

LIPOCINE[®]

ENHANCING HEALTH

Enabling oral drug delivery to improve patient compliance

Corporate Presentation

March 12, 2018



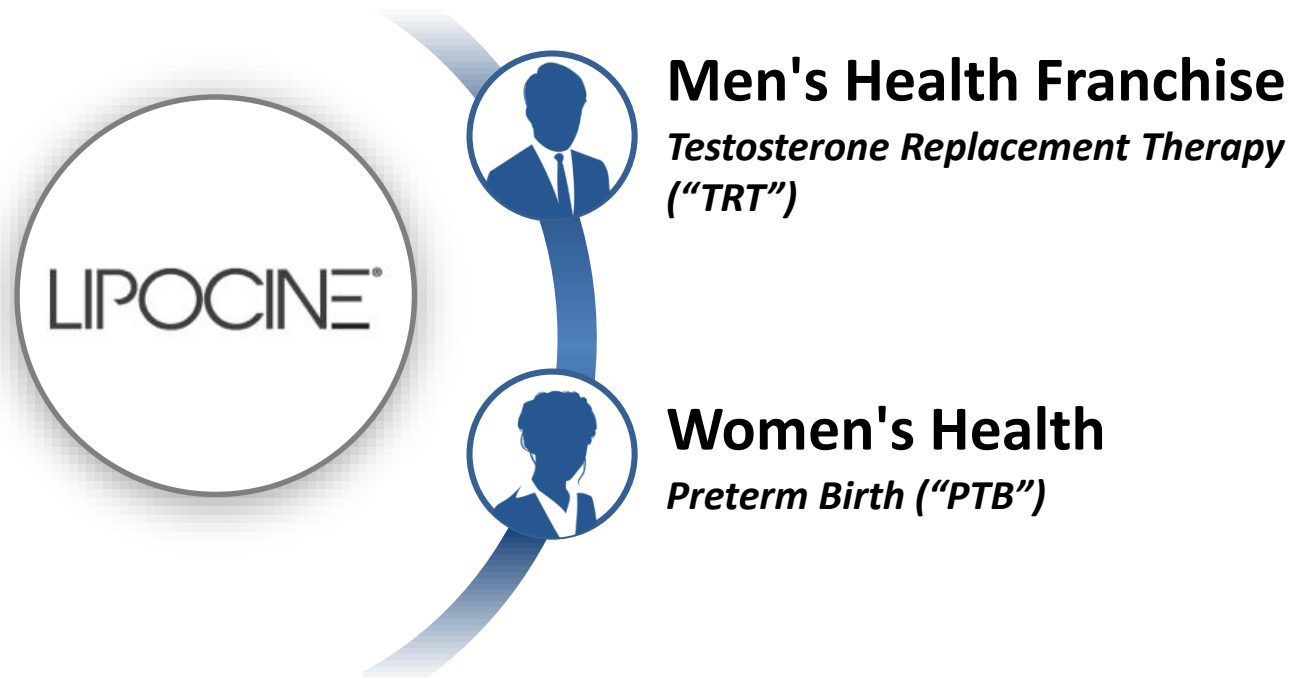
Forward-Looking Statements

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 FDA review process related to our resubmitted NDA for TLANDO™, 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, the potential advantages of the Company’s product candidates and the Company’s capital needs. Among other things, the projected commencement and completion of the Company’s clinical trials may be affected by difficulties or delays. We may encounter delays or other issues in the FDA approval process, including that the FDA may determine there are deficiencies in our resubmitted NDA. We are also subject to risks related to the possibility of an advisory committee meeting related to TLANDO™. In addition, the Company’s results may be affected by its ability to manage its financial resources, difficulties or delays in developing manufacturing processes for its product candidates, preclinical and toxicology testing and regulatory developments. Delays in clinical programs, whether caused by competitive developments, adverse events, patient enrollment rates, regulatory issues or other factors, could adversely affect the Company’s financial position and prospects. Prior clinical trial program designs and results are not necessarily predictive of future clinical trial designs or results. If the Company’s product candidates do not meet safety or efficacy endpoints in clinical evaluations, they will not receive regulatory approval and the Company will not be able to market them. The Company may not be able to enter into any strategic partnership agreements. The Company’s commercial success depends on its ability to manufacture, market and sell products without infringing the proprietary rights of third parties. Operating expense and cash flow projections involve a high degree of uncertainty, including variances in future spending rates due to changes in corporate priorities, the timing and outcomes of clinical trials, competitive developments and the impact on expenditures and available capital from licensing and strategic collaboration opportunities. If the Company is unable to raise additional capital when required or on acceptable terms, it may have to significantly delay, scale back or discontinue one or more of its drug development or discovery research programs. The Company is at an early stage of development and may not ever have any products that generate significant revenue. The forward-looking statements contained in this presentation are further 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.

Unique Specialty Pharmaceutical Company

Advanced Pipeline



Proprietary Drug Delivery Platform

Significant Unmet Need In Both Therapeutic Areas

Late-Stage Pipeline

Oral Product Candidates Targeting Significant Opportunities

PRODUCT (Indication)		PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	NDA	
MEN'S HEALTH	TLANDO™ (Oral Testosterone Replacement Therapy, TRT)						NDA PDUFA Date May 8, 2018
	LPCN 1111 (Next Gen. Oral TRT)				FDA Meeting 1Q 2018*		
WOMEN'S HEALTH	LPCN 1107 (Prevention of Preterm Birth, PTB)				Food/Fat Effect Study 2H 2018		

* Meeting occurred and awaiting FDA meeting minutes

Lipocine is Positioned for Success Because.....

Significant Advantages over Existing Approved Products

TRT Franchise

TLANDO™

- Patient preferred first oral option
- Positive head to head clinical results vs the \$ market leader
- No additional doctor visits as fixed dose

LPCN 1111

(Next generation potential once-daily oral T)

- Potential for sustained and enhanced revenues with QD dosing
- Positive top-line Phase 2b study results

Prevention of Preterm Birth

LPCN 1107

- Poised to be First oral to the market
- Potentially better PTB results
- Orphan drug designation
 - Major contribution to patient care

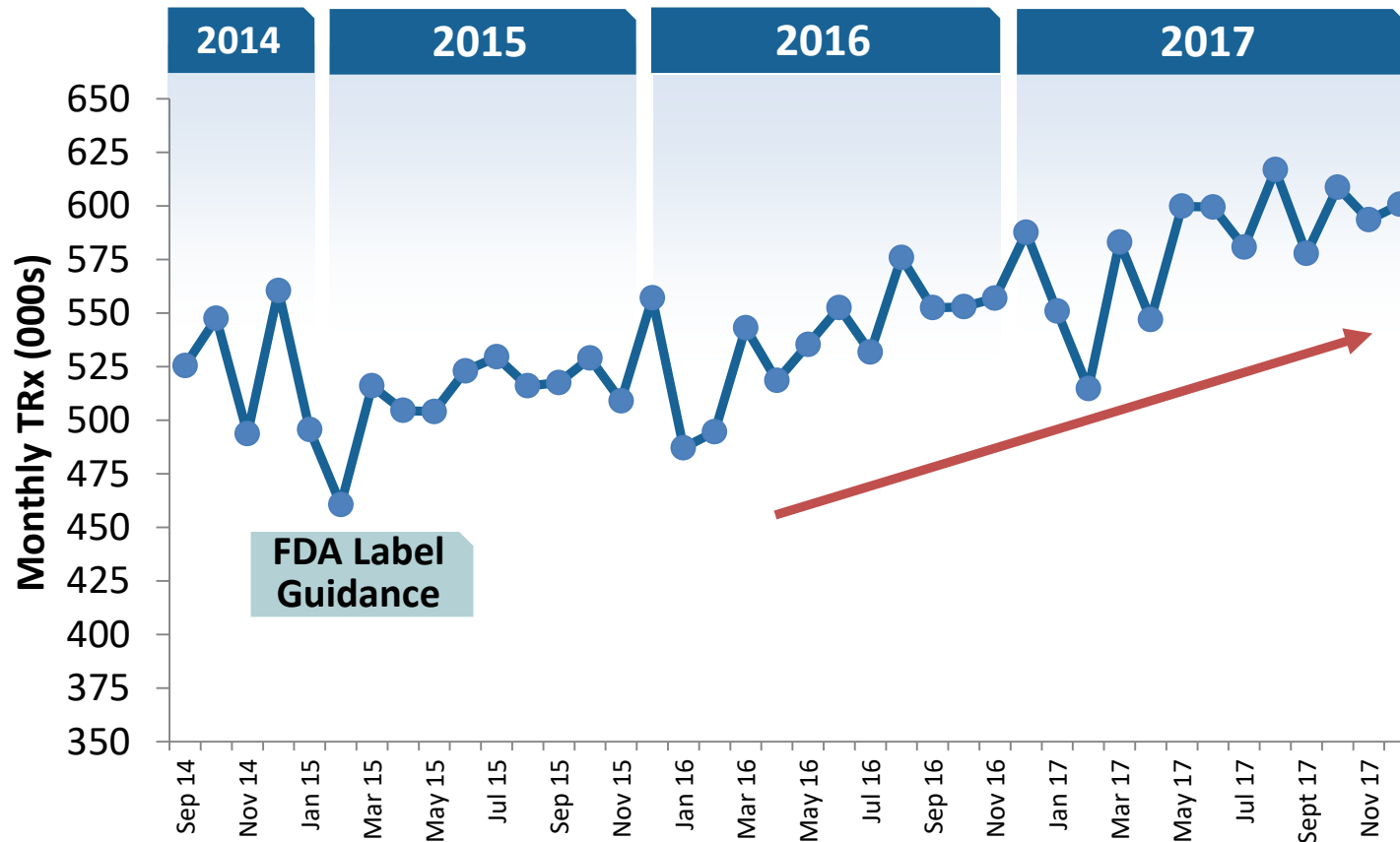
Significant Technical and Commercial Expertise on the team

