LIPOCINE®

ENHANCING HEALTH

Corporate Presentation

Enabling Oral Drug Delivery to
Improve Patient Compliance

January 2021

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 products and product candidates, FDA’s approval of TLANDO™, the expected timing of Phase 3 trials for TLANDO XR and LPCN 1107 and 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

Innovative Product Candidates for Metabolic and Endocrine Disorders

Propriety Drug Delivery Platform

PRODUCT *(Indication)*	PRE-CLINICAL	PHASE 1	PHASE 2	PHASE 3	NDA
TLANDO™ *(Oral Testosterone for Testosterone Replacement Therapy "TRT")*	→	→	→	→	**Tentative Approval**
LPCN 1144 *(Oral Testosterone for Non-Cirrhotic NASH)*	→	→	***LiFT* Phase 2 Clinical Study Ongoing**		
TLANDO XR *(Long Acting Oral Testosterone for Testosterone Replacement Therapy "TRT")*	→	→	→	**Next Step: Food Effect Study**	
LPCN 1148 *(Oral Testosterone for Cirrhosis)*	→	→	**Next Step: POC Phase 2 Clinical Study**		
LPCN 1107 *(Oral HPC for Prevention of PTB)*	→	→	→	**Phase 3 Dose Identified**	

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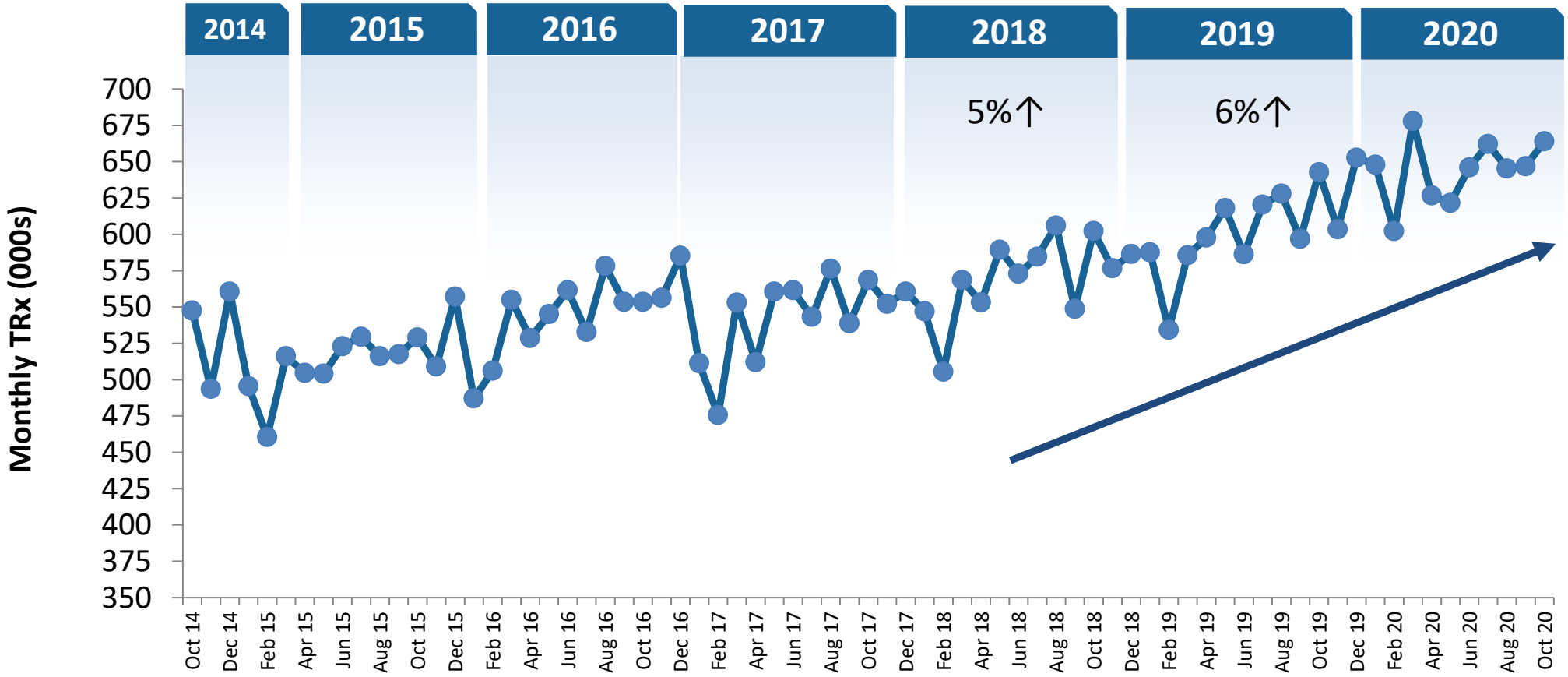
TLANDO™

The Convenient TRT without Titration Requirement

Monthly TRT TRx Trend

TRT Market is Growing



Last 12 months (Nov 2019 – Oct 2020) TRx of 7.7 million

Source: IMS database
TRx = Total prescriptions

Issues with Current TRT Options

Potential Barriers To Newly Diagnosed and Existing Patients

- **Black box warning**
  - Secondary exposure to testosterone
  - Pulmonary oil micro embolism (POME) and anaphylactic shock
- **Inconvenient application or painful injection**
- **High incidence of erythrocytosis was reported in patients on non-oral**
  - 67% on injectable T, 35% on pellets*
- **Most require dose titrations -** Majority of patients are not on efficacious dose at start of therapy and require up titration
  - Avg titration time to reach efficacious dose takes 3-6 months
  - Finding appropriate dose through titration is burdensome for physicians and patients
  - Requires additional clinic/pharmacy visits and invasive samplings
- **Poor persistence with products requiring titration**
  - 50-80% drop off in 3-6 months
  - Insufficient T levels at the beginning of therapy is one of the top reasons patients stop using TRT

