A NOVEL ORAL TESTOSTERONE (TLANDO™) THERAPY RESTORES TESTOSTERONE TO EUGONADAL LEVELS WITHOUT DOSE TITRATION

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Introduction
Most marketed Testosterone Replacement Therapy (TRT) products require multiple titration visits to achieve steady-state eugonadal T levels in hypogonadal men. Most marketed TRTs Require At Least 1 Titration Visit. Challenges of single point PK-based dose titration in clinical practice: Most TRTs Require At Least 1 Titration Visit. TLANDO™ is a novel oral Testosterone Undecanoate (TU) product absorbed via the intestinal lymphatic pathway. TLANDO™ is a novel oral Testosterone Undecanoate (TU) product absorbed via the intestinal lymphatic pathway.

Objectives
To evaluate whether TLANDO™ with fixed dose regimen is efficacious and safe in restoring eugonadal T levels in hypogonadal men.

Methods
- SOAR Trial (NCT02081300) with titration
  - A 52-week, multicenter, open-labelled, active controlled (topical T, N=105) study with TLANDO™ (225mg BID starting dose) in hypogonadal men (N=210)
  - Titrated to 300mg BID in case of Cavg<300 ng/dl or to 150mg BID in case of Cmax>1500 ng/dl at Week 4 and Week 8
  - At Week 3: Pre-titration PK (fixed dose)
  - At Week 13: Post-titration PK
- Dose Validation Study (NCT03242590) with fixed dose regimen
  - A prospective 24-day, multicenter, single arm study with fixed dose TLANDO™ (225mg BID in hypogonadal men (N=95)
  - To validate if the fixed dose TLANDO™ is efficacious and safe

Consistent Population in SOAR and DV Studies
- Demographics
  - Age: Mean (SD) 58.0 (5.9) vs 52.6 (10.2)
  - Race: Black or African American: n (%) 15 (15.8) vs 32 (32.0)
  - White: n (%) 77 (81.1) vs 172 (161.6)
  - Asian & Others: n (%) 3 (3.2) vs 6 (0.6)
  - Weight: kg (SD) 203.6 (38.7) vs 197.1 (15.0)
  - BMI: kg/m² (N=94) 32.8 (5.5) vs 32.0 (5.9)

Robust PK Profile Independent of Titration
- Cmax and Cavg of TLANDO™ remained stable independent of low, moderate or high fat amounts.

Conclusion
- TLANDO™ reliably restores T levels to eugonadal range in hypogonadal subjects without need for titration.
- The efficacious fixed dose TLANDO™ treatment has potential to improve patients’ compliance.
- No additional titration visit, ease to prescribe dosing regimen, and less physician counselling

References
1. Axiron® label (Testosterone topical solution); 2. Xyosted® label (Testosterone Enanthate injectable); 3. Jatenzo® label (Testosterone Undecanoate oral capsule); 4. Shackleford et al., J Pharmacol Exp Ther 2003

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