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Pegozafermin Phase 2b (ENLIVEN) Topline Results in Nonalcoholic Steatohepatitis (NASH)

Nasdaq: ETNB

Powerful Science
Meaningful Medicines
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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, or intentions relating to product candidates, potential market opportunities, patient acceptance of pegozafermin, estimates of market size, the potential clinical benefit, effect on the histology and safety and tolerability profile of pegozafermin (formerly BIO89-100), the clinical potential of pegozafermin, potential indications for pegozafermin, the anticipated dosing regimen for pegozafermin, if approved, the timing of regulatory meetings or discussions, 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 under the caption “Risk Factors” and elsewhere in such report and in other subsequent disclosure documents filed with the U.S. Securities and Exchange Commission.

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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.

Pegozafermin – A Potentially Differentiated and Foundational NASH Drug

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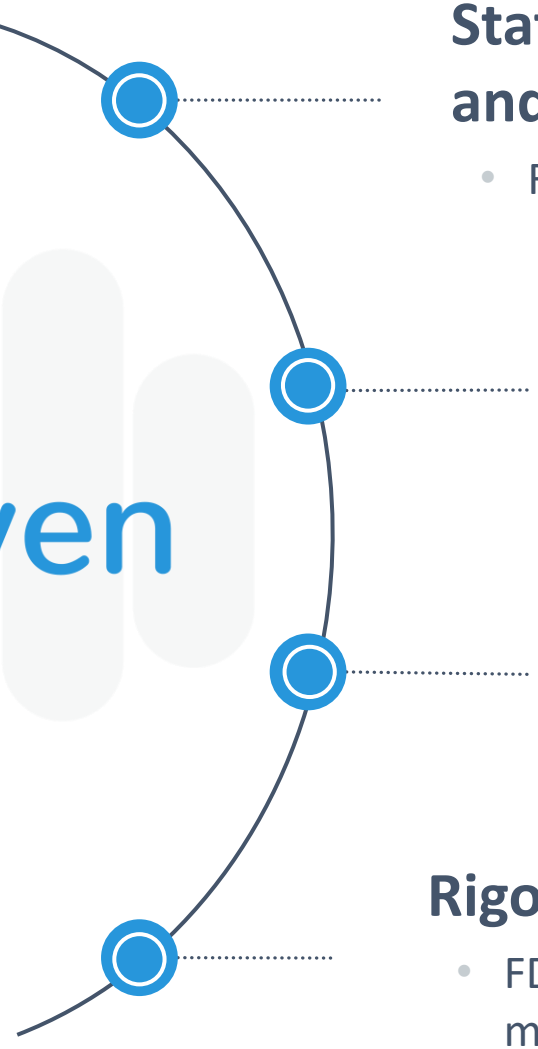


Statistically Significant Results on Fibrosis Improvement and NASH Resolution

- Fibrosis improvement – 3.5x and NASH resolution – 12-14x placebo rate

Significant Results with Weekly and Every-Two-Week Dosing on Both Endpoints

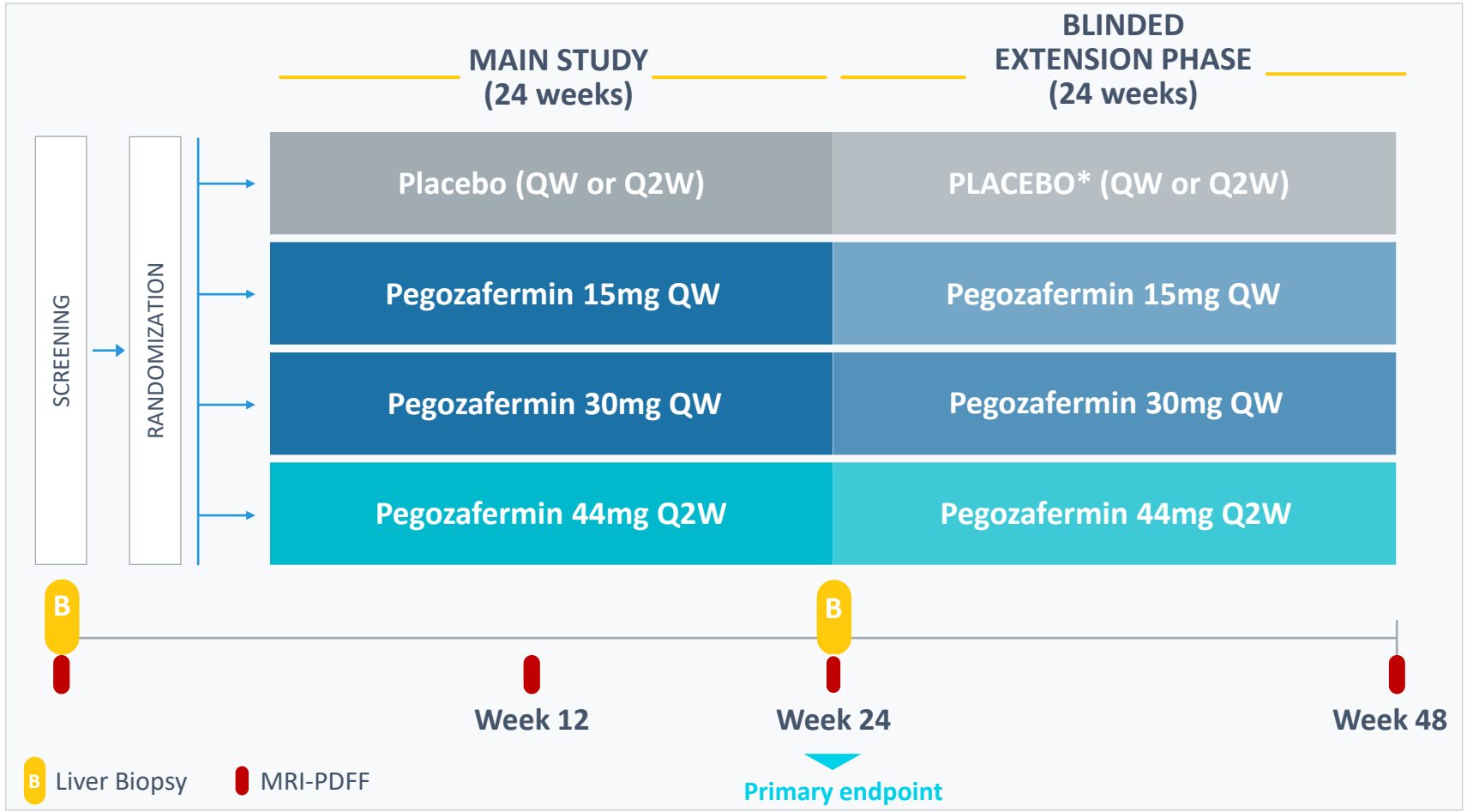
- Only drug in the category pursuing this optionality

Favorable Safety and Tolerability Profile

Rigorous Trial Increases Our Confidence in Phase 3

- FDA guidance on endpoints and analysis; Rigorous biopsy reading methods; Large study

ENLIVEN Trial Design



PRIMARY ANALYSIS POPULATION

- F2-F3 NASH; NAS ≥4

PRIMARY ENDPOINTS

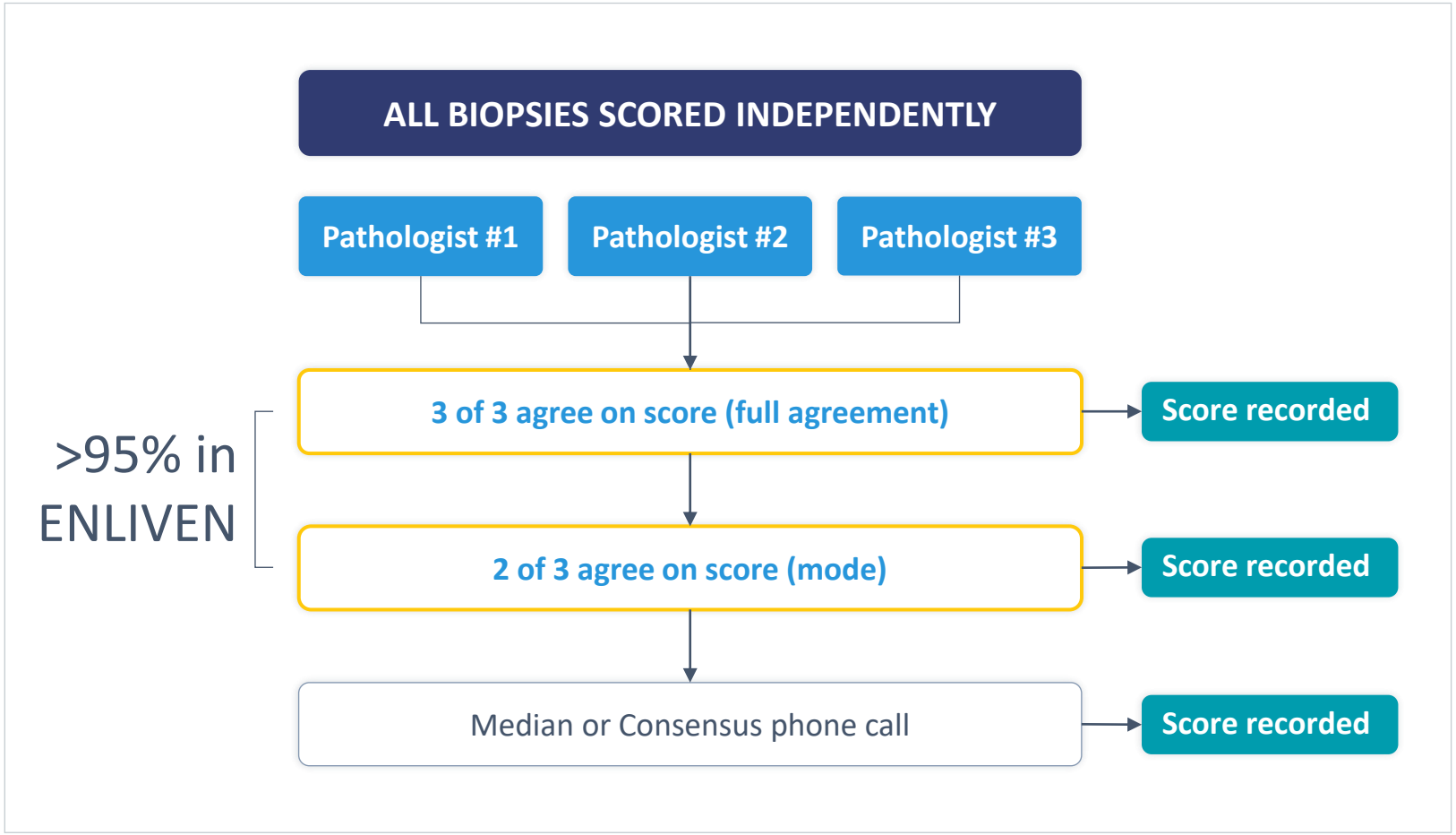
- ≥1-stage fibrosis improvement with no worsening of NASH[1]
- NASH resolution with no worsening of fibrosis[2]