LIPOCINE®
ENHANCING HEALTH

TLANDO™

Monthly TRT TRx Trend

TRT Market is Approaching Heights Experienced in 2013 and Growing



Annual estimates of 7.0 million TRx

2017 Gross Annual Sales - \$1.7B

Source: IMS database
TRx = Total prescriptions

LIPOCINE
ENHANCING HEALTH

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

TLANDO™: Advisory Committee Meeting

BRUDAC Results and Path Forward

Voting Question: Is the overall benefit/risk profile of TLANDO™ acceptable to support approval as a testosterone replacement therapy?

Results: 6 Yes 13 No

- Voting rationale:
 - All 13 “No” votes cited lack of Ambulatory Blood Pressure Monitoring (“ABPM”)
 - Confirmation of Serum T measurement reliability (ex vivo conversion assessment)

Path Forward

- Initiating ABPM study ahead of PDUFA date
 - Protocol submitted under IND for review and comments
- Initiating Phlebotomy study ahead of PDUFA date to confirm no ex-vivo conversion of TU to T
 - Protocol submitted under IND for review and comments
- Initiated legal and government affairs activities in support of TLANDO approval

Comparative Oral TU Product Profiles*

TLANDO™ vs Jatenzo™

TLANDO™

- No ABPM data, but large clinic blood pressure (“BP”) database with no BP increase
- No Major Cardiac Adverse Events over 12 studies
- Mean dose: 225 mg BID
- GI effects comparable to topical gel
- Standard serum based T measurements

Jatenzo™

- Clinically meaningful BP increase in ABPM study
- Major Cardiac Adverse Events Reported in multiple studies
- All lipid parameters adversely changed compared with active control
- Mean dose: 325 mg BID (40% on 396 mg BID)
- 12% reported GI adverse events
- Atypical plasma based T measurements

* From Jatenzo briefing document for Jan 9th BRUDAC meeting

TRT and Blood Pressure

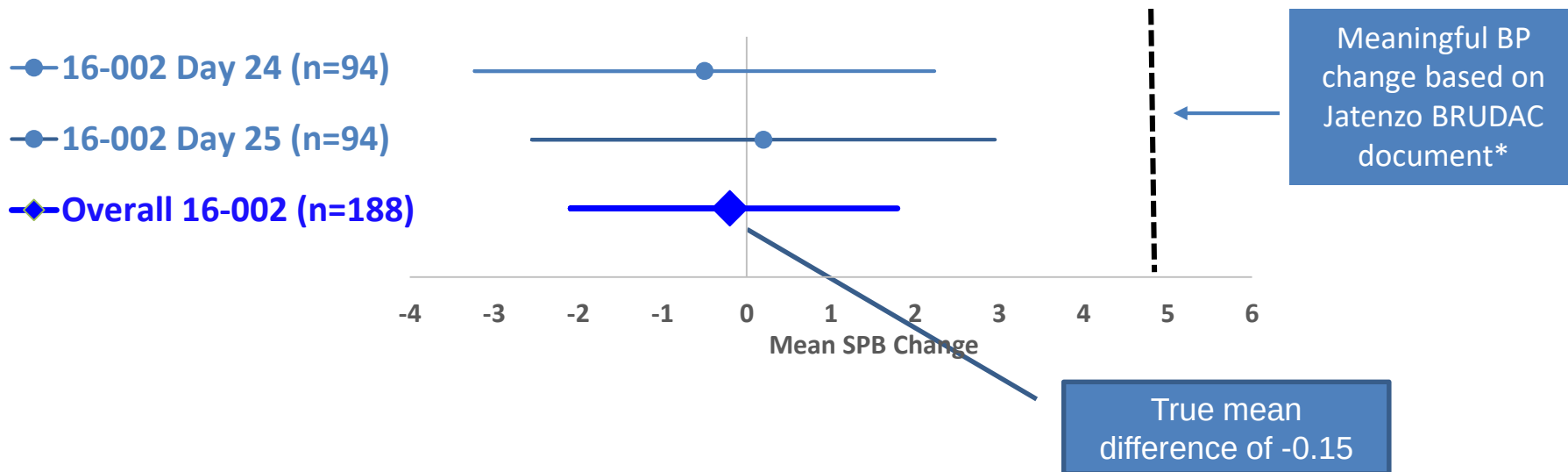
Overview

- Long-term study underway to determine definitive link between TRT use and cardiovascular (CV) outcome, if any
- Blood pressure effects are surrogate marker of potential CV risk
- No known blood pressure effects with any approved TRT product
- No ABPM study requirement for any prior approved TRT product
- No request to perform ABPM study for TLANDO™ in any prior FDA interaction/communication (i.e., CRL, post-action meeting, DV protocol review)
- Clinic BP measurement is standard methodology for non-hypertensives trials and TRT products

