Background

- Reactogenicity (grade 3) at Day 0 was associated with a 14% decrease in SF-36 PF post-dose 1 that returned to pre-vaccination values by Day 3.

- Conclusions

  - Overall, the PF and GL of subjects age ≥70 years were not significantly affected by a first RZV dose.
  - Grade 3 reactogenicity was associated with a clinically relevant, but transient, decrease in SF-36 PF 1–7 days post-dose 1.
  - The group who experienced grade 3 reactogenicity had lower SF-36 PF post-dose 1 than those groups with grade 0–2 reactogenicity.
  - Data following the second RZV dose will be available next year.

- It is important to collect data on reactogenicity and quality of life to inform future decisions about the impact of reactogenicity on patient QoL.

Table 1. Summary of quality of life assessments

<table>
<thead>
<tr>
<th>SF-36</th>
<th>Day of assessment</th>
<th>PF (0–100)</th>
<th>VR (0–100)</th>
<th>MH (0–100)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Vaccination</td>
<td>Day -7</td>
<td>76.8 ± 6.8</td>
<td>60 ± 11</td>
<td>81.8 ± 5.8</td>
</tr>
<tr>
<td>Day 1</td>
<td>76 ± 6.8</td>
<td>50 ± 10</td>
<td>81 ± 5.8</td>
<td></td>
</tr>
<tr>
<td>Day 3</td>
<td>76 ± 6.8</td>
<td>50 ± 10</td>
<td>81 ± 5.8</td>
<td></td>
</tr>
</tbody>
</table>

Grades: 0–1 = no or mild reactogenicity; 2 = moderate reactogenicity; 3 = severe reactogenicity.

Table 2. Mean SF-36 PF scores per and post-first RZV dose by day, reactogenicity grade and symptom type

<table>
<thead>
<tr>
<th>Day of assessment</th>
<th>Grade 0</th>
<th>Grade 1–2</th>
<th>Grade 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Vaccination</td>
<td>76.8 ± 6.8</td>
<td>60 ± 11</td>
<td>81.8 ± 5.8</td>
</tr>
<tr>
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<td>50 ± 10</td>
<td>81 ± 5.8</td>
</tr>
</tbody>
</table>

Diary cards were completed by 401 (99.8%) participants.

Grade 3 reactogenicity was associated with a clinically relevant, but transient, decrease in SF-36 PF 1–7 days post-dose 1.

Table 3. Area-under-the-curve (AUC) of the EQ-5D utility scores pre- and post-first RZV dose by reactogenicity grade

<table>
<thead>
<tr>
<th>Reactogenicity grade</th>
<th>Pre-Vaccination</th>
<th>Post-dose 1</th>
<th>Post-dose 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade 0</td>
<td>0.277 (±0.5498)</td>
<td>0.218 (±0.5093)</td>
<td>-0.247 (±0.7223)</td>
</tr>
<tr>
<td>Grade 1–2</td>
<td>0.277 (±0.5498)</td>
<td>0.218 (±0.5093)</td>
<td>-0.247 (±0.7223)</td>
</tr>
<tr>
<td>Grade 3</td>
<td>0.277 (±0.5498)</td>
<td>0.218 (±0.5093)</td>
<td>-0.247 (±0.7223)</td>
</tr>
</tbody>
</table>

Figure 3. Mean EQ-5D utility score by Day -7 to Day 7 by reactogenicity grade

- Overall, the PF and GL of subjects age ≥70 years were not significantly affected by a first RZV dose.
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References

7. GlaxoSmithKline Biologicals SA funded this study (NCT02979639).
8. The Impact of Reactogenicity After Administration of the Recombinant Zoster Vaccine Upon the Physical Functioning and Quality of Life of Older Adults

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Figure 1. Study design

- Study objectives: To assess the impact of reactogenicity after administration of the recombinant zoster vaccine (RZV) on quality of life (QoL) and health-related quality of life (HRQoL) in older adults.

Figure 2. Solicited symptoms pre- and post-first RZV dose

- Solicited symptoms: Fever*, headache, muscle pain, and fatigue (33.5% [all grades] and 3.3% [grade 3]).

Figure 3. Mean SF-36 PF scores pre- and post-first RZV dose by day, reactogenicity grade and symptom type

- In participants with grade 3 reactogenicity, mean SF-36 PF scores transiently decreased by approximately 10 points from Day 0 to Day 1 post-first RZV dose and recovered by Day 3.

Figure 4. Mean SF-36 PF scores pre- and post-first RZV dose by age (A) and by gender (B) and overall

- Mean SF-36 PF scores transiently decreased by approximately 10 points from Day 0 to Day 1 post-first RZV dose and recovered by Day 3.

Figure 5. Mean EQ-5D utility score by Day -7 to Day 7 by reactogenicity grade

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The Impact Of Reactogenicity After Administration Of The Recombinant Zoster Vaccine Upon The Physical Functioning And Quality Of Life Of Older Adults

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CONFLICT OF INTEREST

KES reports grants from the GSK group of companies during the study. MJL reports grants and fees for Advisory Board from the GSK group of companies during the study, as well as grants and fees for Advisory Board and speaker at international meetings from Merck, outside the submitted work. MJL has a patent Merck issued. KG, MEI, LAF and DC are employees and LO a former employee of GSK group of companies. LO and DC own GSK stock options. LO is an employee of CureVac AG and is inventor on a patent owned by GSK and relevant to RZV. SM is a freelance consultant for GSK group of companies. NPK reports grants from GSK group of companies during the study, as well as grants from Merck, Pfizer, Sanofi Pasteur, MedImmune, Protein Science and Dynavax outside the submitted work. KU reports personal fees from Janssen, Novo Nordisk, Amgen, Sanofi, and Regeneron outside the submitted work. DB, MC, CF, PH and MN report no potential conflict of interest.

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