# 89bio

# Pegozafermin (BIO89-100) Phase 1b/2a NASH Histology Cohort Topline Results

Nasdaq: ETNB

January 24, 2022

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## Pegozafermin – Growing Evidence of Strong Profile in Non-Alcoholic Steatohepatitis (NASH)

✓ Previously reported data from the phase 1b/2a study results showed:

- Significant effect on liver and cardio-metabolic parameters
- Low incidence of treatment-related adverse events (AEs)
- Potential for every two-week dosing

Robust data from histology cohort (cohort 7) consistent with previous findings and validate pegozafermin's effect on histology

- Meaningful changes on key histology endpoints NAS >2pt., NASH Resolution, & Fibrosis
- Significant changes on non-invasive tests (NITs), glycemic control (HbA1c), lipid markers and body weight
- Favorable safety and tolerability profile

#### Results from phase 2b ENLIVEN study in >200 NASH F2/F3 patients expected in 1st half 2023



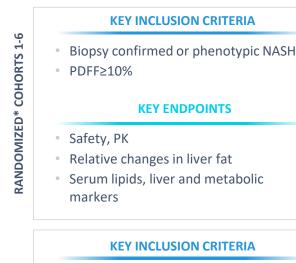
# Phase 1b/2a NASH Trial Design – Randomized and Open-Label Cohorts



Cohort 7: 19/20 (95%) patients completed treatment and had end-of-treatment biopsies; 1 patient discontinued treatment due to withdrawal of consent

Biopsies were centrally read at baseline and end of treatment by a single pathologist MRI dataset: 18 patients with Week 20 MRI; PD data: 19 subjects with Week 20 data





- F2-F3 NASH; NAS ≥4
- MRI-PDFF≥8%

**OPEN-LABEL COHORT 7** 

#### **KEY ENDPOINTS**

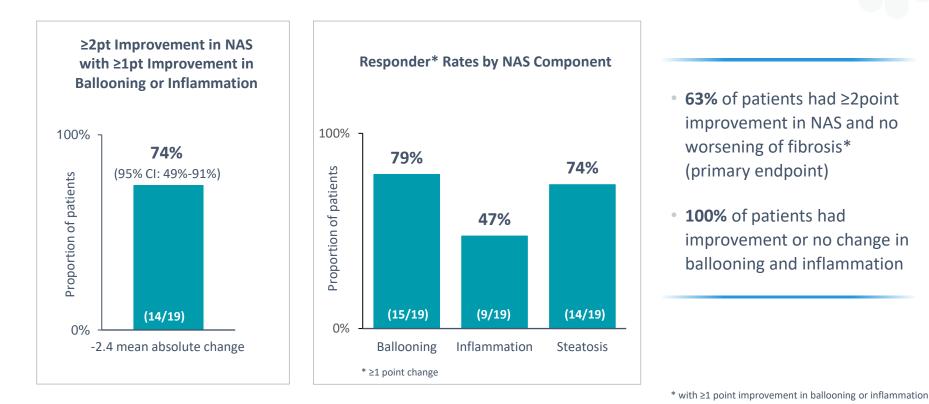
- ≥2 point improvement in NAS
- NASH Resolution
- Fibrosis Improvement
- Safety/tolerability

# **Baseline Characteristics**

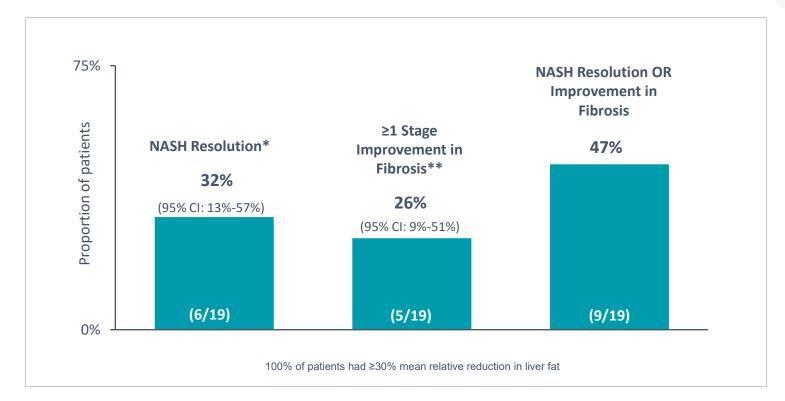
<b>Parameter</b> Mean or %	<b>Cohort 7</b> (n=20)	<b>Cohorts 1-6</b> (n=81)
Age (years)	58.4	51.9
Female	75.0%	61.7%
Weight (kg)	104.6	93.6
BMI (kg/m²)	37.0	34.6
Type 2 Diabetes	85.0%	45.7%
% F2 / % F3	35% / 65%	NA
NAS	5.3	NA
MRI-PDFF (%)	21.1	21.3
ALT (U/L)	47.1	41.5
AST (U/L)	36.1	31.0
Pro-C3 (ng/mL)	19.3	11.9
VCTE (kPA)	14.3	7.3
Triglycerides (mg/dL)	170.0	174.3



