LIPOCINE®

ENHANCING HEALTH

Enabling Oral Drug Delivery to Improve Patient Compliance

Corporate Presentation

May 28, 2019

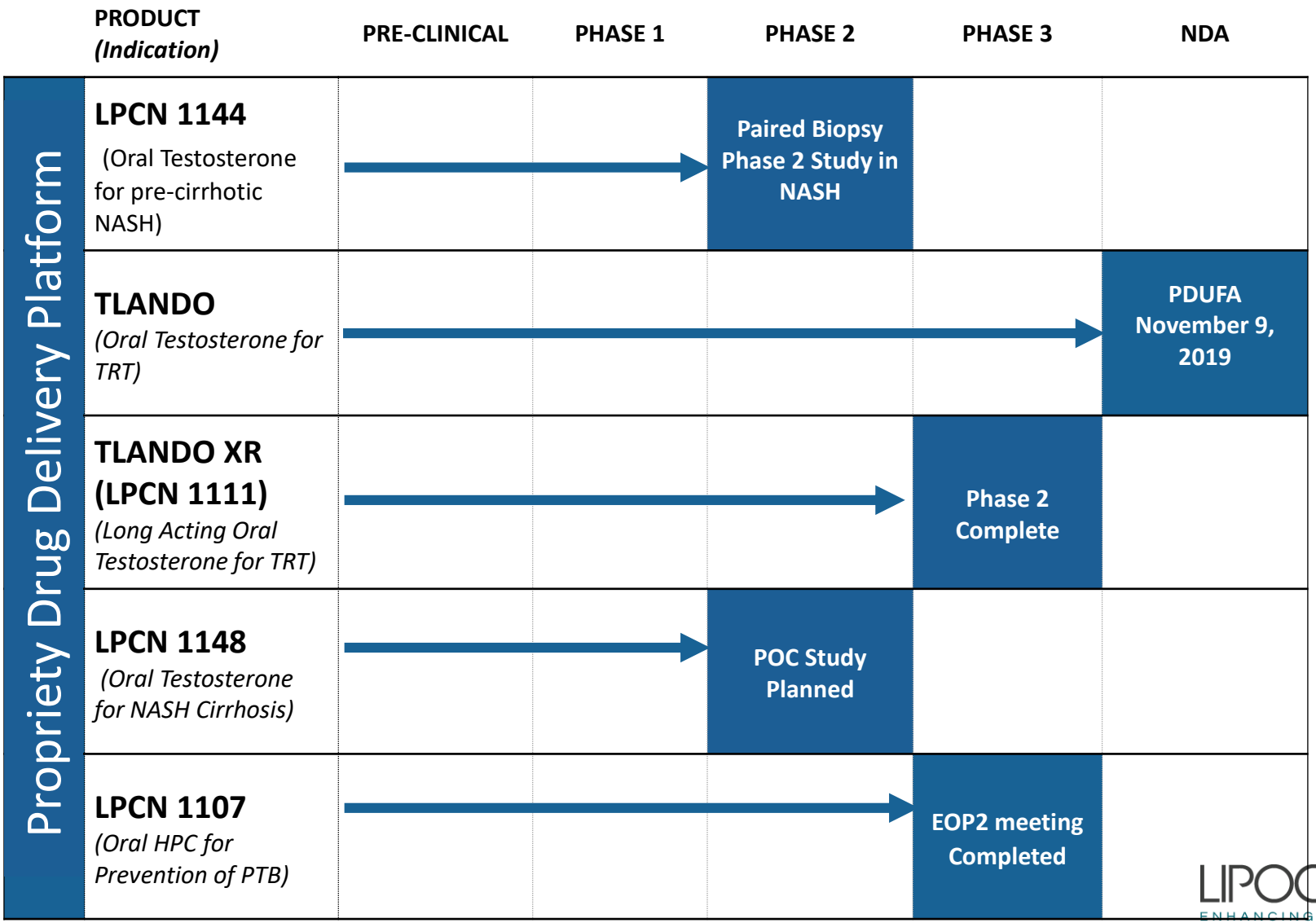
Forward-Looking Statements

This presentation contains forward-looking statements about Lipocine Inc. (the "Company"). These forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements relate to the Company's product candidates, the expected timing of the resubmission of the NDA for TLANDO, FDA review process related to our resubmitted NDA for TLANDO™, the expected timing of Phase 2 studies for LPCN 1144 and LPCN 1148, clinical and regulatory processes and objectives, potential benefits of the Company's product candidates, intellectual property and related matters, all of which involve known and unknown risks and uncertainties. Actual results may differ materially from the forward-looking statements discussed in this presentation.

Accordingly, the Company cautions investors not to place undue reliance on the forward-looking statements contained in, or made in connection with, this presentation. Several factors may affect the initiation and completion of clinical trials and studies, the potential advantages of the Company's product candidates and the Company's capital needs. The forward-looking statements contained in this presentation are qualified by the detailed discussion of risks and uncertainties set forth in the Company's annual report on Form 10-K and other periodic reports filed by the Company with the Securities and Exchange Commission, all of which can be obtained on the Company's website at www.lipocine.com or on the SEC website at www.sec.gov. The forward-looking statements contained in this document represent the Company's estimates and assumptions only as of the date of this presentation and the Company undertakes no duty or obligation to update or revise publicly any forward-looking statements contained in this presentation as a result of new information, future events or changes in the Company's expectations.

Clinical Stage Biopharmaceutical Company

Metabolic and Endocrine Focus



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LPCN 1144

Targeted for Non-Alcoholic Steatohepatitis ("NASH")

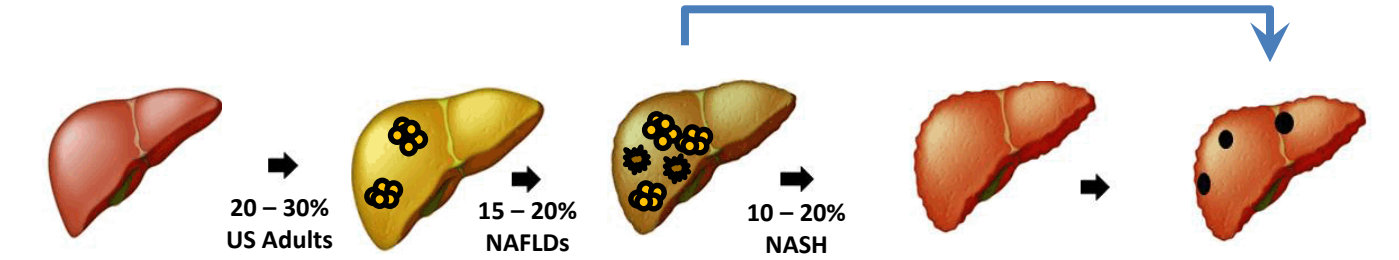
A silent killer that affects 30 million Americans[1]

1. CNBC; published December 30, 2018

Non-Alcoholic Fatty Liver Disease ("NAFLD")

No Approved Product for the Treatment of NAFLD/NASH

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



Eligible for Liver Transplantation

LFTs: Liver function test, especially Alaninine amino transferase (ALT) and Aspartame amino transferase (AST)
NASH: Non-alcoholic Steatohepatitis, TG: Triglyceride

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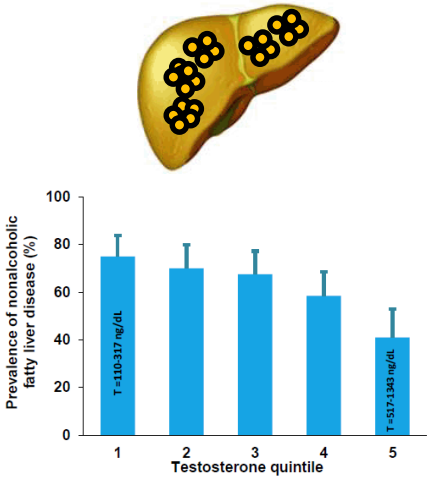
Clinical Relationship Between Testosterone and NAFLD

Across the Full Disease Spectrum

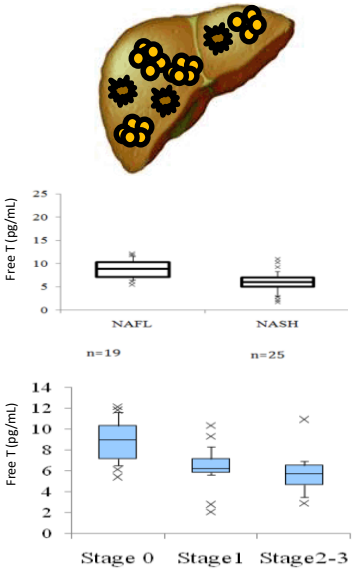
Hepatic Steatosis

"Men with low testosterone are at high risk for NAFLD." [1]



