up to 50%*** of treated patients are **refractory to current standard of care**
- **56% of patients** have hepatic fat
- **Up to 70%** of patients have other dyslipidemias or Type 2 Diabetes

Diagnosis and treatment rates expected to increase in the future

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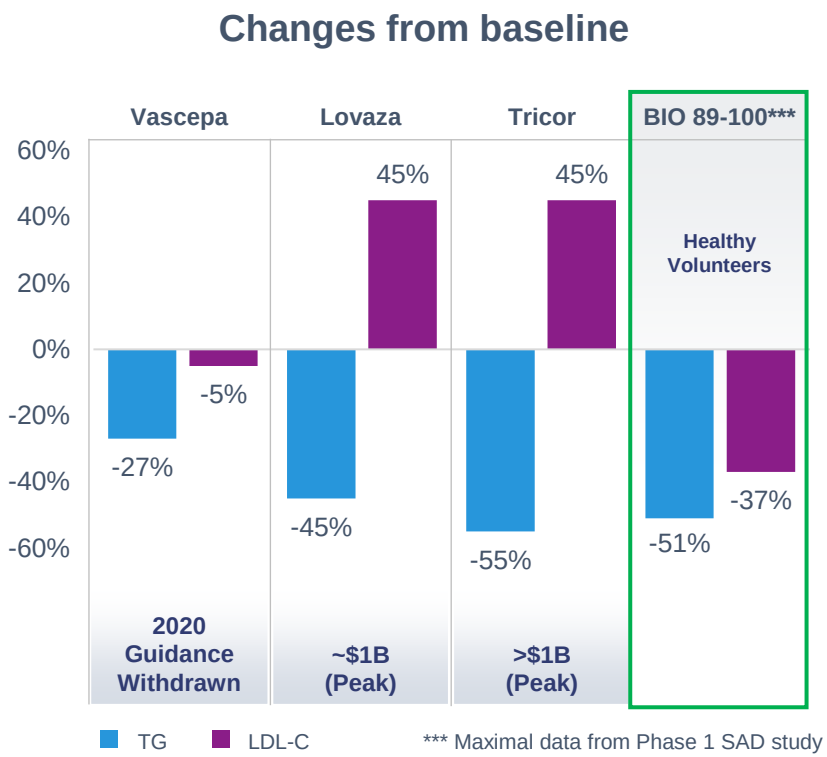
* 50% is based on registrational trials of Vascepa and Epanova (at 4mg/day dose) approved in SHTG

BIO89-100 Has a Highly Differentiated Profile

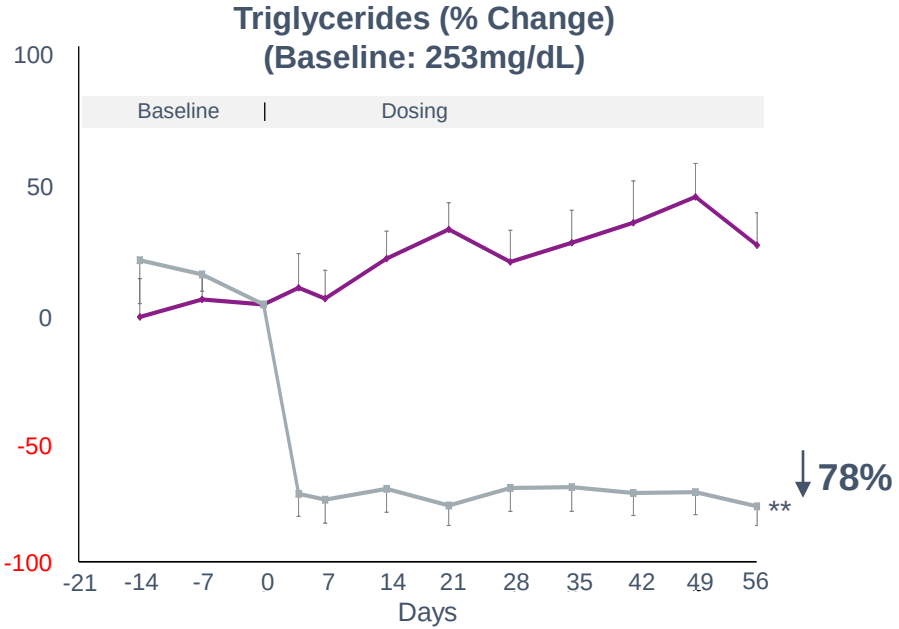
	FISH OILS		FIBRATES	FGF21 Analogs
	Vascepa (EPA)	Lovaza (EPA+DHA)	Tricor	
Reduce Hepatic Fat	–	–	–	✔
Improve LDL-C	–	Worsens LDL	Worsens LDL	✔
Glycemic Control	–	–	–	✔
Tolerability/ Safety	May prolong bleeding time		Myopathy LDL and LFT increases DDI	✔ GI effect**

