IMPACT OF A NEW ORAL TESTOSTERONE UNDECANOATE (TLANDO™) ON BLOOD PRESSURE AND CARDIOVASCULAR RISK

MP45-14

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Introduction

- Cardiovascular (CV) risk of chronic use of testosterone replacement therapy (TRT) is unclear.

Objective

- To assess the effects of TLANDO™ (fixed dose oral TRT) on BP (specifically, SBP changes in CV risk categories based on Framingham Risk Score) in hypogonadal men

Methods

- A 16-week, multicenter, single arm, 24-hr ambulatory blood pressure monitoring (ABPM) study in hypogonadal men (n=138)
- 126 completed study and 118 are available for 24-hr ABPM data

BP: Blood Pressure, SBP: Systolic BP
Results

Demographics
• Mean Age, BMI: 53.8 yrs, 33.1 kg/m\(^2\)
• Comorbidities: obesity (30%), T2D (24%), hypertension (48%)

Minimal Effects on 24-Hr BP
• SBP: BL=127mmHg, \(\Delta = \uparrow 3.8\)mmHg
• DBP: BL=79mmHg, \(\Delta = \uparrow 1.2\)mmHg

Lowered BP of Subjects with SBP>140mmHg at BL (n=25)
• SBP: BL=151.1mmHg, \(\Delta = \downarrow 3.0\)mmHg
• DBP: BL=86.3mmHg, \(\Delta = \downarrow 1.4\)mmHg

Effect on HTN Status
• 1% subjects had a new start or an increase of anti-hypertensive medication

SBP Change Based on FRS*

<table>
<thead>
<tr>
<th>CV Risk Category</th>
<th>N</th>
<th>24-hr SBP Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low CV Risk</td>
<td>40</td>
<td>(\uparrow 2.6)mmHg</td>
</tr>
<tr>
<td>Moderate CV Risk</td>
<td>74</td>
<td>(\uparrow 4.8)mmHg</td>
</tr>
<tr>
<td>High CV Risk</td>
<td>4</td>
<td>(\downarrow 1.8)mmHg</td>
</tr>
</tbody>
</table>

* Framingham Risk Score

TLANDO™ Effect on Hematocrit (HCT)
• Mean HCT CBL is 3.2%
• 4.6% subjects (n=6) had HCT > 54% at EOS

Safety with TLANDO™
• Well tolerated, no deaths, no drug-related SAEs, no MACEs