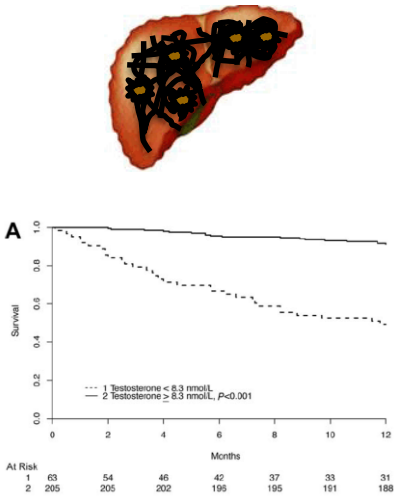
NASH

"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;

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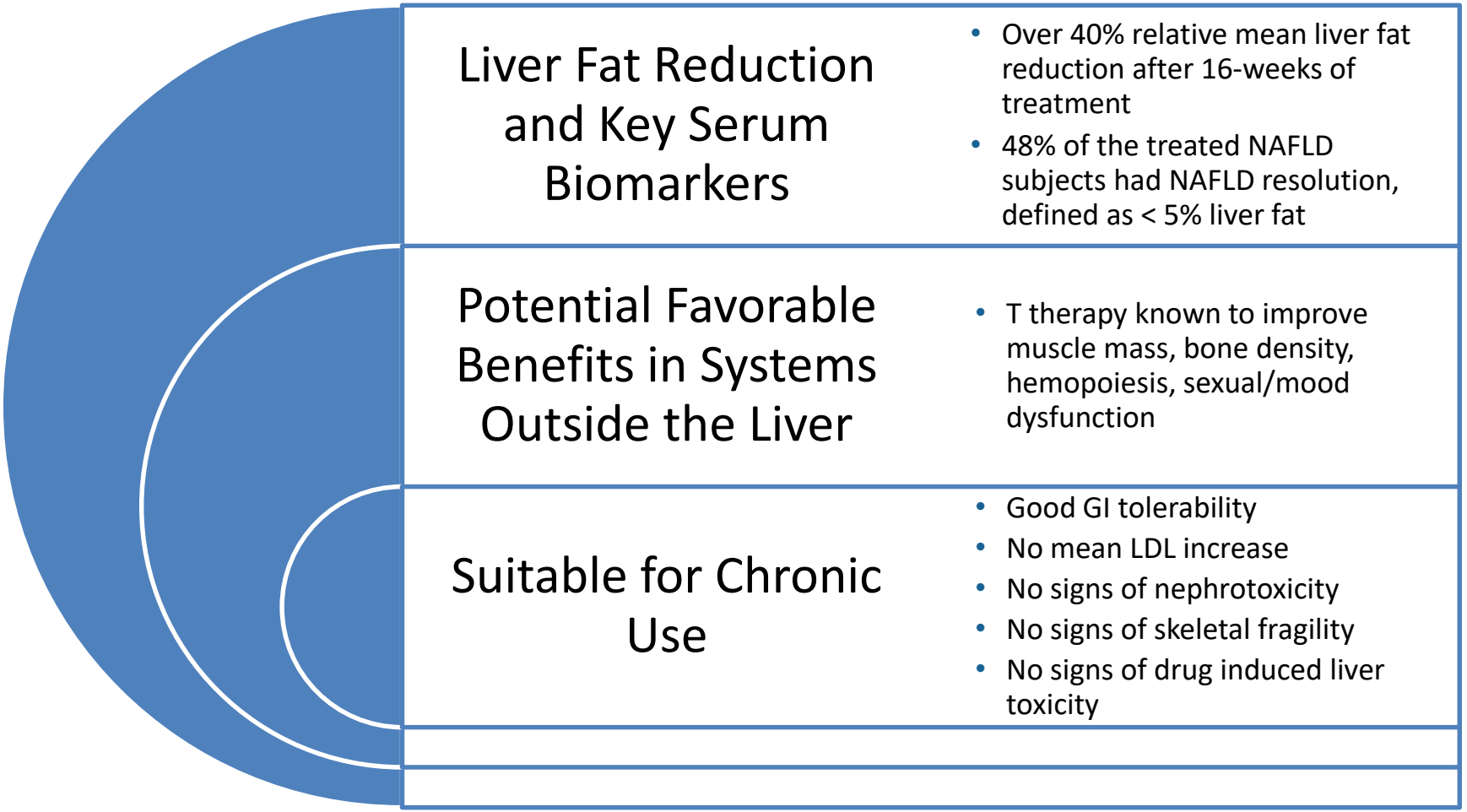
LPCN 1144: A Differentiated Oral NASH Therapy Candidate

Prodrug of Endogenous Testosterone



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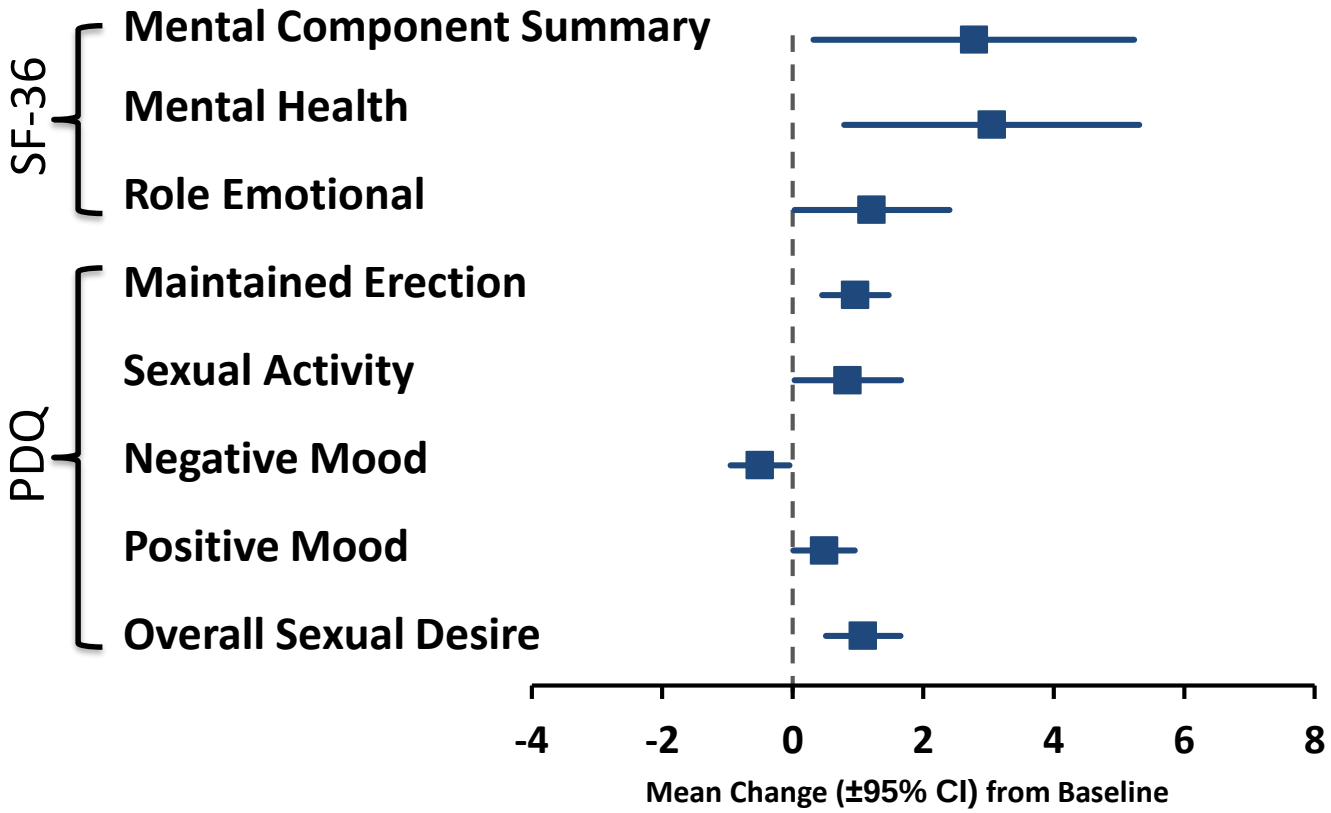
LPCN 1144: Additional Health Benefits

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)

