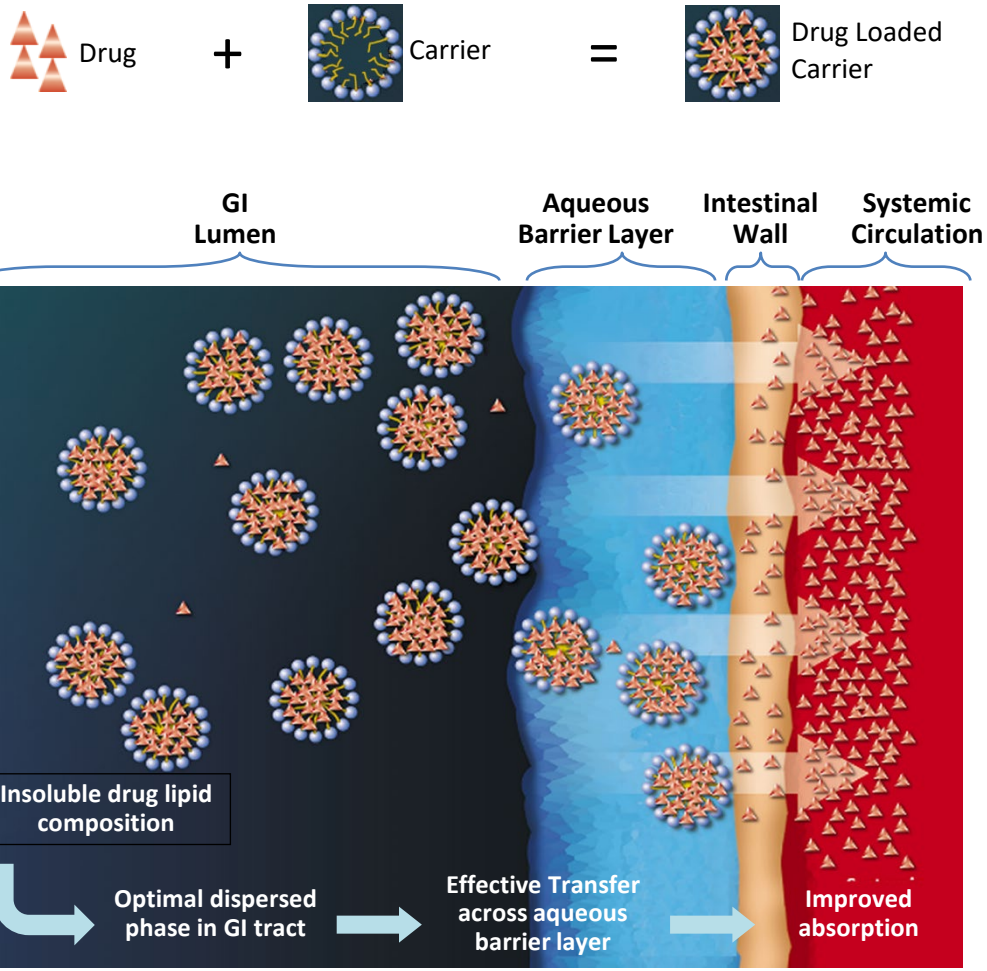
LPCN 1144

for Nonalcoholic Steatohepatitis (NASH)

Oral Androgen Receptor Agonist

Validated Proprietary Lip'ral Technology Platform



Giliyar et al. Drug Delivery Technology, Jan 2006, Vol 6 No.1

- Invented by Renowned Formulation Experts
- Validated Through a Recent FDA Drug Approval

TLANDO® (testosterone undecanoate) CIII

- Subject to Multiple Prior Partnerships

Halozyme · Abbott · élan · SCHWARZ PHARMA · ADAMS RESPIRATORY THERAPEUTICS™

- Protected by Robust WW Patent Portfolio
  >30 Issued & Pending Patents

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LPCN 1144 (Testosterone Ester): Partnering Opportunity

Unique Mechanism of Action with Fast Track Designation

Targets High Unmet Need

Potential to be "best in class"

Unique benefit to risk

- Compelling P2 Biopsy Results in the FDA approvable endpoint
- Safety support with 72 weeks exposure