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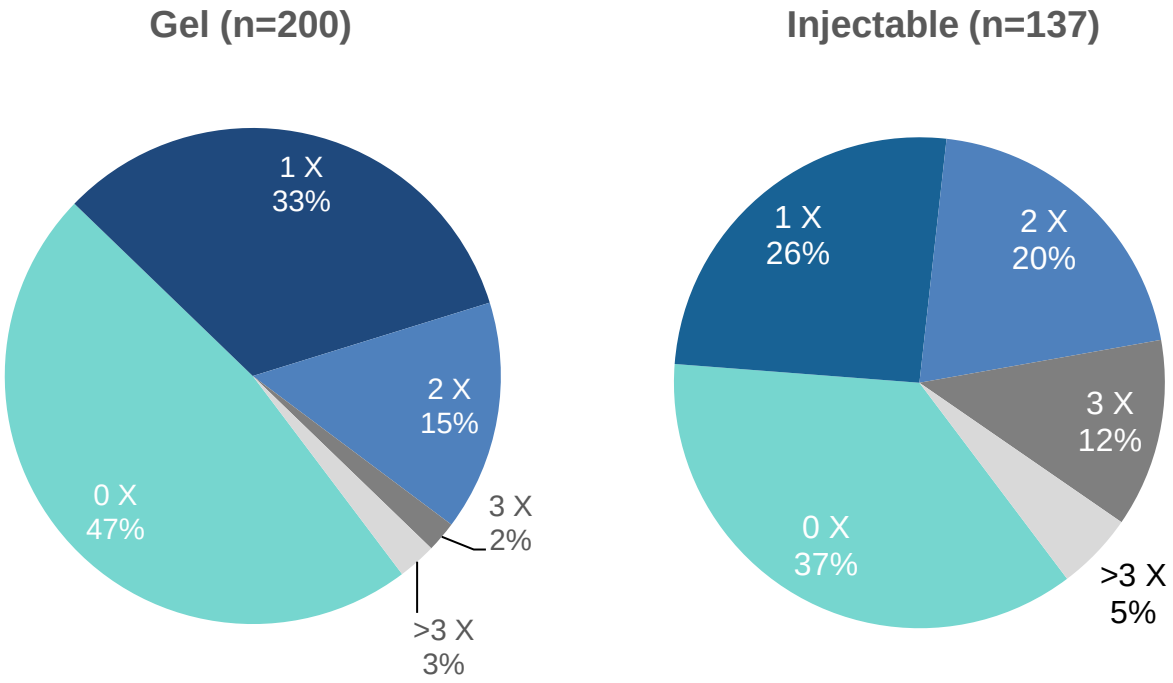
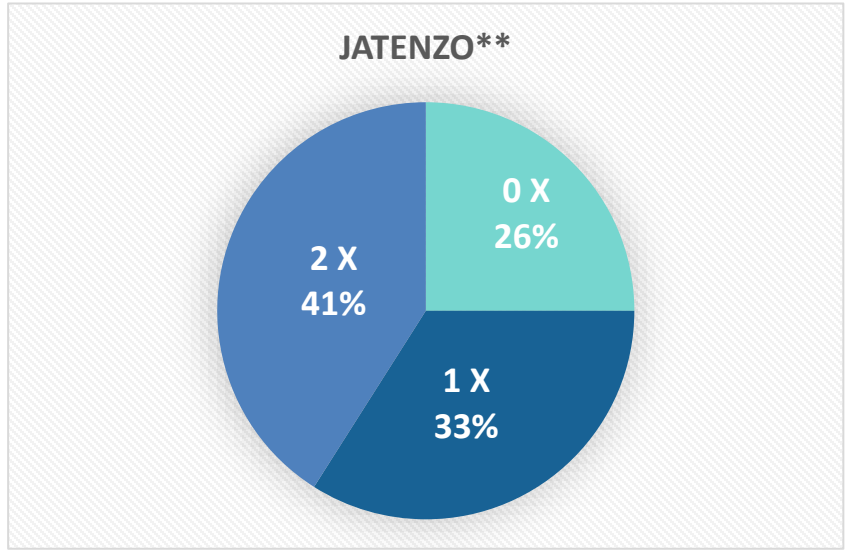
*Pastuszak et al. Sex Med. 2015

Most TRTs Require Dose Titration in Majority of Patients

Majority of Patients are Not on Efficacious Dose at the Start of Therapy



Number of Current TRT Dose Adjustments by Form*



- 74% of patients required dose adjustments
- 97% of dose adjusted patients required up titration

* 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?

**Jatenzo CLAR-15012 clinical study results

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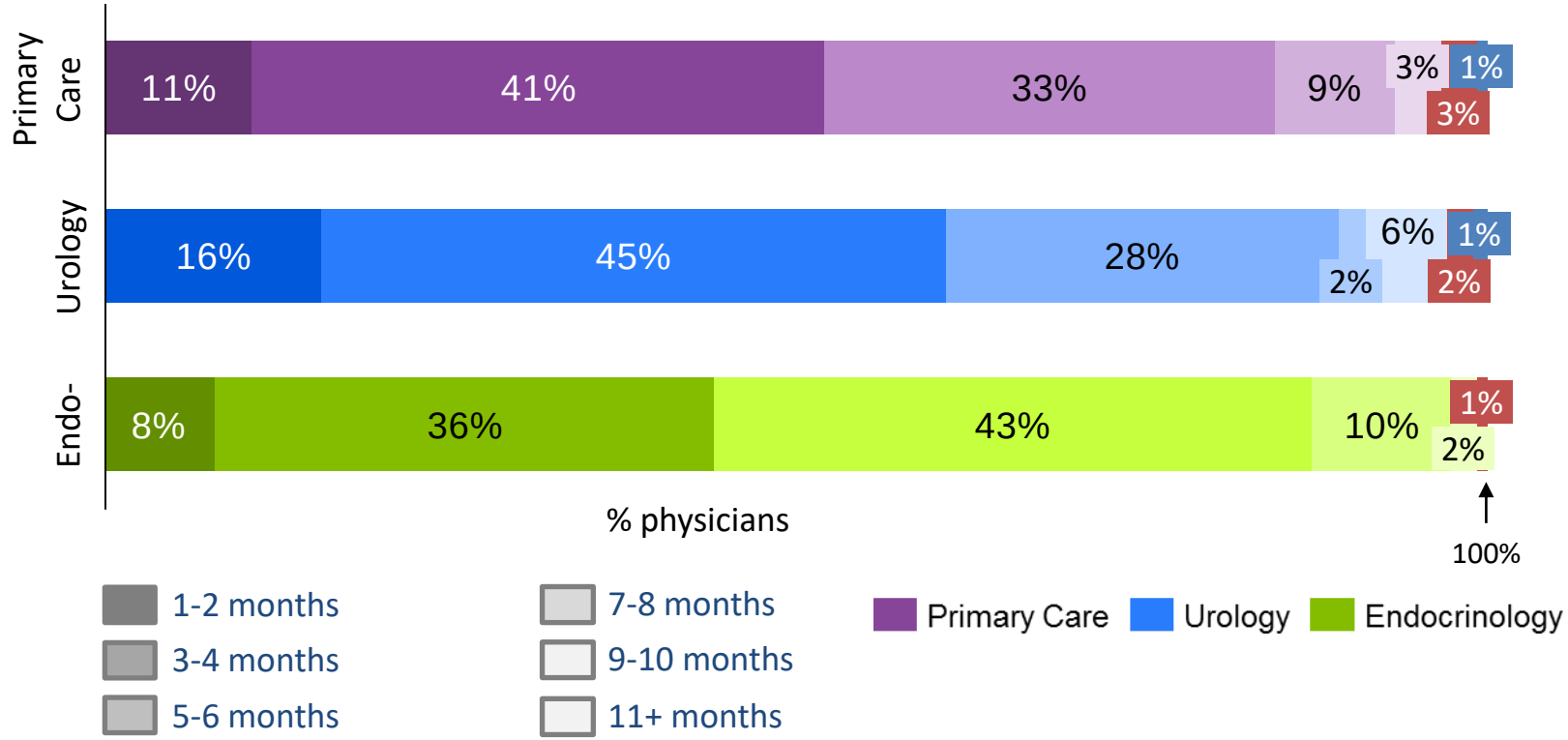
Physician Research Data*

Typical Titration for TRT Takes 3-6 Months to Reach Efficacious Dose for Majority of Patients

Average titration time to steady state dose

N = 402 physicians; 150 primary care, 102 urology, 150 endocrinology



1.18: How long, typically, does it take to titrate a patient to their steady state dose?

*QuintilesIMS-Lipocine, Physician Quantitative Survey, Nov 2017

TLANDO: De-Risked Regulatory Profile

Eligible to Launch After March 27, 2022

Current Status

- Tentative approvals are clearances for drugs to be marketed, but for the existence of patents or market exclusivities
- Initial launch supplies manufactured
- Business development efforts in progress

Opportunities

- Post COVID pandemic launch
- Adequate time for launch preparation/partnering
- Improves TLANDO XR regulatory prospects