KEY SECONDARY EFFICACY ENDPOINTS

- ≥2-point change in NAS with no worsening of fibrosis
- Non-invasive liver markers (liver fat, liver injury, fibrosis markers)

1 Improvement in liver fibrosis by ≥1 stage and no worsening of steatohepatitis defined as no increase in NAS for ballooning, inflammation, or steatosis (FDA draft guidance).
2 Resolution of steatohepatitis is defined as absent fatty liver disease or isolated or simple steatosis without steatohepatitis and a NAS score of 0-1 for inflammation, 0 for ballooning and any value for steatosis (FDA draft guidance).
*Some placebo patients were re-randomized in the extension phase to receive pegozafermin.
NAS, NAFLD Activity Score; MRI-PDFF, Magnetic resonance imaging-estimated proton density fat fraction; QW: Every week; Q2W: Every 2 weeks

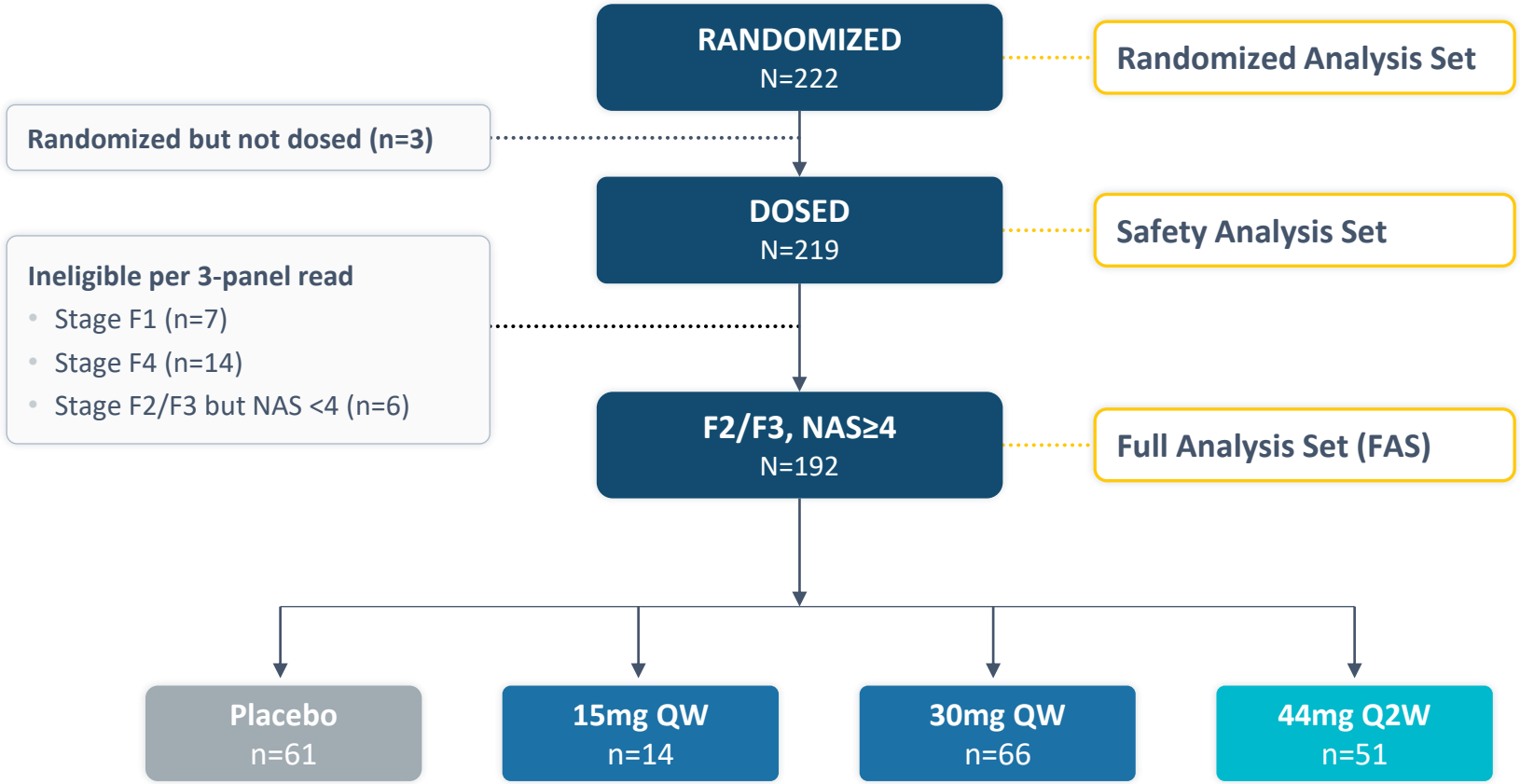
Rigorous Biopsy Reading Method Designed to Identify Drug Effect



- All biopsies scored independently by three pathologists (on 4 components of NASH-CRN criteria)
- Pathologists underwent protocol-specific harmonization training before and during trial
- Pathologists were blinded to subject, treatment and sequence

Designed to reduce impact of individual reader bias and inter-reader variability

Patient Disposition and Analysis Sets



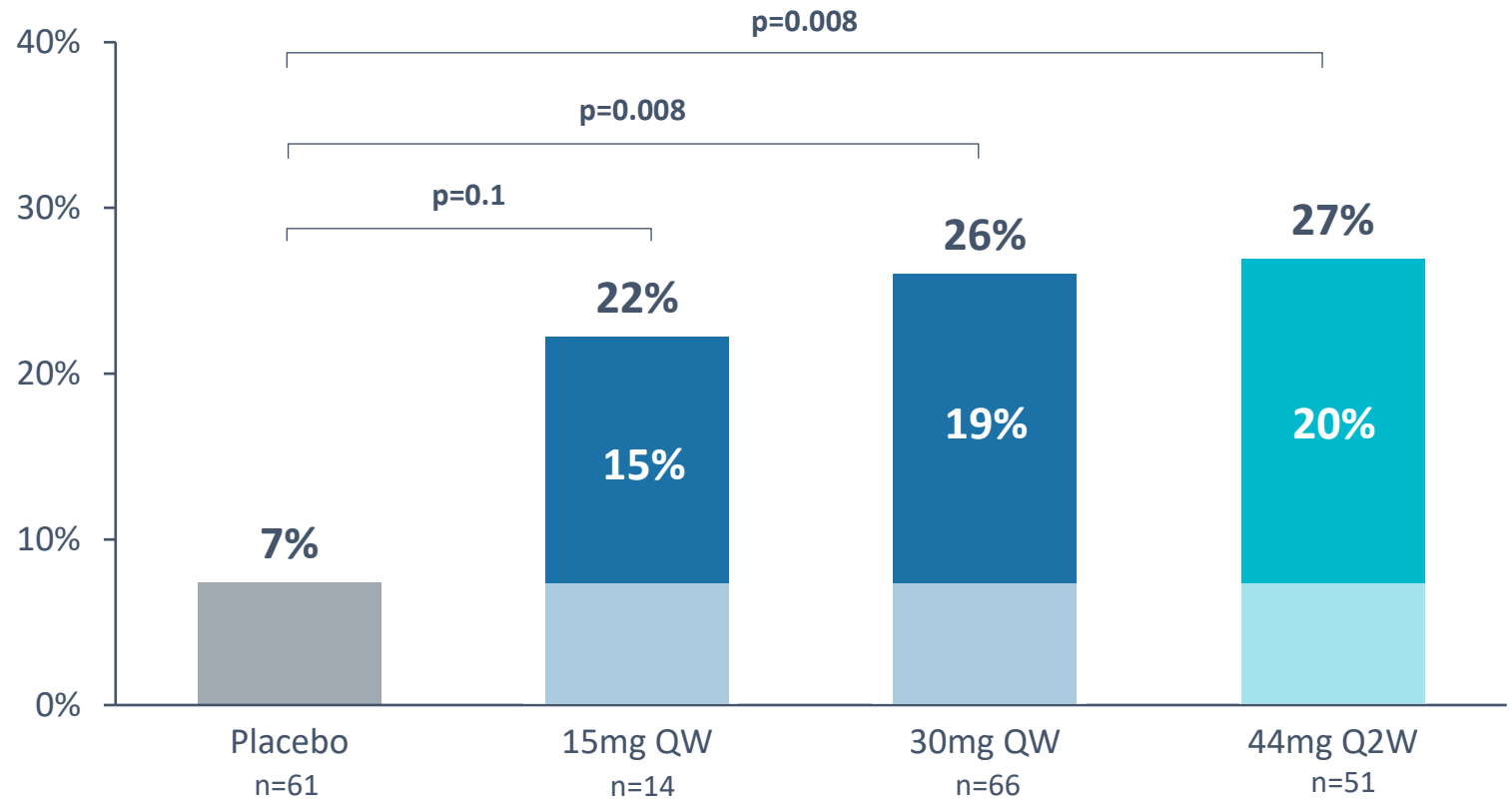
Analysis Sets were prospectively defined
Completer Analysis Set = FAS subjects with biopsies at both baseline and Week 24 (n=164).
MRI-PDFF Analysis Set = all subjects in FAS with baseline and at least one post-baseline MRI-PDFF assessment (n=181).

