SOAR

STUDY OF ORAL ANDROGEN REPLACEMENT

LIPOCINE® INCORPORATED

Top-line Efficacy Results

September 24, 2014

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LPCN 1021 Overview

- LPCN 1021 has the potential to be a leader in Testosterone Replacement Therapy (TRT)
- LPCN 1021 is a twice-a-day Oral TRT product candidate with three simple dosing options
  - Positive top-line efficacy results in Phase 3 clinical study
  - Safety portion of Phase 3 clinical study is on-going
- Target label—consistent with TRT class label for other approved products

LPCN 1021 Target Success Criteria:

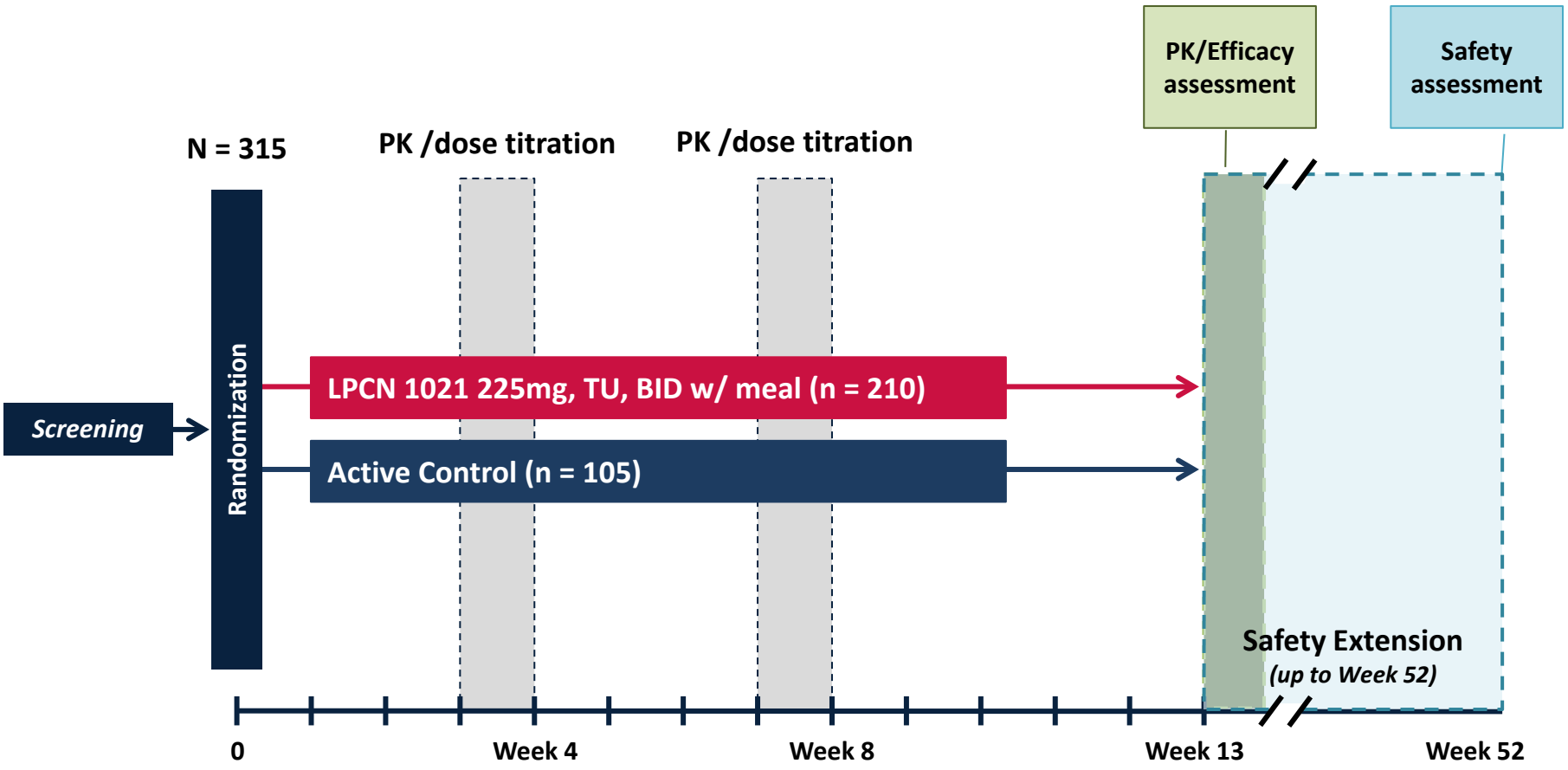
Current Regulatory Paradigm[1]

