

**LIPOCINE®**  
ENHANCING HEALTH

**TLANDO®  
(LPCN 1021)**

The Convenient Oral Testosterone  
Replacement Therapy without  
Titration Requirement





## Easy to use and prescribe

For testosterone replacement therapy ("TRT") in adult males indicated for conditions associated with a deficiency or absence of endogenous testosterone

Based on proprietary Lip'ral Technology for efficient absorption of insoluble actives

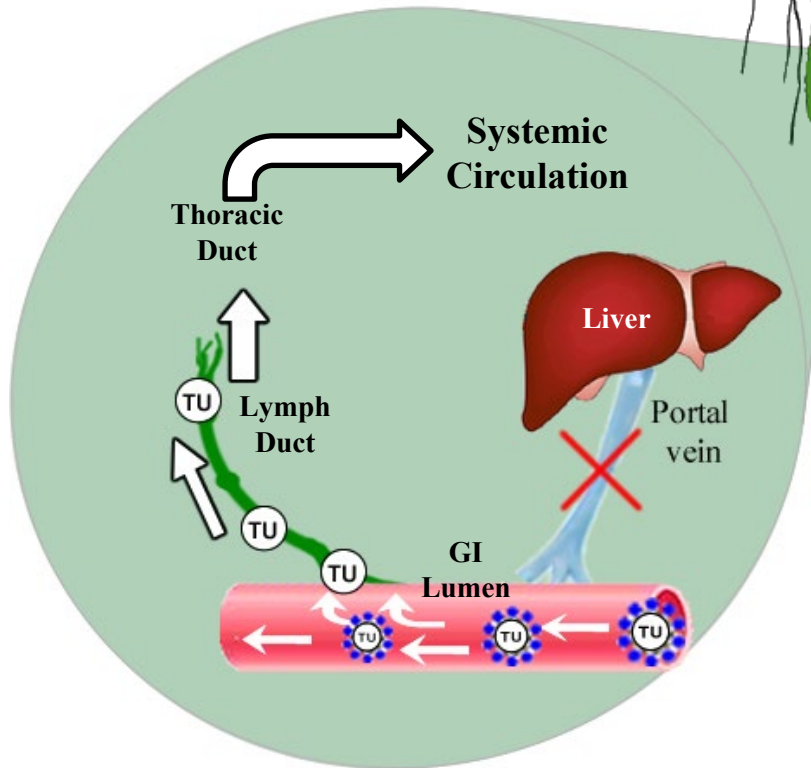
225 mg testosterone undecanoate taken orally twice daily with food

Lymphatically delivers oral testosterone to avoid first pass metabolism/chronic liver toxicity