Baseline Characteristics Well Balanced Across Dose Groups

Parameter Mean or %	Placebo (n=71)	15mg QW (n=21)	30mg QW (n=73)	44mg Q2W (n=57)	Total (n=222)
Age (years)	56	55	55	55	**56**
Female	55%	43%	69%	65%	**61%**
BMI (kg/m^2)	38	38	35	36	**37**
Type 2 Diabetes	69%	86%	62%	61%	**66%**
Fibrosis Stage (% F3)	66%	43%	64%	53%	**60%**
NAFLD Activity Score	5.0	4.8	5.3	5.2	**5.1**
Liver Fat Content (MRI-PDFF)	16.7%	15.8%	16.7%	15.8%	**16.4%**
Liver Stiffness (VCTE, kPa)	14.1	11.2	12.5	13.2	**13.0**
PRO-C3 (ng/mL)	50	62	54	52	**53**
ALT (U/L)	50	61	60	56	**56**
AST (U/L)	41	48	47	42	**44**
HbA1c, overall population (%)	6.6	7.0	6.6	6.7	**6.7**
Triglycerides (mg/dL)	170	186	175	165	**172**

Source: Randomized Analysis Set.
ALT, alanine aminotransferase; AST, aspartate aminotransferase; BMI, body mass index; NAFLD, nonalcoholic fatty liver disease; PRO-C3, N-terminal type III collagen propeptide; VCTE, Vibration-controlled transient elastography.

Pegozafermin Demonstrated Statistical Significance on Fibrosis Improvement with Weekly and Every-Two-Week Dosing



	Placebo	15mg QW	30mg QW	44mg Q2W
Relative Risk*	1.0	**2.9**	**3.5**	**3.6**

Relative risk is calculated by dividing drug response by placebo response

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* Relative risk presented is calculated by dividing the drug response by placebo response. Relative risk calculated using statistical methods show similar results.
Source: Full Analysis Set; multiple imputation analysis via Cochran-Mantel-Haenszel (CMH) test stratified by type 2 diabetes mellitus (T2DM) status (yes vs. no) and fibrosis stage (F2 vs. F3).

Pre-Specified Additional Analyses Confirm Robustness of Primary Efficacy Results

Fibrosis Improvement Without Worsening of NASH at Week 24

	30mg QW	44mg Q2W
Completer Analysis Set (n=164)		
Effect Size (placebo-adjusted)	19%	20%
p-value	0.009	0.008
Intent-to-treat (ITT; missing data = non-responder); (n=192)		
Effect Size (placebo-adjusted)	15%	16%
p-value	0.019	0.015

Source: FAS for ITT and Completer Analysis Set

Clinical Data in Pre-Cirrhotic Patients

≥1 Stage Fibrosis Improvement with No Worsening of NASH (placebo-adjusted)

	89bio		Intercept	Madrigal Pharmaceuticals		inventiva		novo nordisk	akero
	Pegozafermin Phase 2b | 24 weeks Multiple Imputation[1]		**Ocaliva** Phase 3 | 72 weeks	**Resmetirom[2]** Phase 3 | 52 weeks		**Lanifibranor** Phase 2b | 24 weeks		**Semaglutide** Phase 2 | 72 weeks	**Efruxifermin** Phase 2b | 24 weeks Completers Analysis
Drug response as multiple of placebo response*	**3.5**	**3.6**	2.3	1.7	1.9	1.1	1.6	1.3	2.0	2.0
	19%	20%	13%	10%	12%	3%	17%	10%	19%	21%
	p=0.008	p=0.008	p<0.001	p=0.0002	p<0.0001	p=ns	p=0.04	p=ns	p<0.05	p<0.05
	30mg QW (n=66)	44mg Q2W (n=51)	25mg (n=308)	80mg (n=316)	100mg (n=321)	800mg (n=63)	1200mg (n=69)	0.4mg QD (n=56)	28mg (n=38)	50mg (n=34)

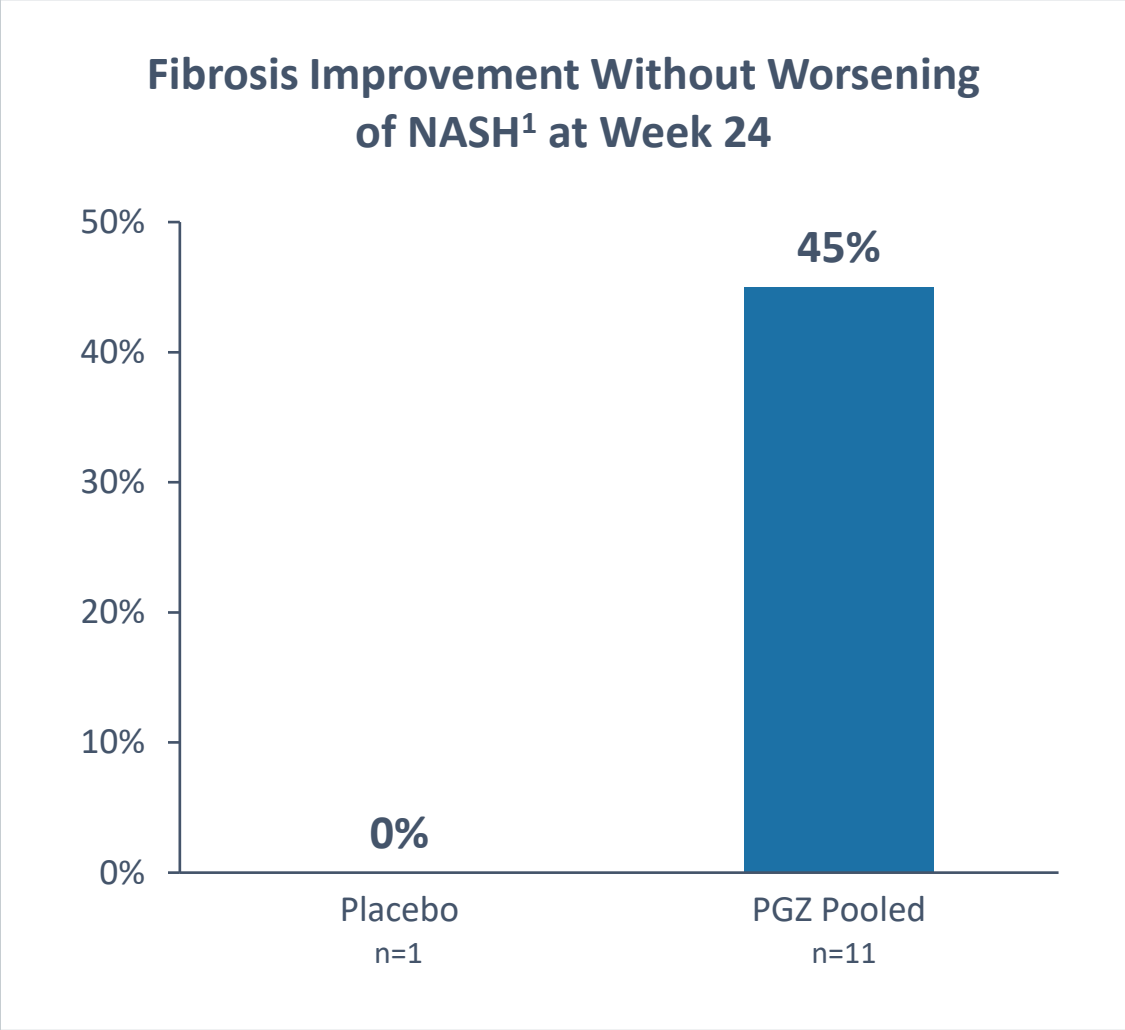
*Drug response as multiple of placebo response is calculated by dividing drug response by placebo response

[1] Results same for Completer Analysis Set

[2] ≥1 stage fibrosis improvement with no worsening of NAS

Note: These data are derived from different clinical trials at different points in time, with differences in trial design and patient populations. As a result, cross-trial comparisons cannot be made, and no head-to-head clinical trials have been conducted.

