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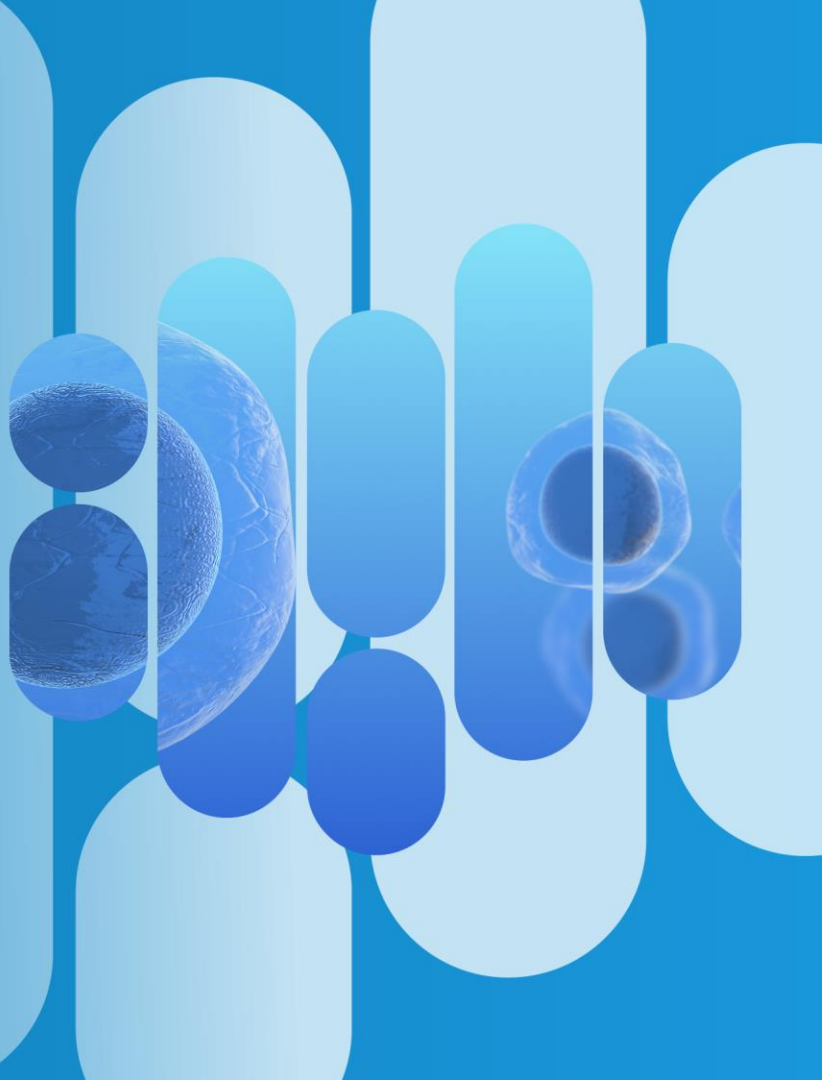
# BIO89-100
# Phase 1b/2a Topline Results

Nasdaq: ETNB

September 14, 2020



# Disclaimer

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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.

# BIO89-100: Promising Benefit-Risk Profile with Convenient Dosing

## EFFICACY RESULTS

- Significant benefits across key liver parameters observed across all dose groups
  - Up to **60%** reduction in liver fat versus baseline and up to **70%** versus placebo
  - Up to **44%** reduction in ALT (**35** U/L decrease in high ALT group)
  - Up to **27%** reduction in Pro-C3
- Significant responder rates— Up to **88%** and **71%** of subjects showed fat reduction ≥30% and ≥50%
- Significant improvements in lipids—triglycerides, non-HDL and LDL

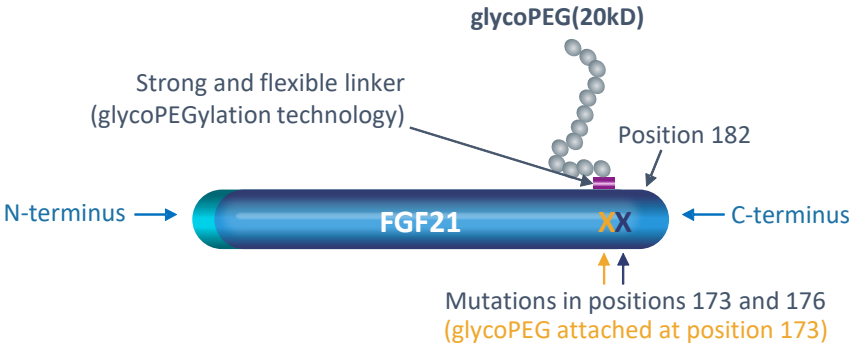
## SAFETY RESULTS & TOLERABILITY

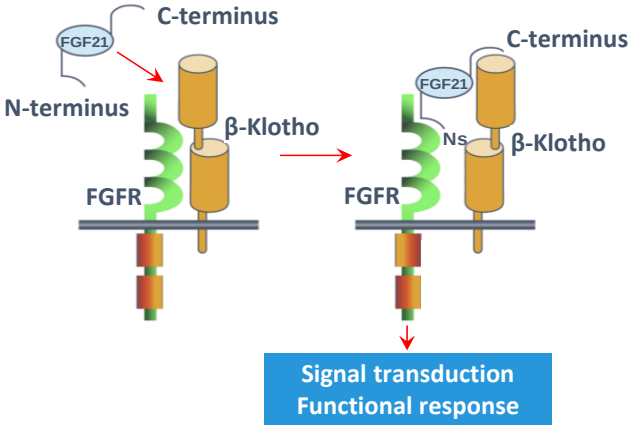
- Well tolerated at all doses with low incidence of adverse events that occurred in ≥ 10% of subjects
- Very low frequency of gastrointestinal events and similar profile to placebo
- No hypersensitivity or tremor observed: no adverse effects on heart rate or blood pressure

