LPCN 1144

Targeted for Non-Alcoholic Steatohepatitis (“NASH”)
Forward-Looking Statements

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Non-Alcoholic Fatty Liver Disease ("NAFLD")
No Approved Product for the Treatment of NASH

Fatty liver is a reversible condition wherein large vacuoles of triglyceride (TG) fat accumulate in liver cells via the process of steatosis.

Healthy Liver
- 20 – 30% US Adults

Fatty Liver
- ↑ TGs
- ↑ LFTs
- ↑ Liver fat

NASH Liver
- 15 – 20% NAFLDs
- ↑ Steatosis
- ↑ Ballooning
- ↑ Inflammation
- ↑ Fibrosis

Cirrhotic Liver
- 10 – 20% NASH
- Late stage of fibrosis

Hepatocellular Carcinoma

Eligible for Liver Transplantation

LFTs: Liver function test, especially Alanine amino transferase (ALT) and Aspartame amino transferase (AST)
NASH: Non-alcoholic Steatohepatitis, TG: Triglyceride
NASH Pathogenesis
Risk Factors and Clinical Progression

Lipid Metabolism Disorders
• Dyslipidemia
• Insulin resistance
• Obesity
• T2 diabetes
• Metabolic syndrome

Inflammation
• Lipid peroxidation
• Mitochondrial dysfunction
• Oxidative stress
• Apoptosis
• Pro-inflammatory cytokine activation

Fibrosis
• Scarring
• Advanced cell damage

The removal of pro-fibrotic inputs or the strengthening of anti-fibrotic inputs is expected to stimulate scar resolution*

Liver contains built-in mechanisms for scar resolution, but these become smothered or inactivated in the face of relentless damage*

≥5% liver fat accumulation

Unmet Need in Pre-Cirrhotic NASH
Currently No Approved Product to Treat Pre-Cirrhotic NASH

Rationale for Using LPCN 1144 Alone or in Combination to Treat Pre-Cirrhotic NASH

- Multi-dimensional mechanism of action/efficacy across the full NASH disease spectrum
- Tolerable and suitable for chronic use
- Majority of biopsy confirmed NASH adult males have low testosterone
- Sarcopenia in patients with NAFLD is associated with a higher likelihood of having steatohepatitis or advanced liver fibrosis
- Sexual dysfunction is an underappreciated comorbidity in male NASH patients

Clinical Relationship Between Testosterone and NAFLD Across the Full Disease Spectrum

**Hepatic Steatosis**
“Men with low testosterone are at high risk for NAFLD.” ¹

**NASH**
“Levels of free T decreased significantly with the increased incidence of lobular inflammation, hepatocyte ballooning, NAFLD activity score, and fibrosis.” ²

**Cirrhosis**
“Low T levels in cirrhotic men are associated with the combined outcome of death or transplantation.” ³

1 Kim et al, Gastroenterol 2012; 2 Sumida et al, Gastroenterol Hepatol 2015; 3 Sinclair et al, Liver Trans 2016;
Estimated LPCN 1144 Target Market
Reportedly 75% of NASH Male Patients Have Total T less than 372 ng/dL\(^1\)

83M NAFLD patients in 2015\(^2\)

~17M NASH patients in 2015\(^2\)

~8M Male NASH patients\(^3\)

NASH cases are projected to increase 63% from 17 million cases in 2015 to 27 million cases in 2030\(^2\) with no approved drug

2. Estes et al, *Hepatol* 2018
3. About 50% of males are accounted in the whole NASH population.
## LPCN 1144: Multidimensional Mechanism of Action Across the Full Spectrum of NASH Pathogenesis