Descriptive Analysis Data of Cirrhotic (F4) Patients from ENLIVEN

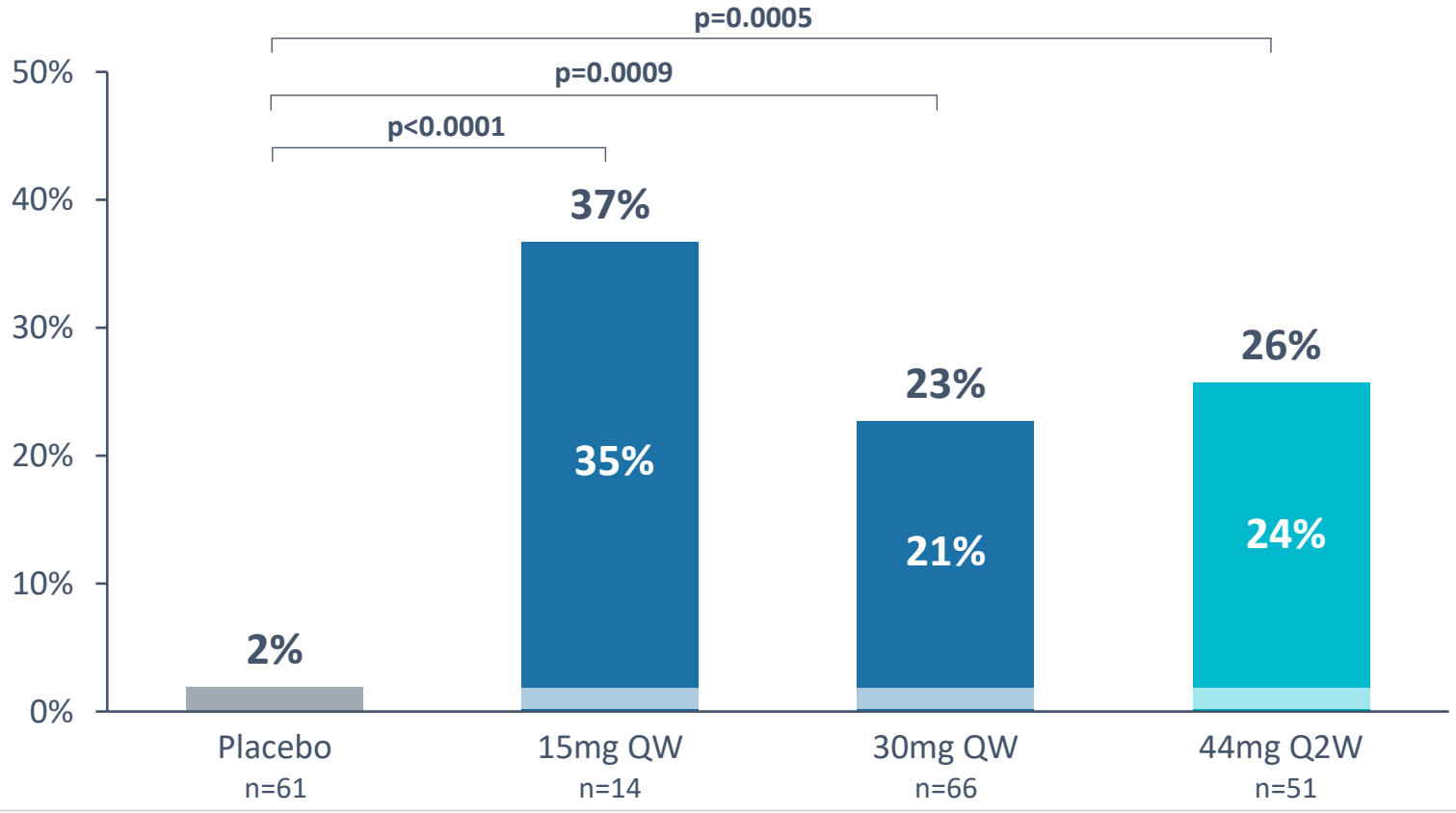


- 5/11 patients had fibrosis improvement without worsening of NASH[1]
- An additional 4 patients had fibrosis improvement only (9/11 total treated patients)

12/14 F4 patients enrolled in ENLIVEN had follow-up biopsies at week 24

[1]Improvement in liver fibrosis by ≥1 stage and no worsening of steatohepatitis defined as no increase in NAS for ballooning, inflammation, or steatosis.

Pegozafermin Demonstrated Statistical Significance on NASH Resolution at All Doses



	Placebo	15mg QW	30mg QW	44mg Q2W
Relative Risk*	1.0	**18.8**	**11.8**	**13.5**

Relative risk is calculated by dividing drug response by placebo response

* Relative risk presented is calculated by dividing the drug response by placebo response. Relative risk calculated using statistical methods show similar results.
Source: Full Analysis Set; multiple imputation analysis via Cochran-Mantel-Haenszel (CMH) test stratified by T2DM status (yes vs. no) and fibrosis stage (F2 vs. F3).

Pre-Specified Additional Analyses Confirm Robustness of Primary Efficacy Results

NASH Resolution Without Worsening of Fibrosis at Week 24

	30mg QW	44mg Q2W
Completer Analysis Set (n=164)		
Effect Size (placebo-adjusted)	21%	24%
p-value	0.0009	0.0004
ITT (missing data = non-responder); (n=192)		
Effect Size (placebo-adjusted)	17%	20%
p-value	0.0019	0.0009

Source: FAS for ITT and Completer Analysis Set

Clinical Data in Pre-Cirrhotic Patients

NASH Resolution with No Worsening of Fibrosis

	89bio	Intercept	Madrigal Pharmaceuticals	inventiva	novo nordisk	akero
	Pegozafermin	Ocalivia	Resmetirom[2]	Lanifibranor	Semaglutide	Efruxifermin
	Phase 2b | 24 weeks Multiple Imputation[1]	Phase 3 | 72 weeks	Phase 3 | 52 weeks	Phase 2b | 24 weeks	Phase 2 | 72 weeks	Phase 2b | 24 weeks Completers Analysis
Drug response as multiple of placebo response*	**11.8**	**13.5**	1.9	2.6	3.0	1.7	2.1	3.5	3.1	5.1
	21%	**24%**	3%	16%	20%	17%	26%	44%	32%	61%
	p=0.0009	**p=0.0005**	p=ns	p<0.0001	p<0.0001	p=0.039	p=0.002	p<0.001	p<0.01	p<0.001
	30mg QW (n=66)	44mg Q2W (n=51)	25mg (n=308)	80mg (n=316)	100mg (n=321)	800mg (n=63)	1200mg (n=69)	0.4mg (n=56)	28mg (n=38)	50mg (n=34)

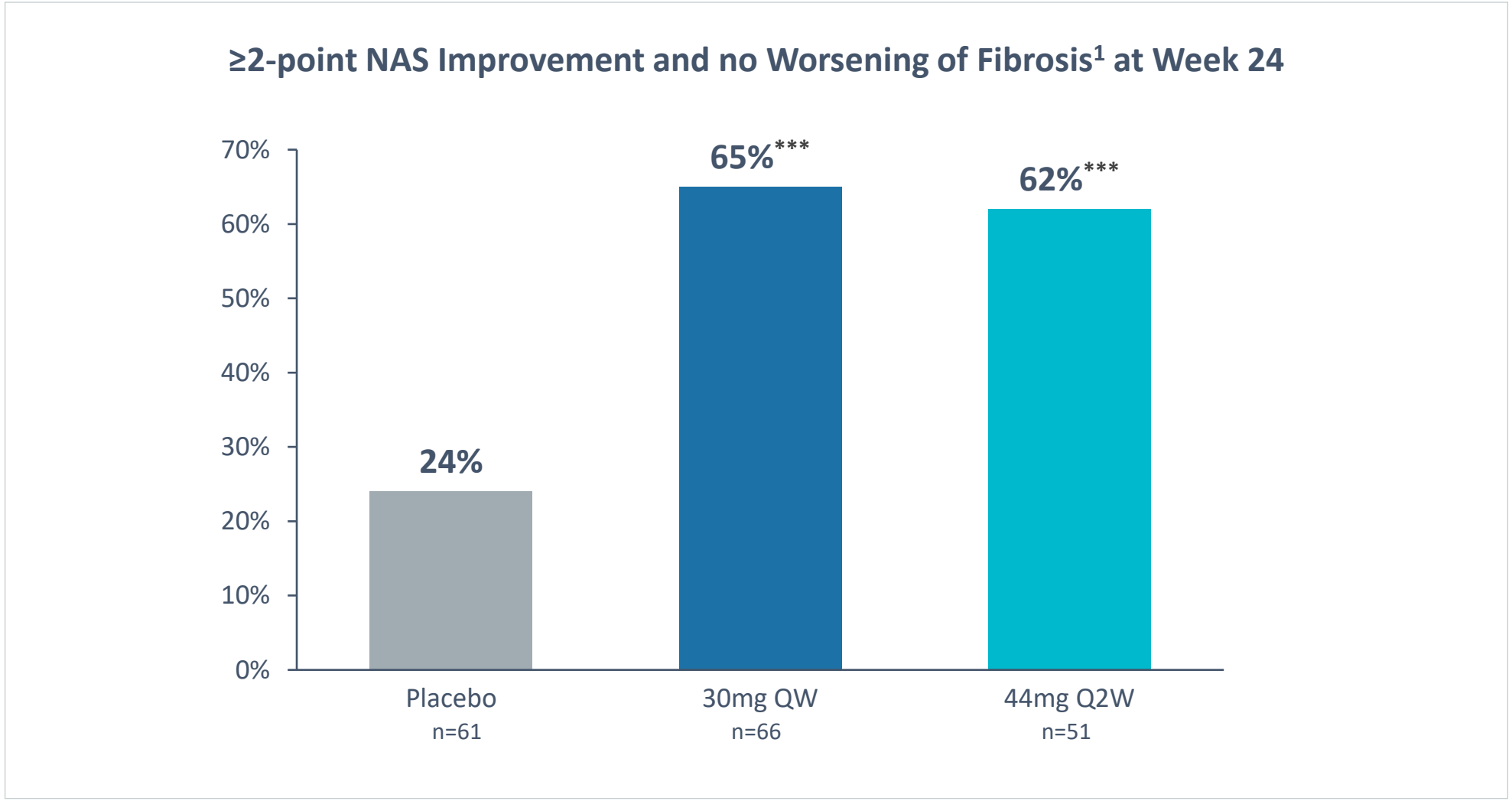
* Drug response as multiple of placebo response is calculated by dividing drug response by placebo response

[1] Results same for Completer Analysis Set

[2] NASH resolution with ≥2 point reduction in NAS and no worsening of fibrosis

Note: These data are derived from different clinical trials at different points in time, with differences in trial design and patient populations. As a result, cross-trial comparisons cannot be made, and no head-to-head clinical trials have been conducted.