Mono- or adjunct therapy

Differentiated profile

- Oral
- Sexual/mental benefit
- Musculoskeletal improvement
- Weight neutral approach

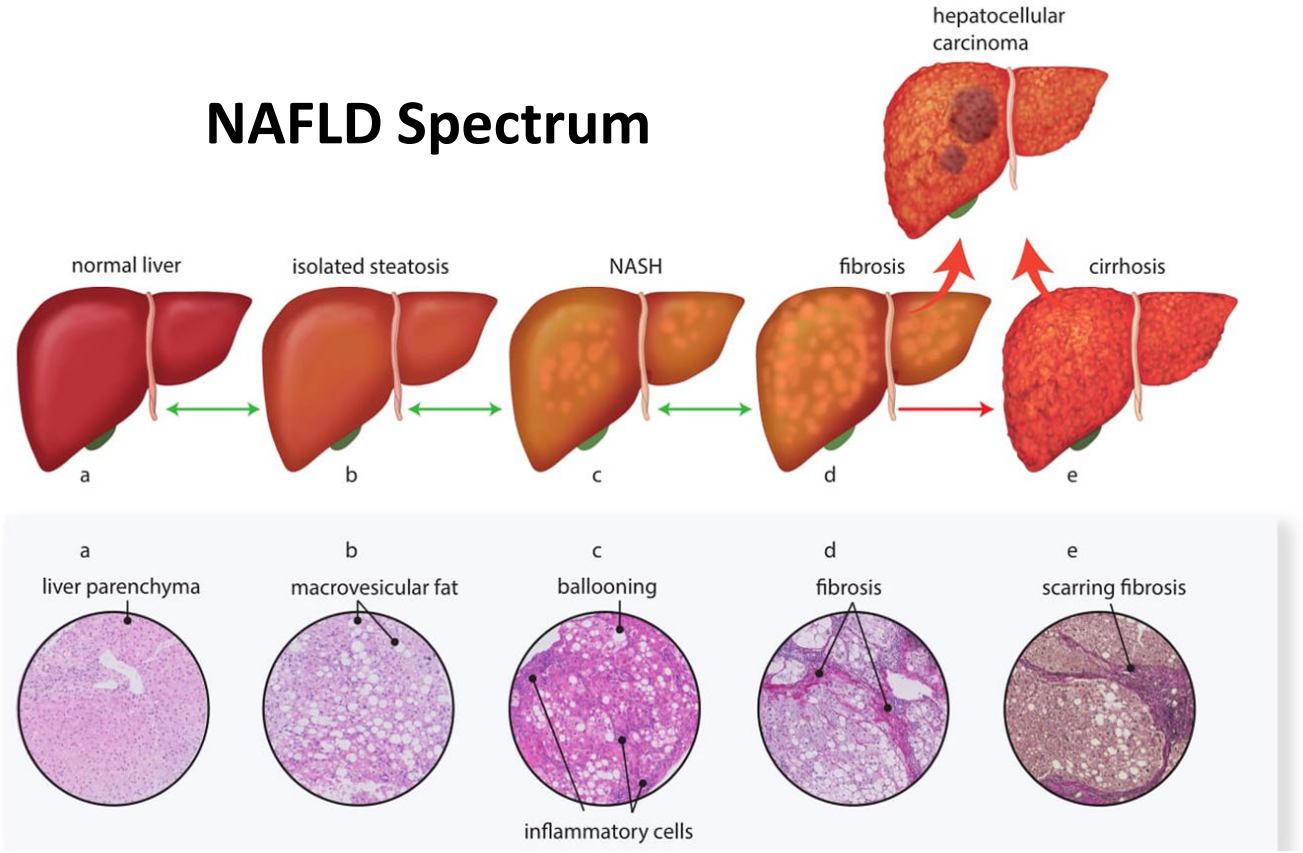
Strong IP Coverage

Accelerated approval pathway

LPCN 1144: Market Potential

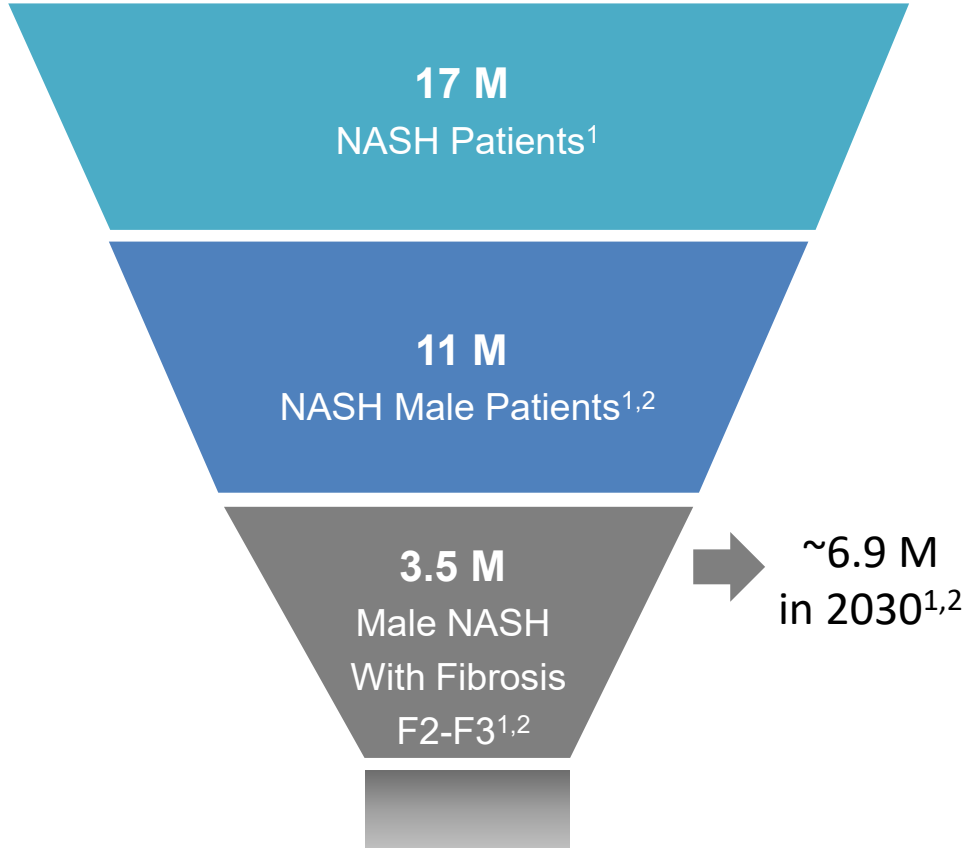
NASH, A Silent Liver Disease Epidemic

NAFLD Spectrum



European Journal of Endocrinology 183, 3; 10.1530/EJE-20-0065

Current Target Population



Multibillion Dollar Market Opportunity[3]

1. Estes et al., Hepatol 2018. 2. Williams et al., Gastroenterology 2011. 3.LifeSci Partner Analysis 2022