<table>
<thead>
<tr>
<th>Homeostasis Modifier(^1,2)</th>
<th>Anti-inflammatory(^2/)Antioxidant/Immuno-modulator(^3)</th>
<th>Regeneration Booster(^5,6)</th>
<th>Anabolic Agent(^9)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alter lipid, cholesterol, and glucose metabolism</td>
<td>Restore mitochondrial turnover and normalizes oxygen consumption(^4)</td>
<td>Stimulate satellite cells and myocyte precursor resulting in cell differentiation and myocyte proliferation(^7)</td>
<td>Increase muscle mass, bone density in men with liver disease(^10)</td>
</tr>
<tr>
<td>Reduce visceral abdominal fat</td>
<td>Modify activity of hepatic lipase, and skeletal muscle/adipose lipoprotein lipase</td>
<td>Increases circulating endothelial progenitor cells (“EPC”) (^8)</td>
<td></td>
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</tbody>
</table>

LFS was an open-label, multi-center single-arm 16-week study (N=36) with LPCN 1144 in hypogonadal males.

LF = liver fat
LPCN 1144: Liver Fat Study Results
Meaningful Relative Liver Fat % Change and Responder Rate

**Mean Relative Liver Fat % Change**

<table>
<thead>
<tr>
<th>% Liver Fat CBL (±SEM)</th>
<th>Mean Relative Liver Fat % Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>BL ≥ 5%</td>
<td>-33%</td>
</tr>
<tr>
<td>BL ≥ 8%</td>
<td>-42%</td>
</tr>
<tr>
<td>BL ≥ 10%</td>
<td>-40%</td>
</tr>
</tbody>
</table>

**Responder Rate for Relative Liver Fat % Change**

<table>
<thead>
<tr>
<th>% of Responders</th>
<th>BL ≥ 5%</th>
<th>BL ≥ 8%</th>
<th>BL ≥ 10%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Responder Rate</td>
<td>71%</td>
<td>80%</td>
<td>75%</td>
</tr>
</tbody>
</table>

* Responder rate for relative change is % of patients with at least 30% for relative change from baseline.
LPCN 1144: Liver Fat Study Results
Liver Fat Based Subject Distribution at Each Visit

Longer Therapy Improved Liver Fat Reductions and Proportion of Subjects with Disease Resolution

Baseline Pre treatment
- NAFLD Free: 38%
- LF < 5% (NAFLD Free): 24%
- 5% ≤ LF < 8%: 6%
- 8% ≤ LF < 10%: 32%
- LF > 10%: 12%

N=34

8 Week Treatment
- NAFLD Free: 55%
- LF < 5% (NAFLD Free): 21%
- 5% ≤ LF < 8%: 18%
- 8% ≤ LF < 10%: 15%
- LF > 10%: 12%

N=33

16 Week Treatment
- NAFLD Free: 65%
- LF < 5% (NAFLD Free): 15%
- 5% ≤ LF < 8%: 15%
- 8% ≤ LF < 10%: 12%
- LF > 10%: 9%

N=34
LPCN 1144: Reduction in Liver Enzyme Levels

- Placebo Controlled 4 Week Study (M12-778)

**Graph:**
- ALT: LPCN 1144 225mg BID: -47.4%, LPCN 1144 300mg BID: -47.3%
- AST: LPCN 1144 225mg BID: -11.5%, LPCN 1144 300mg BID: -11.0%
- ALP: LPCN 1144 225mg BID: -15.8%, LPCN 1144 300mg BID: -21.0%
- GGT: LPCN 1144 225mg BID: -6.6%, LPCN 1144 300mg BID: -16.7%
LPCN 1144: Post-hoc Analysis Methods

• Analyses were performed involving hypogonadal male cohorts with baseline liver enzymes* and lipids**
  – Active-controlled, randomized, open label study (SOAR) NCT02081300, (N=210) with 52 week treatment - 225mg ± 75mg BID
  • Treatment arm: LPCN 1144
  • Control arm: Topical T Gel

* ALT, AST, ALP, GGT; Persistent elevated ALT is a biomarker often used in clinical diagnosis of NAFLD/NASH
** Triglyceride is strongly associated with non-alcoholic fatty liver disease
LPCN 1144: Reductions of Elevated ALT in Patients at Risk of NAFLD