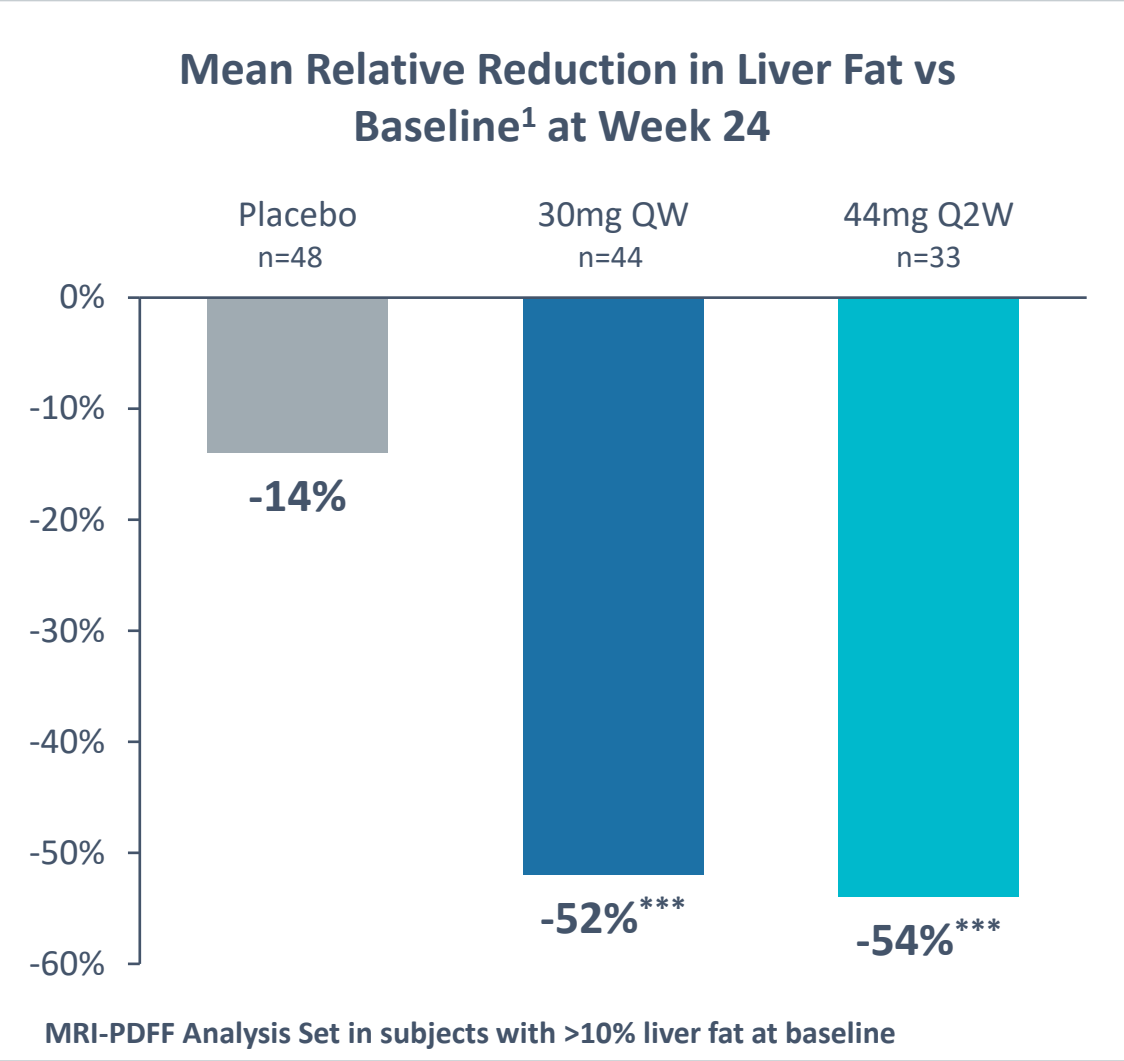
Pegozafermin Demonstrated Statistical Significance on ≥2-point NAS Improvement



Results for the 15mg QW dose: 37%

[1] Full Analysis Set. Analysis via Cochran-Mantel-Haenszel (CMH) test stratified by T2DM status (yes vs. no) and fibrosis stage (F2 vs. F3)
***p<0.001 versus placebo.

Pegozafermin Demonstrated Robust Liver Fat Reduction with High Responder Rates by MRI-PDFF at Week 24



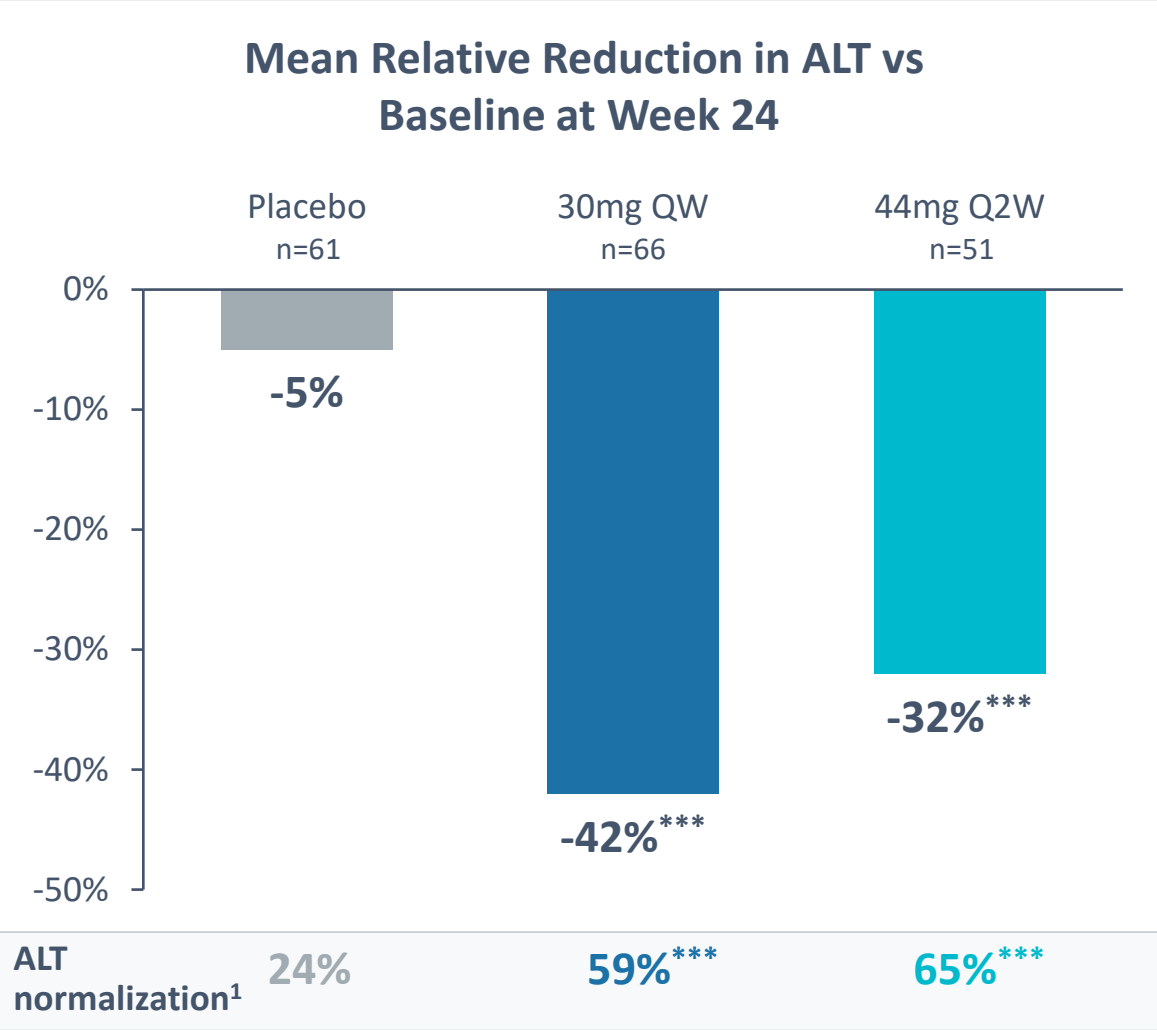
Proportion of Patients Achieving ≥50% Reductions in Liver Fat[2] at Week 24

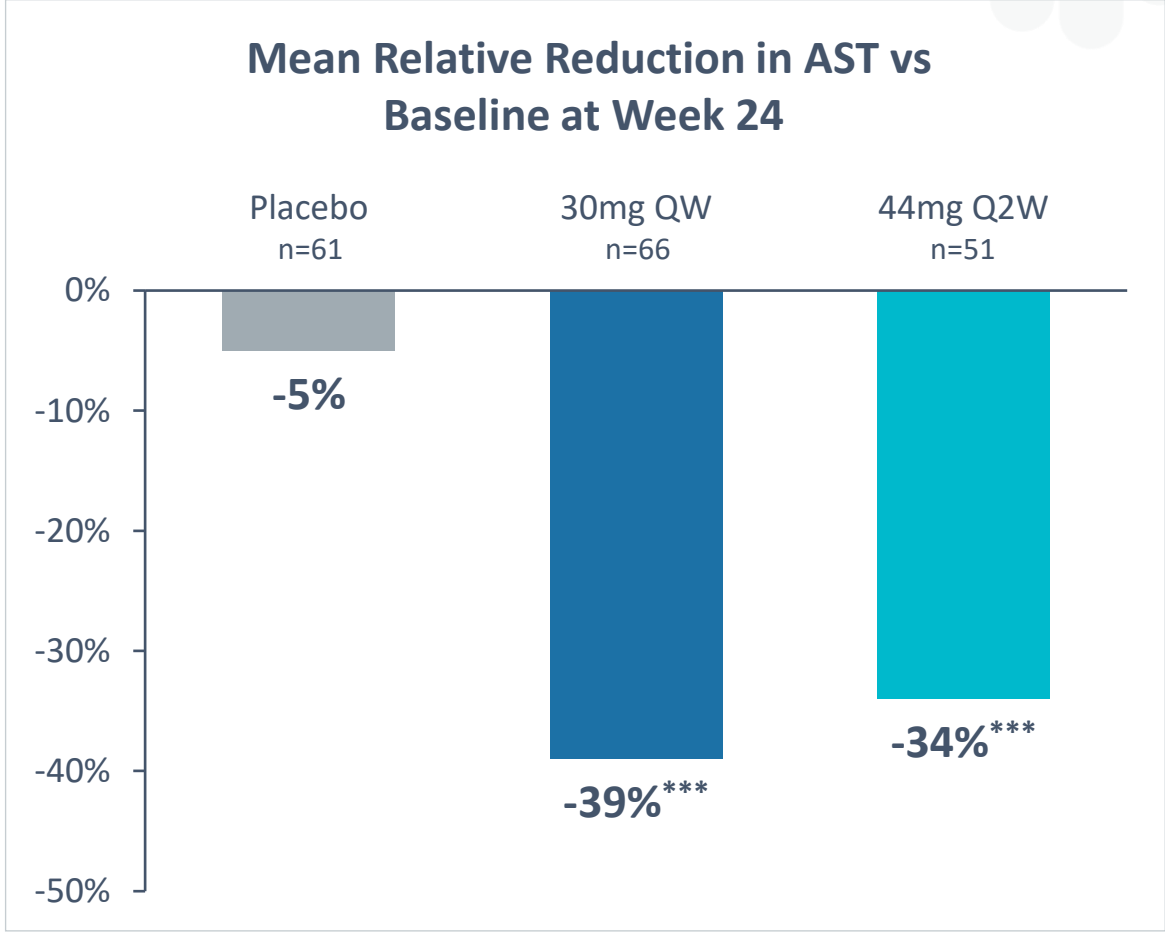
Placebo (n=48)	30mg QW (n=44)	44mg Q2W (n=33)
13%	66%***	67%***

Results for the 15mg QW dose: -33% (n=12; p=ns)

[1]Analysis via mixed model repeated measure (MMRM). [2]Analysis via Cochran-Mantel-Haenszel (CMH) test stratified by T2DM status (yes vs. no) and fibrosis stage (F2 vs. F3).
***p<0.001 versus placebo

Pegozafermin Demonstrated Significant Improvements in Markers of Liver Injury (ALT and AST)





ALT Results for the 15mg QW dose: -38% (n=14; p<0.01)

[1]ALT normalization defined as patients with ALT ≥30 U/L at baseline (n=133) with end-of-study ALT <30 U/L.