## POTENTIAL BEST-IN-CLASS DOSING REGIMEN

- Results seen with weekly and two-week dosing

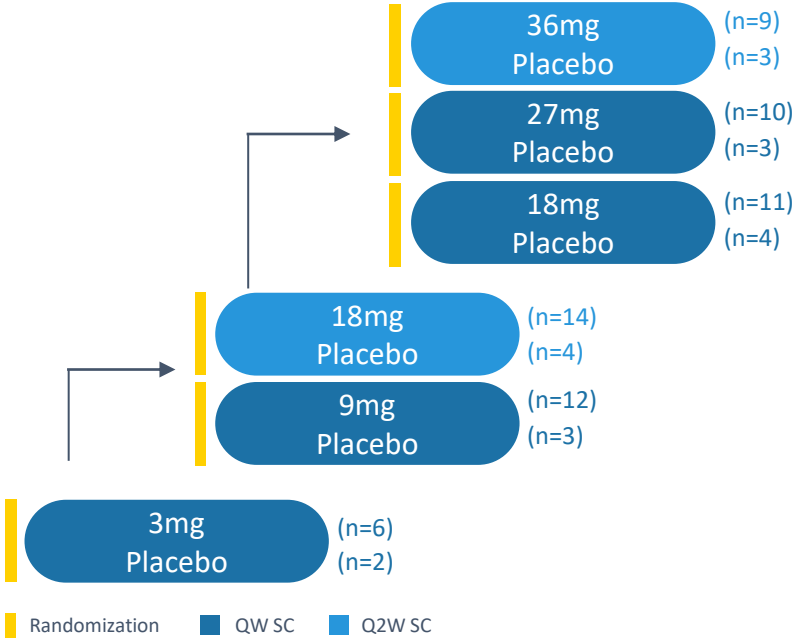
# BIO89-100 Is An FGF21 Optimally Engineered To Balance Potential for Efficacy and Long Dosing Interval




- FGF21 is an endogenous metabolic hormone that regulates energy expenditure and glucose and lipid metabolism
- Proprietary glycoPEGylation technology with site-specific mutations
- Long half-life of 55-100 hours vs. native FGF21 half-life of < 2 hours based on single ascending dose study
- Low nanomolar potency against FGF receptors 1c, 2c, 3c, similar to native FGF21; no activity against receptor 4 (leads to increased LDL)

# BIO89-100-002: Trial Design




- 12-week treatment duration + 4-week safety follow up
- Placebo (n=19) combined across cohorts for analysis

## KEY INCLUSION CRITERIA

- NASH* or phenotypic NASH (PNASH)#
- PDFF≥10%

*Subjects with biopsy-proven F1-3

#Central obesity plus T2DM or evidence of liver injury

## KEY TRIAL ENDPOINTS

- Safety, PK
- Relative changes in liver fat
- Serum lipids, liver and metabolic markers

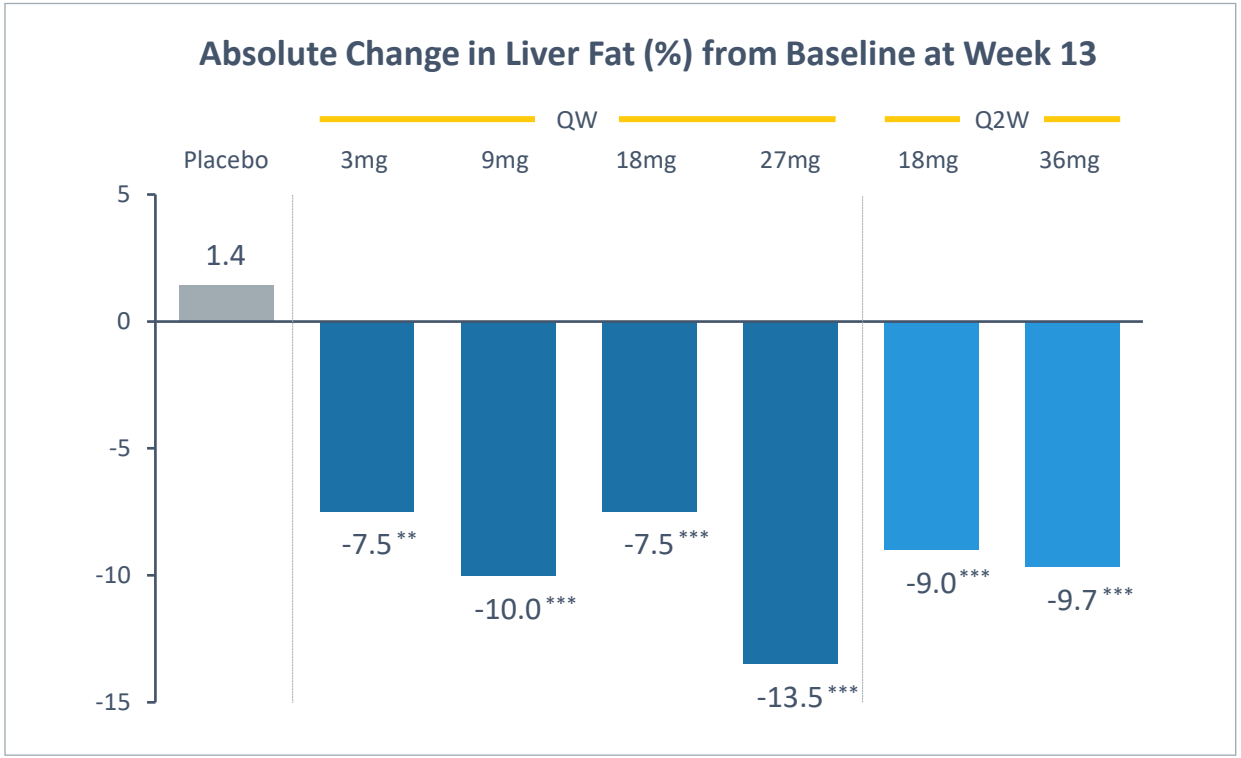
- Randomized, pharmacodynamic (PD) and safety analysis set n=81; Study completers n=71
- MRI analysis set n=75 (subjects with post-baseline MRI)

# Baseline Characteristics

| Parameter Mean or % | Placebo (n=19) | Pooled BIO89-100 (n=62) | 3mg QW (n=6) | 9mg QW (n=12) | 18mg QW (n=11) | 27mg QW (n=10) | 18mg Q2W (n=14) | 36mg Q2W (n=9) |
|---|---|---|---|---|---|---|---|---|
| Age (years) | 52.6 | 51.7 | 56.1 | 49.5 | 51.5 | 52.0 | 51.2 | 52.5 |
| Male/Female | 36.8% | 38.7% | 16.7% | 50% | 27.3% | 20% | 28.6% | 88.9% |
| Weight (kg) | 93.6 | 93.6 | 87.9 | 87.2 | 87.1 | 94.0 | 101.5 | 101.1 |
| BMI ($kg/m^2$) | 33.8 | 34.8 | 34.3 | 32.7 | 32.8 | 36.8 | 37.0 | 34.8 |
| Type 2 Diabetes | 63.2% | 40.3% | 83.3% | 33.3% | 63.6% | 40.0% | 21.4% | 22.2% |
| ALT (U/L) | 38.8 | 42.3 | 45.0 | 32.8 | 38.4 | 53.3 | 39.1 | 50.4 |
| AST (U/L) | 29.0 | 31.5 | 34.5 | 22.8 | 30.9 | 39.0 | 28.8 | 38.1 |
| MRI-PDFF (%) | 21.8 | 21.2 | 22.4 | 21.4 | 19.3 | 22.0 | 21.6 | 20.9 |