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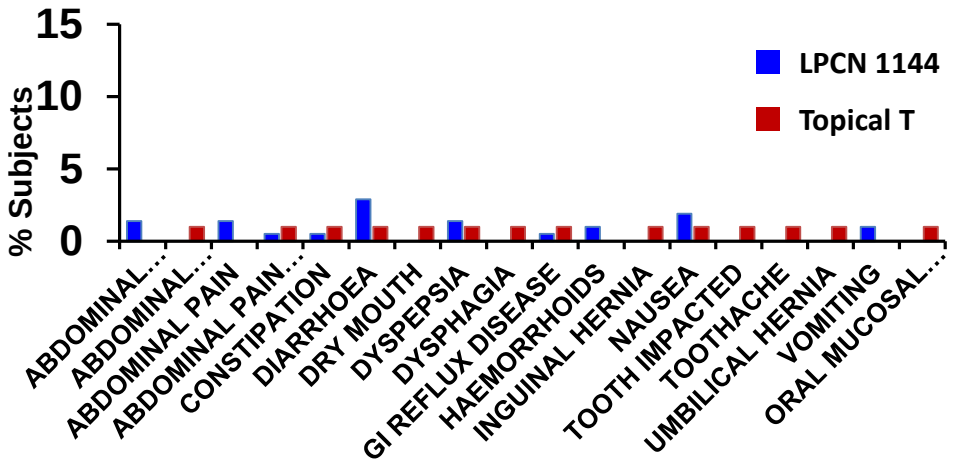
LPCN 1144: Extensive Clinical Safety Database

Demonstrated No Unexpected Risks

- 650+ subjects in 14 studies with up to 52 week exposure
- No drug related SAEs
- No deaths or MACE events

Gastrointestinal Disorders ≥ 1% in SOAR Trial (52 Weeks)



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LPCN 1144: Multidimensional Mechanism of Action

Across the Full Spectrum of NASH Pathogenesis

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

1. Shen and Shi, Int J Endocrinol, 2015
2. Kelly and Jones, J Endocrinol, 2013
3. Sinclair et al., J Gastroenterol Hepatol, 2015
4. Linda Vignozzi et al., University of Florence, IT, unpublished, 2018
5. A. Francavilla et al., Digest Dis Sci, 1989
6. Vic et al., Hepatol 1982
7. Sinha-Hikim et al., J Clin Endocrinol Metab, 2004
8. Liao CH et al., Andrology, 2013
9. Gentile MA et al., J Mol Endocrine, 2010
10. Sinclair et al., J Gastroenterol Hepatol 2016

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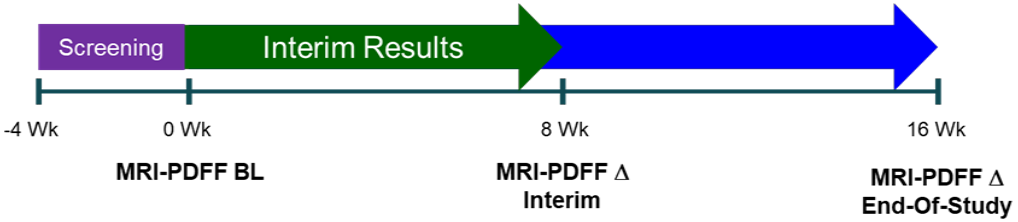
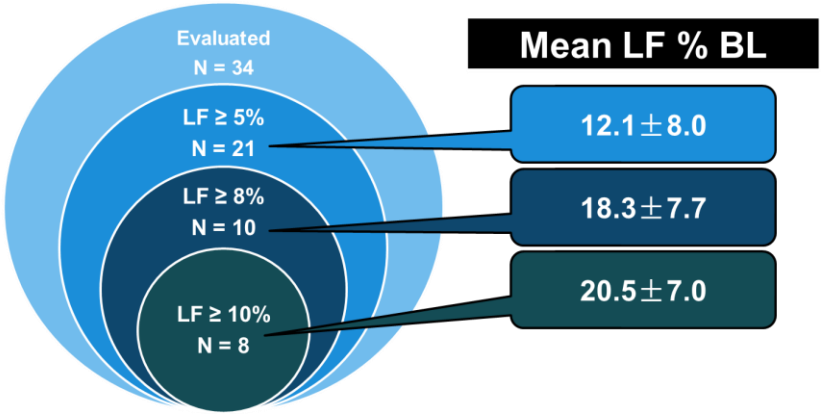
LPCN 1144: Liver Fat Imaging Study ("LFS")

Study Design and Baseline Liver Fat Subject Distribution

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





LF = liver fat

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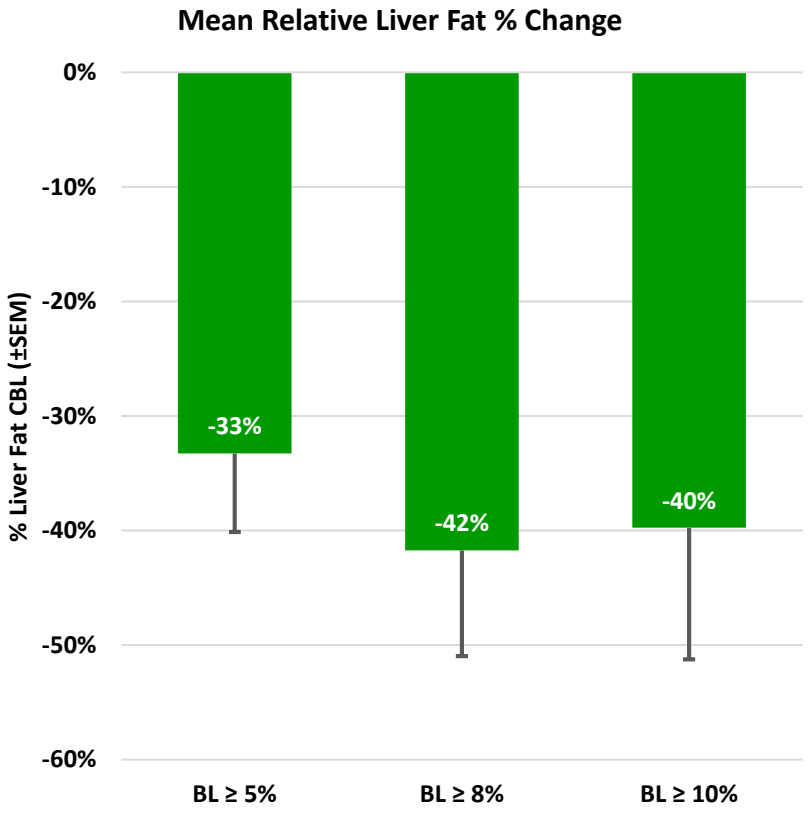
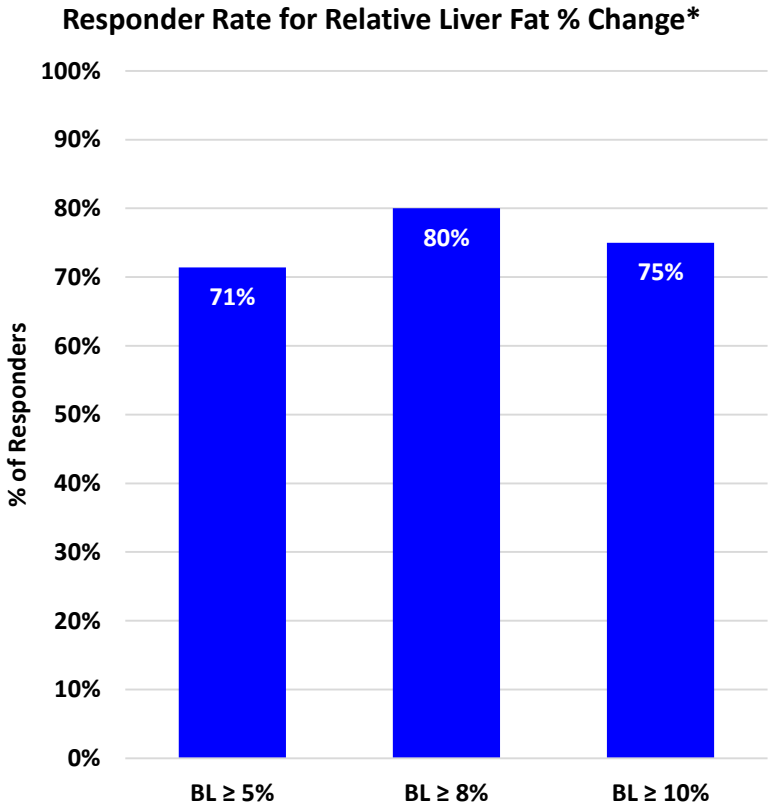
LPCN 1144: Liver Fat Study Results

Meaningful Relative Liver Fat % Change and Responder Rate





* Responder rate for relative change is % of patients with at least 30% for relative change from baseline.