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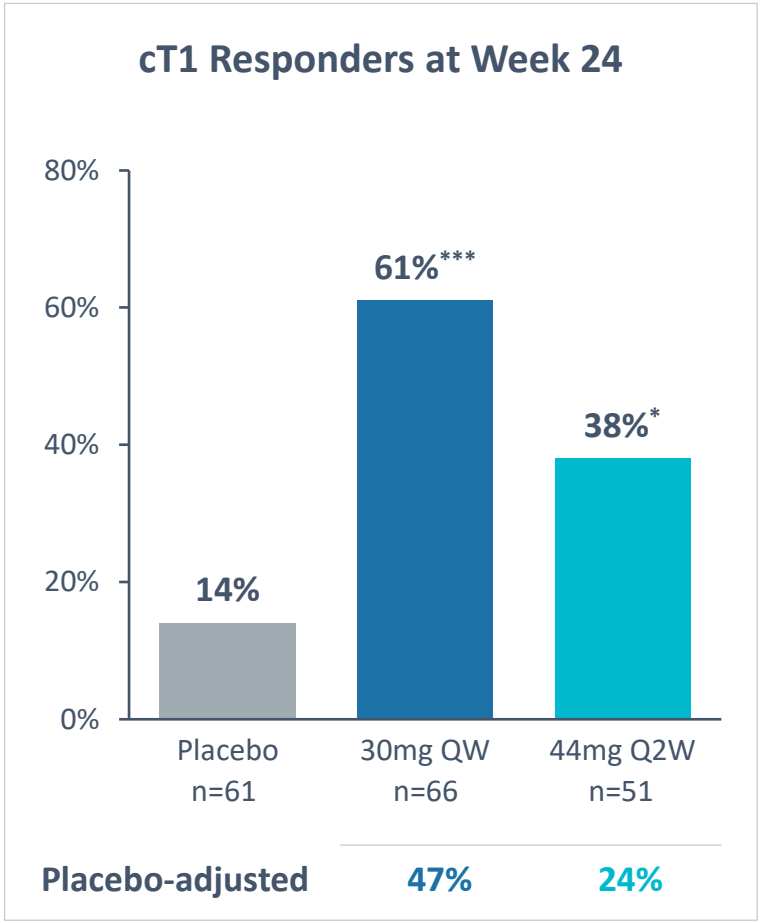
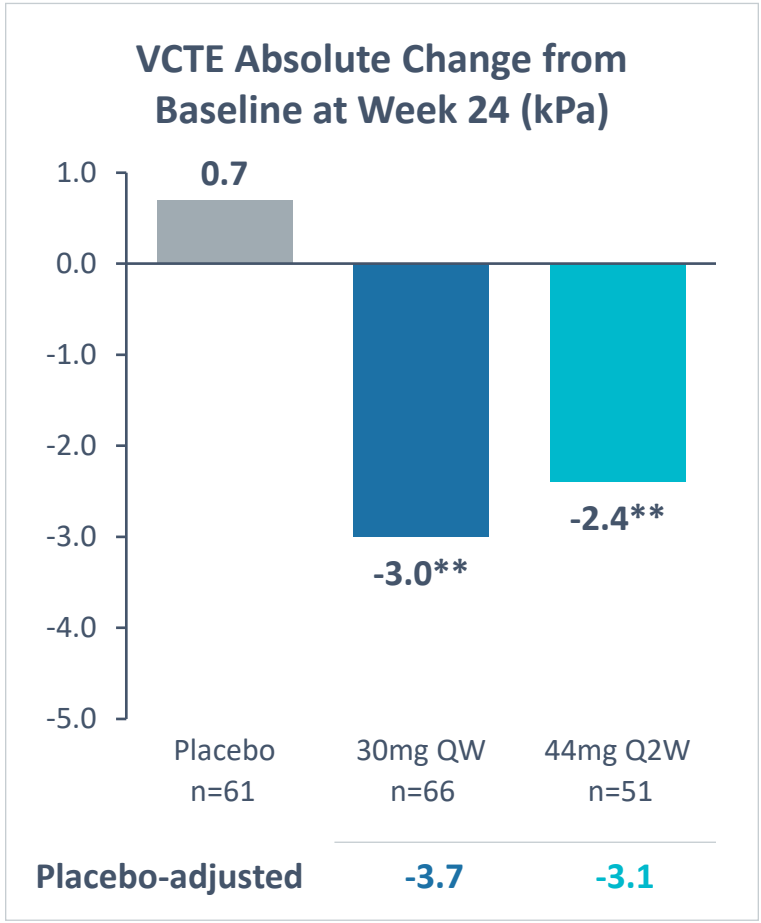
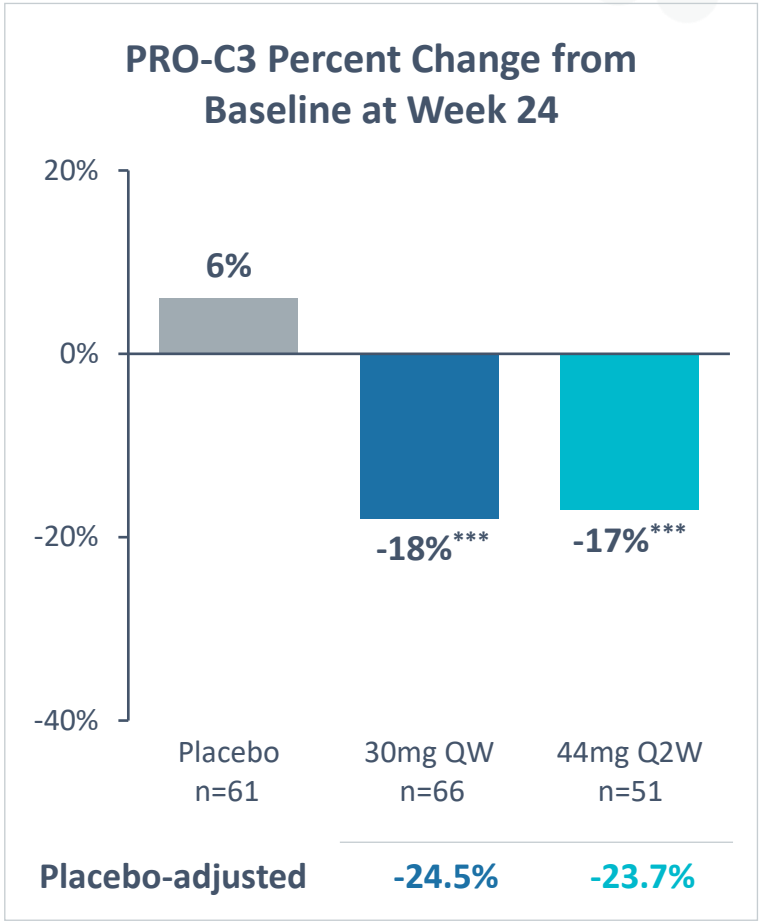
Source: Full Analysis Set: Analysis via mixed model with repeated measure (MMRM). Data presented as LS Means.
***p<0.001 versus placebo.

Pegozafermin Demonstrated Significant Reductions in Non-Invasive Markers (NITs) of Hepatic Inflammation and Fibrosis







Results for the 15mg QW dose: cT1 40% (n=10; p=ns); VCTE -1.6 kPa (n=14; p=ns); PRO-C3 -5% (n=14; p=ns).

Source: Full Analysis Set for FibroScan and PRO-C3 assessments and MRI-PDFF analysis set for cT1, Analysis via MMRM for cT1 and PRO-C3, ANCOVA for VCTE. A patient is designated a cT1 responder with ≥80 msec reduction as compared to baseline. cT1 analysis was performed at sites where available.
*p<0.05, **p<0.01, ***p<0.001 versus placebo.