Baseline characteristics were similar between NASH (n=15) and PNASH (n=66) subjects

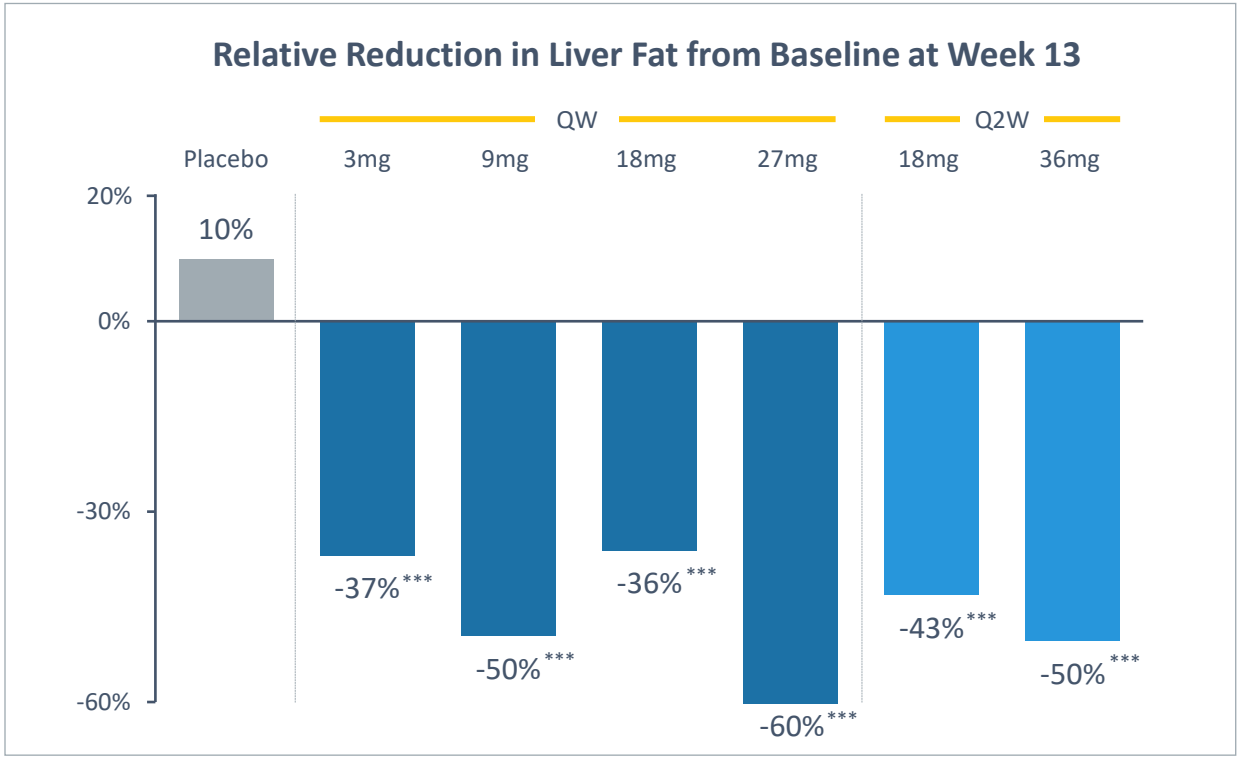
# BIO89-100 Significantly Reduces Liver Fat Across All Dose Groups




- Up to **43%** of subjects normalized their liver fat (<5%)
- BIO89-100 significantly reduced liver volume up to 15%
- Changes in liver fat were similar between NASH and PNASH subjects

MRI Analysis Set; MMRM LS Mean; * p<0.05; ** p<0.01; *** p<0.001 versus placebo

# BIO89-100 Reduces Liver Fat in Significant Percentage of Subjects

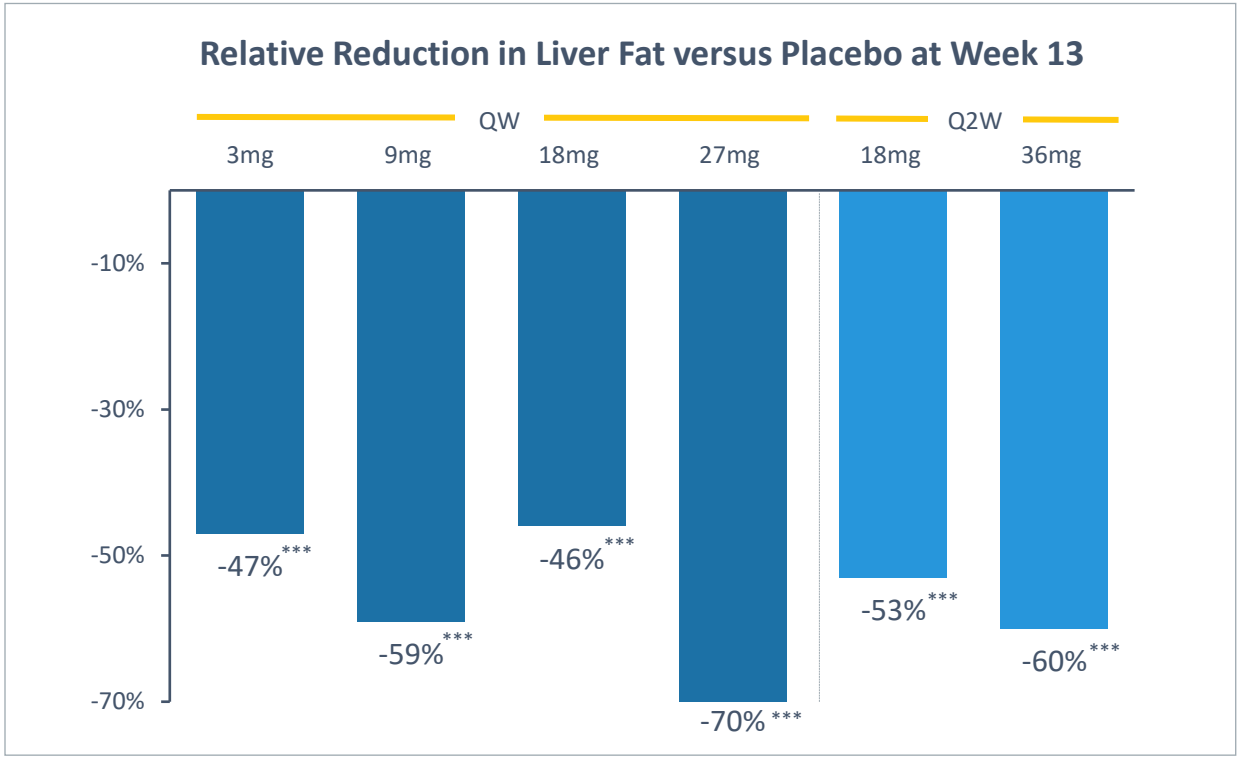



**Proportion of Subjects with ≥30% Relative Reduction in Liver Fat**

| | | |
|---|---|---|
| | Placebo | 0% |
| QW | 3mg | 60%** |
| QW | 9mg | 82%*** |
| QW | 18mg | 60%** |
| QW | 27mg | 86%*** |
| Q2W | 18mg | 69%** |
| Q2W | 36mg | 88%*** |