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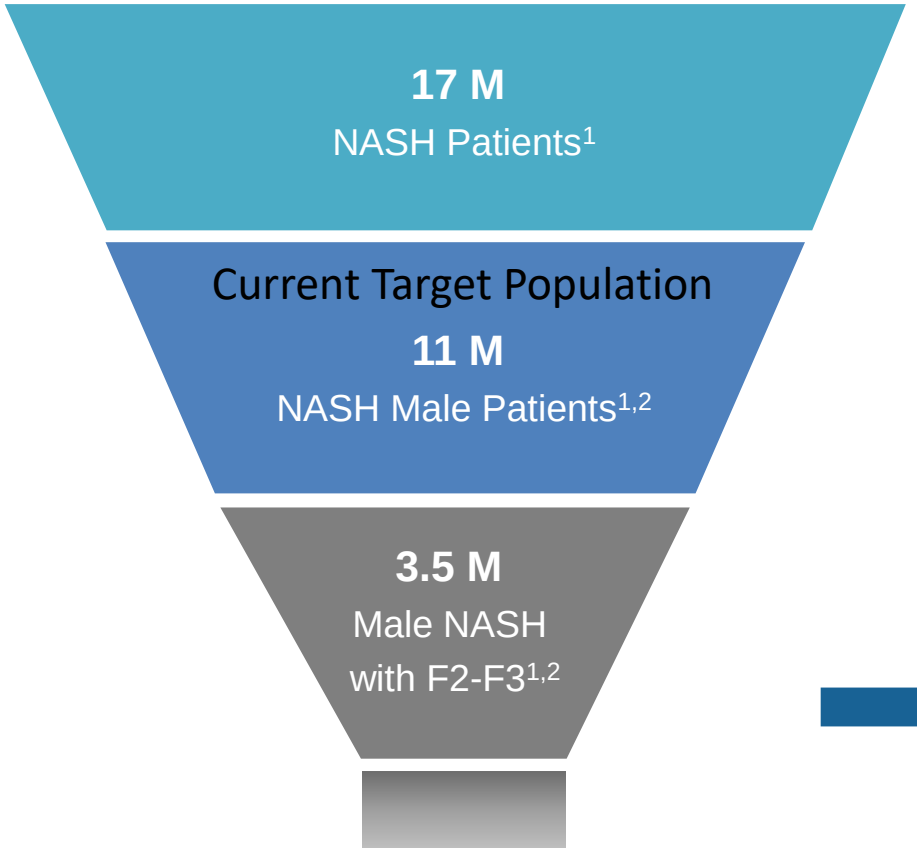
LPCN 1144

for Non-Cirrhotic NASH

LPCN 1144: Rationale to Target Non-Cirrhotic Male NASH Patients

Currently No Approved Treatment



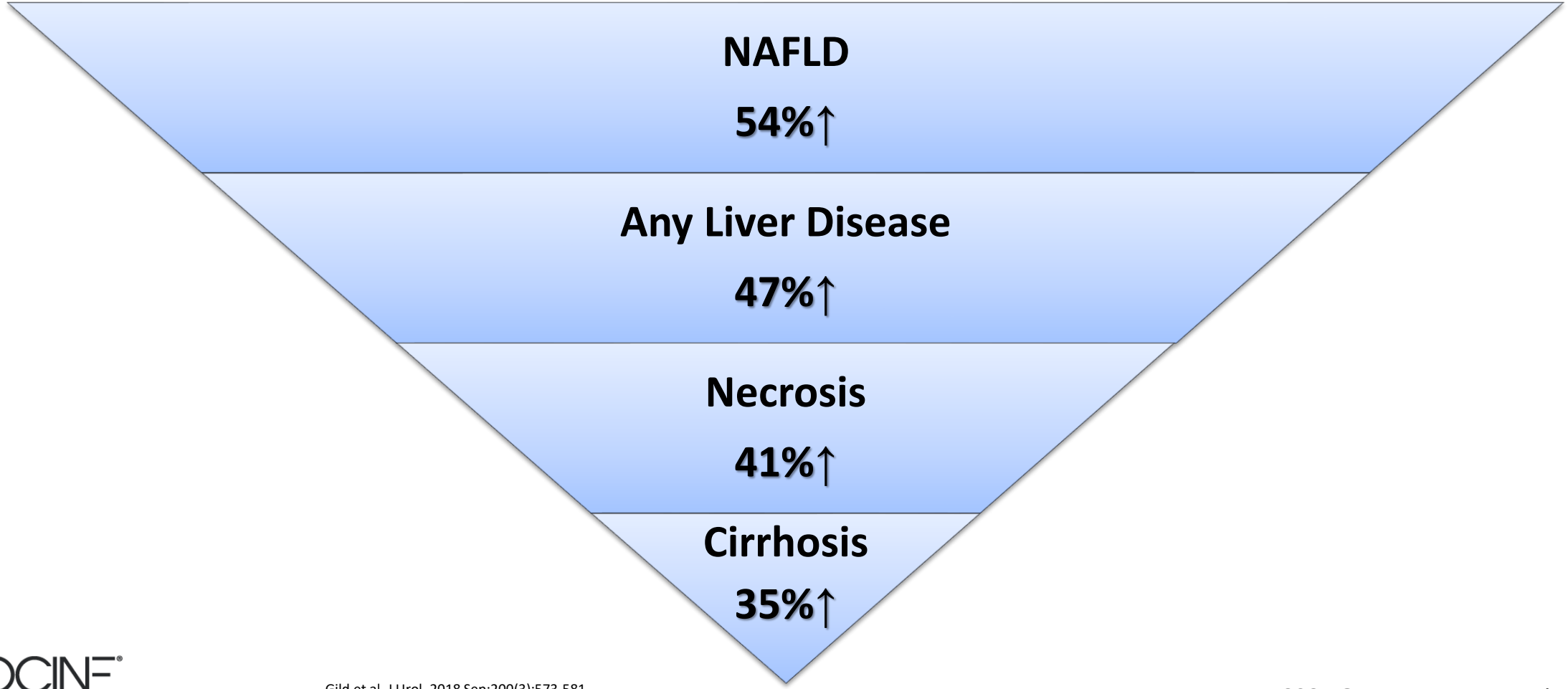
Multi-billion $ Opportunity*

1. Estes et al., Hepatol 2018. 2. Williams et al., Gastroenterology 2011. *2015 data

Association Between Testosterone and Liver Disease – Clinical Evidence

Liver Disease in Men Undergoing Androgen Deprivation Therapy (ADT) for Prostate Cancer