* From Jatenzo briefing document for Jan 9th BRUDAC meeting

TLANDO™ DV Study Blood Pressure Data

Systolic Clinic BP Measurement - Change From Baseline

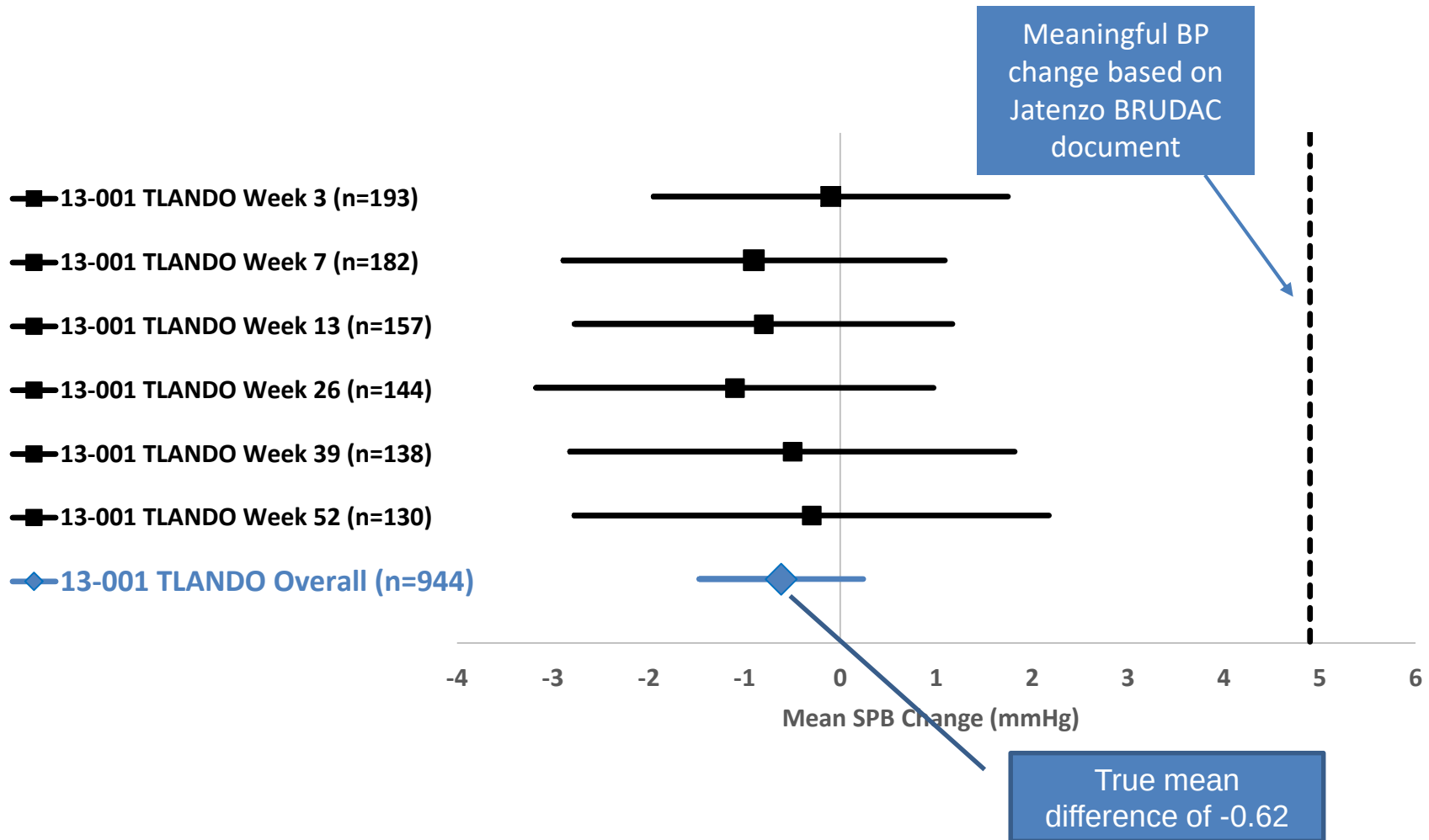


✓ Minimal Change in BP from Baseline in DV Study

* From Jatzeno briefing document for Jan 9th BRUDAC meeting

TLANDO™ SOAR Study Blood Pressure Data

Systolic Clinic BP Measurement - Change From Baseline



✓ Minimal Change in BP from baseline at each visit throughout the SOAR study

Oral TU: Dose - Systolic BP Relationship

Dose level appears to play a role on blood pressure changes

Oral TU	Mean Single SBP		Mean Triplicate SBP		Mean ABPM Daytime SBP	
	Study / Dose	Δ SBP from baseline	Study / Dose	Δ SBP from baseline	Study / Dose	Δ SBP from baseline
TLANDO	LPCN 13-001 Wk3 / pre-titration <u>225mg BID</u>	-0.1				
TLANDO	LPCN 16-002 Day24 / Fixed <u>225mg BID</u>	-0.5				
	LPCN 16-002 Day25 / Fixed <u>225mg BID</u>	0.2				
JATENZO	CLAR 12011 Day114 /post titration mean <u>241mg BID</u>	0.1	CLAR 15012 Visit2 / pre-titration <u>237mg BID</u>	0.2		
JATENZO	CLAR 09007 Day30 / Pre-titration <u>316mg BID</u>	3.0	CLAR 15012 Day102 / mean <u>325mg BID</u>	3.4	CLAR 15012 Day102 / mean <u>325mg BID</u>	5.05
	CLAR 09007 Day90 / mean <u>292mg BID</u>	3.0				

Oral TU Blood Pressure Effects

Summary

- No significant increase in clinic measured BP with TLANDO™ in multiple visits across multiple studies at the indicated dosing regimen of 225 mg BID
- Dosing regimen appears to play a role on any blood pressure effects
- Clinic BP and ABPM measurements are similar*
- Multiple visit clinic measurements more likely to identify any BP trend

*From Jatenzo briefing document for Jan 9th BRUDAC meeting

LPCN 1111
QD

TLANDO

LPCN 1111

LPCN 1111: Next-Generation Oral TRT

Potential Once-Daily Dosing

- Novel prodrug of testosterone for oral delivery
- Once-daily potential expected to sustain and improve market share of oral T franchise
- Once-daily feasibility established in Phase 2a and 2b clinical trials
 - Single-daily oral dose provides T levels in eugonadal range
- Development status
 - Next steps:
 - Preclinical toxicity study complete, data analysis on-going
 - FDA meeting in 1Q 2018 to discuss results of preclinical toxicity study and the Phase 3 study design

LPCN 1107

LPCN 1107: Prevention of Preterm Birth (PTB)

An Unmet Medical Need

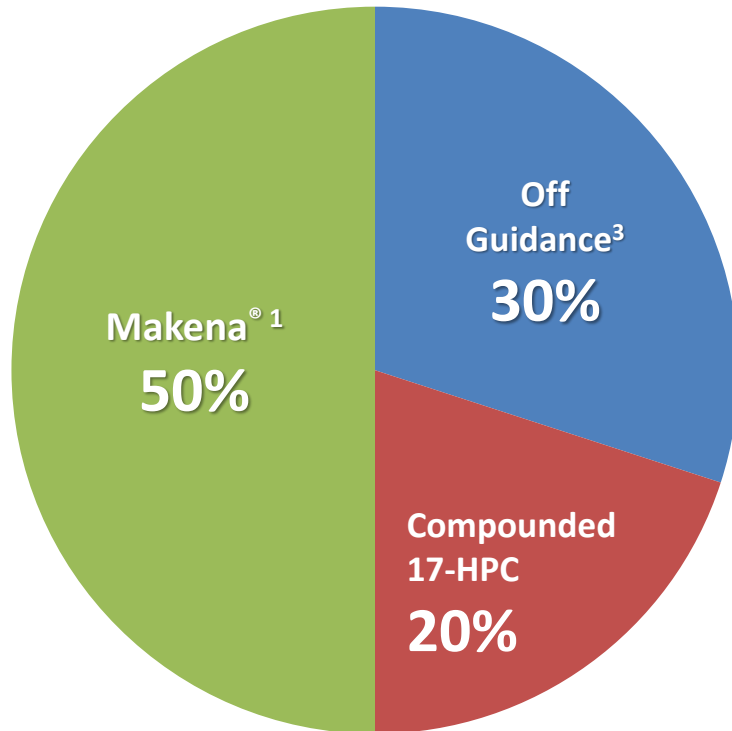


¹Pediatric Research (2006) 60, 775–776

LPCN 1107: Prevention of Preterm Birth (PTB)

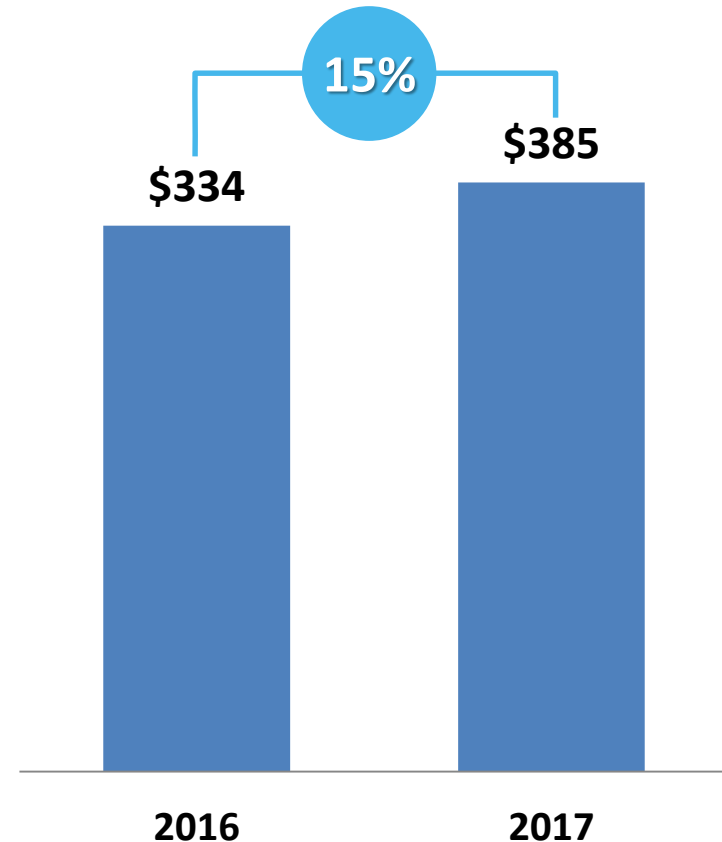
United States PTB Prevention Market Landscape

December 31, 2017



\$1B Market Opportunity²

Makena Net Revenue (\$M)



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.

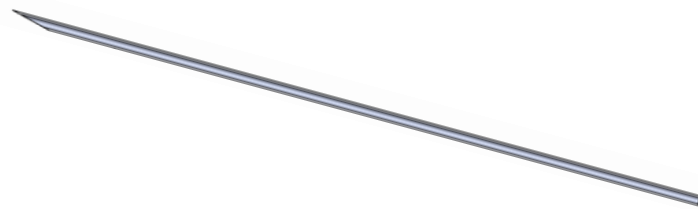
2. Based on 140,000 patients, >16 injections/patient and net revenue of ~\$425-\$450/injection.

3. Off guidance represents patients treated outside of guidance of Society for Maternal Fetal Medicine, including patients treated with unapproved therapies and untreated patients.