MRI Analysis Set; MMRM LS Mean; * p<0.05; ** p<0.01; *** p<0.001 versus placebo

# Majority of Subjects on BIO89-100 Achieved ≥50% Reduction in Liver Fat

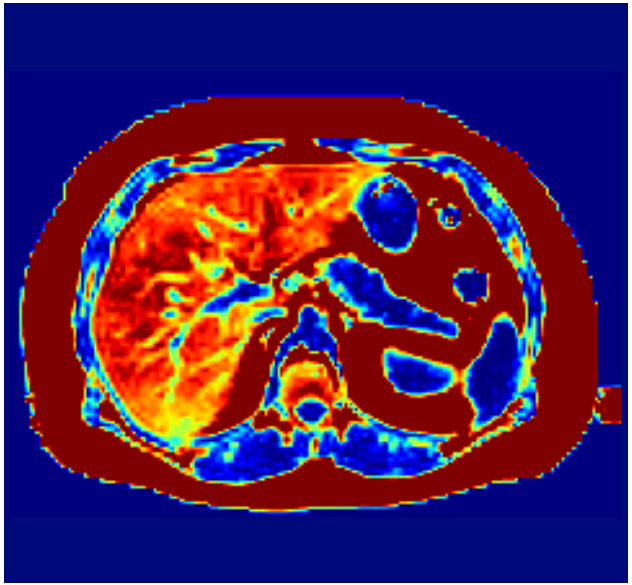


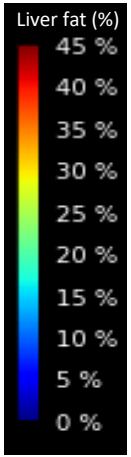

**Proportion of Subjects with ≥50% Relative Reduction in Liver Fat**

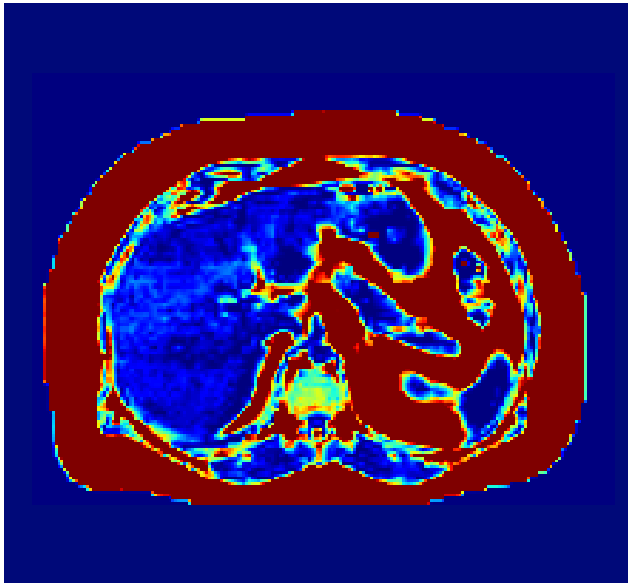
| | | |
|---|---|---|
| | Placebo | 0% |
| QW | 3mg | 20% |
| QW | 9mg | 54%** |
| QW | 18mg | 50%** |
| QW | 27mg | 71%*** |
| Q2W | 18mg | 39%** |
| Q2W | 36mg | 50%** |

MRI Analysis Set; MMRM LS Mean; * p<0.05; ** p<0.01; *** p<0.001 versus placebo

# BIO89-100 Showed Substantial Reduction in Liver Fat and Liver Volume After 12 Weeks of Treatment (Subject at 27mg QW)

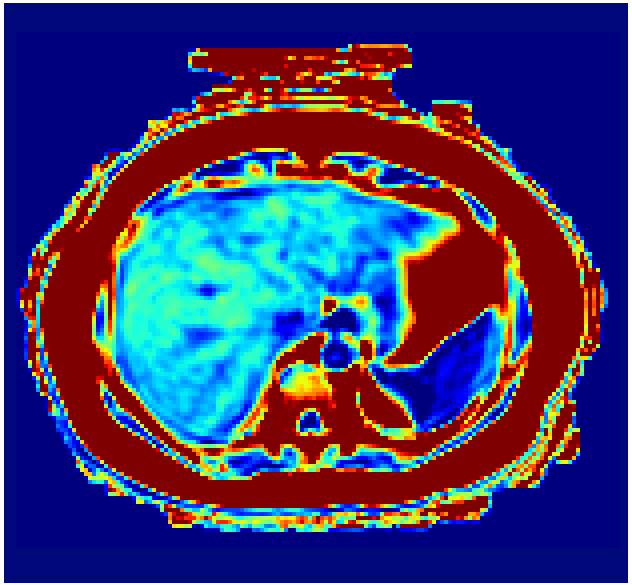


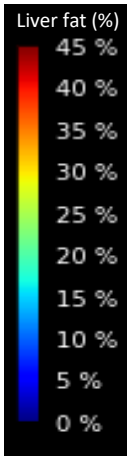


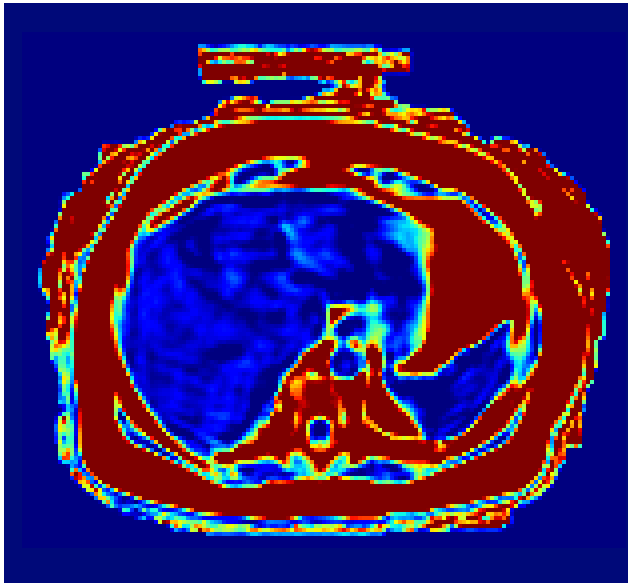



| Parameter | Baseline | Week 13 | % Change |
|---|---|---|---|
| Liver fat | 41.1% | 5.1% | -87.6% |
| Liver volume (L) | 2.2 | 1.4 | -35.4% |