Patients Receiving ADT were Significantly More Likely to Have



Gild et al. J Urol. 2018 Sep;200(3):573-581

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

Improvement of sexual/mood dysfunction

Clinical Experience

Non-invasive dosing regimen

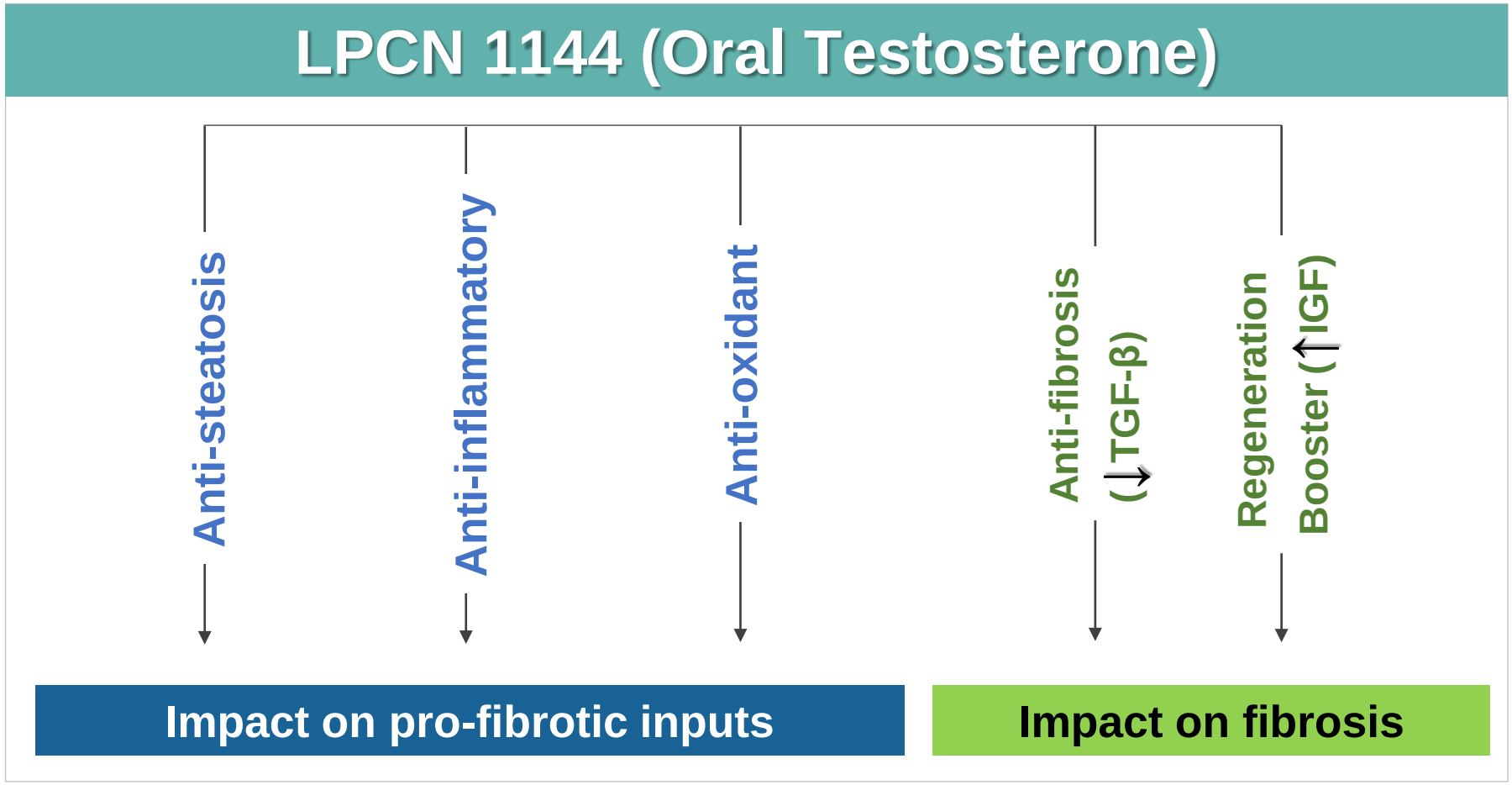
Meaningfully reduced liver fat in POC study

No notable tolerability issues

Improved sexual/mood dysfunction

LPCN 1144: Androgen Receptor Agonist

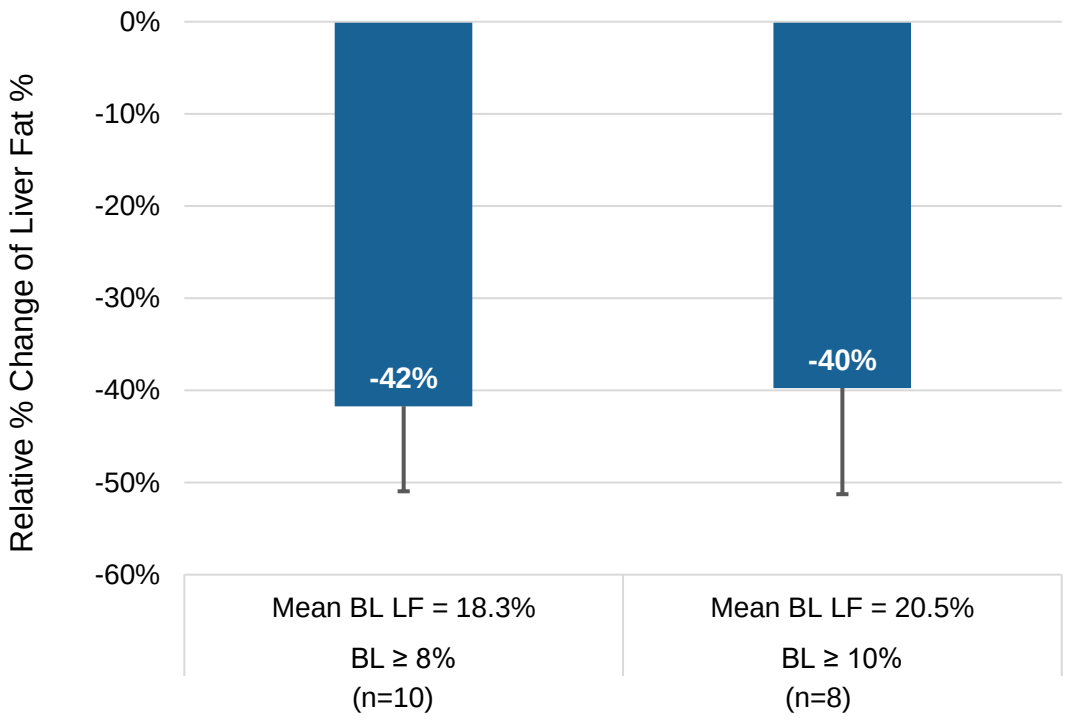
Potential Mode of Action



LPCN 1144: Liver Fat Reduction

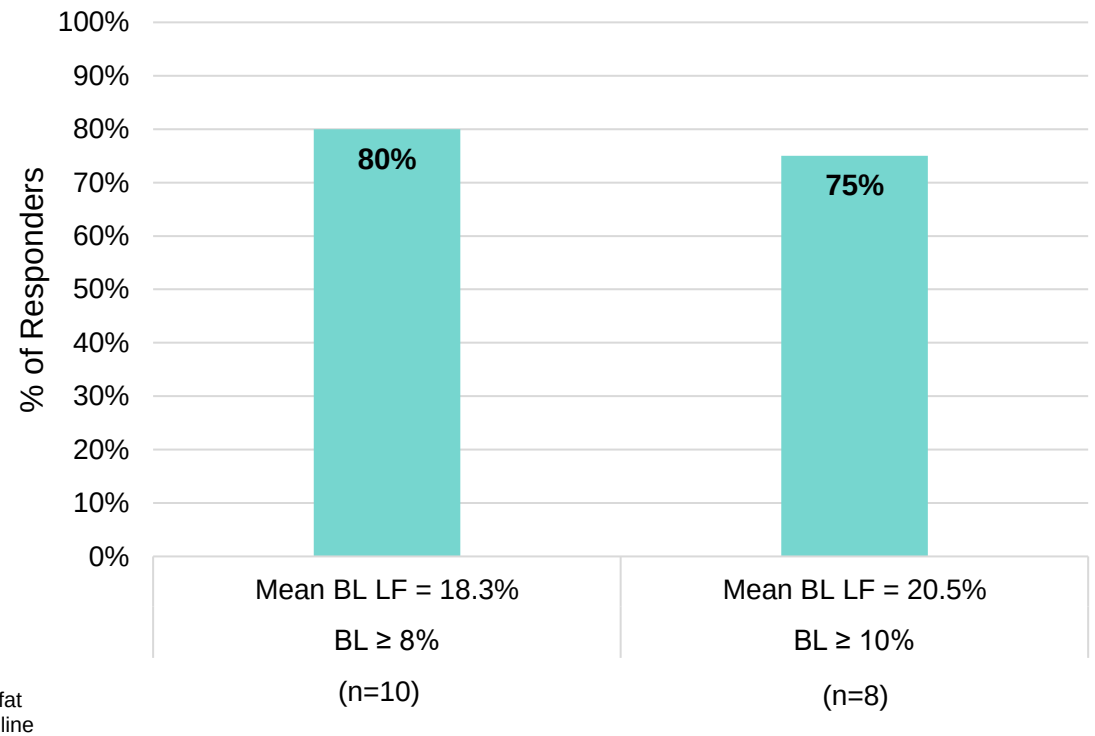
Meaningful Relative Liver Fat % Change and Responder Rate

Mean Relative Liver Fat % Change



LF = liver fat
BL = baseline

Responders with ≥ 30% change for Liver Fat



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Ref: Albhaisi et al., Hepatology Communications, 2020 https://doi.org/10.1002/hep4.1571