LPCN 1107: First Oral PTB Candidate

Characteristics Of The Only Approved Product for PTB

Makena 21 gauge needle

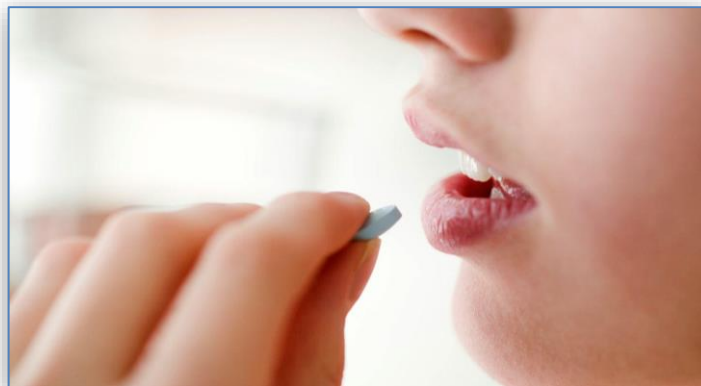


IM HPC, Makena®: Current preterm birth standard of care

- 20-25% patients below reported better efficacy HPC level threshold
- Total of 18-22 injections
 - Viscous oily weekly injection
 - Injection takes up to 1 min
 - 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

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

LPCN 1107: Advancing to Phase 3 Readiness

Phase 3 Special Protocol Assessment – Progress

■ **Concurrence with FDA to date:**

— **Study Design Elements**

- Single Phase 3 study
- Open label, active comparator, two parallel arms (1:1 randomization)
- General inclusion and exclusion criteria and treatment duration
- LPCN 1107 dose of 800 mg BID

— **Endpoints and Analysis**

- Primary endpoint of proportion of PTB < 37 weeks
- Non-inferiority margin of 7%
- Secondary endpoint: Neonatal mortality and morbidity composite index
- Interim analysis with ability to resize the study
 - Study size: 500 to 1000 subjects per arm

■ **Open Items**

- Data from food effect study to inform dosing instructions
- Align on approach to fulfill infant follow up data requirement

■ **Next Steps**

- Continue Interactions with FDA on Phase 3 protocol via Special Protocol Assessment
- Conduct Food/Fat Effect Study in 2H 2018 in preparation of Phase 3 study

Upcoming Milestones

Driving Value in 2018

	Event	Expected Timing
TLANDO™	Initiate ABPM study	1H 2018
	Initiate Phlebotomy study	1H 2018
	PDUFA goal date	May 8, 2018
LPCN 1111	FDA meeting to discuss Phase 3 clinical trial	1Q 2018*
LPCN 1107	Conduct Food/Fat Effect clinical study	2H 2018

* Meeting occurred and awaiting FDA meeting minutes

Key Financial Metrics

Stock Price, Market Cap, Cash Balance

Ticker Symbol	LPCN (Nasdaq Capital Market)
Closing Stock Price (3/8/18)	\$1.60/share
Market Capitalization (3/8/18)	\$34.0 million
Fully Diluted Shares Outstanding (12/31/17)	24.4 million
Cash Balance (12/31/17)	\$21.5 million
Bank Debt (12/31/17)	None*

* On January 5, 2018, the Company borrowed \$10 million from Silicon Valley Bank. The debt and related cash proceeds are not reflected above.

Lipocine Investment Highlights

Innovative Technology with Advanced Products

Proven Proprietary Technology Platform



MEN'S HEALTH

Testosterone Replacement Therapy (“TRT”) Franchise

- **TLANDO™**: Potential first oral TRT option
 - Differentiated product targeting ~\$2.0 billion established US TRT market
 - Poised to meet and exceed unmet need
- **LPCN 1111**: Next generation potential once-daily oral TRT option
 - Positive top-line Phase 2b study results



WOMEN'S HEALTH

LPCN 1107:

Orphan designated oral alternative for the prevention of preterm birth

- EOP2 meeting completed
- Phase 3 protocol submitted to FDA via Special Protocol Assessment

Appendix

TLANDO™

TLANDO™: Potential First Oral Option

Profile Demonstrated Clinically with Target Label Regimen



Efficacy

- Met primary endpoint
 - 80% response rate in “worst-case analysis” vs. FDA requirement of 75%
- Met key secondary endpoint
 - No eligible subjects with T levels >2500 ng/dL
- Other secondary endpoints generally consistent with approved products



Safety

- 525 unique hypogonadal men exposure
- Well tolerated in 52 week exposure
 - AE profile comparable to active control, including GI
 - No cardiac, hepatic or drug related SAEs
- No apparent correlation of the observed C_{max} excursions
 - ADRs
 - AEs
 - Meaningful changes in critical lab parameters



Clear Benefits

- Preferred oral option
 - No risk of accidental T transference
 - Non-invasive
 - Less cumbersome
 - Less burdensome
 - Simpler to prescribe
 - Fewer doctor visits
 - Easier for patients to properly use

TLANDO™ BRUDAC Briefing Document

FDA Blood Pressure Conclusion

- “The 52-week blood pressure data are more reassuring, but are limited by the non-duplicative (single morning) cuff pressure readings, open-label trial design and 38% dropout rate in the Tlando arm. Based on these considerations, FDA cardiologists concluded that we cannot definitively exclude a blood pressure effect with Tlando and recommend that the Applicant perform an ambulatory blood pressure monitoring study to further assess the effects of Tlando on blood pressure and heart rate.”

Hypertension: SOAR Phase 3 Clinical Trial Results

AE's /Discontinuations related to Increased Blood Pressure

System Organ Classification / Preferred Term	TLANDO™ (N=210)	Androgel 1.62% (N=104)
	n (%)	n (%)
Investigations:		
Blood Pressure Increased	1 (0.5)	2 (1.9)
Vascular Disorders:		
Hypertension	6 (2.9)	5 (4.8)
Total	7 (3.4)	7 (6.7)

- Fewer TLANDO™ subjects reported AE's as a result of increased blood pressure / hypertension as compared to Androgel 1.62% subject
 - No AE's in DV or DF Studies related to increased blood pressure / hypertension
-
- No subject discontinuations in SOAR, DV or DF studies related to increased blood pressure / hypertension

SOAR Trial (Study 13-001): Effect on Anti-Hypertensive Therapy

Patients With and Without a History of Hypertension (HTN)

Subjects of Interest	TLANDO N=210 n (%)	AndroGel N=104 n (%)
Baseline diagnosis of HTN or on antihypertensive therapy	100 (47.6)	49 (47.1)
On baseline antihypertensive therapy	86/100 (82.0)	44/49 (89.8)
Increased in antihypertensive dose	2/86 (2.3)	2/44 (4.5)
Without baseline diagnosis of hypertension and not on antihypertensive therapy	110 (52.4)	55 (52.9)
BP >150/90 mmHg ≥2 measurements on study drug ^a	3/110 (2.7)	3/55 (5.5)
Initiation of antihypertensive therapy	0	0

^aJNC 8 JAMA. 2014;311(5):507-520. doi:10.1001/jama.2013.284427 Published online December 18, 2013.