LPCN 1144: *LiFT (Liver Fat Intervention with oral Testosterone)*†

Phase 2 Paired Biopsy Study in Men with NASH (NCT04134091)

Study Design

- Biopsy confirmed male NASH subjects with F1-F3
  Three-arm, blinded, placebo-controlled
  - Hypogonadal and eugonadal men enrolled
  - 1:1:1 randomization
    - Treatment A: 142 mg eq. T twice daily
    - Treatment B: 142 mg eq. T + 238 mg d-alpha tocopherol twice daily
    - Placebo: twice daily
- Treatment duration of 36 weeks

Primary Endpoint:

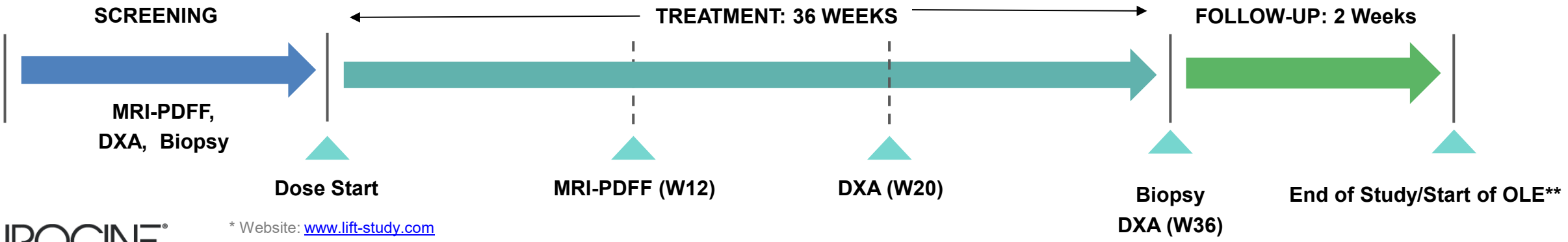
- ✓ Change in hepatic fat fraction via MRI-PDFF (W12)