LPCN 1144: *LiFT (Liver Fat IntervenTion)* Study* Ongoing

Phase 2 Paired-Biopsy Clinical Study in NASH Subjects (NCT04134091)

Study Design

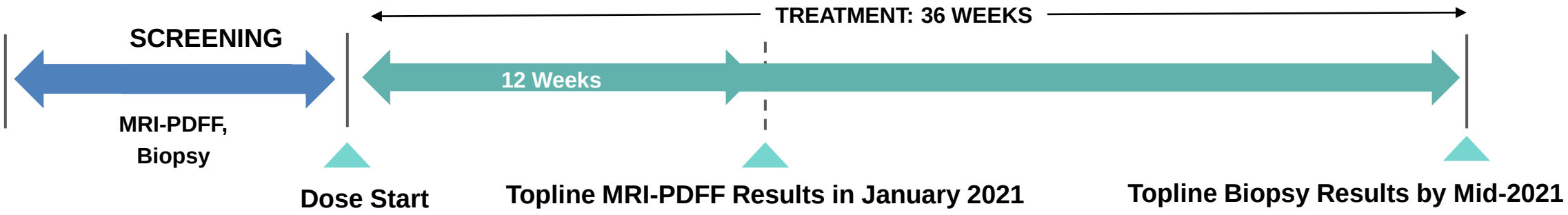
- Three-arm (1:1:1 randomization, two treatments and placebo), multi-center, double-blind
- Biopsy confirmed male NASH subjects per arm with NAS ≥ 4, F1-F3
- Treatment duration of 36 weeks

Primary Endpoint

- Change in hepatic fat fraction via MRI-PDFF

Secondary Endpoints

- Change in NASH activity and fibrosis via liver biopsy scoring
- Change in liver markers, anthropomorphic measures (weight, body mass index (BMI), waist to hip ratio, waist circumference), lipids, insulin resistance, inflammatory/fibrosis markers, and labs
- Change in quality-of-life degree (SF-36 and PDQ) and Physical Activity Questionnaire



* Website: www.lift-study.com

TLANDO XR

(Testosterone Tridecanoate)

Once Daily Oral TRT

TLANDO XR: An Innovative Opportunity

Next Generation TRT Option

- ✓ TLANDO XR is positioned to be the first Oral QD Product
- ✓ TLANDO XR is clinically differentiated from TLANDO
- ✓ Patients and physicians prefer once a day oral testosterone
- ✓ Strong IP (new molecule & proprietary drug delivery technology)
- ✓ Positive Phase 2b study results

Phase 2b Study: Result Summary

Met Primary and Secondary Endpoints

- Once daily dose for 14 days in an open label, multiple dose PK study in hypogonadal men (n=36 subjects)
  - ✓ Phase 3 dose identified
  - ✓ No Drug related SAEs
  - ✓ Drug Related AEs are Mild to Moderate
- Next step: Food effect study

LPCN 1148

for Liver Cirrhosis

LPCN 1148: Oral T for Cirrhosis

Background: Prevalence and Common Causes

Transplant Only Cure for Liver Cirrhosis

High Economic Burden of a Liver Transplant[1]

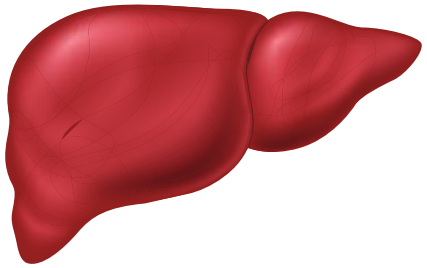
Liver Cirrhosis in US

Over 600K patients with liver cirrhosis[2]

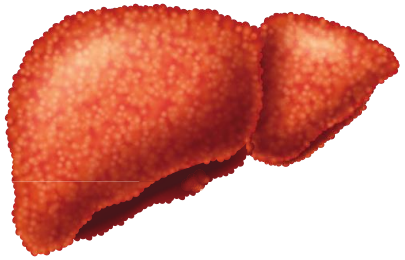
45K deaths in 2017[3]

62% male vs. 38% female on the liver transplant (LT) waitlist[4]

Healthy Liver



Liver with Cirrhosis



Common Causes[5]

- **Alcoholic liver disease**
- **Nonalcoholic Fatty Liver Disease (NAFLD)**
- **Chronic hepatitis B**
- **Chronic hepatitis C**
- **Cryptogenic**

1. Bentley & Phillips, Milliman Research Report 2017
2. Sinclair et al., Liver Transplantation, 2016;
3. Sinclair et al., J Gastroenterol Hepatol. 2016;
4. Sarkar et al. J Hepatol. 2015
5. https://www.niddk.nih.gov/health-information/liver-disease/cirrhosis/symptoms-causes

Unmet Needs For Patients with Liver Cirrhosis

Areas that LPCN 1148 Addresses

Improvement in quality of life while on waiting list

Stay on transplant list

Sarcopenia is a leading contributory cause of removal from the waitlist

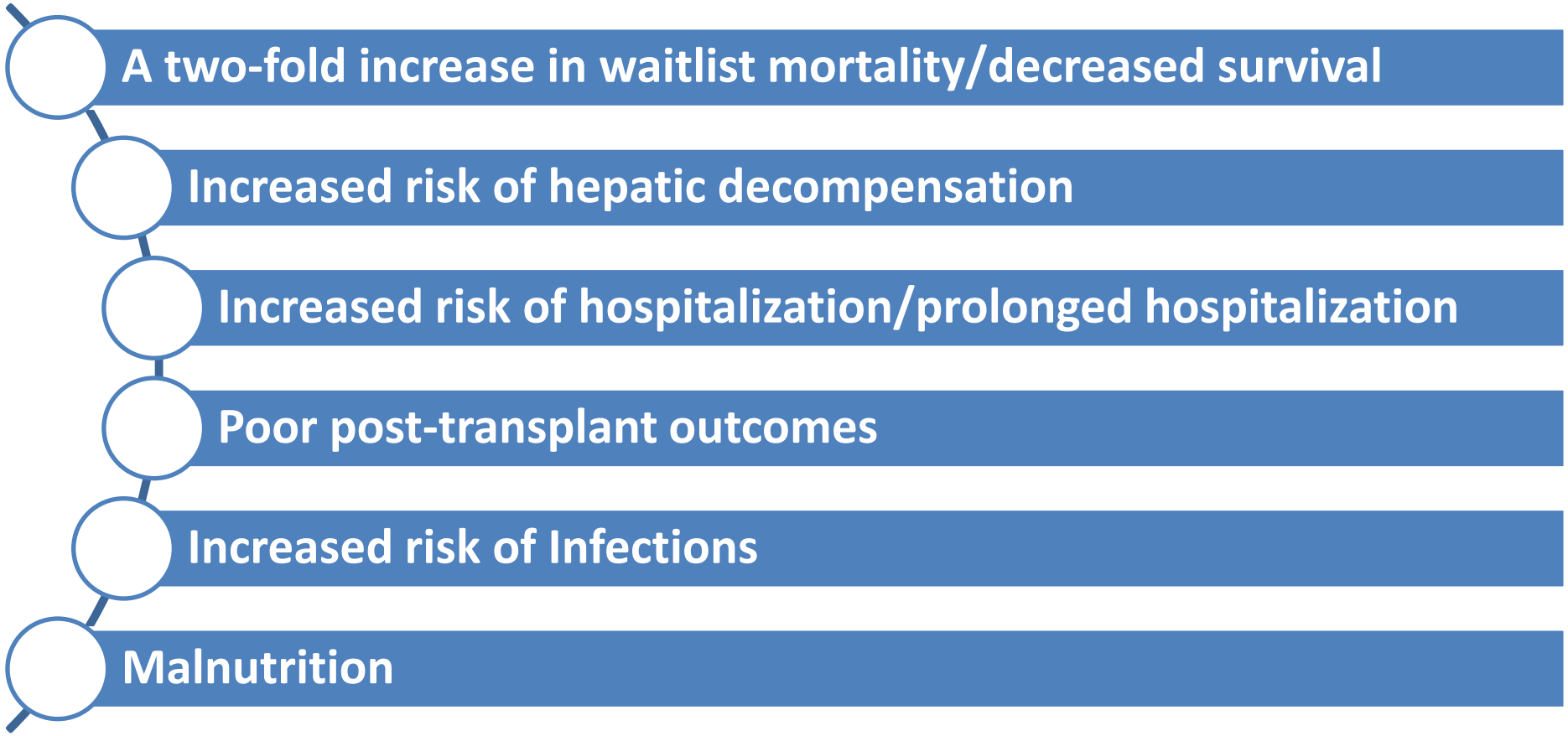
- 40 -70% of cirrhotic patients are sarcopenic