# BIO89-100 Showed Substantial Reduction in Liver Fat and Liver Volume After 12 Weeks of Treatment (Subject at 18mg Q2W)



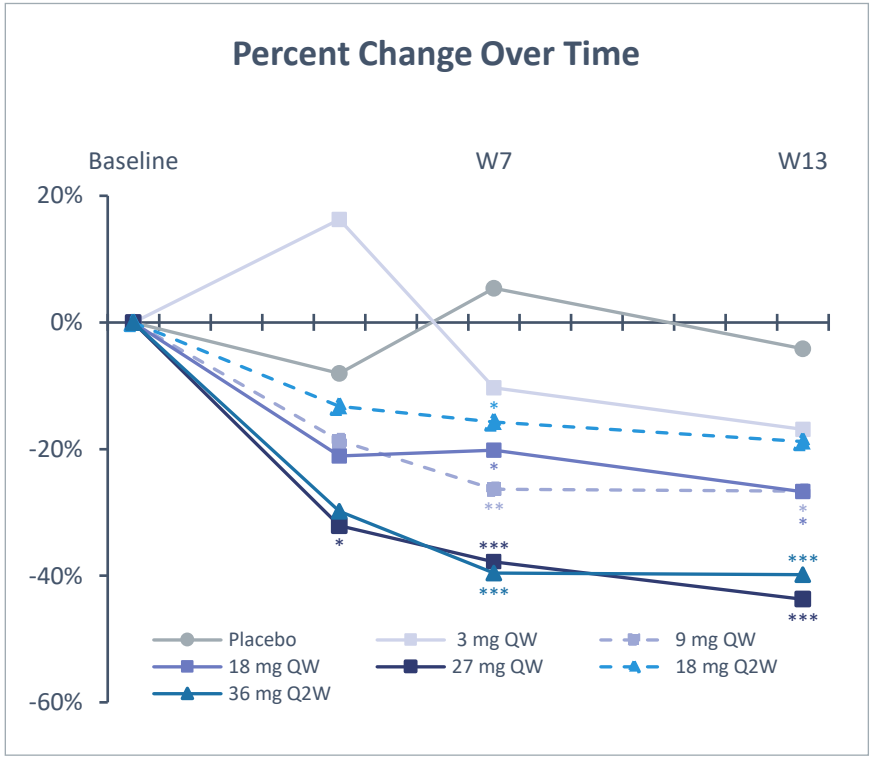


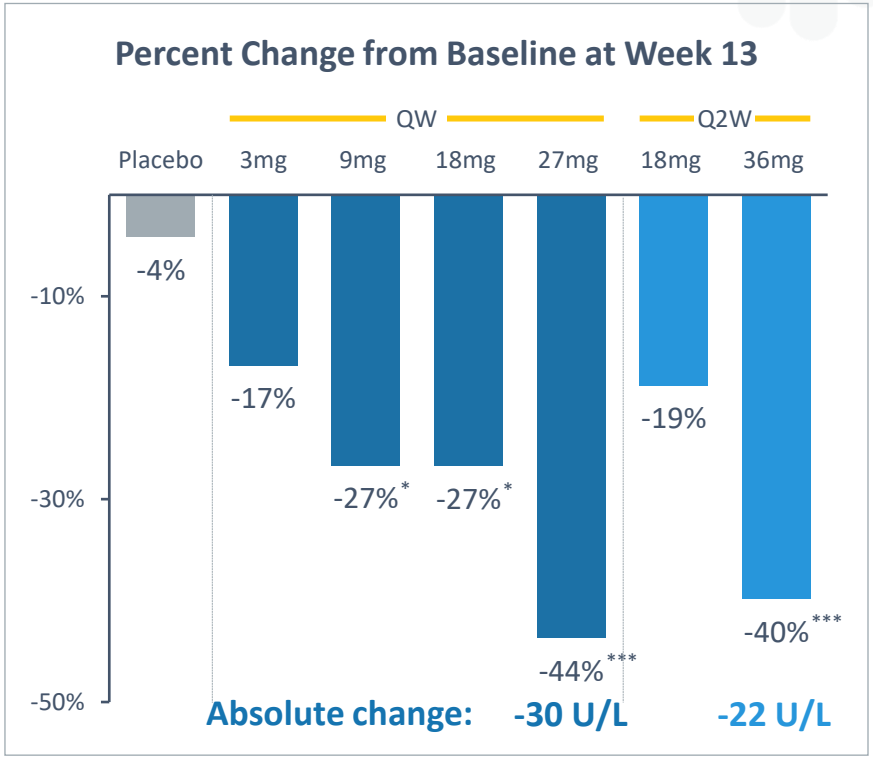



| Parameter | Baseline |
|---|---|
| Liver fat | 16.8% |
| Liver volume (L) | 1.2 |

| Week 13 | % Change |
|---|---|
| 3.5% | -79.2% |
| 0.9 | -27.7% |

# BIO89-100 Significantly Reduces ALT

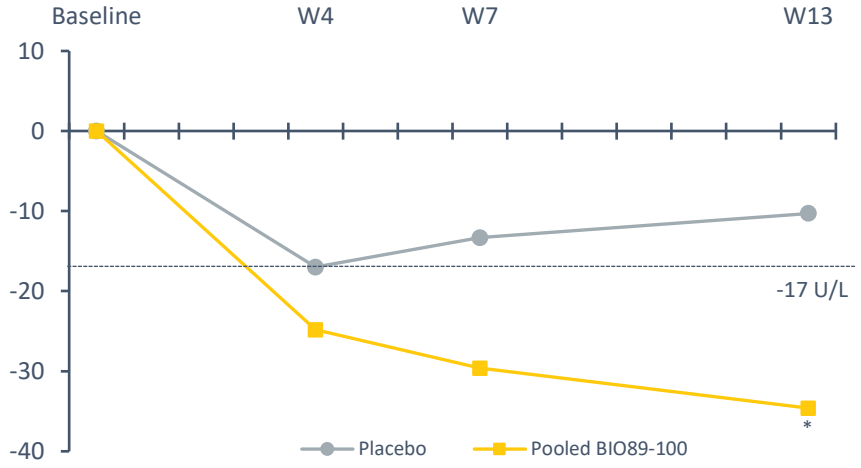



PD Analysis Set; Pre-planned sensitivity analysis; MMRM LS Mean; * p<0.05; ** p<0.01; *** p<0.001 versus placebo