Key Secondary Endpoints:

- ✓ Change in NASH activity and fibrosis via liver biopsy scoring (W36)
- ✓ Change in body composition, liver injury markers

Analysis Sets:

- Safety Set: All randomized subjects (ITT)
- Biopsy Set: All subjects with baseline and EOS biopsies
- NASH Resolution Set: Biopsy set with NAS ≥ 4 and at least 1 point in both inflammation and ballooning



* Website: www.lift-study.com
** Open Label Extension Study (36 weeks)
† Study was not powered to show statistical significance of secondary endpoints

Summary of *LiFT* Results

Study Demonstrates Treatment Potential of LPCN 1144 in NASH

- Met Primary Endpoint – Liver Fat Reduction at Week 12
- Statistical significance NASH resolution with no worsening of fibrosis (a regulatory endpoint)
- Treatment effect observed on fibrosis improvement needs confirmation in a larger study
- Benefits in key liver enzymes and body composition
- Well tolerated with an overall safety profile comparable to placebo

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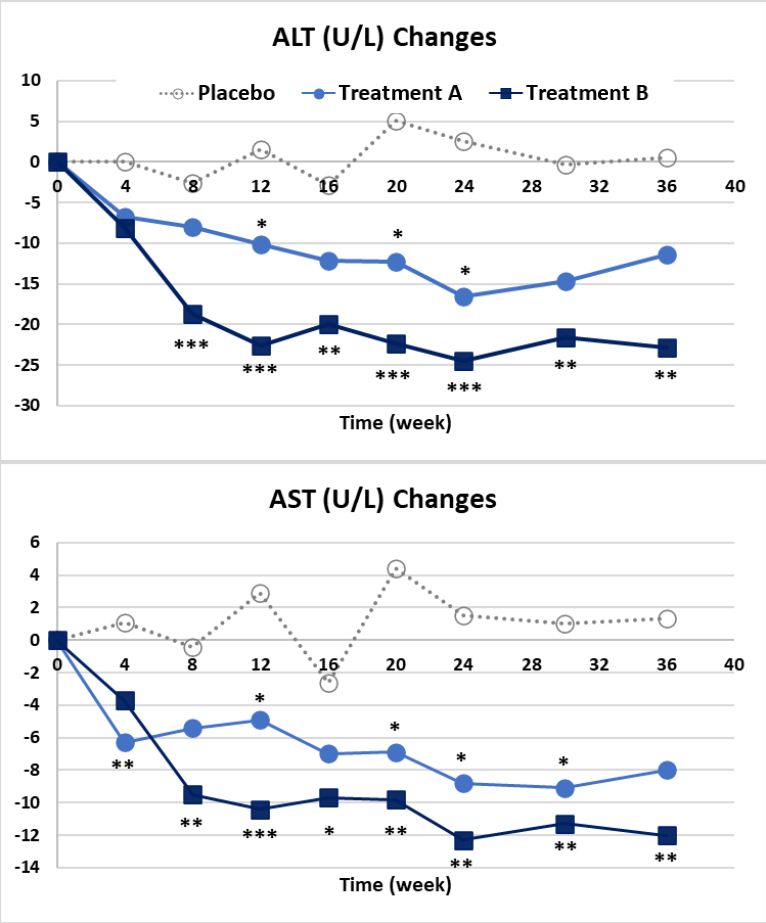
Key Non-Histology Marker Results from *LiFT* Study