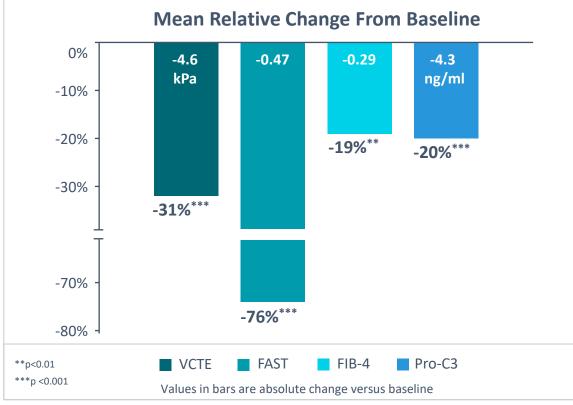
# Pegozafermin Robustly Improved NAFLD Activity Score (NAS) and All Components of NAS

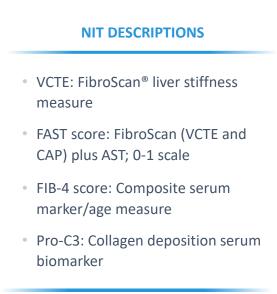


### Pegozafermin Demonstrated Clinically Meaningful Changes on Key Histological Efficacy Endpoints



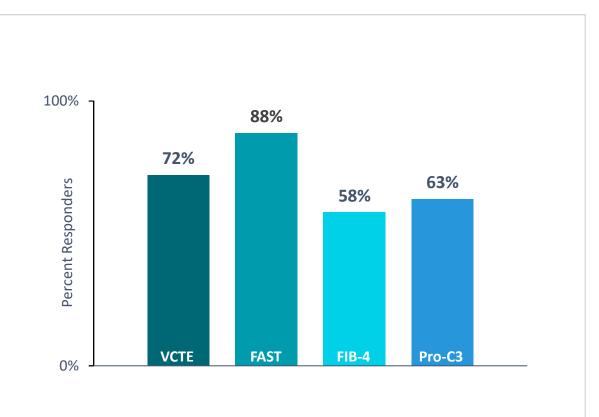
# Pegozafermin Substantially Improved Scores Across Non-Invasive Tests (NITs) Correlated with Advanced Fibrosis





p value for change from baseline based on MMRM analysis
 VCTE and FAST exclude one outlier with poor quality measurement

#### Pegozafermin had High Percentages of Responders Based on Clinically Relevant Thresholds for NITs

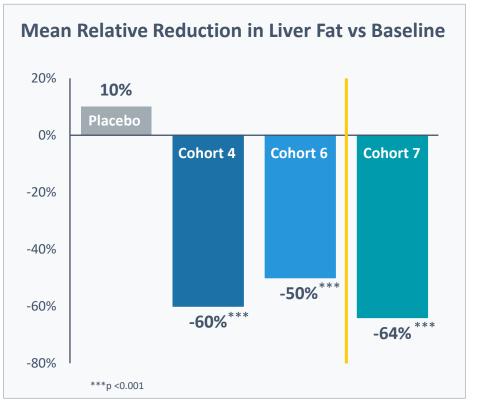


#### **CLINICALLY RELEVANT THRESHOLDS**

- VCTE: >20% reduction correlates with fibrosis improvement
- FAST score: Score ≤ 0.35 predicts
  Fibrosis Stage F0/F1 and NAS <4</li>
- FIB-4 score: Score <1.3 predicts</li>
  Fibrosis Stage FO/F1
- Pro-C3: >15% reduction correlates with fibrosis improvement

Tapper EB, *Am J Gastroenterol*, 2016 Newsome PN, *Lancet Gastroenterol Hepatol*, 2020 Kanwal F, *Gastroenterology*, 2021 Luo Y, *Scientific Reports*, 2018

## Pegozafermin: Robust Liver Fat Reduction with High Responder Rates Consistent with Prior Cohorts



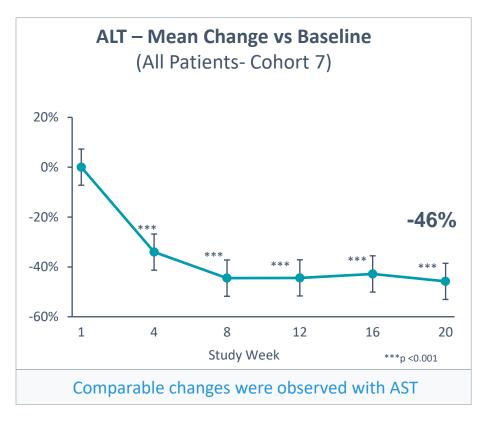
	≥30% Relative Reduction in Liver Fat	≥50% Relative Reduction in Liver Fat
Cohort 7	100%	78%
Cohort 4	86%	71%
Cohort 6	88%	50%