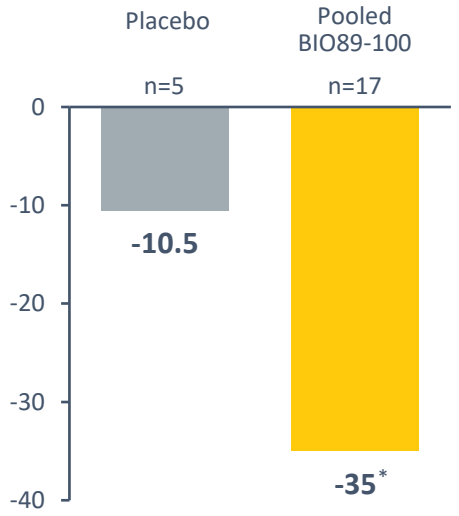
# BIO89-100 has Clinically Meaningful Impact on Subjects with High ALT

**Absolute Change in ALT (U/L)**
**(Baseline ALT > 45 U/L)**




Change in ALT of ≥17 U/L has been correlated with improvement in fibrosis

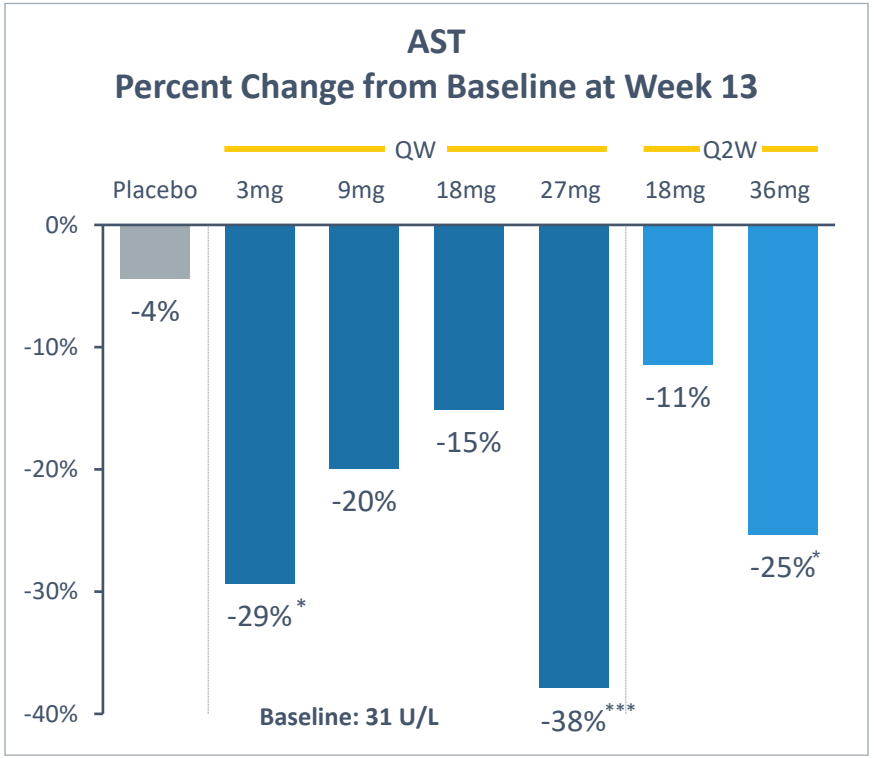
**Absolute Change in ALT at Week 13**
**(Baseline ALT > 45 U/L)**

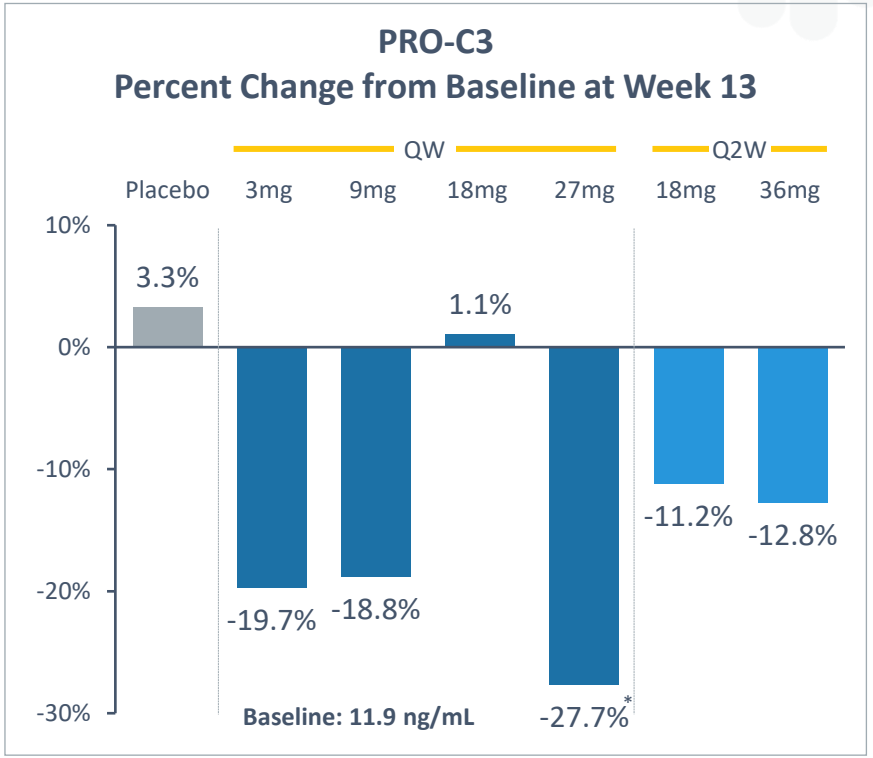





PD Analysis Set in baseline ALT > 45 U/L (placebo n=6, pooled BIO89-100 n=22); Pre-planned sensitivity analysis; MMRM LS Mean; * p<0.05; ** p<0.01; *** p<0.001 versus placebo