- Active Controlled 52 Week Study (SOAR)

** Patients with ALT > 40 U/L at BL (N=42); ALT mean BL = 53.6 U/L

† Patients with ALT > 40 U/L at BL in SOAR Trial
* Metabolic syndrome: obesity + diabetes + hypertension
LPCN 1144: Reductions of Elevated TG in Patients at Risk of NAFLD

- Active Controlled 52 Week Study (SOAR)

In Patients† with NAFLD Comorbidity

<table>
<thead>
<tr>
<th>Condition</th>
<th>TG Mean Change from BL (±SEM), mg/dL</th>
</tr>
</thead>
<tbody>
<tr>
<td>OBS</td>
<td>-40</td>
</tr>
<tr>
<td>T2D</td>
<td>-128</td>
</tr>
<tr>
<td>HTN</td>
<td>-64</td>
</tr>
<tr>
<td>OBS &amp; T2D</td>
<td>-138</td>
</tr>
<tr>
<td>MetS*</td>
<td>-138</td>
</tr>
</tbody>
</table>

Sustained Reduction of Elevated TG**

** Patients† for TG > 200 mg/dL at BL (N=73); TG mean BL = 320 mg/dL

† Patients with TG > 200 mg/dL at BL in SOAR Trial

* Metabolic syndrome: obesity + diabetes + hypertension
LPCN 1144: Oral T
Mean LDL Reduction for Patients with Elevated LDL at Baseline

• 52 Week SOAR Trial

![Graph showing LDL-C change from baseline](image)

- **BL = 114 mg/dL**
  - Overall (N=194)

- **175 mg/dL**
  - Above-Normal at BL* (N=16)

* LDL-C upper normal limit is 160 mg/dL.
LPCN 1144: Oral T

Appreciable % of Patients Experienced Normalization of ALT, GGT, TG, LDL-C, and Lp-PLA2

• 52 Week SOAR Trial

Normalization of Biomarkers with LPCN 1144

<table>
<thead>
<tr>
<th>% of Normalized Patients from Above-normal at Baseline</th>
<th>ALT*</th>
<th>GGT*</th>
<th>TG*</th>
<th>LDL-C*</th>
<th>Lp-PLA2*</th>
</tr>
</thead>
<tbody>
<tr>
<td>52%</td>
<td>31%</td>
<td>34%</td>
<td>56%</td>
<td>52%</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>N</th>
<th>42</th>
<th>36</th>
<th>73</th>
<th>16</th>
<th>25</th>
</tr>
</thead>
<tbody>
<tr>
<td>BL</td>
<td>53.6 U/L</td>
<td>82.2 U/L</td>
<td>320 mg/dL</td>
<td>175 mg/dL</td>
<td>277 ng/mL</td>
</tr>
</tbody>
</table>

* ALT, GGT, TG, LDL-C, and Lp-PLA2 normal range upper limit is 40 U/L, 49 U/L, 200 mg/dL, 160 mg/dL, and 235 ng/mL, respectively
LPCN 1144: Robust ALT Response
Good Potential for Histological Improvement