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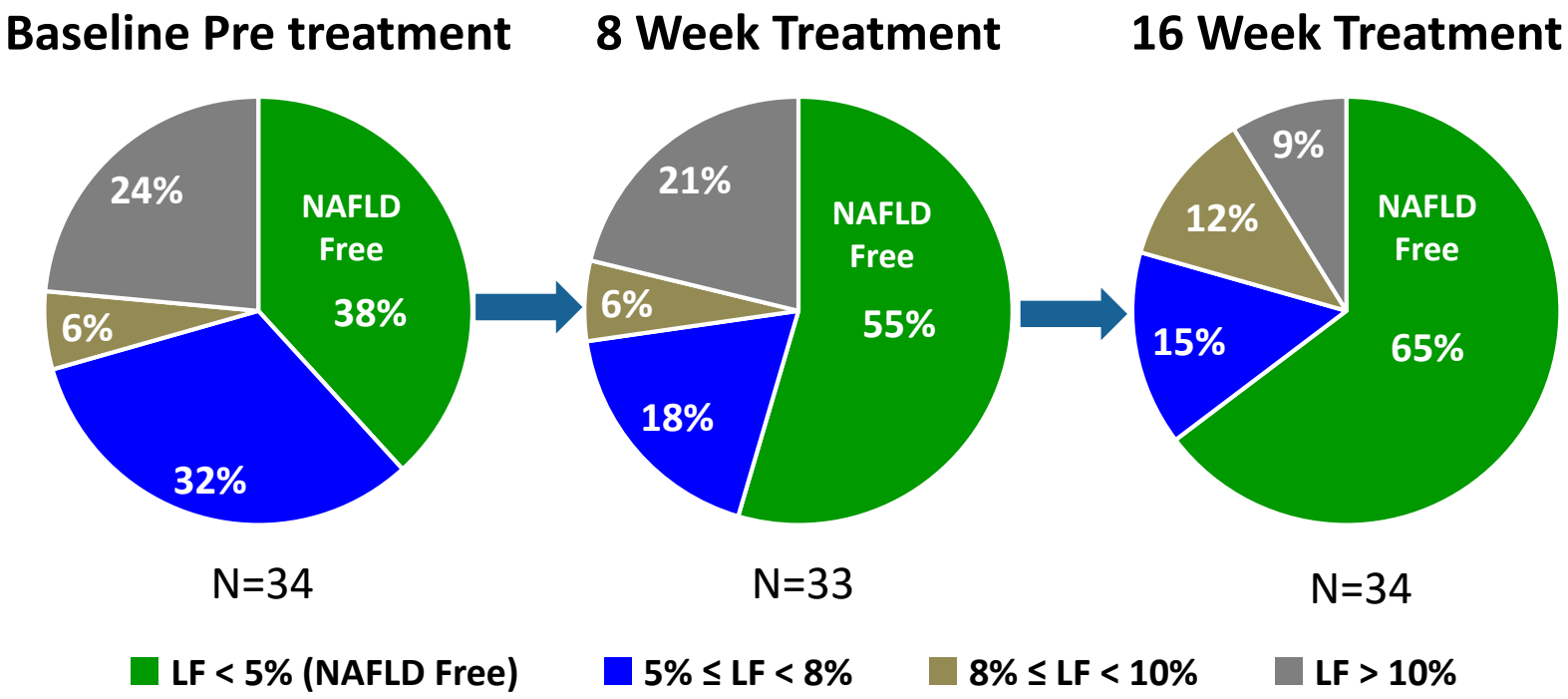
LPCN 1144: Liver Fat Study Results

Liver Fat Based Subject Distribution at Each Visit

Longer Therapy Improved Proportion of Subjects with Disease Resolution



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LPCN 1144: Next Step

Advancing Forward

- Initiating paired-biopsy Phase 2 clinical study in NASH subjects
  - Study Design
    - Three-arm, double-blind placebo controlled
    - Biopsy confirmed NASH male hypogonadal subjects with NAS ≥ 4
    - Paired biopsy at baseline and EOS (36-weeks)
  - First-patient dosed targeted for 3Q 2019

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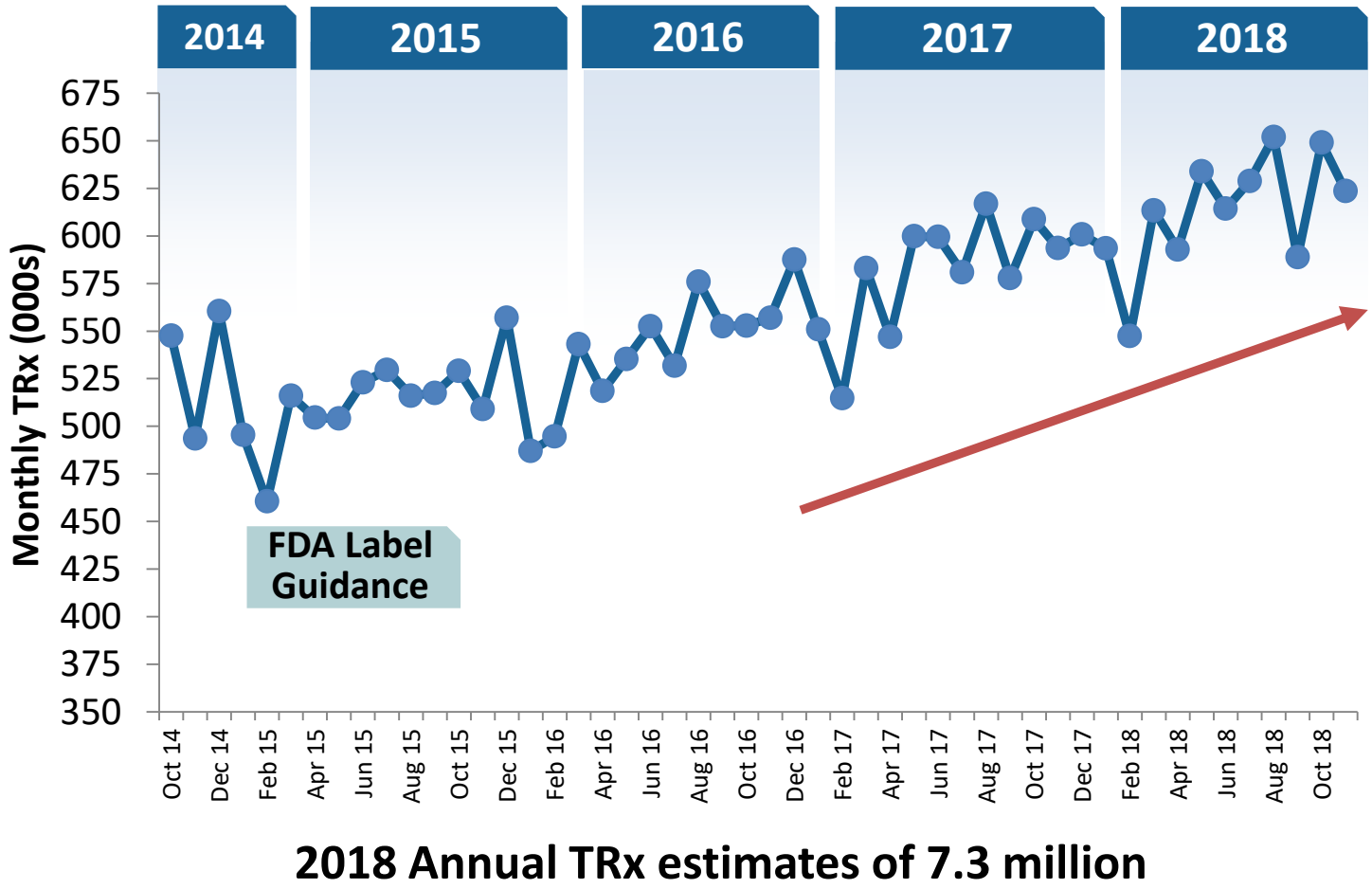
TLANDO™