Liver Enzyme# Reductions and Body Composition Changes

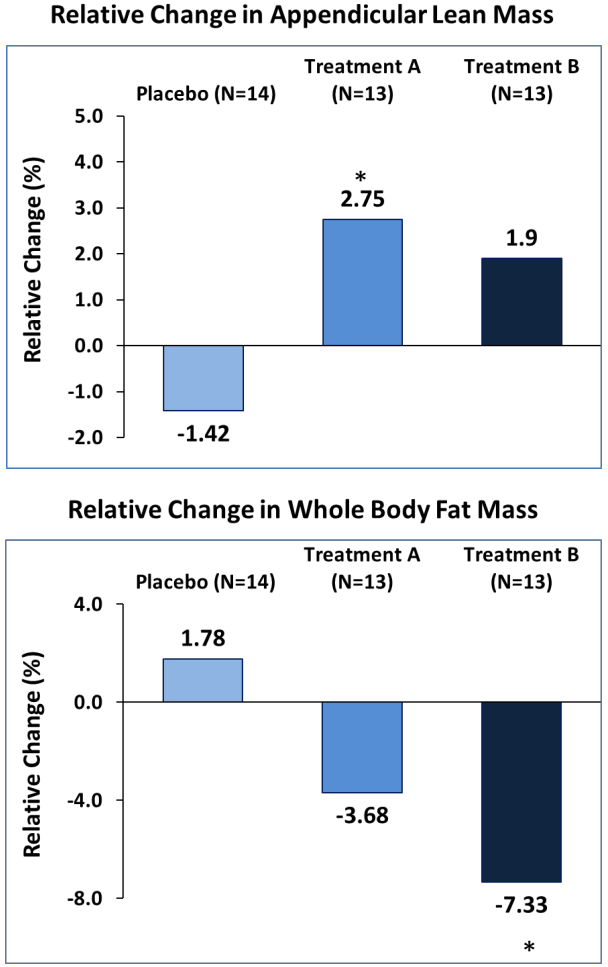
Mean Baseline

	ALT (U/L)	AST (U/L)
Placebo (N=19)	49.0	35.4
Treatment A (N=18)	53.9	32.4
Treatment B (N=19)	51.5	31.9

Liver Injury Marker Reduction



Positive Effects on Body Composition†



† All available data at Week 36 (Last Observation Carry Forward ("LOCF"))
* p < 0.05 vs placebo

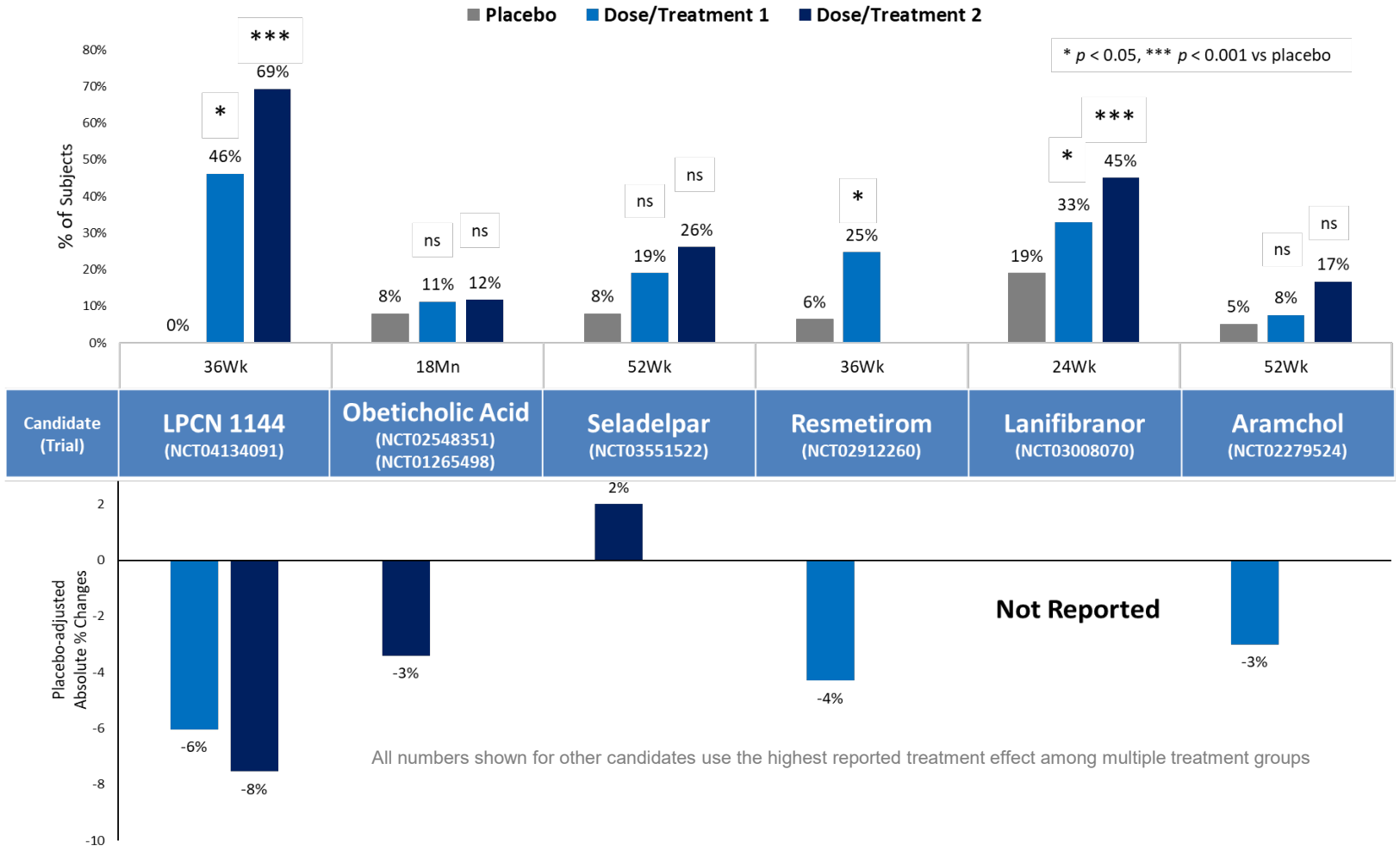
Safety Set with all available data, # ALT: alanine aminotransferase; AST: aspartate aminotransferase
* p < 0.05; ** p < 0.01; *** p < 0.001 vs placebo