✔ Effective – Unchanged or Inconclusive

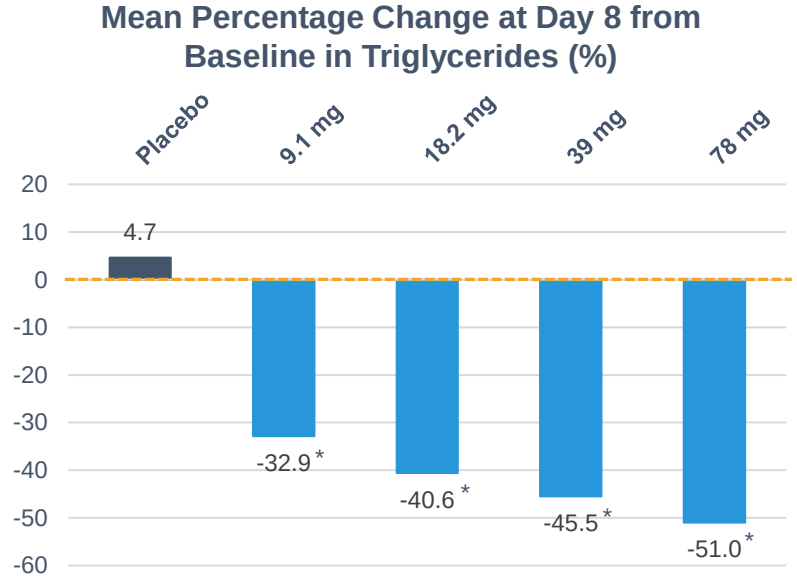


* Conclusions on this slide are not based on head-to-head results
** Observed with some FGF21 analogs

Robust and Durable Reduction in Triglycerides Observed with BIO89-100



Data from study in obese diabetic monkeys



Data from SAD study in healthy volunteers

Vehicle weekly

BIO89-100, 1.0 mg/kg weekly

**p<0.01 (compared to baseline)

* 95% CI exclude 0% change from baseline

SHTG May Represent a Quicker and Less Expensive Path to Market

1. US approval endpoint: TG reduction from baseline; no clinical outcome study required
2. Phase 3 studies precedent*: Single 12-week trials with ~200 - 300 patients

BIO89-100 Anticipated Development Plan

Study	Design
Phase 2 Study	• Adults with TG ≥ 500; N = ~90 • Weekly and every two-week dosing • Primary endpoint: Reduction from baseline in TG • Secondary endpoints: Other lipids, hsCRP, glucose, liver fat (MRI-PDFF) • Timing: Trial initiation in 3Q20 and topline data in 2H21
Registrational Trial**	• Patients with TG ≥ 500 mg/dL; Endpoint = % reduction of TG from baseline

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* Based on Vascepa and Epanova programs
** Registration program to be confirmed with regulatory feedback