Improvement of post transplant survival/outcomes

Yoon and Chen, National Institute on Alcohol Abuse and Alcoholism; Surveillance Report #114, 2019
Scaglione et al., J clin Gastroenterol, 2015; Hart et al., Transplantation, 2016; United Network for Organ Sharing, 2019
Sinclair et al. Aliment Pharmacol Ther, 2016; Lai et al., Am J Transplant, 2014

Sarcopenia in Liver Cirrhosis

Equivalent to Adding Significant Points to the MELD Score



References: Kim and J.W. Jang, World Journal of Gastroenterology, 2015; Sinclair et al., Journal of Gastroenterology and Hepatology (Australia), 2016; Moctezuma-Velazquez et al., Clinical Nutrition, 2018.; Sinclair et al., World Journal of Gastroenterology, 2017. Montano-Loza et al., Clinical and Translational Gastroenterology, 2015; Lai, J.C., et al., Hepatology, 2017; Englesbe et al., J Am Coll Surg, 2010.

MELD Score: Model For End-Stage Liver Disease Score

LPCN 1107

Prevention of Preterm Birth

Unmet Medical Need

Preterm Birth is a Significant Public Health Issue in the U.S

- One Preterm birth (PTB) every minute[1]
- ≥ $26 billion economic impact[2]
- 10% of all US pregnancies[3]
- A leading cause of neonatal mortality and morbidity
- Medical costs for PTB infants are ~10x higher than for full term infants[4]

1. Pediatric Research (2006) 60, 775–776
2. Institute of Medicine of the National Academies. Jul.200
3. National Vital Statistics Reports, Vol 67, No. 8, Nov 7, 2018: Centers for Disease Control and Prevention (2017)
4. J. Maternal-Fetal and Neonatal Medicine, Dec. 2006, 19(12), 773–782

LPCN 1107: Potential To Be The Standard of Care for Prevention of PTB

Oral Hydroxyprogesterone Caproate (HPC)

- Convenient dosing
- No injection site reactions
- First oral enabling technology
- Solid IP coverage
- Orphan drug designated
- Next Step: Pivotal study agreement w/ FDA

Impact of Potential Market Withdrawal of Makena and Its Generics

An Opportunity for LPCN 1107

- No approved standard of care for prevention of PTB
- Improved market potential
- Enriched target population: Not losing high risk patients to active control (injectable IM)
- May not require a non-inferiority study; Easier to recruit patients for placebo-controlled trial(s)
- Advanced “Phase 3 ready” oral candidate targeting PTB

Upcoming Milestones

Near Term Value Drivers

	Event	Expected Timing
TLANDO™	Full Approval	**March 28, 2022**
LPCN 1144	*LiFT* Primary Endpoint Results	**January 2021**
	LiFT Biopsy Results	**Mid 2021**

Key Financial Metrics

Stock Price, Market Cap, Cash Balance

Ticker Symbol	**LPCN (Nasdaq Capital Market)**
Closing Stock Price (12/28/20)	**$1.39/share**
Cash Balance (9/30/20)	**$23.8 million**
Bank Debt (9/30/20)	**$6.4 million**

Appendix

TLANDO™ Attributes*

Convenient Oral Route

- No inadvertent transference or Pulmonary Oil Micro Embolism risks
- Single strength and dose

TRT without titration requirement

- Enables selection of an effective dose at the start of therapy without delay
- No “efficacy gap” upon switching from other TRTs
- No additional pharmacy and clinic copays to reach efficacious dose
- No dose adjustment clinic and pharmacy visits
- No dose adjustment invasive samplings
- No titration decision errors

Bioequivalent exposure in low/med/high fat food

Not Known to Produce Hepatic Adverse Events Associated with 17-methylated Testosterone

*Pending final approval

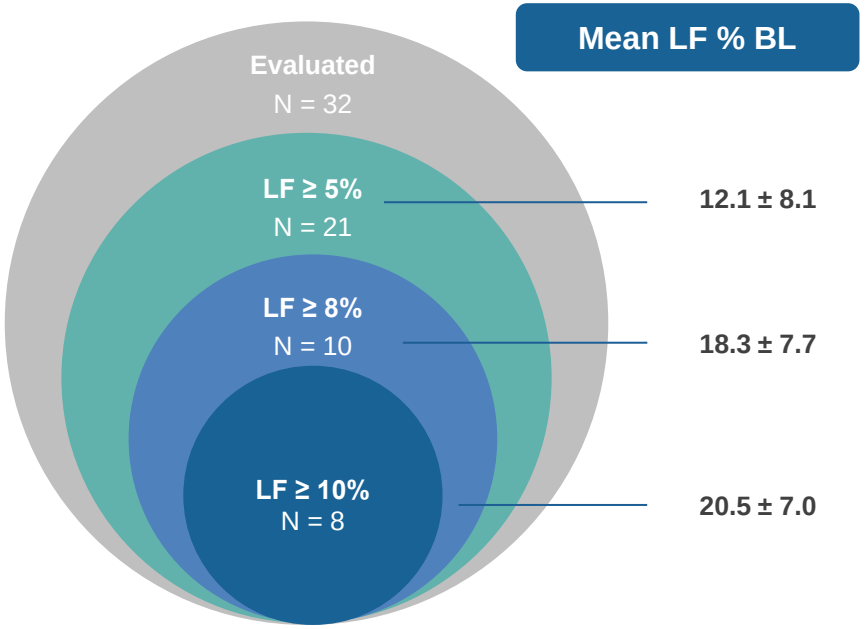
Physician Research: Physicians View No Titration Product as Positive

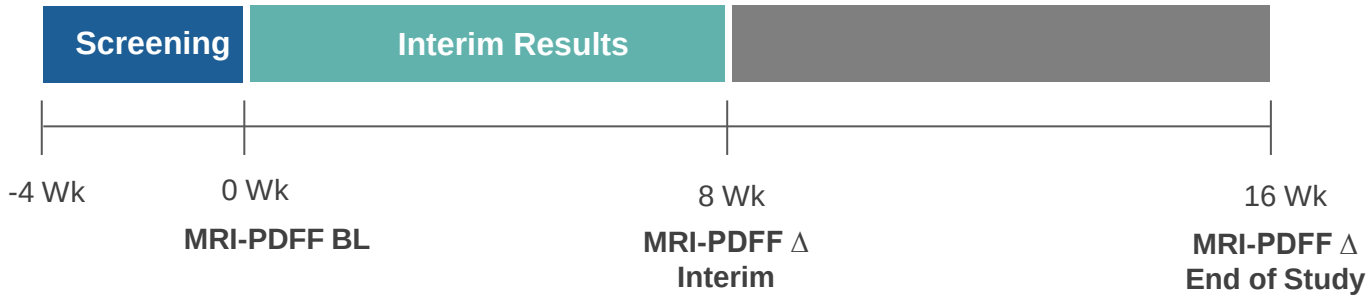
- Cited “easy/less titration” as an important advantage of TLANDO™
- Finding the adequate TRT dose through titration is burdensome for physicians and patients

