Immunogenicity of the Adjuvanted Recombinant Zoster Vaccine in Immunocompromised Adults

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Disclosures

- Peter Vink, Mamadou Drame, David O. Willer and Bruno Salaun are employees of the GSK group of companies and declare financial and non-financial relationships and activities. Alemnew F. Dagnew and Anne E. Schuind were employees of the GSK group of companies. Peter Vink, Mamadou Drame, David O. Willer, Alemnew F. Dagnew and Anne E. Schuind hold shares in the GSK group of companies.
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Immunocompromised (IC) populations are at increased risk of Herpes Zoster (HZ)

Disease*- and/or therapy-induced immunosuppression

* Diseases listed are the ones studied in the IC program of RZV.
The adjuvanted recombinant zoster vaccine (RZV) demonstrated high efficacy in preventing HZ in IC populations. Immunocompromised (IC) populations are at increased risk of Herpes Zoster (HZ). We present the immunogenicity of RZV in five IC populations ≥18 years of age.

- **Autologous hematopoietic stem cell transplant (auHSCT) recipients**
- **Renal transplant (RT) recipients**
- **Hematologic malignancy (HM) patients**
- **Patients with solid tumors (ST) on chemotherapy**
- **Human immunodeficiency virus-infected (HIV) adults**

The adjuvanted recombinant zoster vaccine demonstrated high efficacy in preventing HZ in IC populations:

- **68.2%**
- **87.2%**

95% CI: 55.56–77.53
95% CI: 44.25–98.59

Safety results related to these studies are available on Poster #37, Adult Vaccines Session.

*Diseases listed are the ones studied in the IC program of RZV. 1. Bastidas et al, JAMA, 2019 (primary analysis); 2. Dagnew et al, Lancet Infect Dis, 2019 (post-hoc analysis). CI, confidence interval.*
Multicenter studies in IC populations were randomized, observer-blinded, placebo-controlled.
Study identifiers and cohorts

<table>
<thead>
<tr>
<th>IC populations</th>
<th>auHSCT</th>
<th>HM</th>
<th>RT</th>
<th>ST</th>
<th>HIV</th>
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<td>CMI</td>
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<td>217 198</td>
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</tbody>
</table>

RZV; Placebo. ATP, according to protocol; N, participants in ATP cohort for humoral immunogenicity or CMI (cell-mediated immunity).
Anti-gE GMCs peaked at 1M post-last RZV vaccination

Anti-gE GMC (mIU/mL)

auHSCT  HM  RT  ST  HIV

Pre-vaccination  1M post-last vaccination

N=82  N=217  N=121  N=87  N=49  N=82  N=217  N=121  N=87  N=49

100000
10000
1000
100
10

N, number of participants in each group; M, month. Error bars depict two-sided exact 95% confidence intervals.
Anti-gE GMCs peaked at 1M post-last RZV vaccination and were maintained above baseline at 12M post-last RZV dose, in all IC populations.

**gE**, glycoprotein E; **GMC**, geometric mean concentration; **N**, number of participants in each group; **M**, month. Error bars depict two-sided exact 95% confidence intervals.
Anti-gE GMCs peaked at 1M post-last RZV vaccination in both age groups of IC populations.

GMC, geometric mean concentration; N, number of participants in each group; YOA, years of age. Error bars depict two-sided exact 95% confidence intervals.

*ZOE-50 represent the humoral immune responses in adults ≥50 YOA. HIV-infected adults were not divided by age group and immunogenicity analyses were only done overall.
Anti-gE GMCs peaked at 1M post-last RZV vaccination and were maintained above baseline at 12M post-last RZV dose, in both age groups of IC populations.

GMC, geometric mean concentration; N, number of participants in each group; YOA, years of age. Error bars depict two-sided exact 95% confidence intervals.

*ZOE-50 represent the humoral immune responses in adults ≥50 YOA. HIV-infected adults were not divided by age group and immunogenicity analyses were only done overall.
CD4 T-cell frequencies peaked in all IC populations at 1M post-last RZV dose

N, number of participants in each group; Q1, Q3, first and third quartiles.
CD4 T-cell frequencies peaked in all IC populations at 1M post-last RZV dose, and persisted up to 12M post-last RZV dose.
**CD4 T-cell frequencies peaked at 1M post-last RZV dose in both age groups of IC populations**

- **N**, number of participants in each group; **YOA**, years of age; **Q1, Q3**, first and third quartiles.

- *ZOE-50* represent the cell-mediated immune responses in adults ≥50 YOA from the pivotal efficacy trial (Cunningham et al., JID, 2018).

- HIV-infected adults were not divided by age group and immunogenicity analyses were only done overall.

### Frequencies of gE-specific CD4 T-cells

<table>
<thead>
<tr>
<th>Group</th>
<th>Pre-vaccination</th>
<th>1M post-last vaccination</th>
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<tbody>
<tr>
<td>18–49 YOA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>auHSCT</td>
<td>N=16</td>
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<tr>
<td>HM</td>
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<tr>
<td>≥50 YOA</td>
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<td>auHSCT</td>
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<td>N=39</td>
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<tr>
<td>RT</td>
<td>N=19</td>
<td>N=20</td>
</tr>
<tr>
<td>ST</td>
<td>N=16</td>
<td>N=13</td>
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</tbody>
</table>

- **ZOE-50** reached 50% at 1M post-last vaccination in both age groups.
CD4 T-cell frequencies peaked at 1M post-last RZV dose and persisted up to 12M post-last RZV dose in both age groups of IC populations.

N, number of participants in each group; YOA, years of age; Q1, Q3, first and third quartiles.

*ZOE-50 represent the cell-mediated immune responses in adults ≥50 YOA from the pivotal efficacy trial (Cunningham et al, JID, 2018). HIV-infected adults were not divided by age group and immunogenicity analyses were only done overall.
At 1 month post-last vaccination, RZV induced robust humoral and CMI responses, that lasted up to at least 12M post-last vaccination in all IC populations evaluated.

Humoral responses in the IC populations were robust, despite the severity of the IC conditions studied and the administered immunosuppressive therapies.

CMI responses were similar across IC populations and adults ≥50 YOA, with a potent response occurring even in ST patients receiving their second RZV dose on the same day of cytotoxic chemotherapy administration.

We demonstrated that RZV is immunogenic in severely IC populations, of which efficacy was demonstrated in 2 populations: autologous HSCT recipients and HM patients.
RZV immunogenicity and safety data (for safety see poster #37, Adult Vaccines Session) support a favorable benefit-risk profile of RZV vaccination in IC adults ≥18 YOA, who are at an increased risk of HZ.
Thank you