Targeted for Testosterone Replacement Therapy

Annual TRx ~7M

Monthly TRT TRx Trend

TRT Market is Growing



2018 Annual TRx estimates of 7.3 million

Source: IMS database
TRx = Total prescriptions

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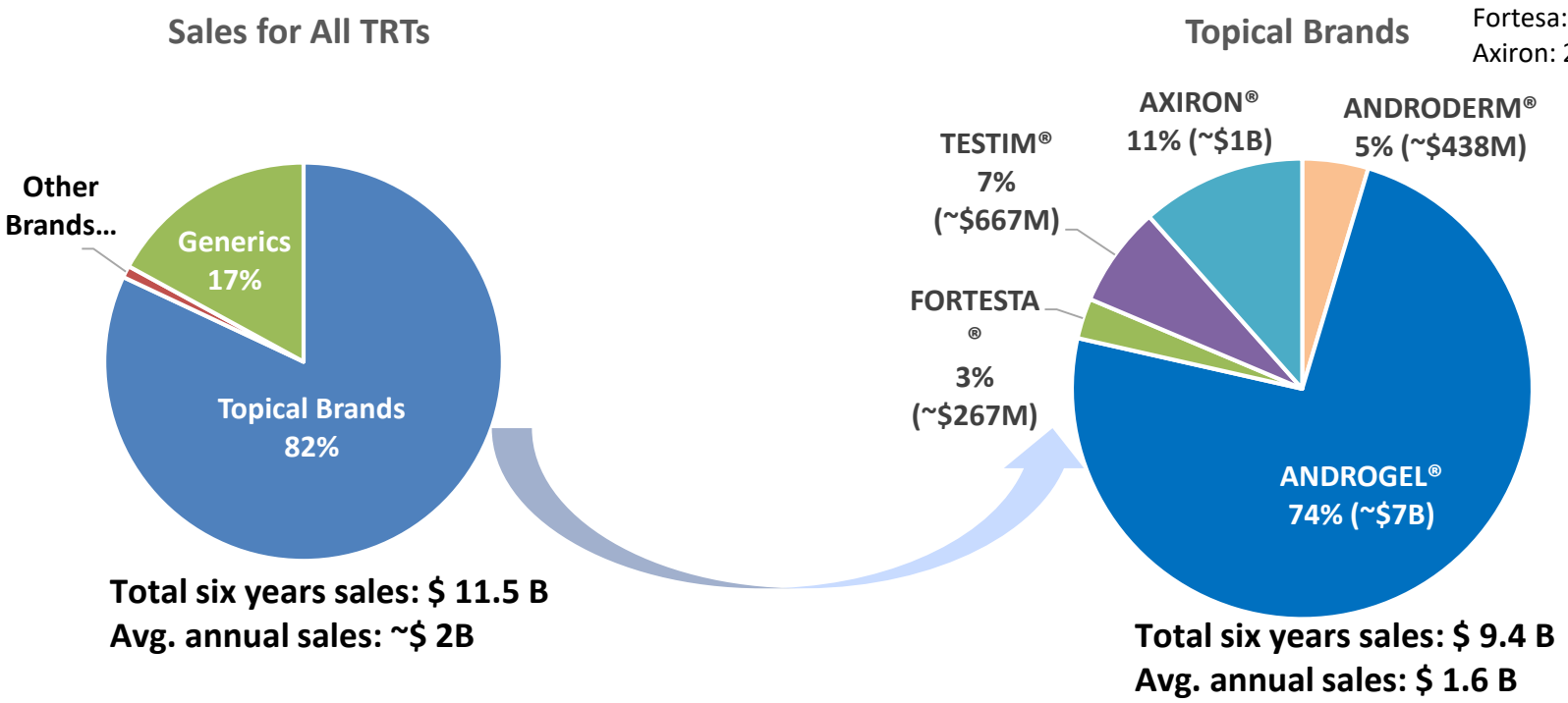
Cumulative TRT Sales Last Six Years*

Branded Topicals Dominated TRT Sales

Year launched
Androderm: 1995
Androgel: 2000
Testim: 2003
Fortesa: 2011
Axiron: 2011



Source: IMS
*Feb 2013 to Jan 2019

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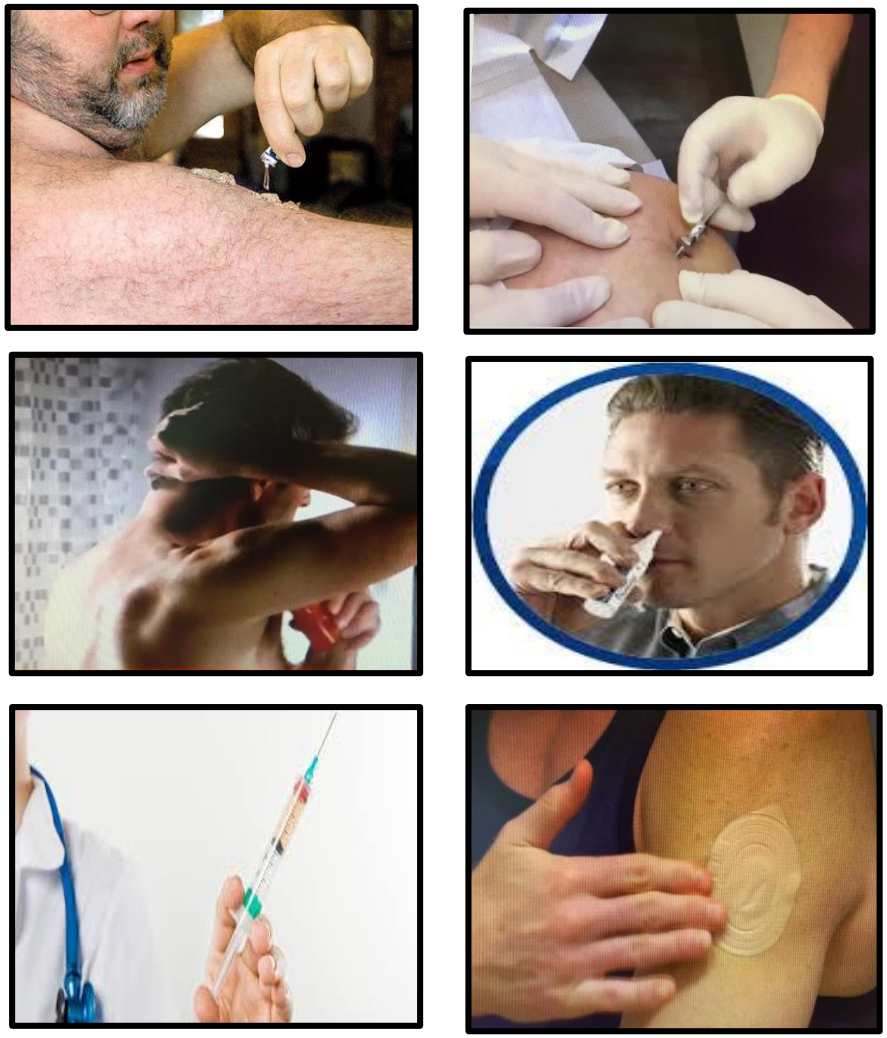
Issues with Current Non-oral TRT Options

Potential Barrier To Newly Diagnosed and Existing Patients



- **Black Box Warning**
  - Secondary exposure to testosterone
  - Pulmonary oil micro embolism (POME) and anaphylaxis shock
- **Inconvenient application or painful injection**
- **Poor persistence reflects need for oral**
  - Average days on therapy is 100 days
- **More than 50% of patients need dosage adjustment**
  - Burdensome for patients due to multiple doctor visits

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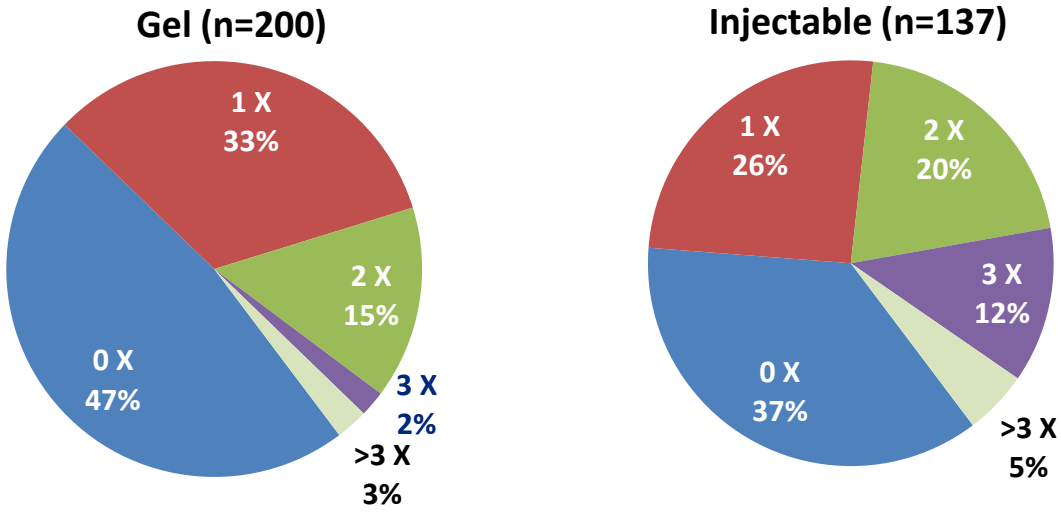
Current TRT Dosing Regimes

Over 50% of Patients Require Dose Adjustment with Current TRT Therapies



Number of Current TRT Dose Adjustments by Form*

* Current TRT n=412
Q16. Since you started using your current testosterone medication, how many times was the dose adjusted up or down until you reached your current dose level?