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) of LPCN 1144 225 mg BID in hypogonadal males





LF = liver fat
BL = baseline

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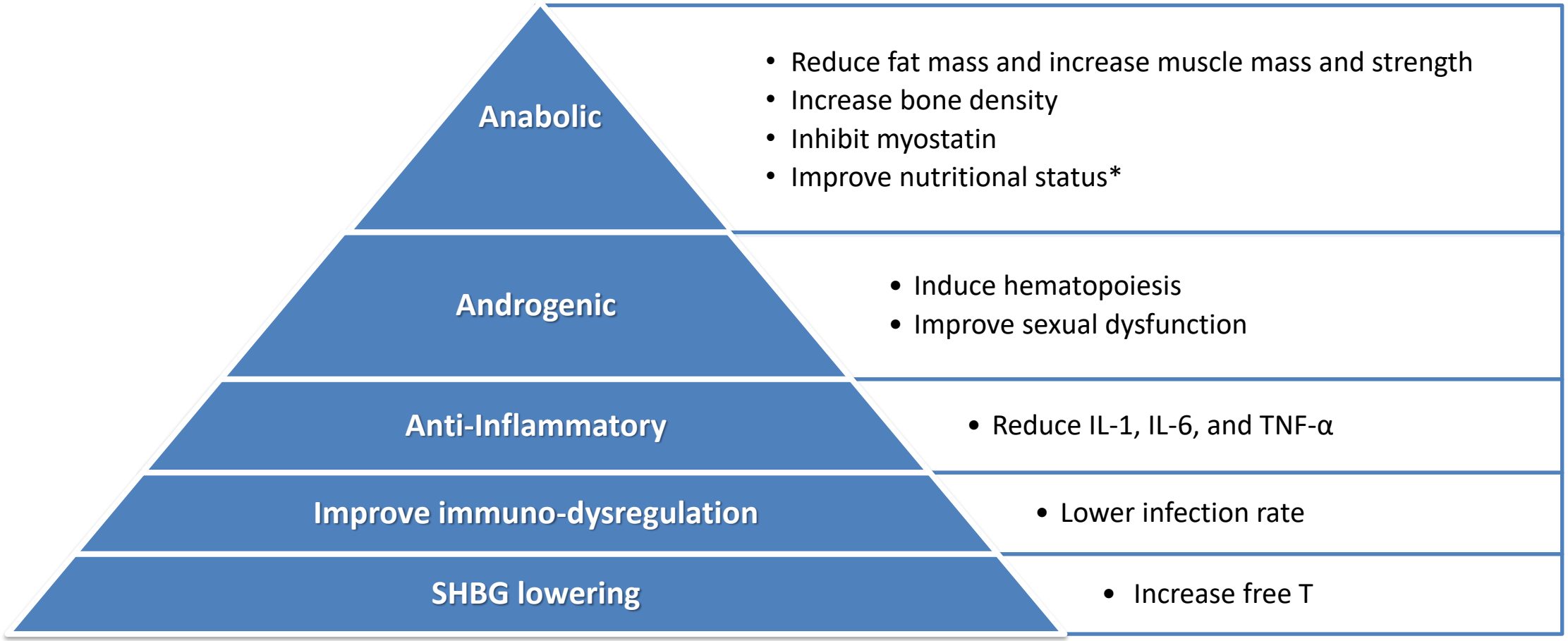
Ref: Albhaisi et al., Hepatology Communications, 2020 https://doi.org/10.1002/hep4.1571

LPCN 1148 in Cirrhotic Patients

Potential Key Effects



References: Trivedi and Tapper, Gastroenterol Rep (Oxf), 2018; Berzigotti et al., Hepatology, 2017; Chen and Dunn, Clin Liver Dis (Hoboken), 2018; Sinclair et.al, Liver international, 2016; Neff et al., Digestive Diseases and Sciences, 2004; Puliyel et al., Australian and New Zealand Journal of Medicine, 1977; Brown et al., Cleve Clin Q, 1960; Girolami M, Am Geriatr Soc, 1958; Neff et al., Transplant Proc, 2004; Wells R., The Lancet, 1960; Yurci et al., Clinics and Research in Hepatology and Gastroenterology, 2011; Muting D., Verh Dtsch Ges Inn Med, 1969; Gluud C., Liver, 1984.
*individual's health condition as it is influenced by the intake and utilization of nutrients

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Enabling Oral Drug Delivery to Improve Patient Compliance

LPCN 1107

Prevention of Preterm Births

Preterm Birth (PTB)

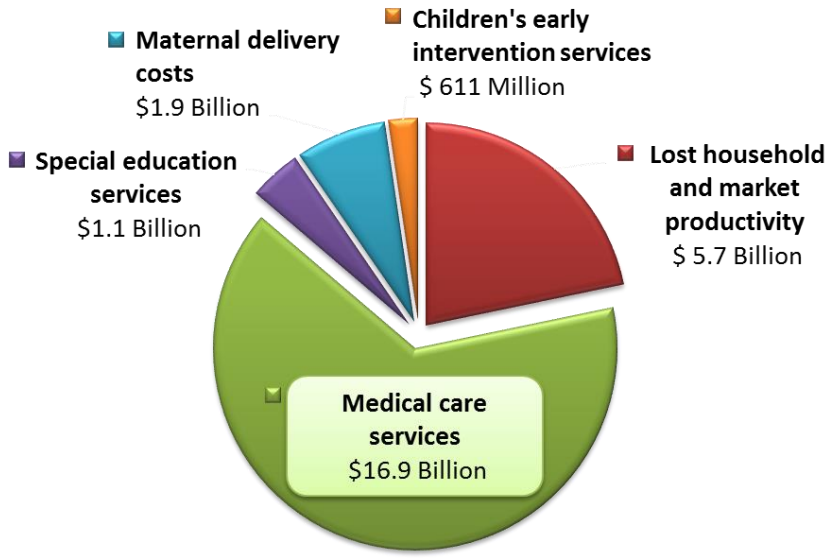
Basic Facts

- Risks of adverse outcome for preterm infants rise sharply with decreasing gestation
- Early PTB babies have higher rates of death and disability
  - PTB <35 week has ~6x more relative death risk in first 28 days than full term babies

Gestational Age	Average Length of Stay (Days)	Average Hospital Charges (Dollars)
All Admissions	13.2	$76,164
<32 weeks	46.2	$280,811
32-33 weeks	20.3	$102,182
34-36 weeks	9.8	$51,083
37-38 weeks	5.9	$37,137
39-41 weeks	4.9	$29,771
42+ weeks	6.5	$47,282

Length of Stay and Hospital Charges Among Special Care Nursery Admissions

Source: National Perinatal Information System/Quality Analytic Services; www.npic.org.
From: March of Dimes Perinatal Data Center, 2011



Economic Impact of PTB on the US Health System

*: Behrman et al. Preterm Birth: Causes, Consequences, and Prevention. Washington, DC: The National Academies Press, 2006, 329-354