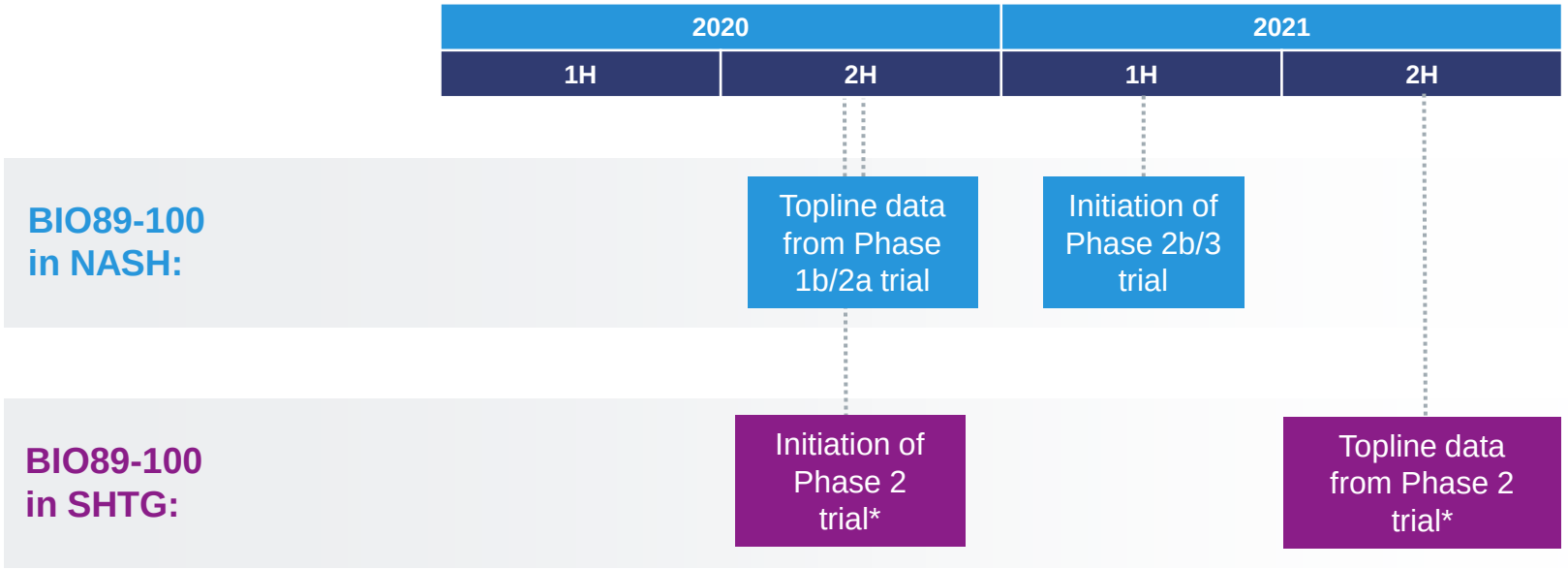
Financial Position Summary

Cash, cash equivalents and short-term investments

- $73.9* million (as of June 30, 2020)
- In July 2020, 89bio received approx, $78.3 million in net proceeds from an underwritten offering of common stock
- Debt facility for a tranched secured term loan of up to $15.0 million entered into on April 7, 2020

* This amount is preliminary, has not been audited and is subject to change pending completion of our unaudited financial statements for the quarter ended June 30, 2020. Our full financial results for the fiscal quarter ended June 30, 2020 have not been finalized

Significant Near-Term Anticipated Clinical Milestones



* Subject to conducive external environment

89bio - Investment Highlights

FGF21 IS A HIGHLY PROMISING VALIDATED MECHANISM OF ACTION

- Broad metabolic effects **plus** direct impact on liver

BIO89-100 IS A DIFFERENTIATED FGF21 ANALOG

- GlycoPEGyated molecule with robust biologic effects, favorable dosing, and tolerability
- Compelling pre-clinical and early human data