Oral TU Mean Doses

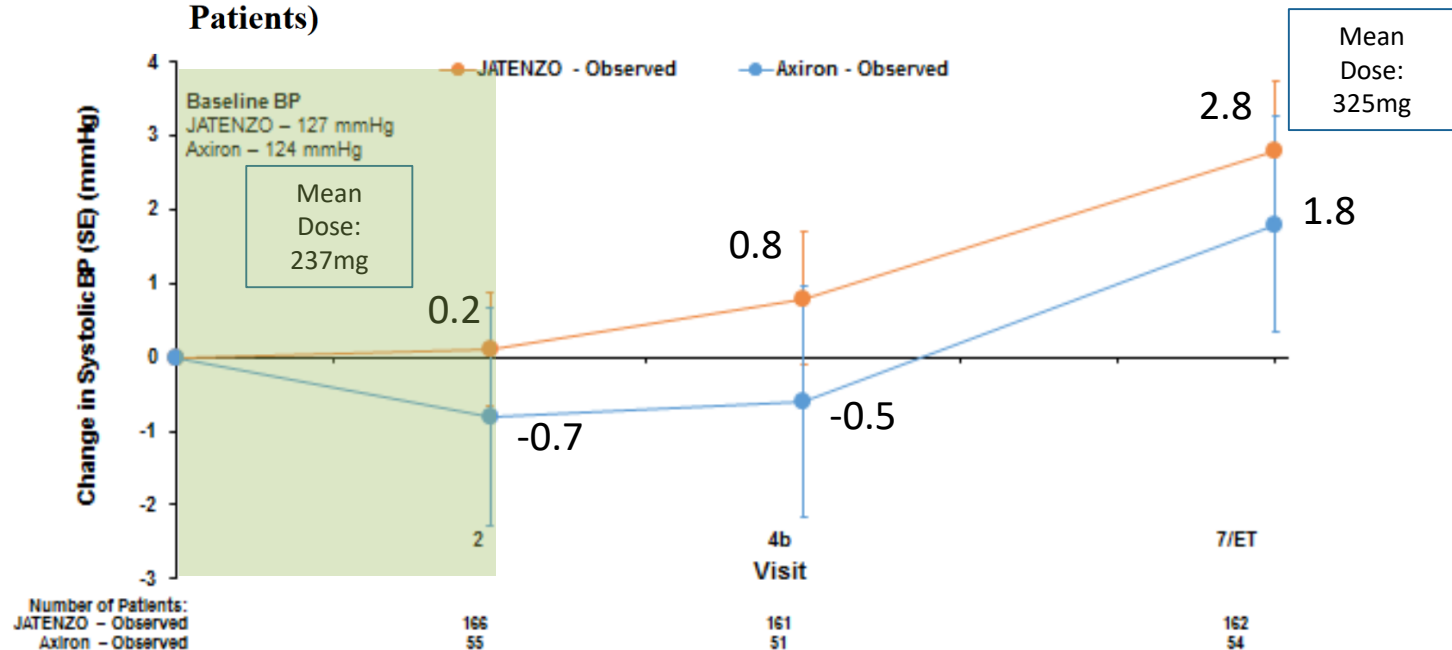
TLANDO™ vs. JATENZO

	TLANDO		JATENZO		
	13-001	16-002	CLAR-09-007	CLAR 12-011	CLAR-15-012
Mean Dose (BID)	213mg	225mg	292mg	241 mg	325mg
Dose Distribution					
Starting dose (BID)	225mg	225mg	316mg	316mg	237mg
Down-titrated	32% (150mg)		22.7% (158mg - 237mg)	72%	1.9% (158mg - 198mg)
No changed	52% (225mg)	100% (225mg)	72.4% (316mg)	?	26% (237mg)
Up-titrated	16% (300mg)		5.6% (395mg - 474mg)	?	72% (316mg - 396mg)

Jatenzo™ Duplicative Clinic Blood Pressure Results* Over Time

Dose Level Appears to Have a Role in Blood Pressure Increase

Figure 10: Study CLAR-15012: Mean Change From Baseline ($\pm$ Standard Error) in Clinic Systolic Blood Pressure by Treatment Group (All Treated Patients)



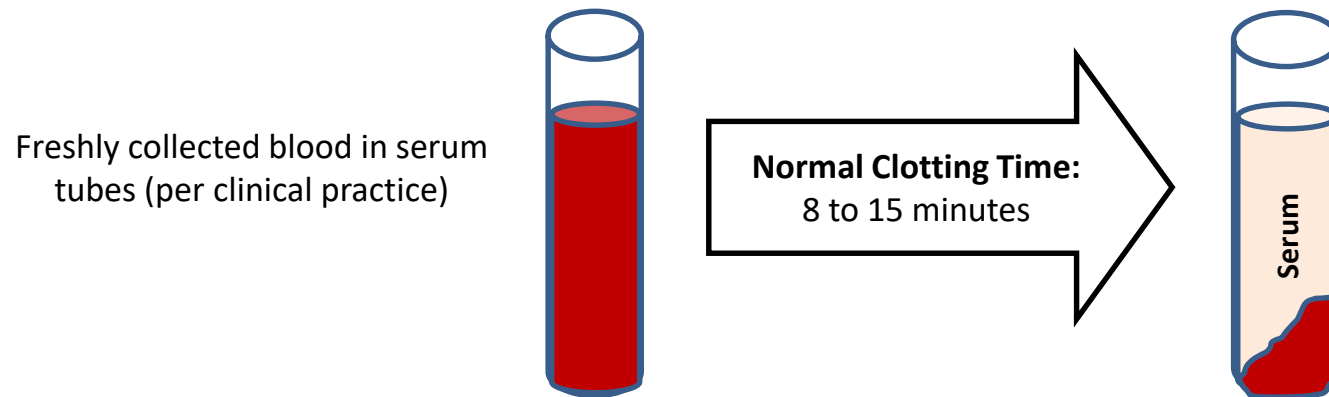
Abbreviations: BP = blood pressure; ET = early termination

✓ Minimal Change in BP from Baseline at Visit 2

TLANDO™: Ex-Vivo TU to T Conversion

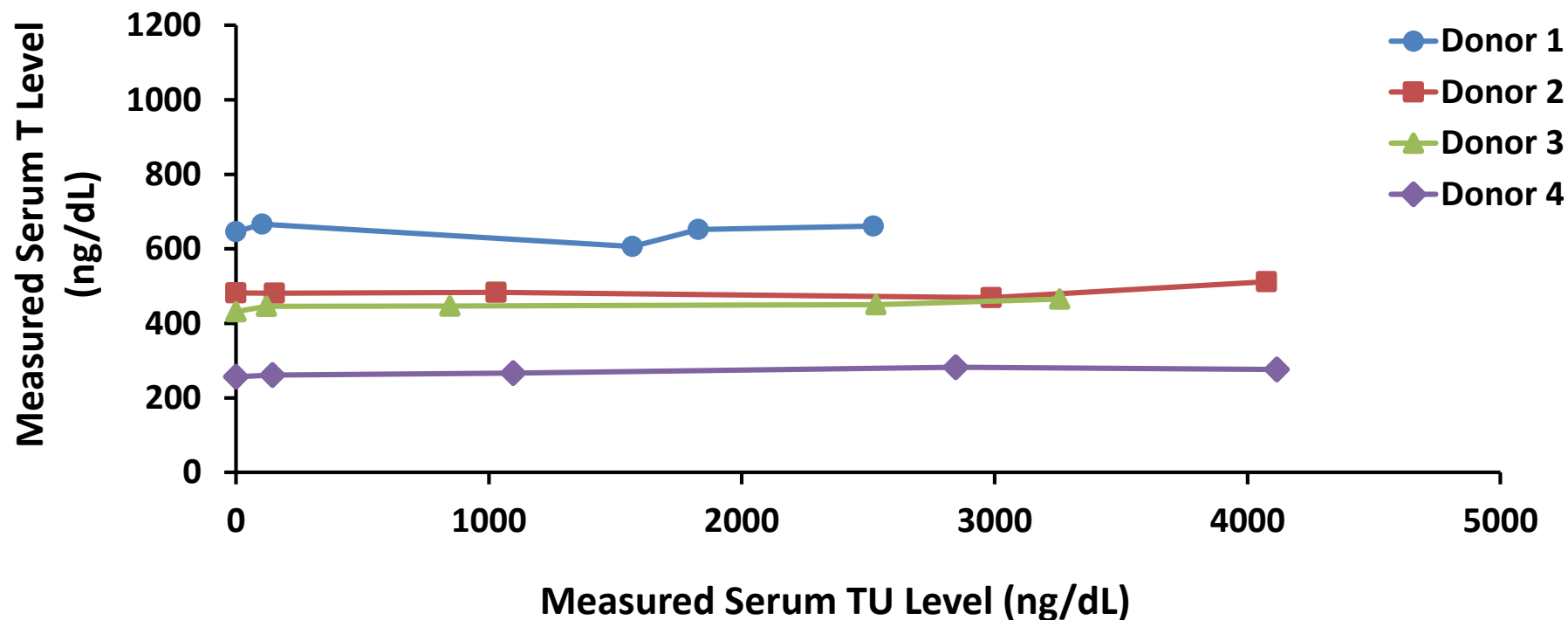
Additional Analysis

- Whole blood collected in plain serum tubes
- TU dissolved in ethanolic PBS solution is spiked into freshly collected blood
- Allowed to clot for 30 minutes at room temperature
- Centrifuged for 15 minutes to harvest serum
- TU and T concentrations are measured from the serum samples