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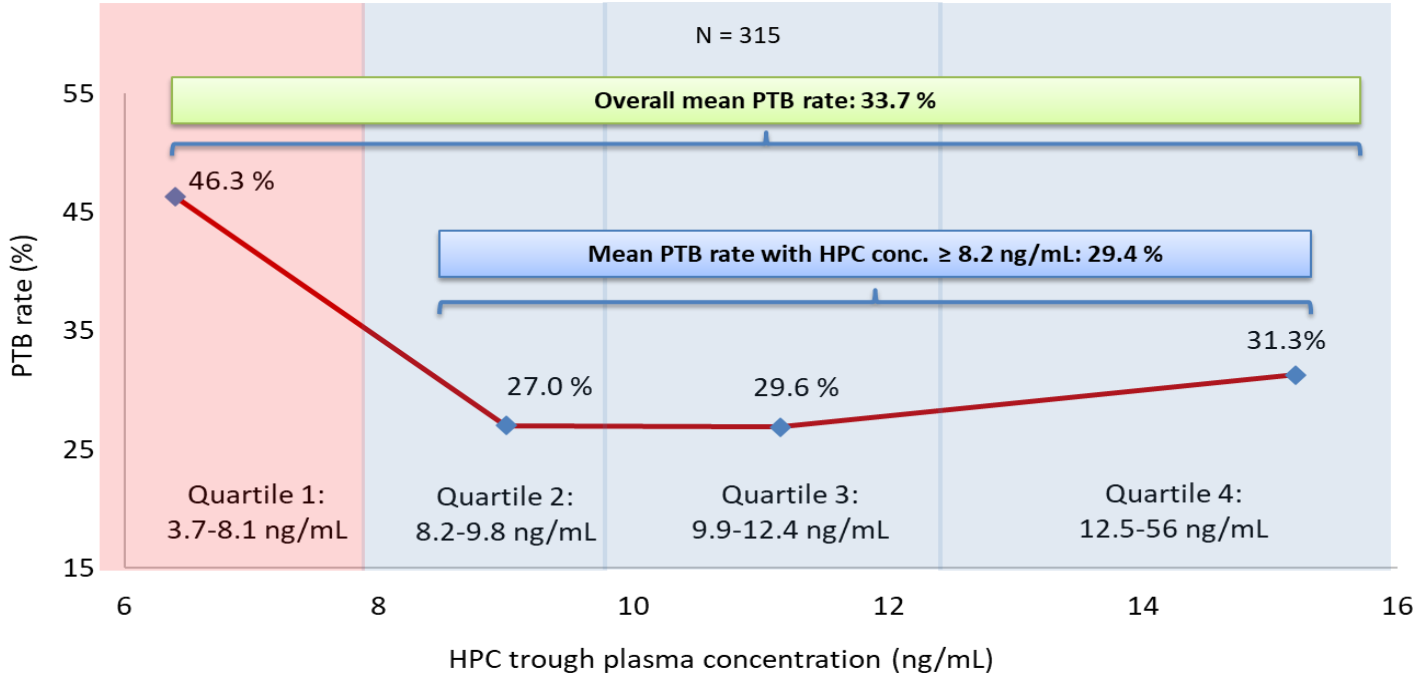
Status of MAKENA and its Approved Generic Equivalents

CDER Proposes Withdrawal of Approval for Makena on October 5, 2020

- Confirmatory (PROLONG) study failed to verify clinical benefit and FDA concluded that the available evidence does not show that Makena is effective for its approved use
- CDER has issued a notice of opportunity for a hearing to AMAG Pharmaceuticals and approved generics to Makena for an opportunity to comment
- Makena and its approved generics will remain on the market until the manufacturers decide to remove the drugs or the FDA Commissioner mandates their removal
- FDA intend to hold a meeting with experts in obstetrics, neonatal care, and clinical trial design to discuss how to facilitate development of effective and safe therapies to treat preterm birth
- Eight approved ANDAs referenced Makena as the basis of submission. Upon withdrawal of Makena's NDA, FDA would also withdraw all eight of ANDAs for drug products containing hydroxyprogesterone caproate that reference AMAG's NDA as their reference listed drug

Impact of HPC Plasma Concentration on PTB rate

PK-PD Correlation: HPC Concentration and PTB Rate[1]



- Lower % (~4.3%) PTB rate can be expected with daily Cavg2 ≥ 8.2 ng/mL compared to overall PTB rate
- 25% of MAKENA (IM HPC) patients with 250 mg/week dosing have levels below the desired “threshold critical for efficacy”

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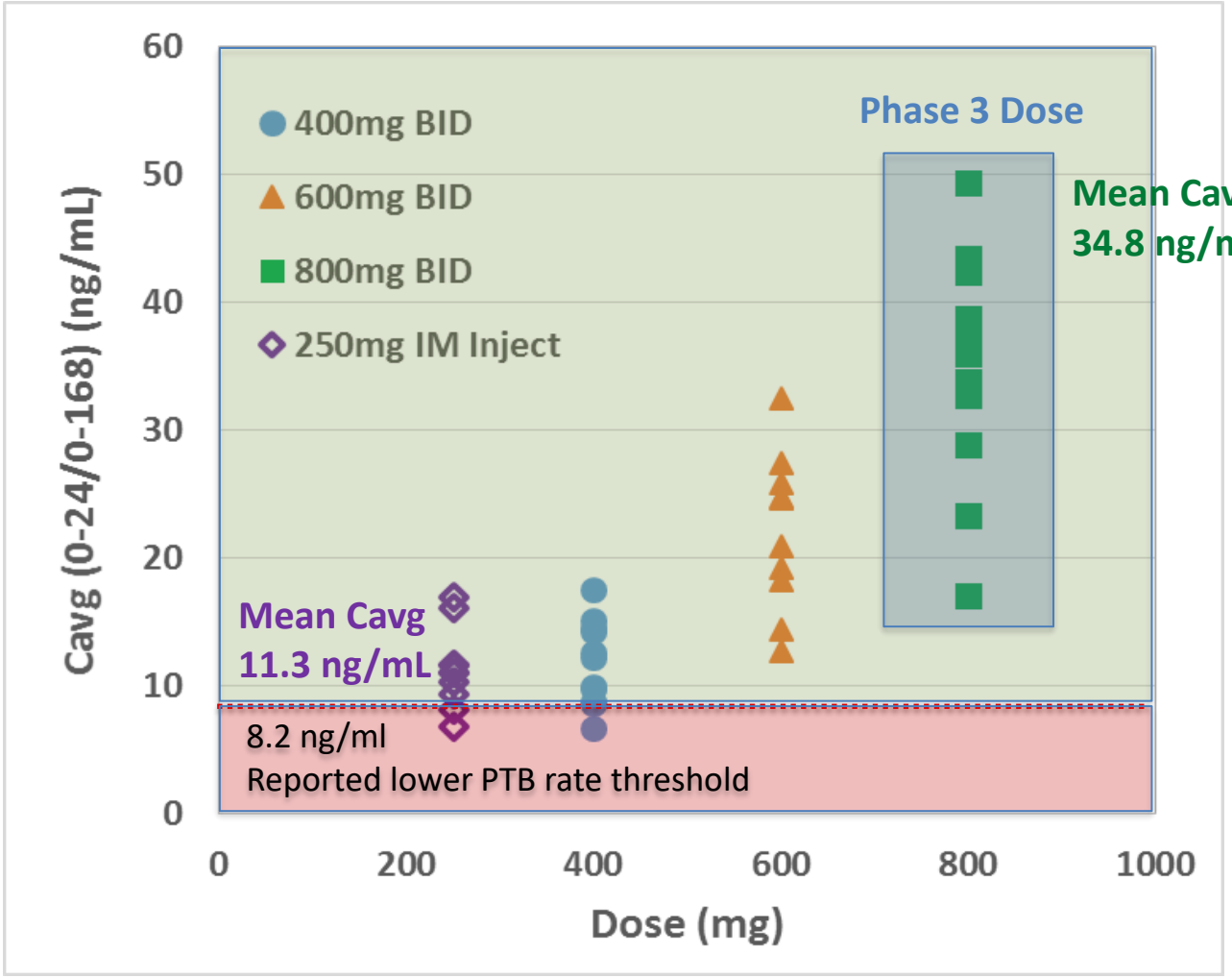
1. Caritis et al., Am J Obstet Gynecol. 2014 (N=315 subjects)
2. Ctrough for IM HPC ≅ Cavg, Makena

Comparative Steady State PK profiles* to 250 mg/week Injectable HPC

LPCN 1107 Target Regimen Results in Higher Target HPC Levels in Majority of Patients



*PK results obtained from post 35 days for weekly IM Injection & post 8 days of BID dosing for oral from the dose finding study