PURSUING TWO PROMISING LARGE INDICATIONS

- NASH: Potential to be a mainstay of therapy
- SHTG: Quicker path to market with competitive differentiation

MAJOR ANTICIPATED MILESTONES

- NASH: Phase 1b/2a topline data late 3Q/early 4Q 2020; Expect Phase 2b/3 initiation in 1H21
- SHTG: Phase 2 initiation 3Q20, topline data 2H21

ESTABLISHED MANUFACTURING EXPERTISE AND IP PROTECTION BEYOND 2038

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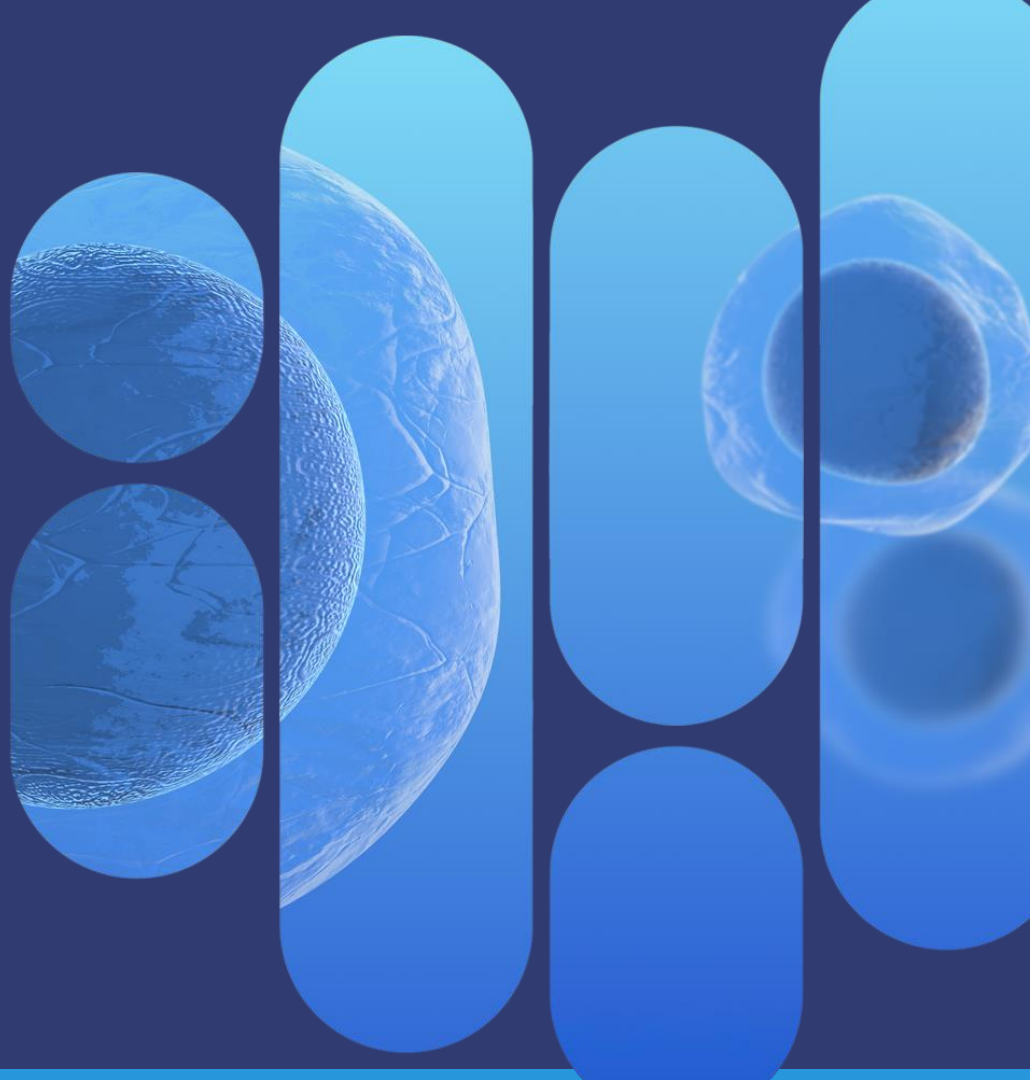
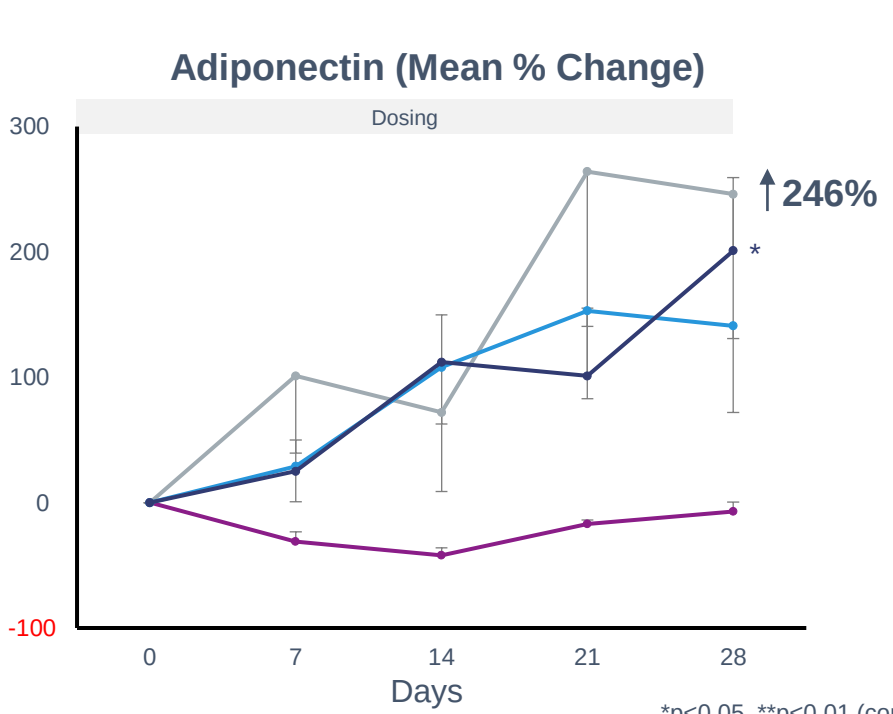
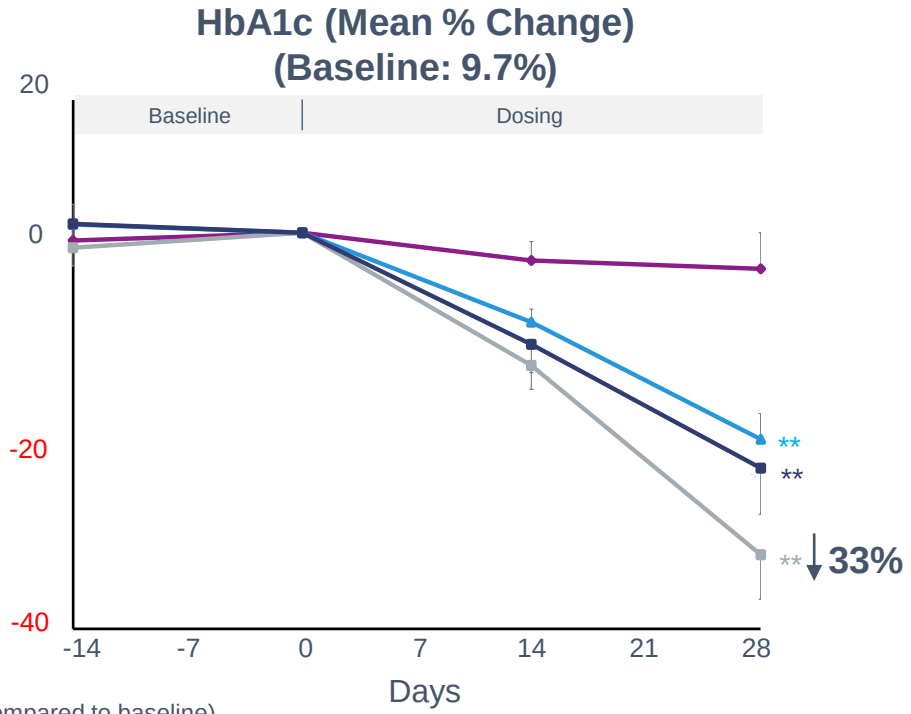
APPENDIX