- Meet primary end points
  - Responder analysis relating to average serum concentration 0 to 24 hours (C_{avg}) and lower bound Confidence Interval (CI)
- Acceptable safety profile
  - Responder analysis relating to peak testosterone levels that is consistent with approved products
  - Long term safety data (at least 100 subjects, 1 year)[2]

(1) September 18, 2014 Joint Meeting of the Bone, Reproductive and Urologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee Meeting, (2) ICH E1 guidance document "The extent of population exposure to assess clinical safety for drugs intended for long-term treatment of non-life-threatening conditions"

Phase 3 Study Design

- Open label, randomized, active-controlled study of LPCN 1021 in men with low testosterone



Dataset Definition

- **Primary Analysis Set**
  - **Efficacy Population (N=152)**: Subjects randomized into the study with at least one PK profile and no significant protocol deviations
    - Imputed missing data by Last Observation Carried Forward (LOCF)
- **Additional Analysis Set**
  - **Safety Set (N=210):** Subjects randomized into the study and took at least one dose of the drug
    - Imputed missing data by Last Observation Carried Forward (LOCF)
    - Treatment failures if no PK data available

Primary Endpoint: Responder Analysis

- Primary endpoint target ≥ 75% subjects should achieve C_{avg} within normal range (300 ng/dL to 1140 ng/dL) and lower bound of 95% CI ≥ 65%

Measure	Efficacy Population	Safety Set
Number of subjects	152	210
% subjects with C_{avg} within normal range	88.2%	80.0%
95 % CI lower bound	81.9%	73.8%

✓ **LPCN 1021 met both the primary endpoint targets in both population sets**

Primary Endpoint: C_{avg} and Distribution in Subjects

- % of subjects with C_{avg} in various ranges

Range	Efficacy Population
C_{avg} < 300 ng/dL	11.2 %
C_{avg} between 300 and 1140 ng/dL	88.2 %
C_{avg} > 1140 ng/dL	0.7 %
Parameter	**Mean (CV)**
C_{avg} (ng/dL)	447 (37%)

✓ **Less than 12% of the subjects' C_{avg} were outside the normal range**

Dataset: Efficacy population, N=152

Final Dose Distribution of Subjects

Dose (mg TU, BID)	% of subjects
150	36%
225*	51%
300	13%

- ✓ **Majority of subjects with final dose of 225 mg BID**

Dataset: Efficacy population, N=152
*starting dose

Titration Outcome

Parameter	% of subjects
% subjects requiring no more than one dose change (either after week 3 or week 7)	85%
% subjects requiring two dose changes (both after week 3 and 7)	15%

✓ **Vast majority of subjects reached final dose with no more than one titration**

Dataset: Efficacy population, N=152

Secondary Endpoints

- Proportion of subjects achieving maximum serum total T concentrations (C_{max}) in predefined C_{max} range

Measure	FDA Threshold	Efficacy Population
Number of subjects		152
C_{max} < 1500 ng/dL	≥ 85 %	82.9%
1800 ≤ C_{max} ≤ 2500 ng/dL	≤ 5 %	4.6%
C_{max} > 2500 ng/dL	None	2.0%

LPCN 1021 Excessive T Repletion Outliers (C_{max}>2500 ng/dL) Characteristics

- Excessive T repletion outliers were observed in three subjects
- These observed excessive T repletion outliers were transient, sporadic, isolated, and not clinically meaningful
  - Lack of dose or dosing time dependency
  - None of these subjects reported any adverse events

Dataset: Efficacy population , N=152

Adverse Events (AE) Summary in LPCN 1021 Arm

- Safety study is on-going
- 3% of the subjects reported a serious adverse event
  - There were no drug related Serious AEs
- 46% of the subjects experienced at least one adverse event
  - Approximately one third of these events were drug related
  - All these adverse events were either mild or moderate (none were severe)
- Hematocrit and PSA increases were noted and consistent with other TRT products
  - 1 subject discontinued due to increase in PSA
  - 1 subject discontinued due to increase in hematocrit

Top Line Results Summary

- Met primary efficacy endpoint by successfully restoring testosterone levels to the normal range in 88% of the subjects
  - Primary endpoint robust to sensitivity analysis
- Lower limit of the 95% confidence interval was 82%
- 85% of the subjects reached final dose with no more than one dose titration
- Majority of subjects ended on 225 mg BID dose
- Proportion of subjects with maximum serum concentrations generally consistent with approved TRT products
- LPCN 1021 treatment was well tolerated with no drug related serious adverse events