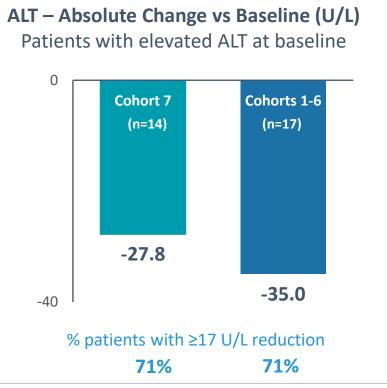
Cohort 7: 27mg QW data at 20 weeks, Cohort 4: 27mg QW data at 13 weeks, Cohort 6: 36mg Q2W at 13 weeks



C7: MRI Analysis Set; p value for change from baseline based on MMRM analysis; Data from week 20 C4 and C6: MRI Analysis Set; MMRM LS Mean; p value vs placebo; Data from week 13

#### Pegozafermin: Clinically Significant Reduction in ALT Consistent with Prior Cohorts





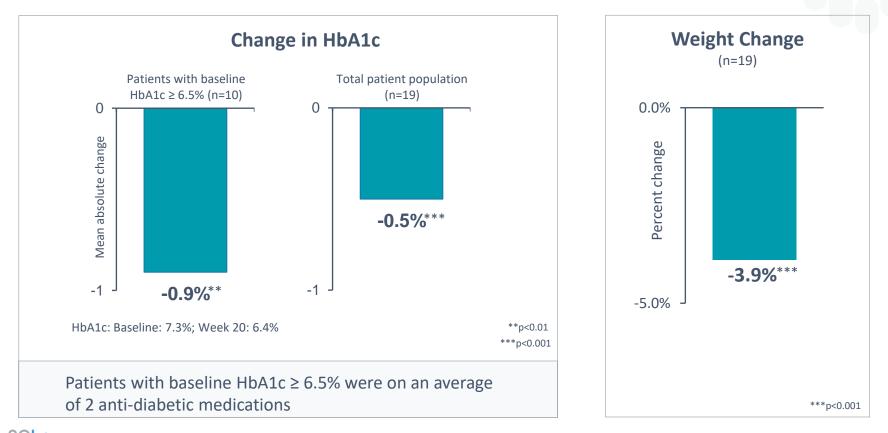
Loomba R, Hepatology, 2020

C7: elevated ALT ≥30 U/L for women and ≥40 U/L for men; Week 20

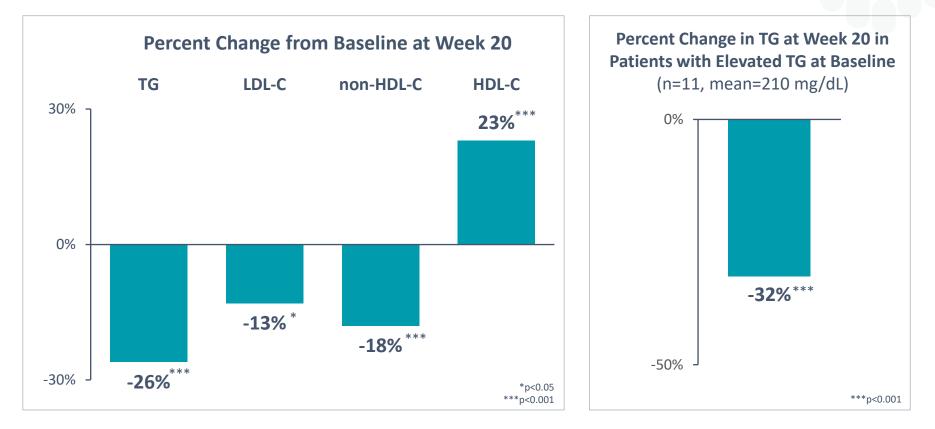
C1-6: PD Analysis Set in baseline ALT > 45 U/L; Pre planned sensitivity analysis; \$10\$ MMRM LS Mean at Week 13

