Safety, Efficacy, and Biomarker Outcomes of a Novel, Intra-Articular, Injectable, Wnt Inhibitor (SM04690) in the Treatment of Osteoarthritis of the Knee: Interim, Exploratory Analysis of Results from a Randomized, Double-Blind, Placebo-Controlled Phase 1 Study

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Background

- Osteoarthritis (OA) is a major cause of disability and physical disability in adults. OA affects about 10% of all adults by the age of 50 and 25% by age 65.
- Treatment options for OA are limited, and research into new therapeutic strategies is urgently needed.

Methods

- SM04690 is a novel, selective Wnt inhibitor that blocks the canonical Wnt pathway.
- The study was a randomized, double-blind, placebo-controlled Phase 1 study.

Results

<table>
<thead>
<tr>
<th>Subject Characteristics</th>
<th>SM04690</th>
<th>Placebo</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>54 (11)</td>
<td>50 (14)</td>
<td>0.29</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>27.5 (4)</td>
<td>27.3 (4)</td>
<td>0.67</td>
</tr>
<tr>
<td>Gender</td>
<td>75% men</td>
<td>75% men</td>
<td>0.84</td>
</tr>
</tbody>
</table>

Safety

- No serious adverse events were reported.
- Mild to moderate adverse events were reported more frequently in the SM04690 group than in the placebo group.

Pharmacokinetics

- PK parameters were evaluated using a non-compartmental approach.
- Pharmacokinetic analyses were consistent with previous studies.

Discussion

- SM04690 showed promising safety and efficacy profiles in the Phase 1 study.
- Further studies are needed to confirm these findings and explore the potential of SM04690 as a treatment for OA.

References