Comparison with Other Oral Drug Candidates

Best in Class in NASH Resolution and Liver Fat Reduction

NASH Resolution with No Worsening of Fibrosis

Absolute Changes of Liver Fat from Baseline



All numbers shown for other candidates use the highest reported treatment effect among multiple treatment groups

Data are derived from published reports of different clinical trials at different points in time, with differences in trial design, size, and patient populations. No head-to-head clinical trials have been conducted. For Resmetirom, reduction 2-point on NAS or resolution of NASH without worsening of fibrosis with at least a 2-pt reduction in NAS.

Reference: Obeticholic acid (Younossi et al, Lancet 2019), Seladelpar (Cymabay, Apr 2021 Corp deck), Resmetirom (Harrison et al, Lancet 2019; Madrigal, June 2019 Corp deck), Lanifibranor (Inventiva, Jul 2021 Corp deck); Aramchol (Raymond James Life Sciences and MedTech Conference 2019)

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Safety Overview of LPCN 1144 Through Week 36

Well-Tolerated with an Overall Safety Profile Comparable to Placebo

- Frequency and severity of TEAEs in both treatment arms were comparable to placebo
- Discontinuance of study drug due to TEAEs: 4 subjects in placebo and 1 subject in treatment arms
- Cardiovascular events were balanced among groups
- No reported cases of hepatocellular carcinoma or Drug Induced Liver Injury ("DILI")
- Weight change from baseline was comparable among groups
- Changes in lipids comparable to placebo

AEs of Interest, n (%)	Placebo	Treatment A	Treatment B
Diarrhea	2 (10.5%)	1 (5.6%)	0 (0%)
Nausea	1 (5.3%)	1 (5.6%)	0 (0%)
Vomiting	none	none	none
Peripheral Edema	2 (10.5%)	1 (5.6%)	1 (5.3%)
BPH	1 (5.3%)	0 (0%)	0 (0%)
PSA Increased	0 (0%)	1 (5.6%)	0 (0%)
Hypertension†	1 (5.3%)	3 (17%)	0 (0%)
Pruritus	1 (5.3%)	1 (5.6%)	0 (0%)

TEAE = Treatment Emergent Adverse Events, BPH = Benign Prostatic Hyperplasia; PSA = Prostate-Specific Antigen; † New or worsening hypertension