Significant Changes in Adiponectin and HbA1c in Diabetic Obese Monkeys With Once Every 2 Weeks Dosing

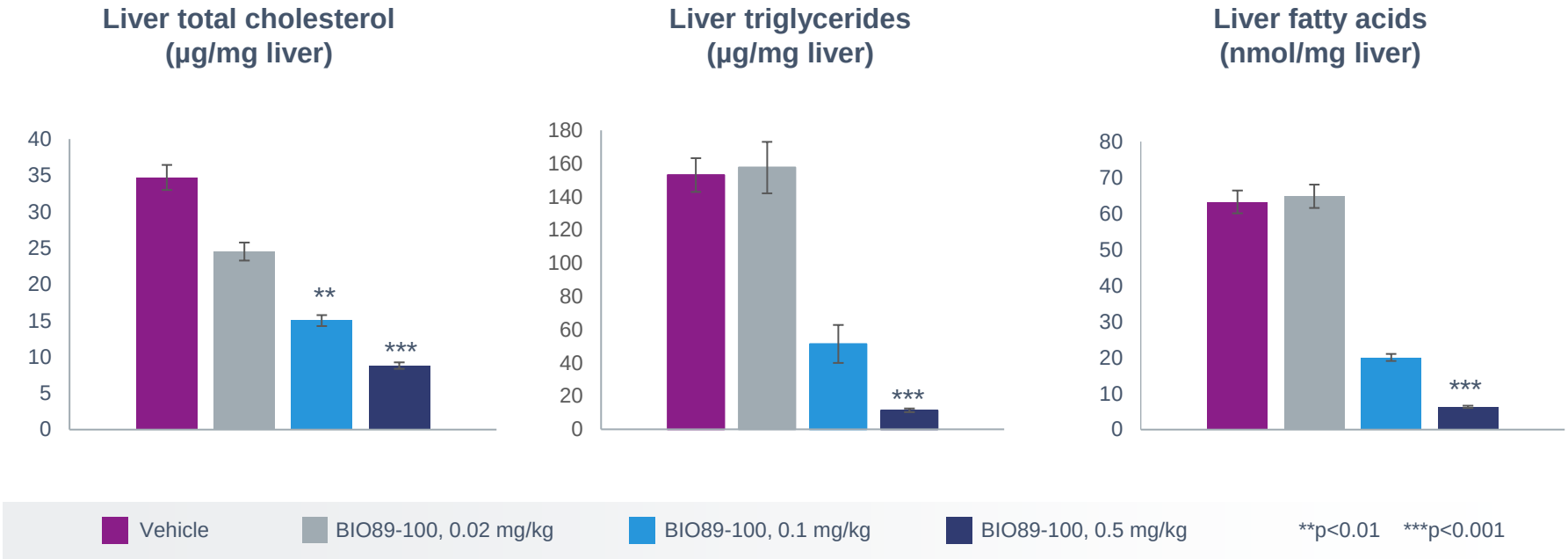




*p<0.05, **p<0.01 (compared to baseline)