# BIO89-100 Significantly Improves Other Important Liver Biomarkers Despite Low Baseline Values

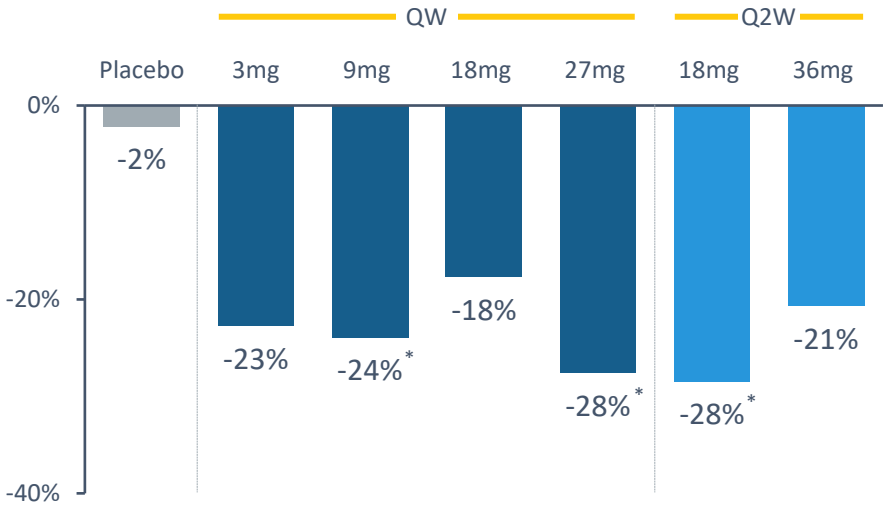


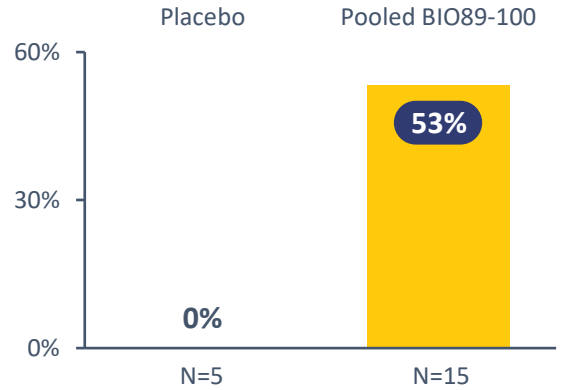

PD Analysis Set; Pre-planned sensitivity analysis; MMRM LS Mean; * p<0.05; ** p<0.01; *** p<0.001 versus placebo

# BIO89-100 Significantly Reduces Triglycerides with Greater Benefit Observed in Subjects with High Triglycerides

## Percentage Change from Baseline at Week 13 (All Subjects)




## TG Normalization# Rate at week 13 (Subgroup with Baseline TG ≥200 mg/dL)



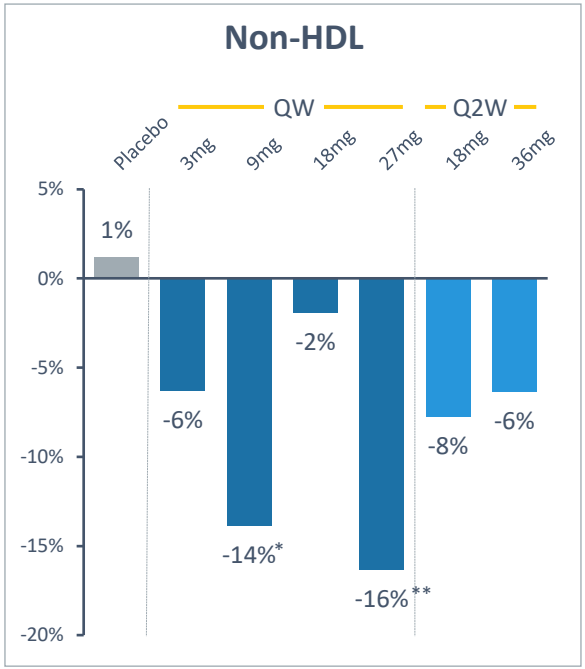

**Decrease from baseline in BIO89-100 treated subgroup with baseline TG ≥200 mg/dL**

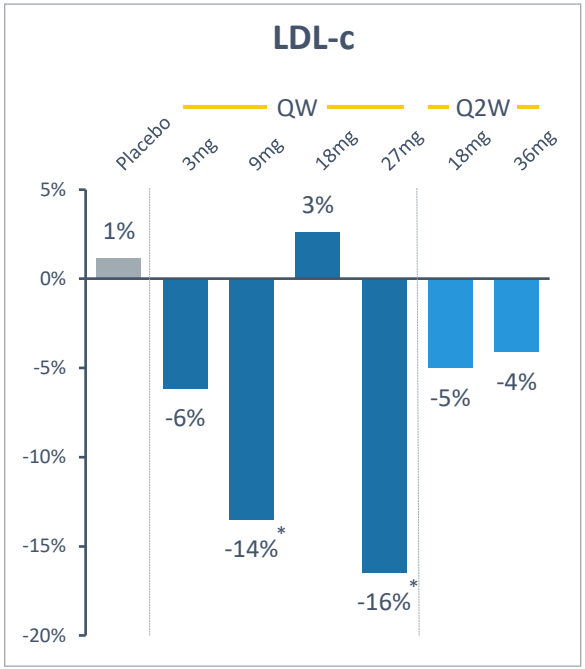
- **TG: 33%-49%**
- **Non-HDL: 8%-29%**

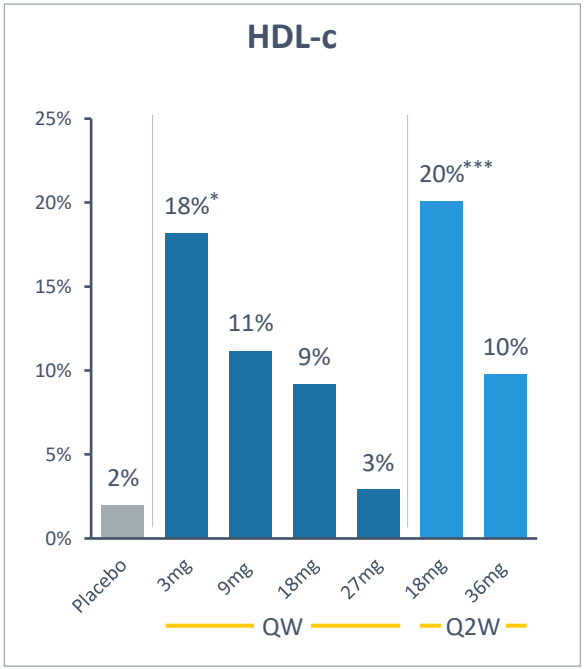
PD Analysis Set; MMRM LS Mean; * p<0.05; ** p<0.01; *** p<0.001 versus placebo; # TG <150 mg/dL

# BIO89-100 Significantly Improves Key Lipid Markers

## Percentage Change from Baseline At Week 13




PD Analysis Set; MMRM LS Mean; * p<0.05; ** p<0.01; *** p<0.001 versus placebo

# BIO89-100 Effect on Glycemic Control

## Change From Baseline At Week 13

| | Placebo | 3mg QW | 9mg QW | 18mg QW | 27mg QW | 18mg Q2W | 36mg Q2W |
|---|---|---|---|---|---|---|---|
| **Adiponectin** Percentage Change | -4.3% | 37.7%* | 25.5%* | 29.1%* | 60.9%*** | 23.1%* | 24.1% |
| **Insulin&** Percentage Change | 10.0% | -8.5% | -9.4% | -22.5% | -6.9% | -39.7% | -34.5% |
| **HbA1c (%)** Absolute Change | <0.1 | 0.6 | 0.1 | 0.1 | -0.3 | -0.1 | 0.5 |

No meaningful changes in weight were observed, except in the 27 mg QW cohort that saw a significant percentage reduction in weight relative to placebo