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TLANDO Attributes

Patient and Physician Preferred Oral Option

Key Advantages of Oral Route:

- No risk of accidental T transference
- Non-invasive; easy to use
- Less cumbersome/burdensome
- Potential for higher persistence/adherence

PCP preferred fixed dosing regimen

- 450mg (225 mg BID) Daily TU capsule orally administered
  - Start off with “right dose” for all patients
- Easy to use for patients and physicians to prescribe
- Fewer doctor visits (No dose adjustment visits for patients)
  - More compliant-generalizable to real world male patient behavior
- Fixed/predictable cost for payers
- No need to get any additional fasting labs

Differentiated hypertension (“HTN”) profile

- ~ 1% new anti-HTN starts or increase in anti-HTN dose
- 32% of subjects with baseline sBP >140 mm Hg experienced a decrease to <140 mm Hg with mean change of -3 mm Hg

Consistent inter-day restoration of T levels

TLANDO = Opportunity

Near Term FDA Decision

TLANDO™
(testosterone undecanoate)
112.5 mg oral capsule (III)

- **TLANDO™ PDUFA date is November 9, 2019**
- **Significant unmet patient and physician needs with current therapies**
- **TLANDO™ is clinically differentiated**
- **TRT prescriptions are growing; Share of voice all time low**
- **$2B+ Market Opportunity**

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TLANDO XR

First Long Acting Oral

TLANDO XR (LPCN 1111): Profile

Once Daily Differentiated Oral TRT

- Once daily oral testosterone
  - New molecule with associated IP
  - Novel prodrug of testosterone for oral delivery through proprietary drug delivery technology
- TLANDO XR proof of concept established
  - Positive Phase 2b study results in hypogonadal men
    - Once daily oral dose provides T levels in the eugonadal range
- Phase 3 daily dose identified based on multiple dose Phase 2 studies in hypogonadal male
- Next steps:
  - Obtain FDA feedback on Phase 3 clinical study design

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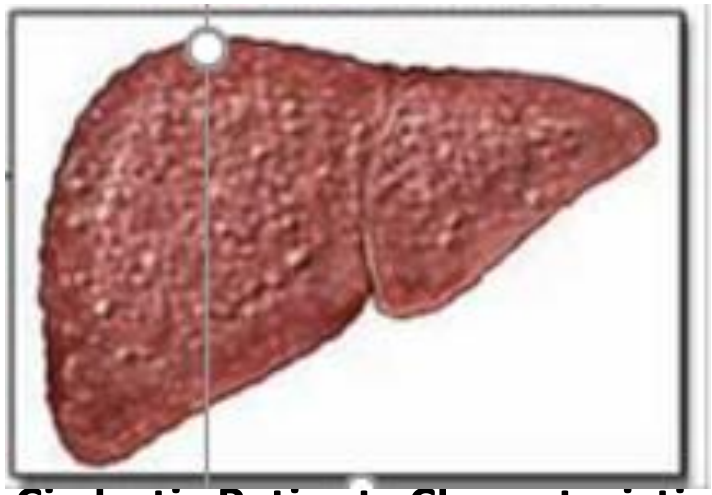
LPCN 1148

For Treatment of NASH Cirrhosis

LPCN 1148: Oral T for NASH Cirrhosis

No FDA Approved Product-Transplant Only Cure

Cirrhotic Liver



US Prevalence

Among NASH population (2015)*:

- Fibrosis grade 4 (cirrhosis) case: 1.3M
- Compensated cirrhosis 1.16M
- Decompensated cirrhosis: 134,400

In 2013, cirrhosis cause mortality was ~38,000** and consistently twice the rate in males as females **

Cirrhotic Patients Characteristics:

- Increased morbidity and mortality
- Symptoms of hypogonadism: altered hair distribution, anemia, sexual dysfunction, testicular atrophy, muscle wasting, fatigue, osteoporosis, gynecomastia
- Late stage symptoms: jaundice, pruritis, hepatic encephalopathy, ascites, anasarca, GI bleeding

*Estes C. et al., Hepatology, 2018;**Yoon and Chen, National Institute on Alcohol Abuse and Alcoholism; surveillance report, 2016

Low Testosterone Increases Adverse Outcome in Male Cirrhotic Patients

T Levels Fall Progressively with Increasing Disease Severity[1]

- Low T reported in up to 90% of NASH cirrhosis patients[2] and is a predictor of mortality[3]
- Low T associated with:
  - Increased risk of major infections, death and/ or transplantation rates[1]
  - Increased risk of for hepatic decompensation[4]
  - Worsening of sarcopenia[4]
  - Higher Child Pugh score grade[4]
  - Severity of portal hypertension and ascites grade[4]
  - Higher MELD score[5]

1. Sinclair et al., Liver Transplantation, 2016
2. Kim et al., Male Hypogonadism, edrs: Winters and Huhtaniemi, 2017
3. Sinclair M. et al., J. of Gastro and Hepatology, 2015
4. Paternostro et al, Hepatol Res 2019;
5. Sinclair et.al, Liver international, 2016

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LPCN 1148: NASH Cirrhosis

Oral T Therapy

Potentially help patients survive longer while waiting for a liver transplant

- T levels positively correlate with muscle mass in men and modulates bone density, hemoglobin production, insulin resistance, and immunity , commonly impaired in cirrhosis[1]
- Testosterone therapy increased muscle mass in men with cirrhosis and low testosterone[2]
- **Next Steps:**
  - Proof of Concept study in male NASH cirrhosis subjects

1. Sinclair M et al., J. of Gastro and Hepatology, 2016
2. Sinclair M et al., J. of Hepatology, 2016

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Upcoming Milestones

Near Term Value Drivers

	Event	Expected Timing
TLANDO™	PDUFA Date	**November 9, 2019**
LPCN 1144	Paired Biopsy Phase 2 First Patient Dosed in NASH Patients	**3Q 2019**

Key Financial Metrics

Stock Price, Market Cap, Cash Balance

Ticker Symbol	**LPCN (Nasdaq Capital Market)**
Closing Stock Price (5/24/19)	**$1.57/share**
Market Capitalization (5/24/19)	**$38.6 million**
Cash Balance (3/31/19)	**$22.5 million***
Bank Debt (3/31/19)	**$9.2 million**

* $5M restricted and becomes unrestricted upon TLANDO approval

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Appendix

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LPCN 1107

High PTB Medical Costs

≥ $26 Billion Economic Impact[3]

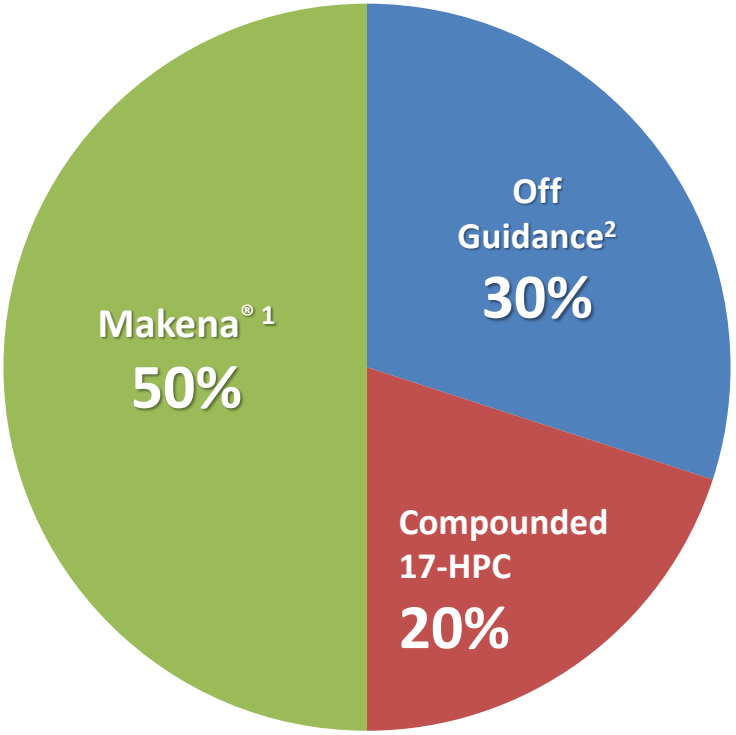
- 12% of all US pregnancies[1] (475 -500K) result in PTB (< 37 weeks)-a leading cause of neonatal mortality and morbidity
- First year medical costs for PTB infants are ~ 10x higher than for full term infants[2]
- 28% of preterm births are to women with histories of early delivery

1. CDC (2010)
2. J. Maternal-Fetal and Neonatal Medicine, Dec. 2006, 19(12), 773–782
3. Institute of Medicine of the National Academies. July 2006