TLANDO™: Ex-Vivo TU to T Conversion with in-vitro TU addition

TU and T Evaluation in Blood/Serum Process

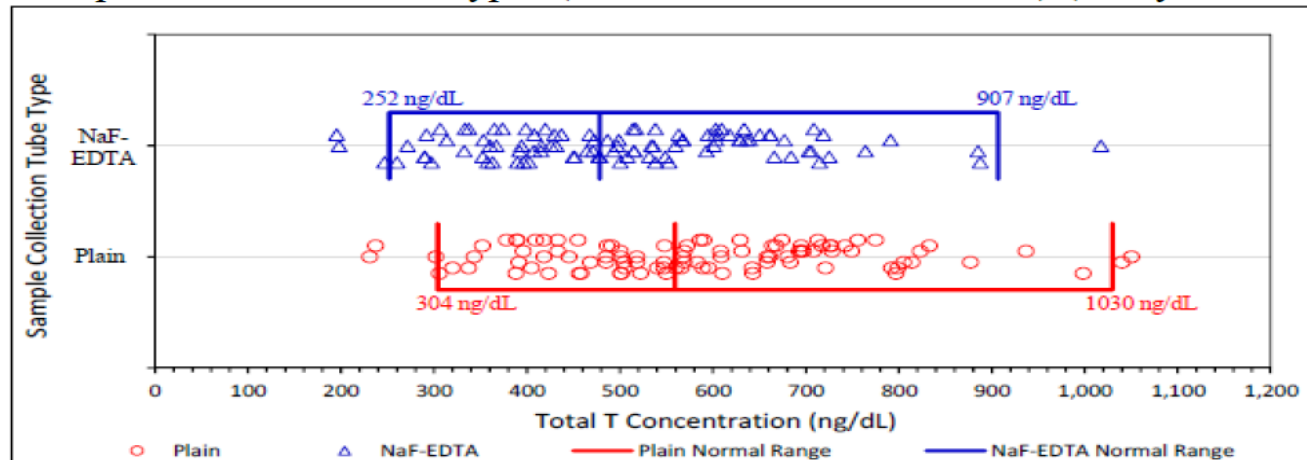


✓ T levels don't increase with increasing TU levels - constant

Evaluation of Testosterone in the without TU addition

- Morning (6 – 10 AM) blood samples from 97 healthy males (19 – 40 yrs old) were drawn in plain serum and NaF – EDTA plasma tubes under fasted condition*

Figure 5: Distributions of Total T Assay Results: Geometric Means and $\pm 2 \times \text{SD}$ Ranges for the 2 Sample Collection Tube Types (Plain vs. NaF-EDTA Tubes) (Study CLAR-16014)



Note 1: Data points are distributed in the vertical dimension only to facilitate visualization

Note 2: Vertical lines identify the geometric mean and $\pm 2 \times \text{SD}$ (for log-transformed data) from the geometric mean

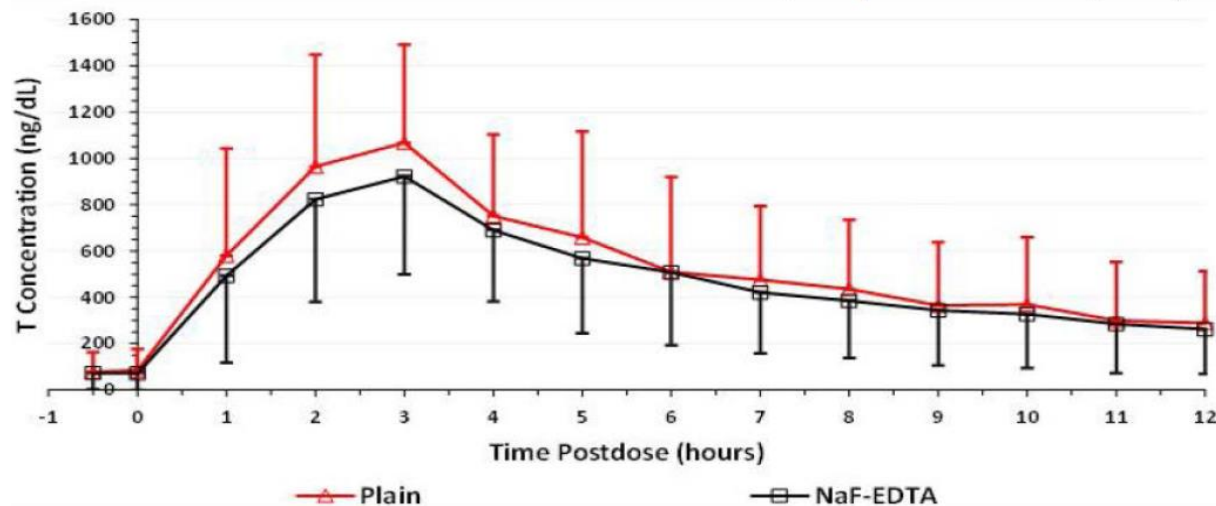
Geometric mean: Plain tube = 559 ng/dL; NaF-EDTA tube = 478 ng/dL

- ✓ T levels from Plasma NaF/EDTA tubes were 14.2% lesser than serum tubes

Evaluation of Testosterone post Oral TU administration

- 14 blood samples from 8 hypogonadal subjects were drawn in plain serum and NaF – EDTA plasma tubes following a single oral dose of 316mg TU*

: Mean (SD) Concentration-Time Profiles for T Following a Single 316 mg Oral TU Dose, for Plain and for NaF + EDTA Collection Tubes (Study CLAR-15013; N=8)



- ✓ Cavg T levels from Plasma NaF/EDTA tubes were 13% lesser than serum tubes

Similar differences between enzyme inhibited plasma and plain serum both in presence and absence of TU suggesting TU do not play a role in the difference

TLANDO™: Ex-Vivo TU to T Conversion

Serum Testosterone Assay Data Are Reliable

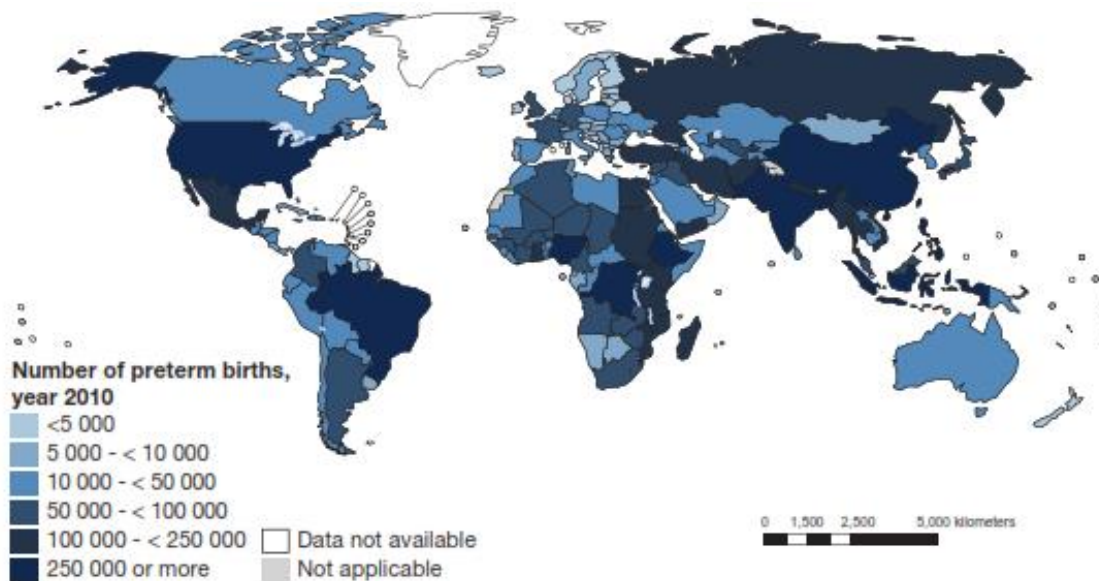
Conclusion:

- No conversion of TU to T occurs ex-vivo during blood collection and serum sample processing
- Treatment outcomes confirm reliability of T measurements
 - Pharmacological effects (e.g., LH/FSH suppression)
 - Testosterone metabolite levels (e.g., E2)