LPCN 1144: Androgen Receptor Agonist

Differentiated NASH Treatment Candidate

Targets Unmet Need

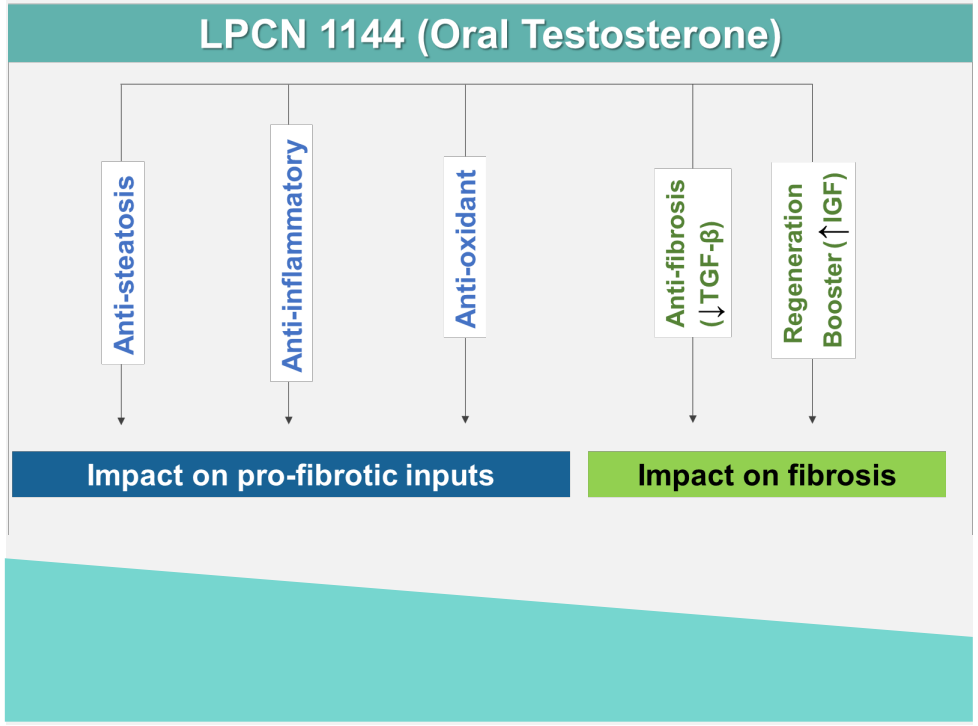
Acceptable benefit to risk ratio

- NASH resolution and/or fibrosis improvement
- Tolerability for chronic use

Improvement of sarcopenia

Address sexual and mental dysfunctions

Potential Mode of Action



Clinical Experience

Noninvasive dosing regimen

Meaningfully reduced liver fat in POC study

Well tolerated in 700+ subjects with up to 52-week exposure

Improved mental and sexual dysfunction

LPCN 1144 Key Considerations

Compelling Opportunity in Non-Cirrhotic NASH

- **Market Opportunity for Non-Cirrhotic NASH**
  - 3.5M male patients annually
- **Competitive Landscape:** Numerous in development (injectables and orals)
  - Resmetirom approved March 2024 (metabolic MOA drug)
- **Unmet Need:**
  - Approved treatment with acceptable risk-benefit profile, NASH resolution with no worsening of Fibrosis or Fibrosis with no worsening of NASH; acceptable for chronic use
  - Oral route of administration preferred
- **Target Label Product Attributes**
  - Oral Administration
  - Unique multifactorial MOA
  - Endogenous molecule
  - Potential reduction in comorbidities

LPCN 1144 Key Considerations (cont)

Compelling Opportunity in Non-Cirrhotic NASH

- **Revenue Sustainability:**
  - Exclusivity supported by IP portfolio with issued and pending patents

- **Clinical Development Opportunity:**
  - Positive P2 study result
  - **Differentiated benefit to risk profile vs competition**: oral, no GI, no musculoskeletal issues, weight neutral, no LDL increase

- **Regulatory Considerations**
  - Need adequate benefit to risk profile for chronic use drug
  - Sub part H option; P2 study and Pivotal study design agreement with FDA
  - Fast-track designation

- **Exploring Partnership Options for LPCN1144**

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