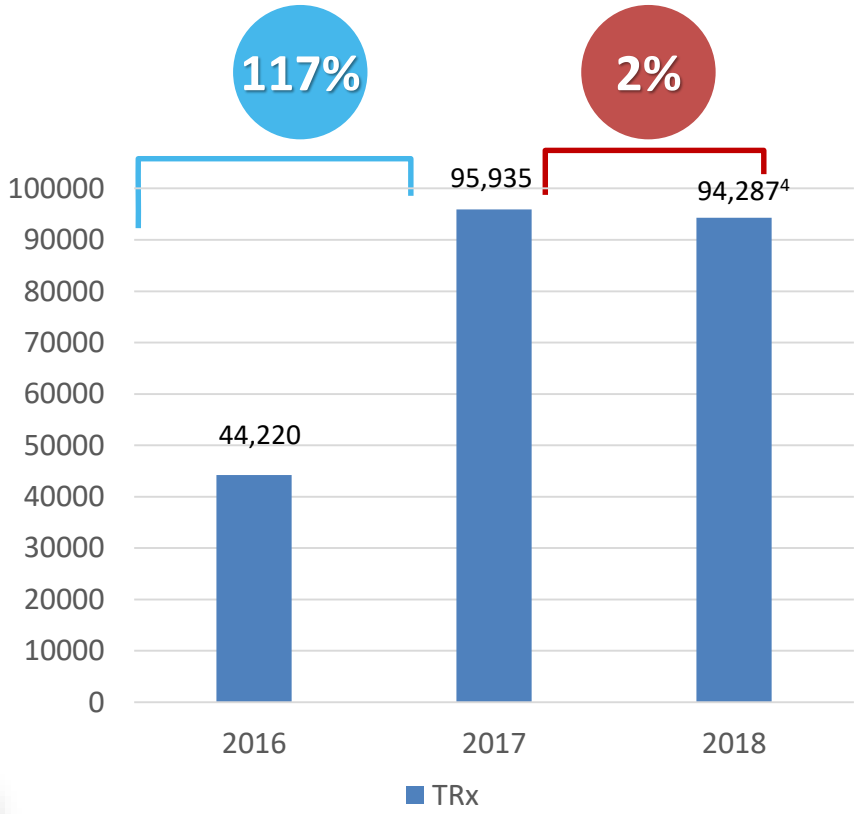
LPCN 1107: Prevention of Preterm Birth (PTB)

United States Market Landscape

December 31, 2017



HPC TRx[3]



$1B Market Opportunity[3]

1. AMAG estimates Makena market share based on distributor dispensing data and all other market share based on physician market research data conducted by AMAG.
2. Off guidance represents patients treated outside of guidance of Society for Maternal Fetal Medicine, including patients treated with unapproved therapies and untreated patients.
3. IMS data
4. Annualized September 30, 2018 data

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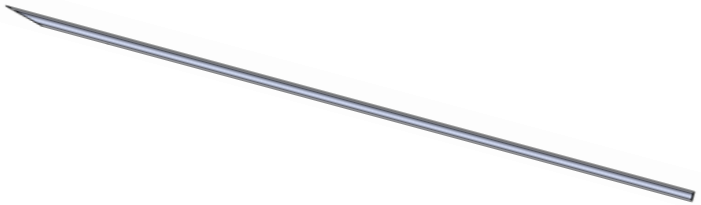
LPCN 1107: First Oral PTB Candidate

Characteristics of the Only Approved Product Options for PTB

Makena 21 gauge needle



IM HPC, Makena®:

- 20-25% patients below reported better efficacy HPC level threshold
- Total of 18-22 injections
  - Injection location: Upper-outer quadrant of the gluteus maximus
  - Weekly visit to/by health care provider
  - ~35% of patients experienced injection site pain during clinical trial
  - ~17% of patients reported site swelling-much greater than placebo during clinical trial

SubQ HPC, Makena®:

- 20-25% patients below reported better efficacy HPC level threshold
- Total of 18-22 injections
  - Approved February 14, 2018
  - Auto injector-ready to use device
  - Injection location: Upper back of the arm
  - Weekly visit to/by health care provider
  - 37.3% of subjects identified injection site pain as a treatment emergent adverse event compared to only 8.2% of subjects in the IM arm

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LPCN 1107: First Oral PTB Candidate

Addresses Unmet Need

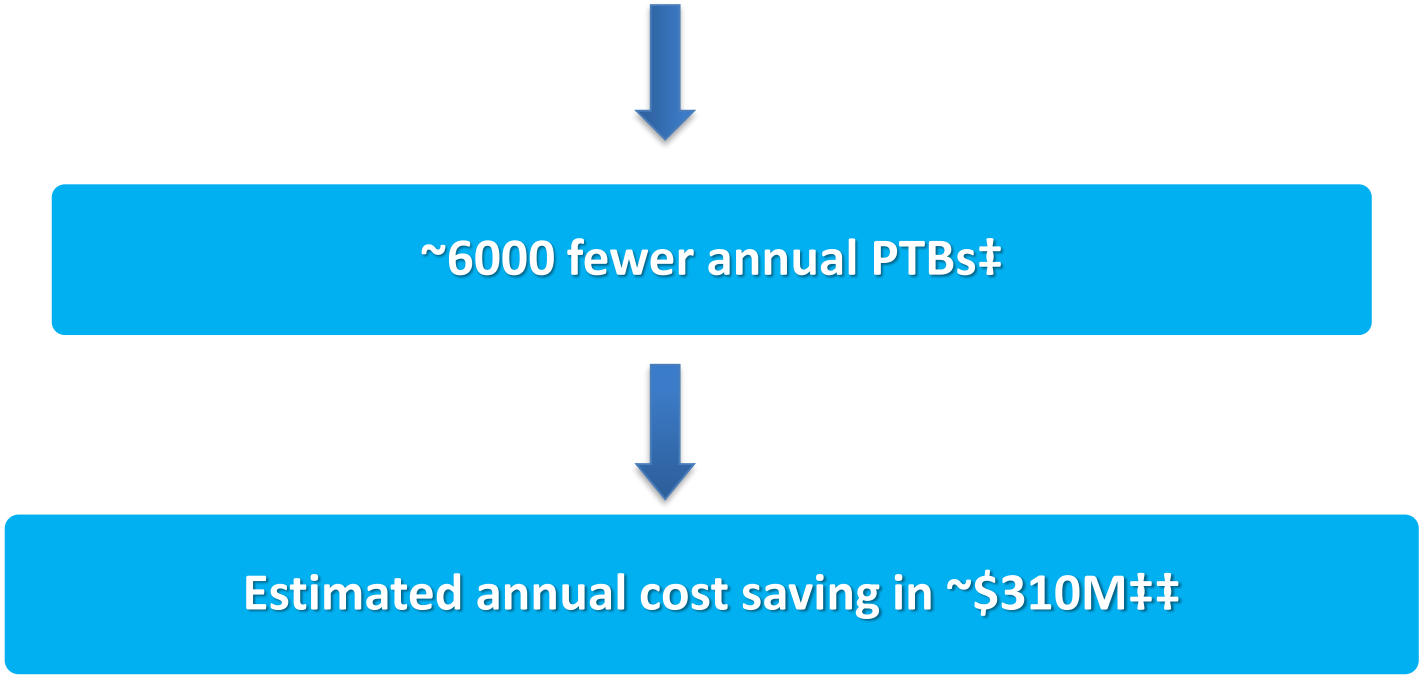
LPCN 1107- Oral HPC

- Potential for superior efficacy with Phase 3 target dose
- No patient discomfort upon administration
- Steady state achieved in 7 days
- Orphan drug designation
  - Major contribution to patient care
- Next steps:
  - Explore partnering opportunities

LPCN 1107: Economic Impact

Potential Lower PTB Rate – US and Resulting Savings

Assuming 4.3% lower PTB rate relative to Makena®



‡: Assuming 100% of 140,000 eligible US population treated

‡‡: Assuming ~$51,600 medical costs/PTB

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LPCN 1107: First Oral PTB Candidate

