Radiographic outcomes were associated with pain and function responses: Post-hoc analysis from a phase 2 study of a Wnt pathway inhibitor, SM04690, for knee osteoarthritis treatment

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Table 1. Demographic characteristics among the ITT population

<table>
<thead>
<tr>
<th>Treatment Group</th>
<th>N</th>
<th>Age (years)</th>
<th>BMI (kg/m²)</th>
<th>Sex</th>
<th>Sex ratio</th>
<th>History of comorbid disease (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo</td>
<td>112</td>
<td>60.4 (9.3)</td>
<td>28.6 (4.5)</td>
<td>61</td>
<td>0.38</td>
<td>0.31</td>
</tr>
<tr>
<td>WP 0.23 mg</td>
<td>117</td>
<td>59.0 (9.1)</td>
<td>28.1 (4.3)</td>
<td>60</td>
<td>0.37</td>
<td>0.31</td>
</tr>
<tr>
<td>WP 0.07 mg</td>
<td>118</td>
<td>60.7 (9.3)</td>
<td>29.2 (4.4)</td>
<td>60</td>
<td>0.37</td>
<td>0.31</td>
</tr>
<tr>
<td>WP 0.03 mg</td>
<td>116</td>
<td>60.5 (9.3)</td>
<td>29.4 (4.6)</td>
<td>60</td>
<td>0.37</td>
<td>0.31</td>
</tr>
</tbody>
</table>

Table 2. Week 52 outcomes by treatment group and analysis group

<table>
<thead>
<tr>
<th>Treatment Group</th>
<th>N</th>
<th>WOMAC Pain (mm)</th>
<th>WOMAC Function (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo</td>
<td>112</td>
<td>61.3 (8.7)</td>
<td>74.8 (5.3)</td>
</tr>
<tr>
<td>WP 0.23 mg</td>
<td>117</td>
<td>60.7 (9.3)</td>
<td>74.3 (5.3)</td>
</tr>
<tr>
<td>WP 0.07 mg</td>
<td>118</td>
<td>60.3 (9.3)</td>
<td>74.0 (5.3)</td>
</tr>
<tr>
<td>WP 0.03 mg</td>
<td>116</td>
<td>59.0 (9.3)</td>
<td>73.9 (5.3)</td>
</tr>
</tbody>
</table>

Conclusions

• In this post-hoc analysis, treatment with SM04690 maintained or increased mJSW with the 0.07 mg dose compared with PBO at 52 weeks in ITT and unilateral symptomatic subjects (with or without WP).
• No group achieved acceptable concordance among the ITT population.
• In UNI and UNI WP, subjects treated with 0.07 mg SM04690 changed in mJSW were concordant with pain and function responses. Concordance analysis can potentially quantify the strength of relationship between radiographic change and clinical outcomes when investigating potential DMOAD treatments in knee OA.
• Findings support further study of SM04690 at a dose of 0.07 mg as a potential DMOAD for knee OA.