LPCN 1107

HPC Concentration and PTB Rates

PTB Prevalence



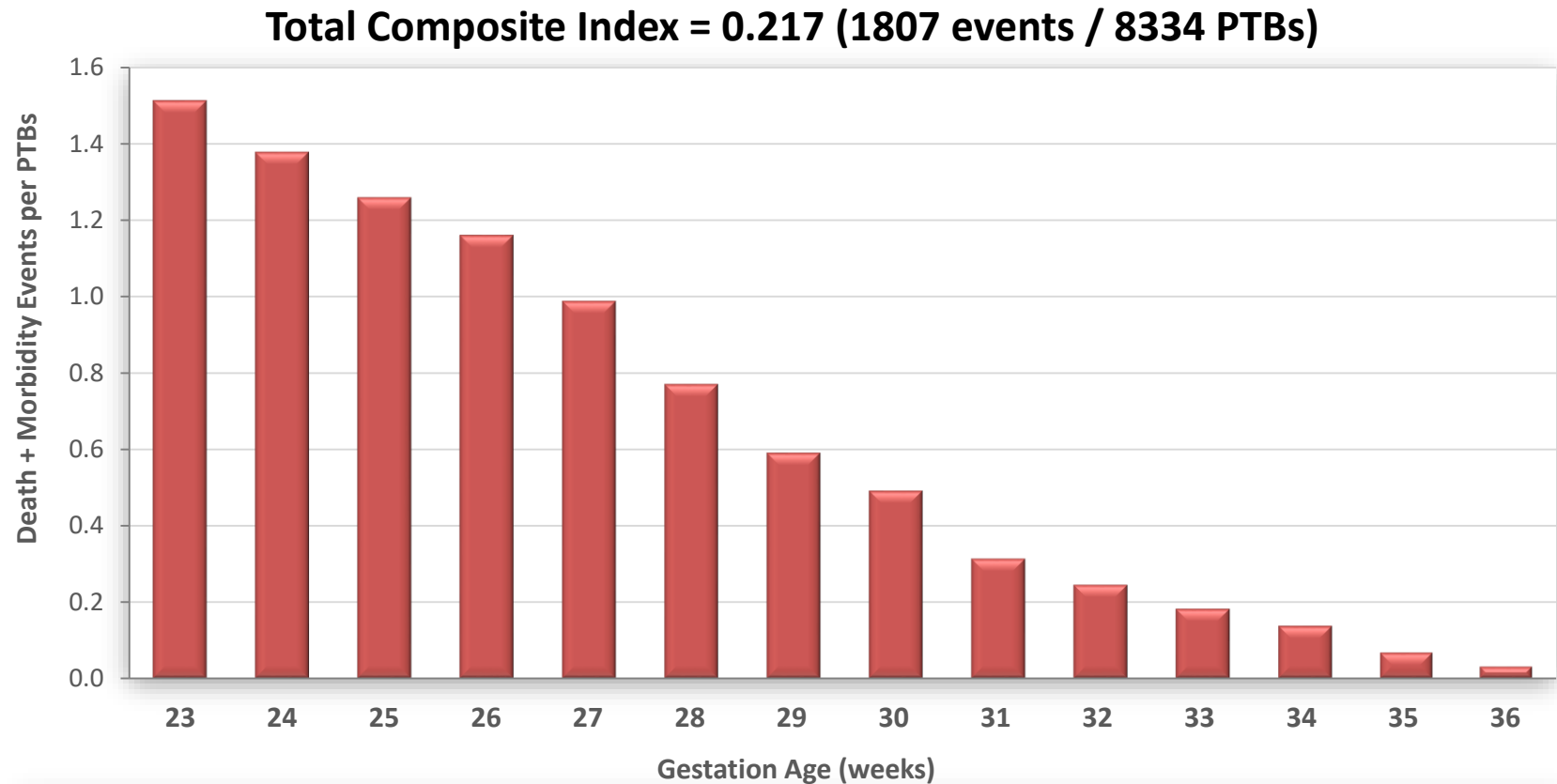
10 Countries Account for **60%** of the World's Preterm Births by Rank:

1. India
2. China
3. Nigeria
4. Pakistan
5. Indonesia
- 6. United States of America**
7. Bangladesh
8. Philippines
9. Dem. Rep. of Congo
10. Brazil

PTB Risk Factors

- **Prior spontaneous PTB**
- Having a short cervix
- African American ethnicity
- Age <18 years or >40 years
- Problem with uterus or cervix-mature cervical dilation
- Certain infections during pregnancy (UTI, vaginal, uterine)
- High blood pressure, stress, diabetes or being underweight or overweight
- Short inter-pregnancy interval (6-18 months)
- Smoking, drinking alcohol or Illicit drug use

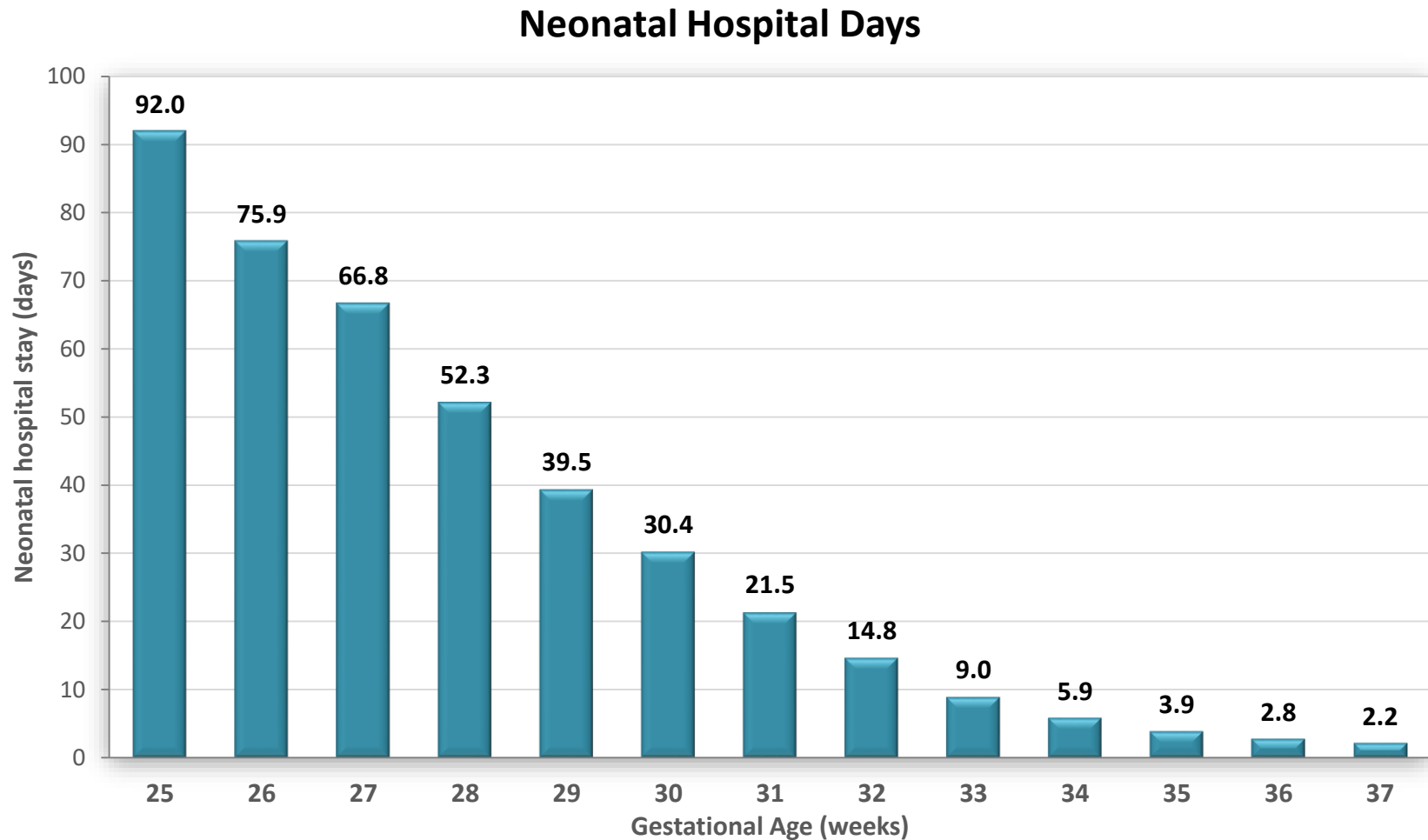
Infant Mortality/Morbidity Related to Gestational Age*



* Composite index is composed of neonatal death, Grade 3 or 4 intraventricular hemorrhage, respiratory distress syndrome, bronchopulmonary dysplasia, and necrotizing enterocolitis.

* Manuck et al., Preterm morbidity and mortality, AJOG, 2016

Benefit of Prolonging Gestation Age*



* Gilbert et al., Obstet Gynecol. 2003

High PTB Medical Costs

≥ \$26 Billion Economic Impact³



- 12% of all US pregnancies¹ (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 infants²
- 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. Jul.200

LPCN 1107: Economic Impact

Potential Lower PTB Rate – US and Resulting Savings

Assuming 4.3% lower PTB rate relative to Makena[®]



~6000 fewer annual PTBs[‡]



