Men: Results from the 52-Week Phase 3 Study

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Introduction and Objectives

LPCN 1021 is a novel oral testosterone undecanoate (TU) formulation, absorbed primarily via lymphatics bypassing the liver. LPCN 1021 has been shown to be safe and efficacious after 13 weeks in a randomized, active-controlled Phase 3 study.1 We report long-term safety and tolerability of LPCN 1021 in hypogonadal subjects who continued receiving treatment for up to 52 weeks.

Methods

Hypogonadal patients (serum T levels < 300 ng/dL) were randomized in a 2:1 ratio to LPCN 1021 or T gel 1.62% (active control) and titrated to a successful dose of the assigned treatment. Following a 13-week efficacy phase, subjects continued receiving their assigned study drug for up to 52 weeks. Subjects returned to the clinic at Weeks 26, 39, and 52 for safety assessments and to provide a 3 to 6 hour post dose blood sample. Safety assessments included an evaluation of adverse events (AEs), clinical laboratory tests, and physical examinations.

Results

210 subjects were randomized to LPCN 1021 and 105 to active control. Eugonadal T levels were restored with LPCN 1021 (Week 13 mean [SD] Cavg of 446 [171] ng/dL) and were reliably maintained throughout 52 weeks. AEs occurred in 67% of LPCN 1021 subjects and 65% of T gel 1.62% subjects. No hepatic, cardiac, or drug-related serious AEs occurred. The most common drug-related AEs (adverse drug reactions, ADRs) for LPCN 1021 and T gel 1.62% were acne (2.9% vs 2.9%, respectively), headache (0.5% vs 3.8%, respectively), weight increase (2.4% vs 0%, respectively), hematocrit increase (1.9% vs 0%, respectively), liver enzyme level increase (1.4% vs 0%, respectively), fatigue (0.5% vs 1.9%, respectively), and hypertension (0.5% vs 1.9%, respectively). All ADRs were mild or moderate in severity. Subjects receiving LPCN 1021 reported few androgenic ADRs with no reports of sleep apnea or oily skin and 1% or fewer subjects reporting peripheral edema and polycythemia. Most lipid parameters (cholesterol, LDL, HDL, and TG) were comparable between treatment groups at Week 52. Other androgenic parameters including hematocrit, hemoglobin, platelet, prothrombin, and PSA showed no significant differences in change from baseline to end of study between treatments.

Conclusions

LPCN 1021 was well tolerated and had a favorable safety profile in the long-term management of hypogonadal subjects. Notably, no hepatic safety concerns were identified and gastrointestinal AEs with oral LPCN 1021 were generally comparable to active control. 1Wang C, et al. Endo Rev. 2015;36(2) Suppl. Abstract OR34-5.

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