PD Analysis Set; MMRM LS Mean; * p<0.05; ** p<0.01; *** p<0.001 versus placebo &Week7 (last measurement)

# Safety Overview

| Treatment Emergent Adverse Event (TEAE) | Placebo (n=18) | 3mg QW (n=7) | 9mg QW (n=12) | 18mg QW (n=11) | 27mg QW (n=10) | 18mg Q2W (n=14) | 36mg Q2W (n=9) |
|---|---|---|---|---|---|---|---|
| **TEAE Leading to Death** | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **TEAE Leading to Discontinuation** | 0 | 0 | 0 | 0 | 1[a] | 1[b] | 0 |
| **Serious Adverse Event**<br>COVID 19 [Not Drug Related] | 0 | 0 | 0 | 0 | 0 | 1 | 1 |

[a] skin rash; [b] hyperglycemia [Not Drug Related]

Safety Analysis Set; one placebo subject received one dose of BIO89-100 3mg and is summarized in 3mg QW group

# Treatment Emergent Adverse Event in ≥ 10% of Pooled BIO89-100 Group

| Preferred Term n (%) | Placebo (n=18) | Pooled BIO89-100 (n=63) | 3mg QW (n=7) | 9mg QW (n=12) | 18mg QW (n=11) | 27mg QW (n=10) | 18mg Q2W (n=14) | 36mg Q2W (n=9) |
|---|---|---|---|---|---|---|---|---|
| Increased Appetite | 0 | 15.9% | 4 | 2 | 0 | 2 | 2 | 0 |
| Diarrhea | 22.2% | 12.7% | 1 | 2 | 0 | 2 | 1 | 2 |
| Headache | 5.6% | 11.1% | 1 | 0 | 0 | 2 | 2 | 2 |

- GI adverse events were similar to placebo; 7.9% of subjects reported nausea in pooled BIO89-100 vs. 16.7% in placebo
- No hypersensitivity AE reported; few mild injection site reaction events reported
- No tremor reported; no adverse effects on blood pressure or heart rate
- Only treatment related AE reported in ≥10% of pooled BIO89-100 group was mild increased appetite

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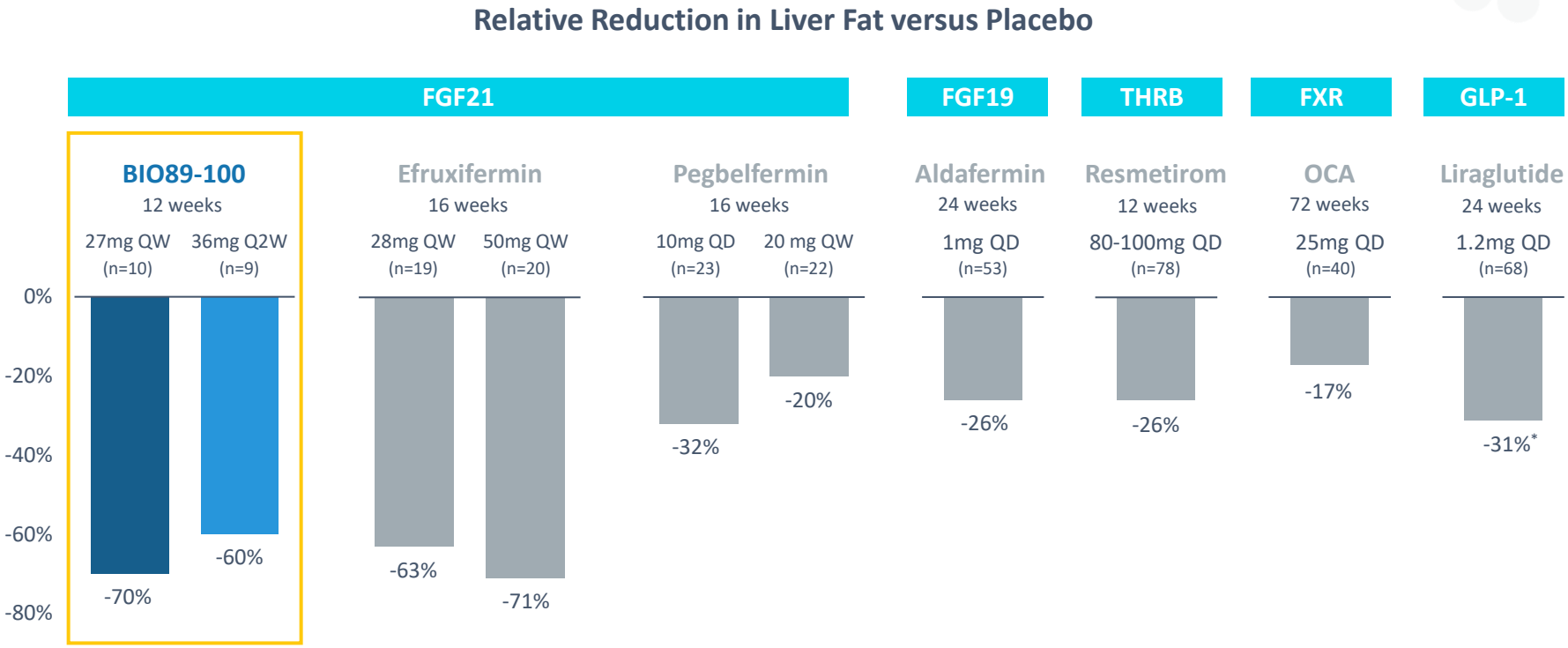
Safety Analysis Set; one placebo subject received one dose of BIO89-100 3mg and is summarized in 3mg QW group

# BIO89-100 Has a Favorable Clinical Profile Relative to Leading Classes in Development for NASH




Note: All data regarding third-party studies on this slide are based on third-party trials, some of which are in different stages of development. Conclusions on this slide are not based in head-to-head results. Efficacy shown here may change in future clinical trials
*Not placebo-controlled

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# BIO89-100 – Demonstrating the Promise of FGF21 in NASH

- ✓ **SIGNIFICANT LIVER FAT REDUCTION**
- ✓ **IMPRESSIVE RESPONDER RATES AT HIGH THRESHOLD (≥50% FAT REDUCTION)**
- ✓ **LARGE, CLINICALLY MEANINGFUL CHANGES IN ALT**
- ✓ **ROBUST LIPID CHANGES – TRIGLYCERIDES, NON-HDL, LDL**
- ✓ **FAVORABLE SAFETY AND TOLERABILITY PROFILE WITH LIMITED GI EVENTS**
- ✓ **UNIQUE DOSING REGIMEN – FIRST EVERY TWO-WEEK FGF21 ANALOG**

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# Powerful Science
# Meaningful Medicines
# Changing Lives

Nasdaq: ETNB

September 14, 2020