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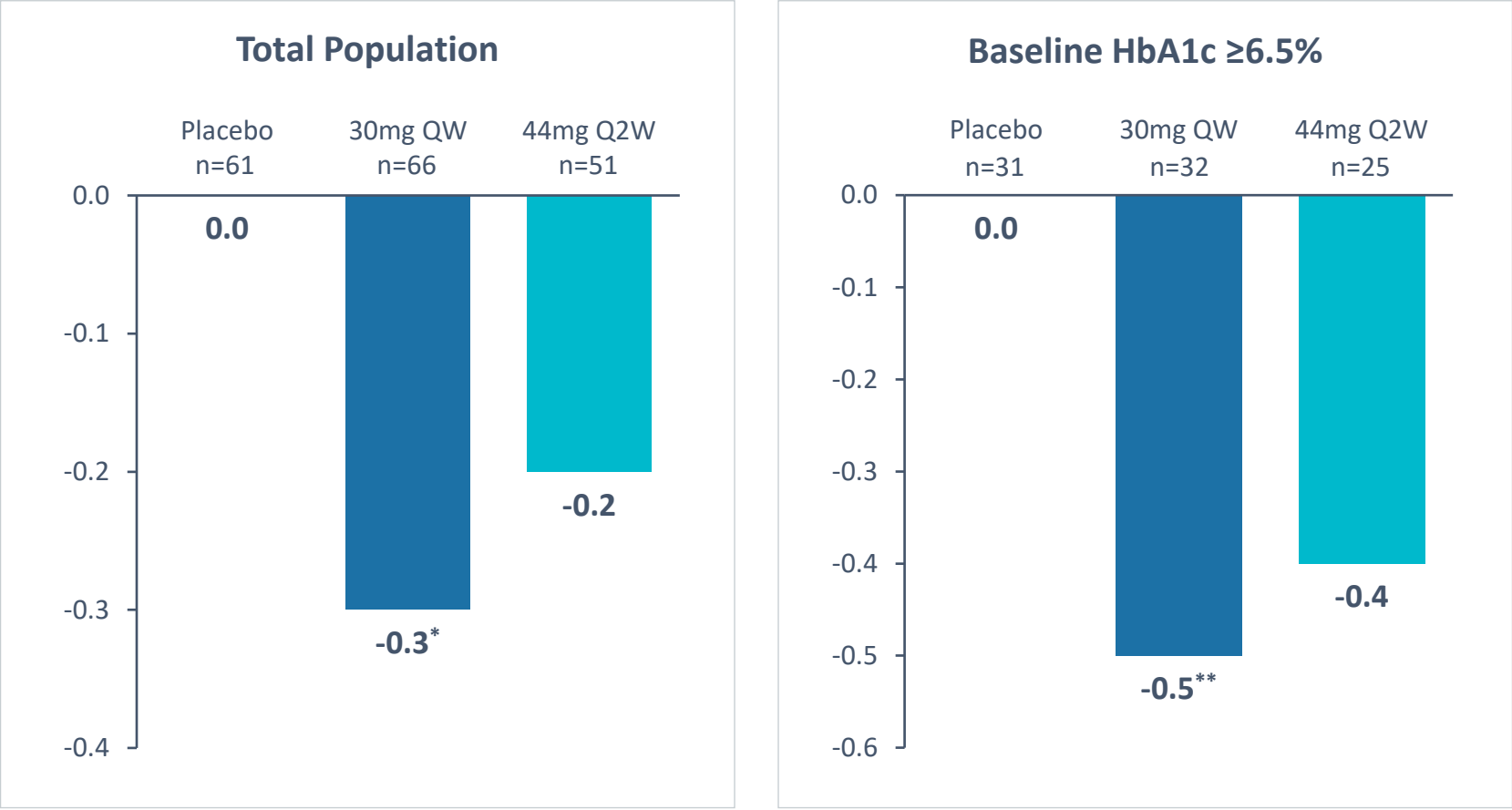
Pegozafermin Demonstrated Meaningful Reductions in HbA1c

Change in HbA1c from Baseline at Week 24

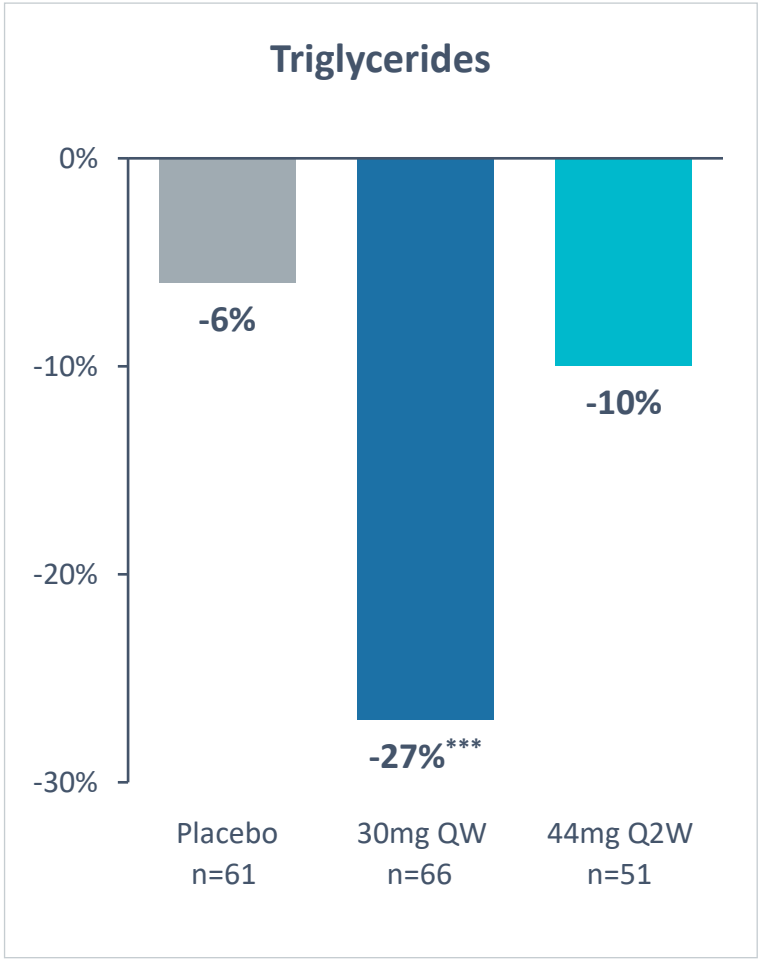


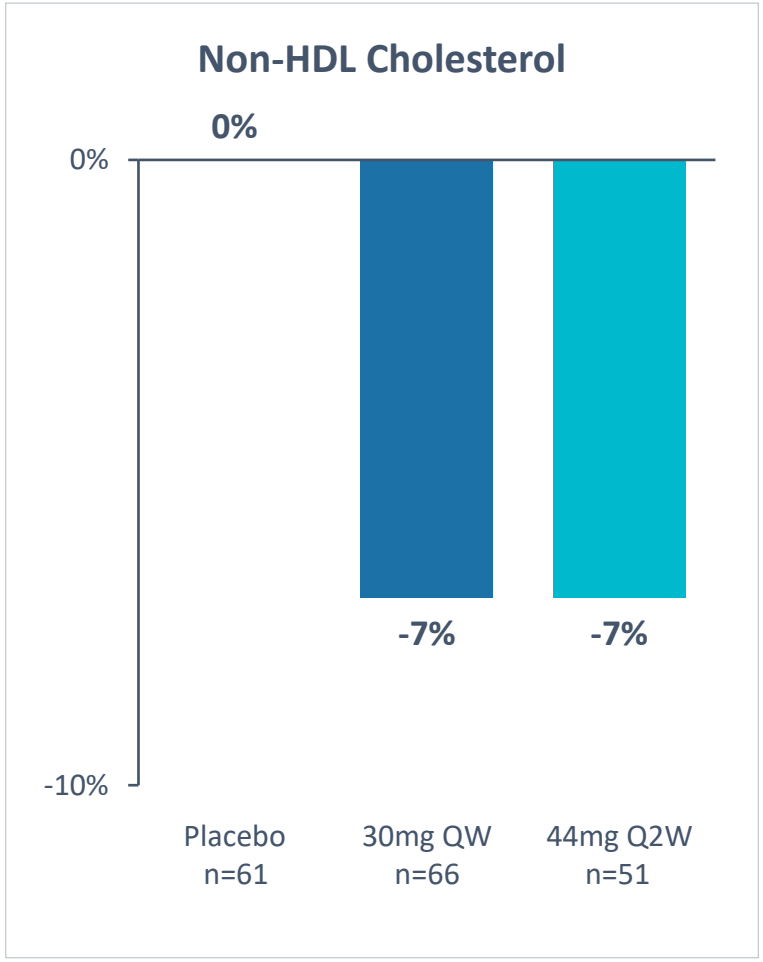
Source: Full Analysis Set for either overall population or FAS with baseline HbA1c ≥6.5%. Analysis via MMRM.

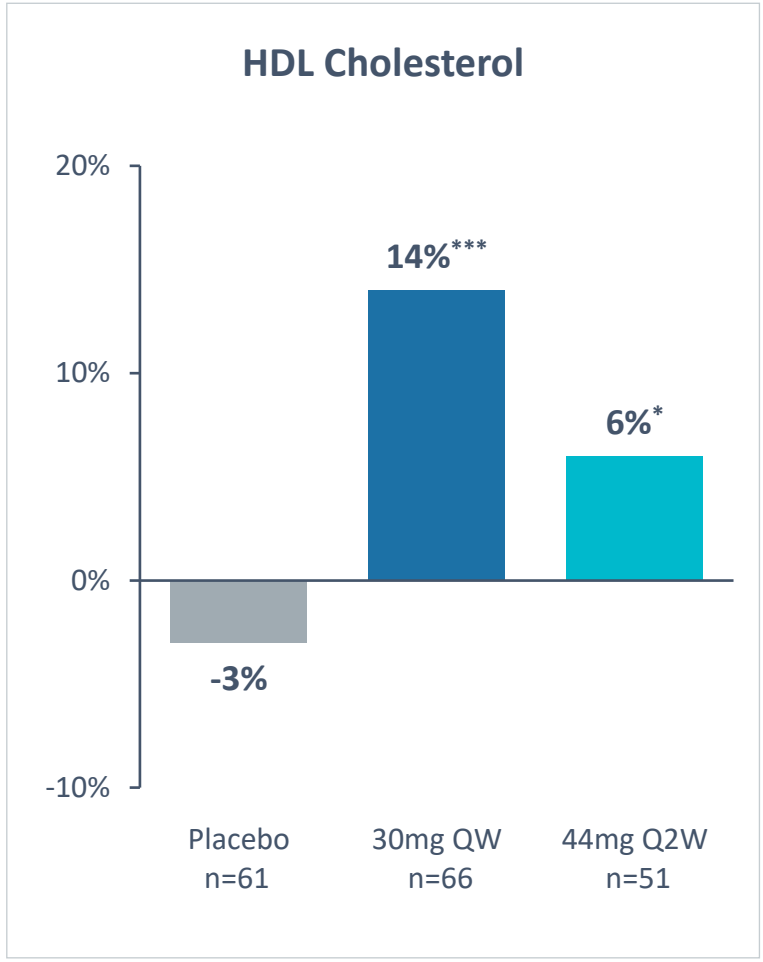
*p<0.05, **p<0.01 versus placebo.