Commercial Outlook/Drivers

First Oral HPC for Prevention of Recurrent PTB

- Preferred route-of-administration is oral

Strong Exclusivity Position

- Orphan Drug Designation
- Technology/IP protection

Potential for Superior Efficacy

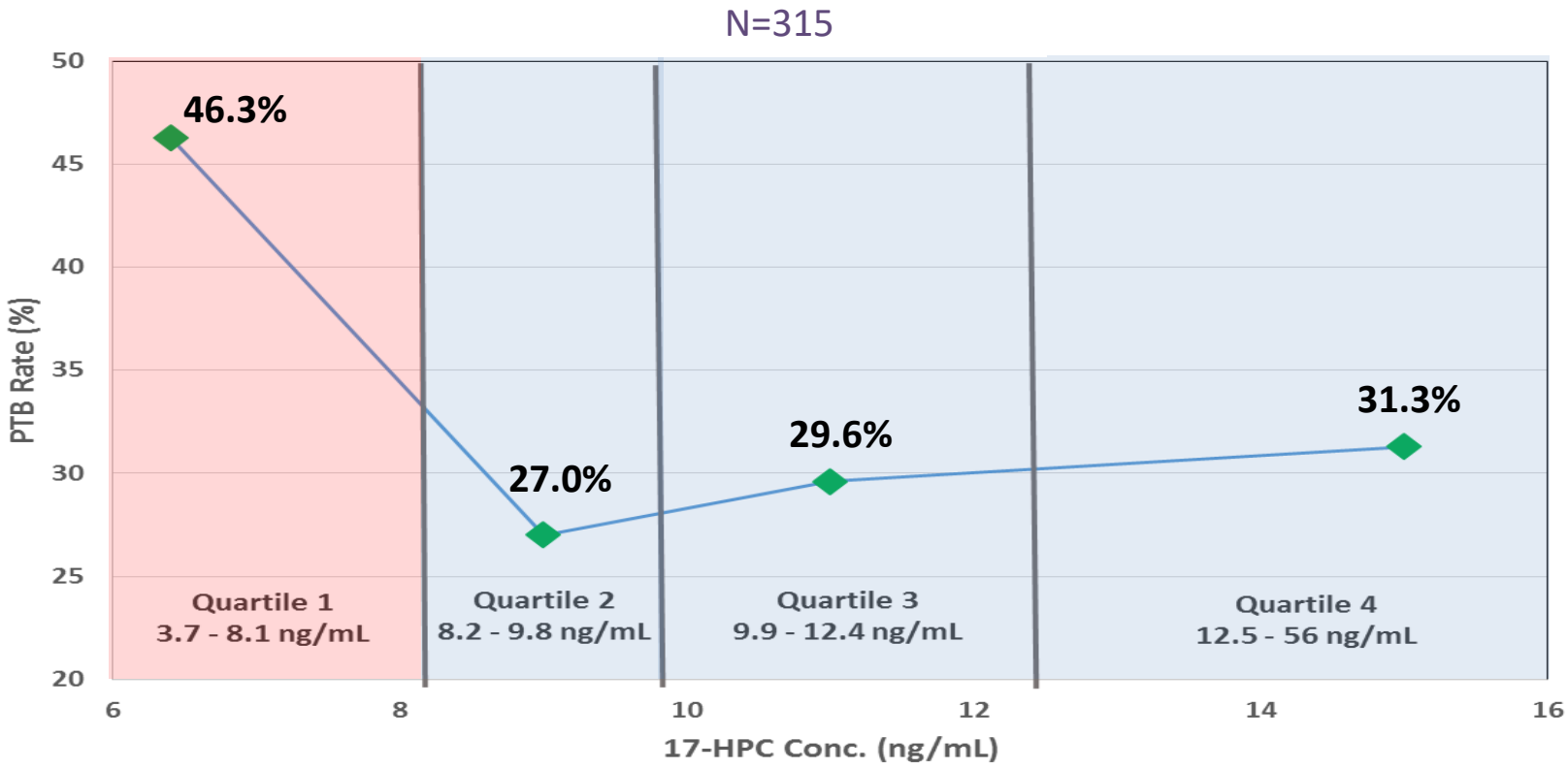
- Fewer PTB babies with significant healthcare cost savings

Strong Pharmaco-Economic Justification

- Minimize travel related cost/time and healthcare provider cost/time
- Premium pricing potential to generic IM injections

LPCN 1107: HPC PK-PD Correlation

HPC Concentration and PTB Rate with IM HPC, Makena[1]



- Lower % PTB rate can be expected with daily C_{avg}[2] HPC levels ≥ 8.2 ng/mL

1. Caritis et al., Am J Obstet Gynecol. 2014 (N=315 subjects)
2. $C_{trough} \cong C_{avg}$ for IM Makena®

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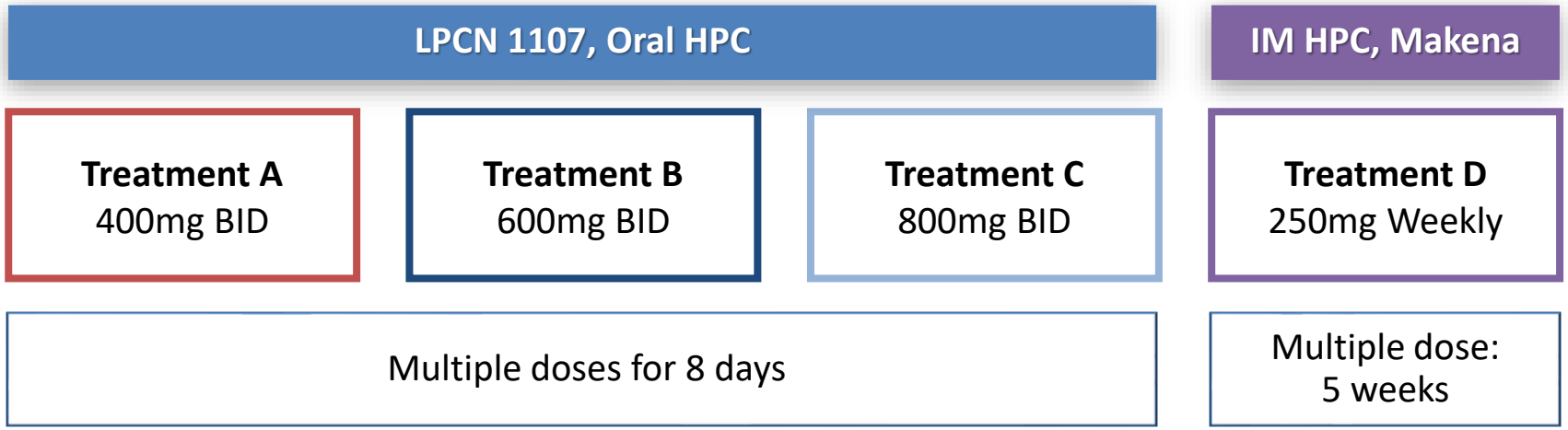
LPCN 1107: Dose Finding Study Design

PK Study: Oral LPCN 1107 vs IM HPC, Makena

- Open-label, four-period, four-treatment study
- 12 healthy pregnant women- Ages 18-35 years; 16-18 weeks gestation
- All subjects received all four treatments



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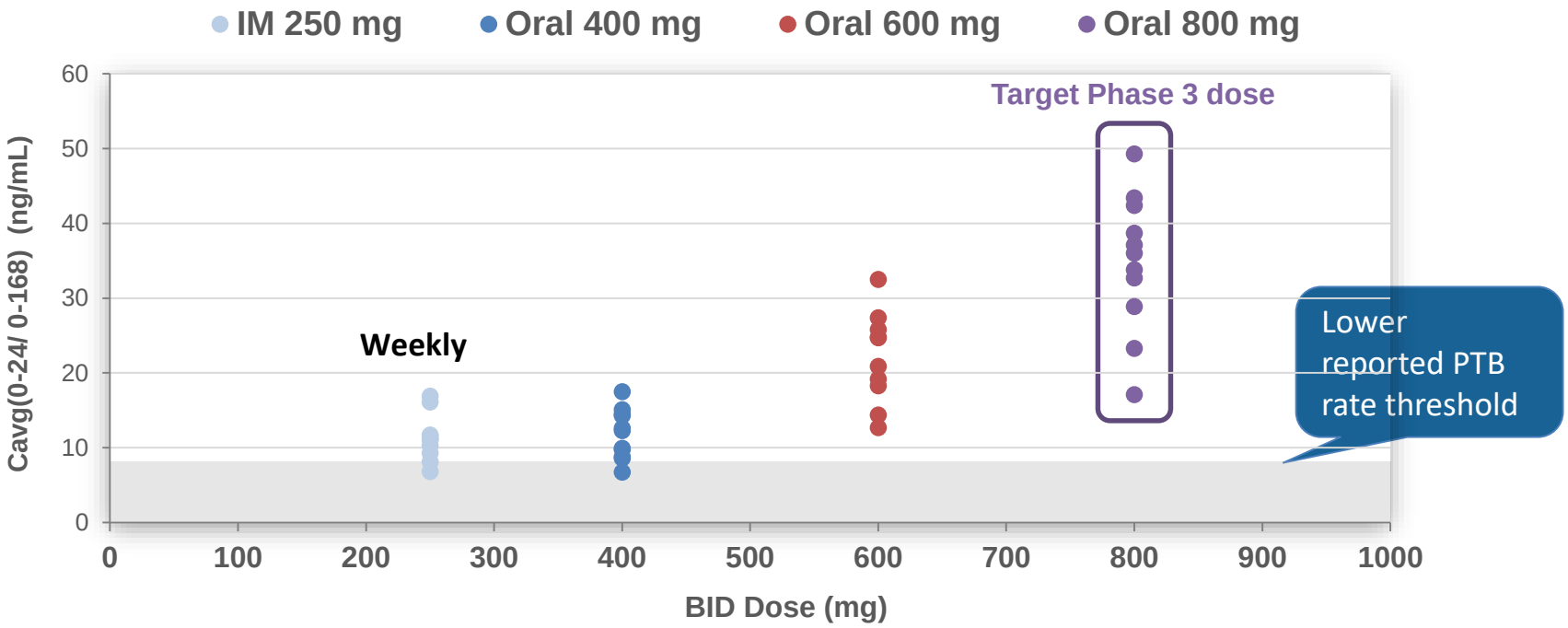
LPCN 1107: Dose-Finding PK Study Results[1]

Oral LPCN 1107 vs IM HPC, Makena



- HPC levels below 8.2 ng/mL:
  - Target LPCN 1107 Phase 3 dose was 0% vs 20% subjects using IM HPC Makena per label
- Average HPC levels at target LPCN 1107 Phase 3 dose
  - ~ 3x greater than the comparator, IM HPC, Makena

1. PK results obtained post 8 days of BID dosing for LPCN 1107 and post 5 weeks for weekly IM HPC, Makena

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