# TLANDO: Not Known to Produce Adverse Events that are Associated with 17-Methylated Testosterone

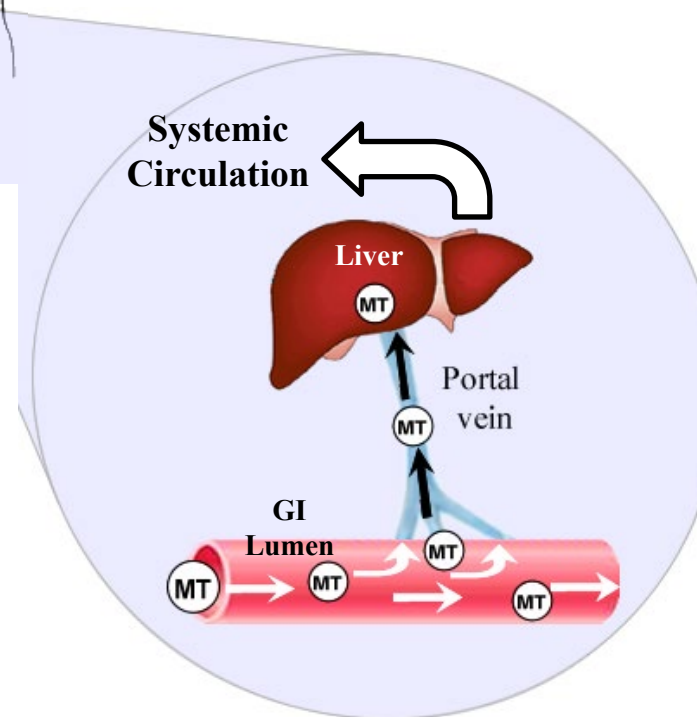
## TLANDO

Transported via Lymph  
Bypass liver “first pass” effect



## METHYL TESTOSTERONE (MT)

Transported via portal Vein  
Prone to liver toxicity



# Issues with Non – Oral TRT Options

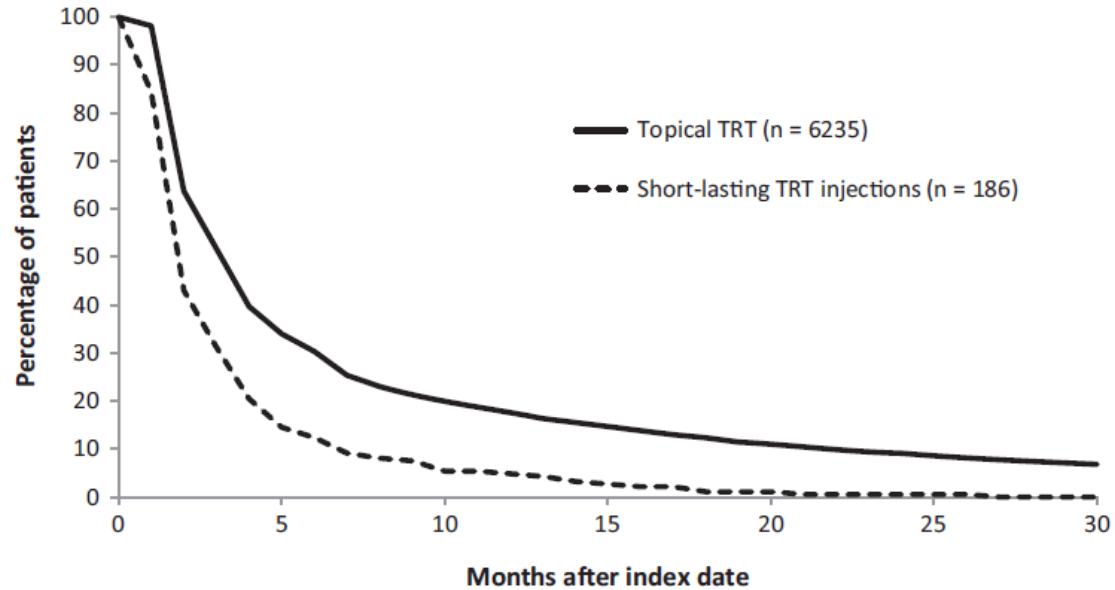
## Potential Barrier To Newly Diagnosed and Existing Patients



- **Black box warning**
  - Secondary exposure to testosterone
  - Pulmonary oil micro embolism (POME) and anaphylaxis shock
- **Inconvenient application or painful injection**
- **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 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