Pegozafermin Demonstrated Meaningful Changes in Serum Lipids

Percent Change in Serum Lipids from Baseline at Week 24







Source: Full Analysis Set. Analysis via van Eltren Test for triglycerides (reported as median) and mixed model with repeated measure (MMRM). Subjects with missing week 24 triglycerides are excluded from the non-parametric analysis. Non-HDL-cholesterol and HDL Cholesterol (reported as LS means) with changes from baseline (absolute or %) as dependent variables.
*p<0.05, **p<0.01, ***p<0.001 versus placebo.

Pegozafermin Was Well Tolerated Across Doses

Low incidence of treatment-related TEAEs

Drug-related TEAEs in ≥10% of patients

Preferred Term	Placebo (n=69)	15mg QW (n=21)	30mg QW (n=72)	44mg Q2W (n=57)
Diarrhea	3%	24%	17%	9%
Nausea	1%	14%	21%	18%
Injection site erythema	3%	14%	14%	5%
Injection site rash	1%	0	10%	4%
Increased appetite	0	10%	13%	5%

Most TEAEs were grade 1 or 2. No tremor reported.

	Placebo	15mg QW	30mg QW	44mg Q2W
Drug-related AEs leading to discontinuation	0	5%[a]	6%[b]	2%[c]
Drug-related Serious Adverse Event (SAE)	0	0	0	2%[c]

Related discontinuations: [a] Diarrhea [15 mg QW] ; [b] Diarrhea [30 mg QW]; Nausea [30 mg QW]; Diarrhea [30 mg QW]; ISR erythema [30 mg QW]; [c] Pancreatitis [44 mg Q2W].
Unrelated discontinuations: Angina [placebo]; Colon CA [30 mg QW]; COVID-19 [30 mg QW].

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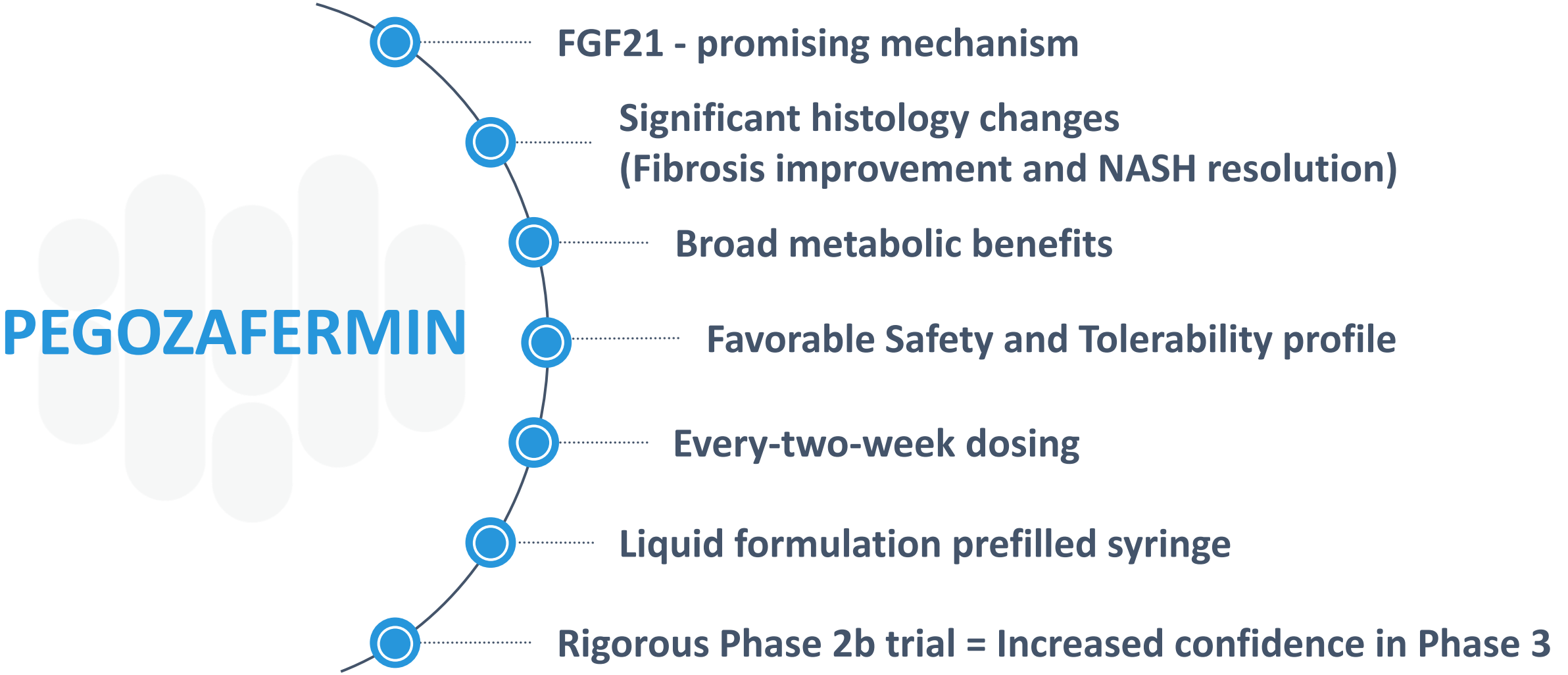
Source: Safety Analysis Set. AE table cutoff ≥10% of patients for placebo, 30mg QW and 44mg Q2W doses.

Pegozafermin – A Potentially Differentiated and Foundational NASH Therapy



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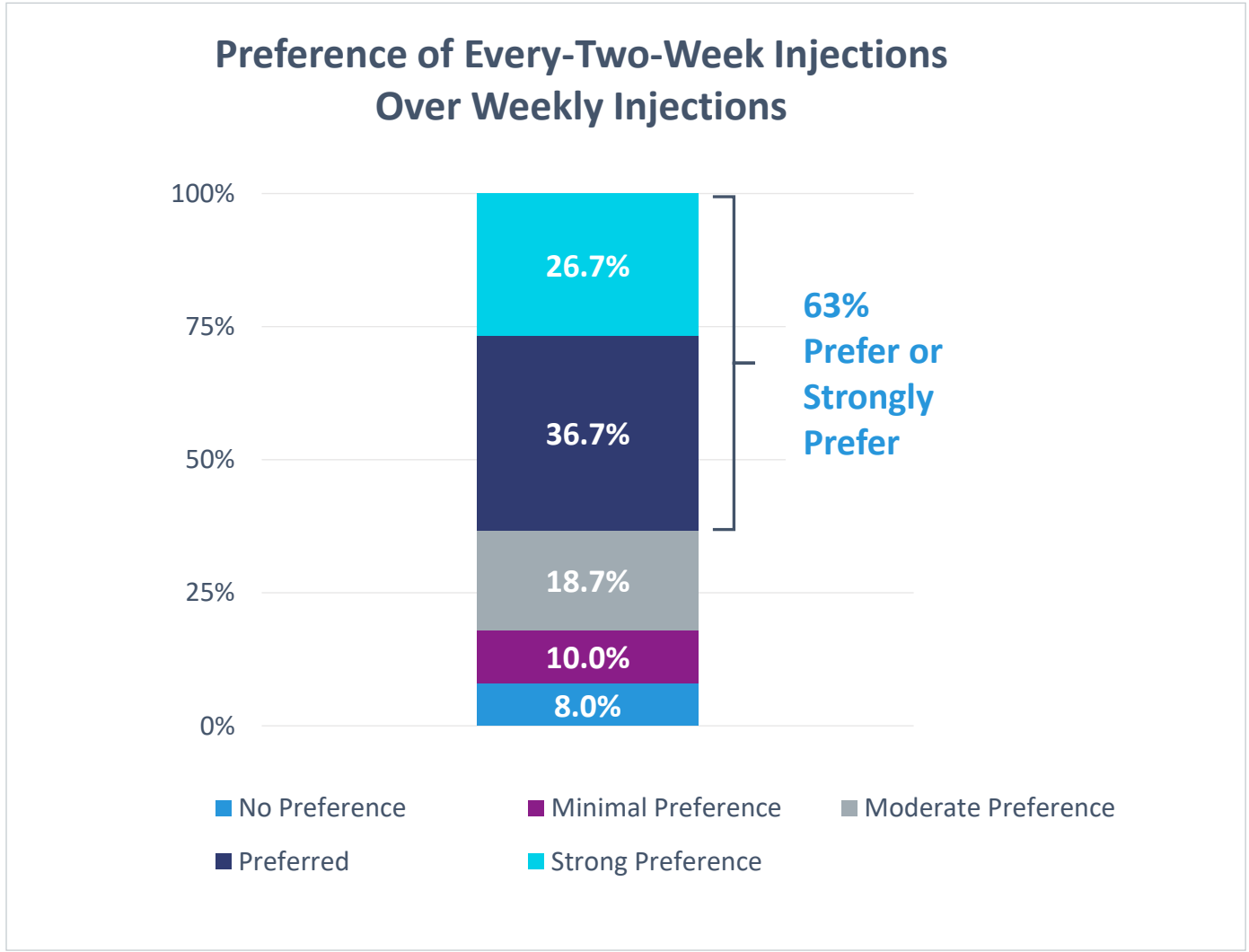
APPENDIX

Over 60% of T2D Patients Prefer or Strongly Prefer Every-Two-Week Injections



- Every-two-week dosing provides opportunity for physicians to optimize therapy to patient preference
- Compliance is important in treatment for chronic, asymptomatic diseases

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Source: primary market research with 150 people with type 2 diabetes, 2019.