- Comparable LPCN1144 ALT response to Vitamin E in PIVENS Trial

<table>
<thead>
<tr>
<th>Histological feature</th>
<th>Vitamin E</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean change in steatosis score</td>
<td>ALT R* (n = 34)</td>
<td>-1.1</td>
</tr>
<tr>
<td>Mean change in inflammation score</td>
<td>ALT NR* (n = 37)</td>
<td>-0.4</td>
</tr>
<tr>
<td>Mean change in Ballooning score</td>
<td>ALT R* (n = 34)</td>
<td>-1.1</td>
</tr>
<tr>
<td>Mean change in Ballooning score</td>
<td>ALT NR* (n = 37)</td>
<td>-0.3</td>
</tr>
<tr>
<td>Mean change in NAS† score</td>
<td>ALT R* (n = 34)</td>
<td>-0.8</td>
</tr>
<tr>
<td>Mean change in NAS‡ score</td>
<td>ALT NR* (n = 37)</td>
<td>-0.2</td>
</tr>
<tr>
<td>Mean change in NAS† score</td>
<td>ALT R* (n = 34)</td>
<td>-3.0</td>
</tr>
<tr>
<td>Mean change in NAS‡ score</td>
<td>ALT NR* (n = 37)</td>
<td>-0.8</td>
</tr>
<tr>
<td>Decrease in NAS by ≥ 2 points</td>
<td>ALT R* (n = 34)</td>
<td>82%</td>
</tr>
<tr>
<td>Decrease in NAS by ≥ 2 points</td>
<td>ALT NR* (n = 37)</td>
<td>32%</td>
</tr>
<tr>
<td>Resolution of NASH‡</td>
<td>ALT R* (n = 34)</td>
<td>44%</td>
</tr>
<tr>
<td>Resolution of NASH‡</td>
<td>ALT NR* (n = 37)</td>
<td>22%</td>
</tr>
<tr>
<td>Mean change in Weight (kg)</td>
<td>ALT R* (n = 34)</td>
<td>-0.9</td>
</tr>
<tr>
<td>Mean change in Weight (kg)</td>
<td>ALT NR* (n = 37)</td>
<td>1.8</td>
</tr>
</tbody>
</table>

* ALT Responders: Patients with ALT > 40 U/L at baseline, ending with ≤ 40 U/L and more than 30% reduction at end of study post therapy
† Total non-alcoholic fatty liver activity score (NAS), comprising the sum of scores for steatosis, inflammation, and ballooning cell injury
‡ Resolution of histological features that fulfill the criteria for diagnosis of NASH

<table>
<thead>
<tr>
<th>% of ALT Responders at EOS</th>
<th>N = 42 †</th>
<th>N = 71 †</th>
</tr>
</thead>
<tbody>
<tr>
<td>vitamin E (Wk 120)</td>
<td>48%</td>
<td></td>
</tr>
<tr>
<td>LPCN 1144 (Wk 52)</td>
<td>43%</td>
<td></td>
</tr>
</tbody>
</table>

† Total N is for patients with ALT > 40 U/L at baseline (ALT normal range is ≤ 40 U/L)
LPCN 1144: Additional Health Benefits
Observed in Hypogonadal Subjects with Elevated ALT*

SF-36, Short Form-36 (0-100); PDQ, Psychosexual Daily Questionnaire (0-7); * ALT > 40 U/L at Baseline in 52 week SOAR Trial (N=33)
LPCN 1144: Gastrointestinal Safety
Gastrointestinal Disorders ≥ 1% in SOAR Trial (52 Weeks)
LPCN 1144: A Differentiated Oral NASH Therapy Candidate
Prodrug of Endogenous Testosterone

| Liver Fat Reduction and Key Serum Biomarkers | • Over 40% relative mean liver fat reduction after 16-weeks of treatment
| • 48% of the treated NAFLD subjects had NAFLD resolution, defined as < 5% liver fat |
| Suitable for Chronic Use | • Good GI tolerability
| • No mean LDL increase
| • No signs of nephrotoxicity
| • No signs of skeletal fragility
| • No signs of drug induced liver toxicity |
| Suitable for Chronic Use | 700+ subjects in 14 studies with up to 52-week exposure |
| Potential Favorable Benefits in Systems Outside the Liver | • T therapy known to improve symptoms of sarcopenia and, sexual/mood dysfunction |
LPCN 1144: Next Step
Advancing Forward

- **LiFT** (Liver Fat intervention with oral Testosterone) Phase 2 paired-biopsy Phase 2 clinical study in NASH subjects – Initiated
  - **Study Design**
    - Three-arm, double-blind placebo controlled
    - Biopsy confirmed NASH male subjects with NAS ≥ 4
    - Paired biopsy at baseline and EOS (36-weeks)
  - First-patient dosing expected in 3Q 2019