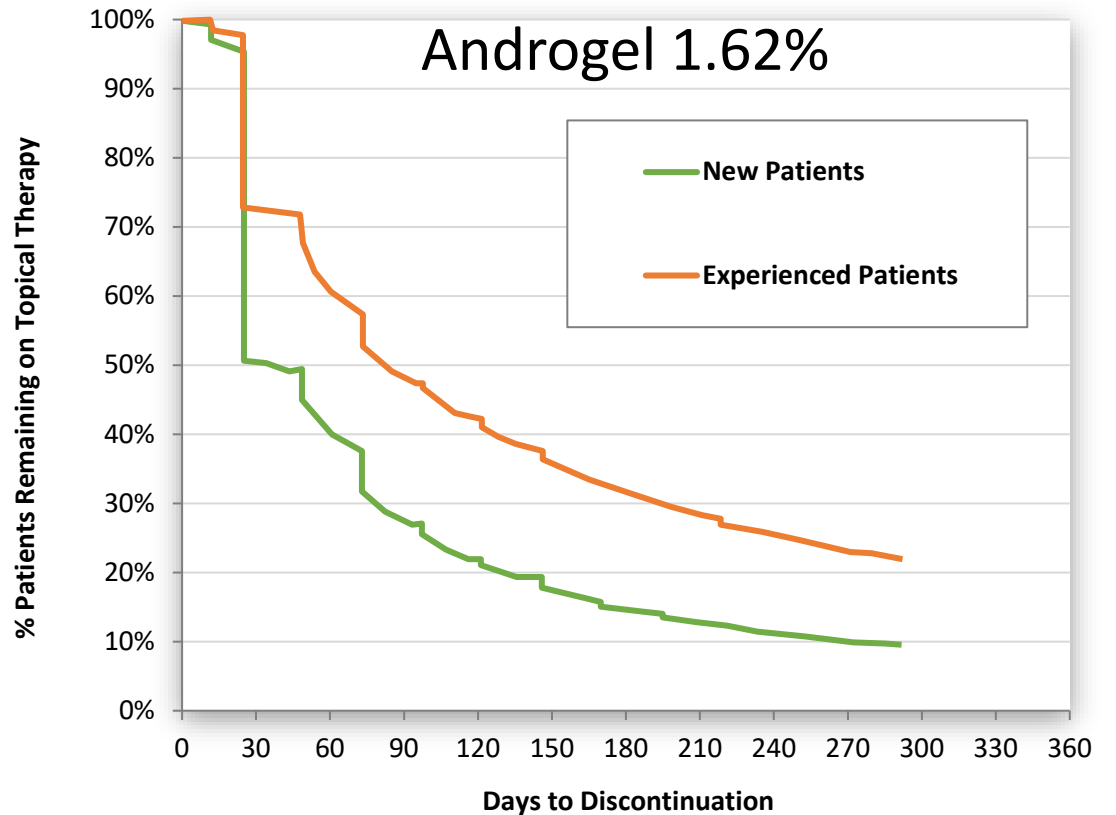
# Persistence Issue with TRTs

## High Discontinuation Rates with Products Requiring Titration



Y-axis represents percentage of patients in the discontinued group who were receiving treatment with topical TRT or short-lasting TRT injections during the follow-up period.  $P < 0.0001$ .

\*Donatucci C, et al. J Sex Med. 2014



Source: Adheris Health 2017  
Cohort Period: February 2016 – January 2017



# TLANDO® Attributes

## ➤ Convenient Oral Route

- No inadvertent transference or pulmonary oil micro embolism risks
- Single strength and dose

## ➤ TRT without titration requirement

- Enables effective dose at the start of therapy
- No “efficacy gap” upon switching from other TRTs
- No additional pharmacy and clinic visits and copays to reach efficacious dose
- 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**



## 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

# Differences Between TLANDO™ and Other Orals

# Comparative Label Differentiation Summary

Attributes	TLANDO	JATENZO	KYZATREX	ANDRIOL (Not shown to restore T to Eugonadal range)
Capsule form	Hard	Soft		
Dosage Strength (mg)	112.5	158, 198, 237	100, 150, 200	40
Dosing Options	One	Five		Three
Titration required	No	Yes		
Additional visit and invasive sampling	No	Yes		N/A
Max Daily Dose (mg)	450	792 (1.8x)	800 (1.8x)	160
T Cavg (ng/dL)	476	403*	393*	<200**
Proven meal fat flexibility	Yes	No		
Shelf-Life	48 months	30 months	24 months	36 months
Proven evidence of Liver Benefits <sup>#</sup>	Yes	No		



# TLANDO® - FDA-Approved Oral Testosterone Replacement Therapy

## Established commercialization partnerships in multiple territories

First and only oral testosterone replacement therapy (TRT) option that does not require dose titration



- **TLANDO® licensed to Verity Pharma for Canada, to Aché for Brazil, to Pharmalink for GCC Countries, and to SPC Korea for South Korea**
- **FDA labeling changes for testosterone products**
  - Removal of Boxed Warning related to an increased risk of adverse cardiovascular outcomes
  - Include results from required post market ambulatory blood pressure (ABPM) studies
- Approved product utilizing Lip'ral technology



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