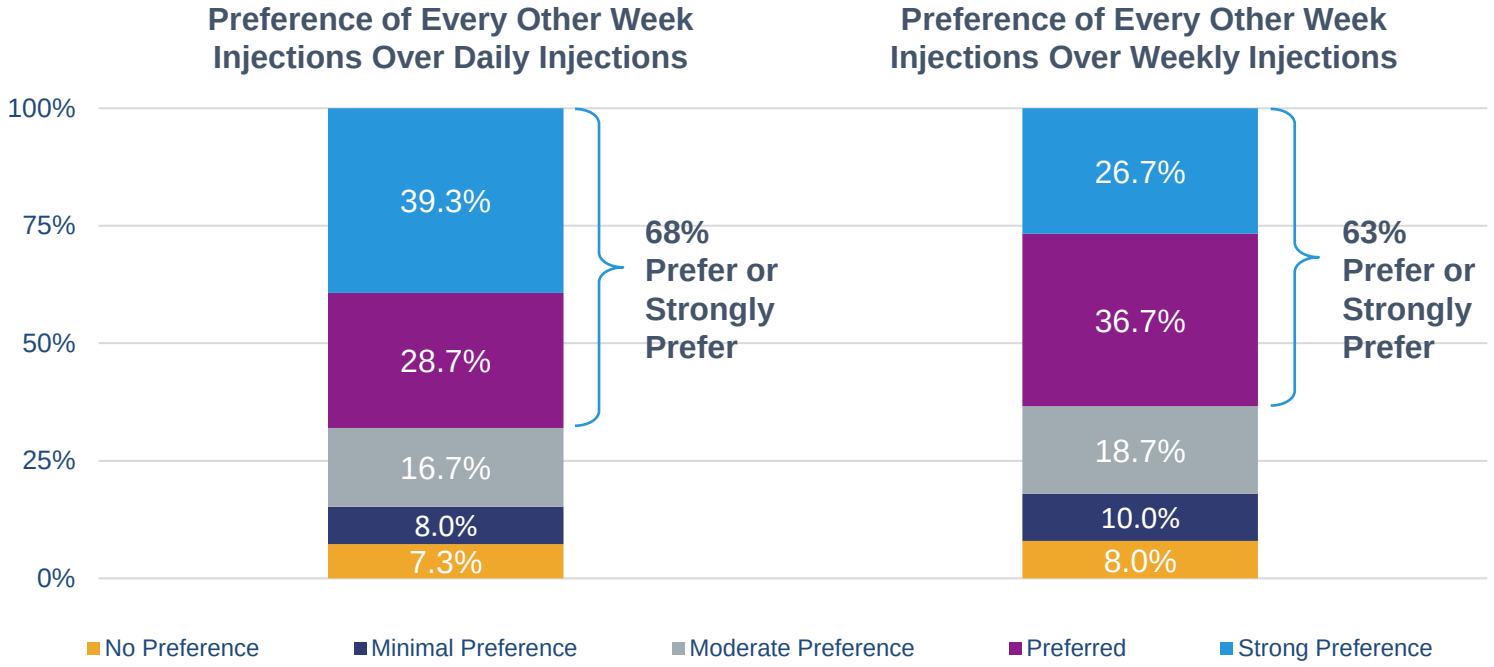
Vehicle weekly | BIO89-100, 1.0mg/kg, weekly | BIO89-100, 1.0mg/kg once every 2 weeks | BIO89-100, 2.0mg/kg once every 2 weeks

Reduction in Liver Cholesterol, Triglycerides and Fatty Acids with BIO89-100 in DIN Model



Note: Obeticholic acid, 25 mg/kg tested as active control – did not separate from control in this study; data presented are mean values

Dosing Preference Study: >60% of T2D Patients Prefer or Strongly Prefer Every Other Week Injections



Study conducted in obese Type 2 diabetics (n=150); dosing preferences for treatment of chronic liver condition
Q's 20 & 22: Please rate your level of preference of "dosing frequency" over "dosing frequency" for long-term use