p value for change from baseline based on MMRM analysis

# Pegozafermin Demonstrated Clinically Meaningful Improvement on HbA1c and Notable Body Weight Reduction



## Pegozafermin Demonstrated Clinically Meaningful Improvements in Lipid Parameters



89bio p value for change from baseline based on MMRM analysis

# Pegozafermin Improves Many Markers of Liver Health and Co-Morbidities Associated with NASH





Cohort 7: 27mg QW data at 20 weeks, Cohort 4: 27mg QW data at 13 weeks

# Pegozafermin Was Well Tolerated Across Doses

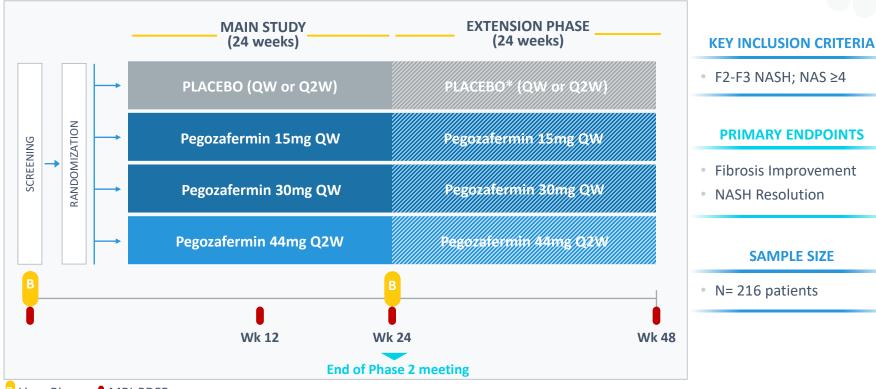
Low Incidence of Treatment-Related AEs in ≥ 10% of Pooled Pegozafermin Group

Preferred Term n (%)	Placebo (n=18)	Cohort 1 3mg QW (n=7)	Cohort 2 9mg QW (n=12)	Cohort 3 18mg QW (n=11)	Cohort 4 27mg QW (n=10)	Cohort 5 18mg Q2W (n=14)	Cohort 6 36mg Q2W (n=9)	Cohort 7 27mg QW (n=20)	Pooled pegoza (n=83)
Increased Appetite	0%	57%	17%	0%	20%	14%	0%	5%	13%
Diarrhea	11%	0%	8%	0%	20%	7%	22%	25%	13%
Nausea	11%	0%	0%	9%	0%	14%	0%	35%	12%

• Pegozafermin shows favorable safety and tolerability profile with no treatment related serious adverse events

- No tremors or hypersensitivity AEs reported; few mild injection site reaction events reported
- In cohort 7, other treatment related AEs observed in ≥10% of patients were vomiting (10%), injection site bruising (10%), injection site erythema (10%) and decreased appetite (10%); no events grade 3+ reported

# Next Step: Phase 2b (ENLIVEN) NASH Trial Design



# **PRIMARY ENDPOINTS**

- **Fibrosis Improvement**
- NASH Resolution

#### SAMPLE SIZE



<sup>B</sup> Liver Biopsy **B** MRI-PDFF

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# Cohort 7 Results Confirm and Extend the Growing Evidence of Pegozafermin's Potential in NASH

✓ Robust effects across key histology endpoints

✓ Impressive results in non-invasive clinically relevant measures of overall liver health

✓ Significant changes in glycemic control, lipids and body weight address key underlying drivers of NASH

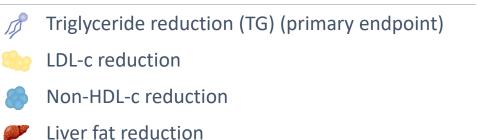
✓ Favorable safety and tolerability profile



Phase 1b/2a Study Results Provide High Level of Confidence in Pegozafermin's Benefits in Severe Hypertriglyceridemia (SHTG)

#### **KEY PARAMETERS OF INTEREST IN SHTG**

#### **PEGOZAFERMIN RESULTS**





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#### **ENTRIGUE Study**

- 8-week study of multiple doses of pegozafermin in patients with baseline TG ≥500 mg/dL
- Primary endpoint is % change in TG from baseline; Key secondary endpoints include other lipid and metabolic parameters and liver fat (MRI-PDFF)
- Results expected 1H22



#### Rohit Loomba, MD, MHSc Director, NAFLD Research Center Professor of Medicine, Director of Hepatology University of California at San Diego

#### **Investment Highlights**

#### Pegozafermin has potential to be a leading drug for liver and cardio-metabolic disorders

 Validated with compelling profile: strong efficacy including histology in NASH, favorable safety/tolerability, and potential best-in-class dosing

#### Pursuing two promising large indications with competitively differentiated profile

- NASH: Potential backbone treatment addressing multiple facets of NASH
- SHTG: Potential to treat TGs and metabolic dysregulation with quicker path to market

#### **Program status/milestones**

- SHTG: Phase 2 ENTRIGUE trial topline data in 1H22
- NASH: Phase 2b ENLIVEN trial topline data in 1H23

#### Strong capital position - \$150.7M\* in pro-forma cash (DEC 31, 2021)





