A Novel Oral Testosterone (TLANDO™) Therapy Restores Testosterone to Eugonadal Levels Without Dose Titration

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On behalf of Lipocine Inc.
Introduction:

- Most approved TRTs require multiple-visit titrations to restore eugonadal T levels in hypogonadal men

Challenges Associated with Dose Titration:

- Patients may not desire/be compliant with additional titration visits
- Patients want to be on a safe and efficacious dose from the start of the therapy
- Patients may have potential dose errors resulting in over/under dosing
- Titration algorithm may be confusing/demanding to prescribe

Objectives:

- To evaluate whether TLANDO™ (Innovative Oral TRT Option) is safe and efficacious in restoring eugonadal T levels with a fixed dose regimen in hypogonadal men
- **Consistent Population in SOAR and DV Studies**

<table>
<thead>
<tr>
<th>Demographics</th>
<th>Statistics</th>
<th>DV Study (N=95)</th>
<th>SOAR Trial (N=210)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>Years (SD)</td>
<td>56.0 (8.9)</td>
<td>52.6 (10.2)</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Black or African American</td>
<td>n (%)</td>
<td>15 (15.8)</td>
<td>32 (15.2)</td>
</tr>
<tr>
<td>White</td>
<td>n (%)</td>
<td>77 (81.1)</td>
<td>172 (81.9)</td>
</tr>
<tr>
<td>Asian &amp; Others</td>
<td>n (%)</td>
<td>3 (3.2)</td>
<td>6 (2.8)</td>
</tr>
<tr>
<td>Weight</td>
<td>kg (SD)</td>
<td>103.6 (18.7)</td>
<td>97.1 (15.0)</td>
</tr>
<tr>
<td>BMI</td>
<td>kg/m²</td>
<td>32.8 (5.5)</td>
<td>30.8 (3.9)</td>
</tr>
</tbody>
</table>

- **Robust PK Independent of Titration**

- **Titration-Independent Efficacy**

- **Safety with TLANDO™**
  - Well tolerated, no deaths, no drug-related SAEs, no MACE up to 52 weeks
  - Improved elevated liver injury markers

- **Oral Fixed Dose TLANDO™**
  - Requires no additional titration visit
  - Easy to prescribe dosing regimen
  - Requires less physician counselling

*SOAR Trial: Dose Titration P3 Study; DV Study: Fixed Dose Validation P3 Study*