Estimated annual cost saving in ~\$310M^{‡‡}

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

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

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

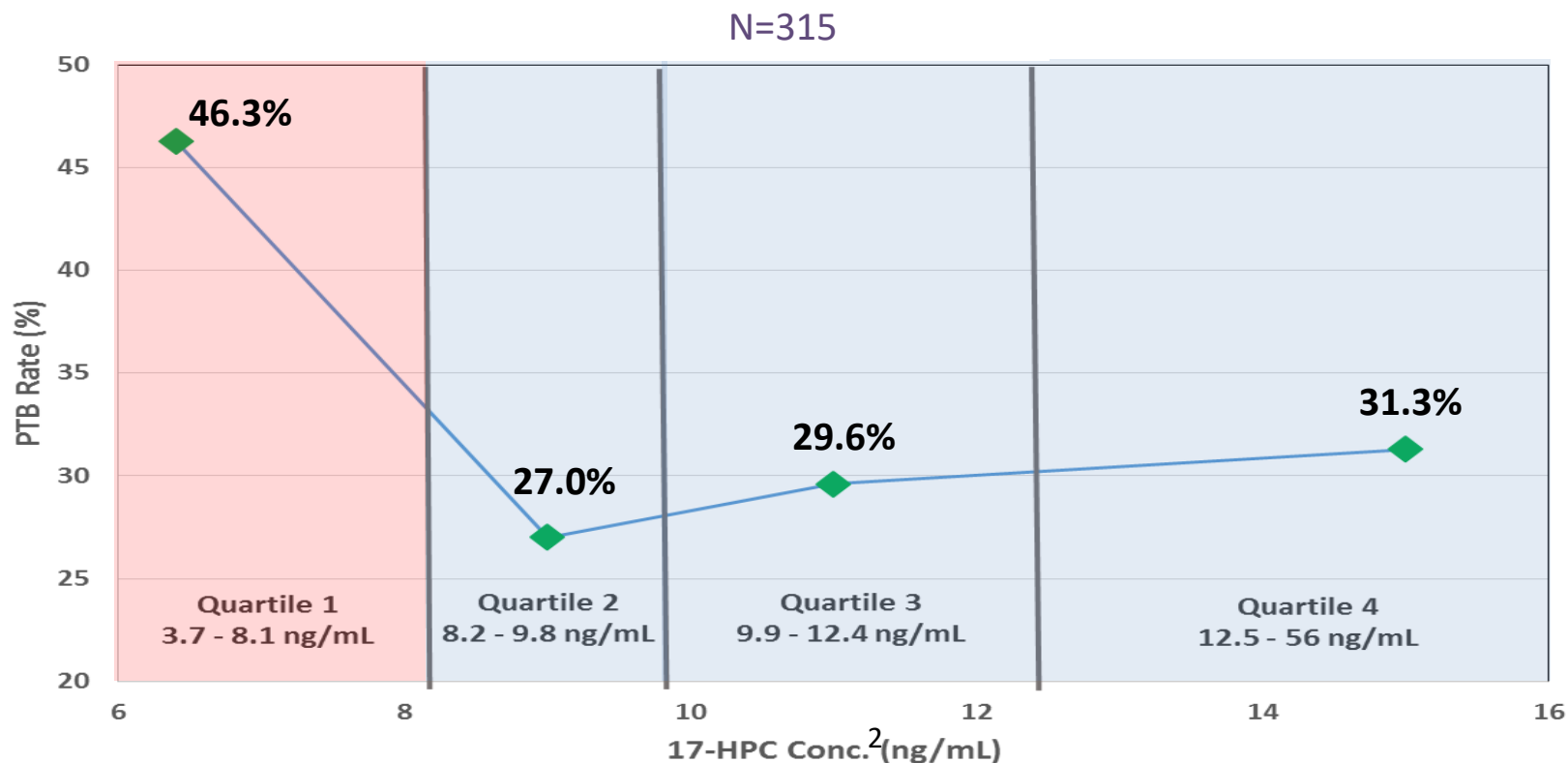
- Fewer PTB babies with significant healthcare cost savings

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, Makena¹



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

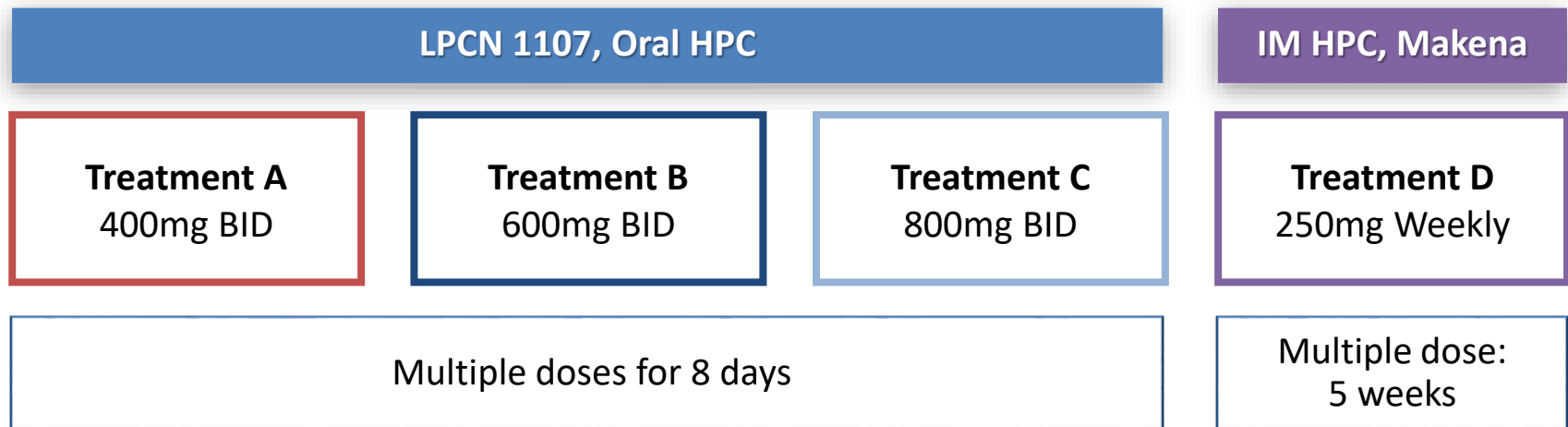
1. Caritis et al., Am J Obstet Gynecol. 2014 (N=315 subjects)

2. $C_{trough} \cong C_{avg}$ for IM Makena®

LPCN 1107: Dose Finding Study Design

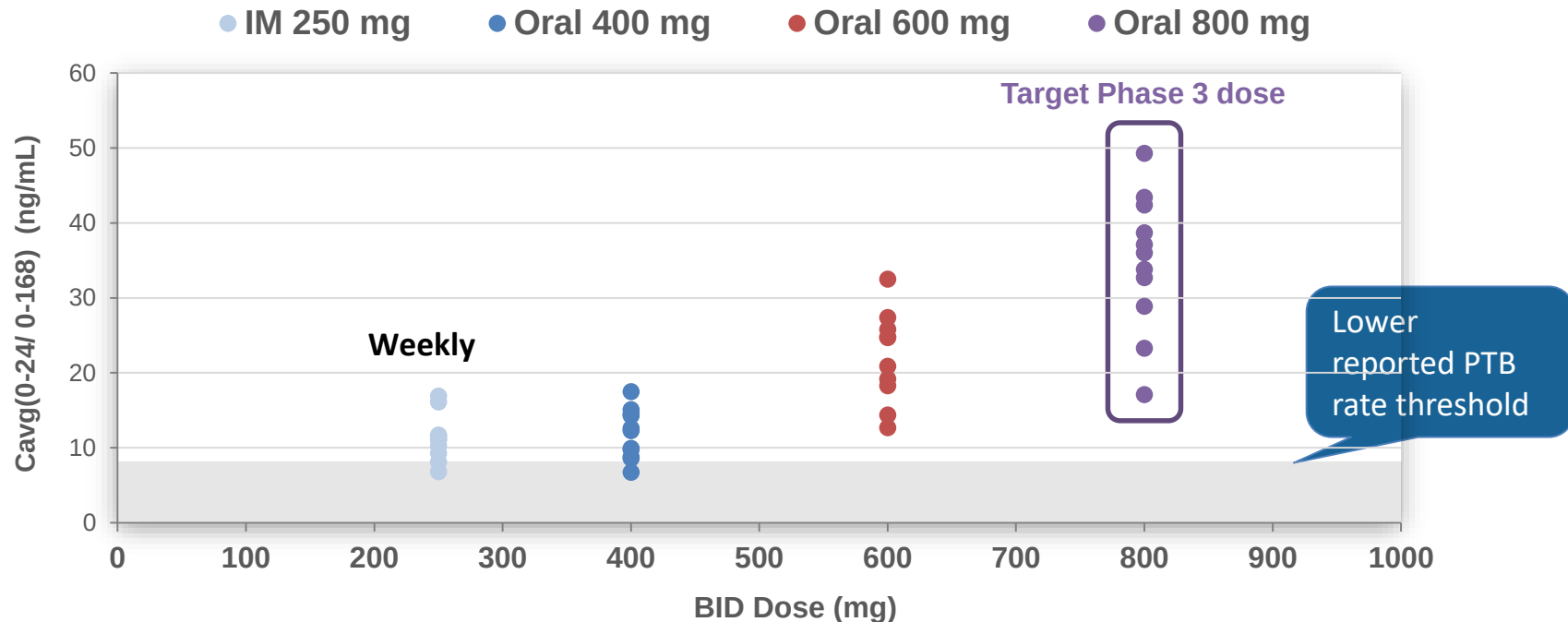
PK Study: Oral LPCN 1107 vs IM HPC, Makena

- 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



LPCN 1107: Dose-Finding PK Study Results¹

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