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IMMUNOGENICITY OF THE ADJUVANTED RECOMBINANT ZOSTER VACCINE IN IMMUNOCOMPROMISED ADULTS

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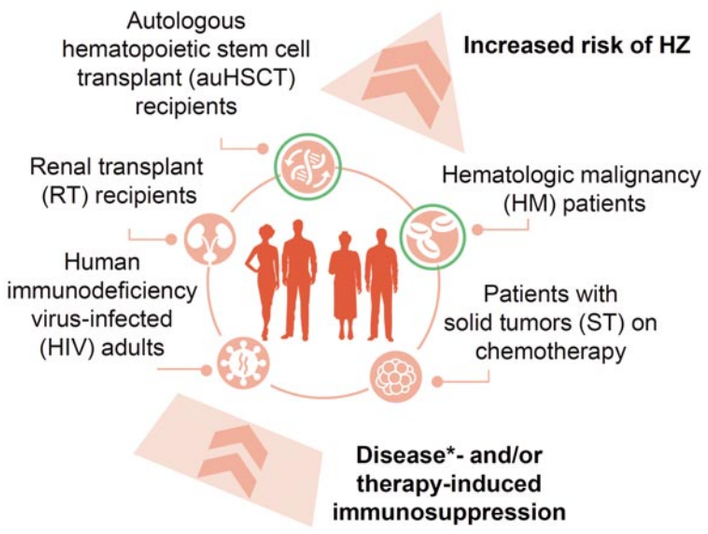
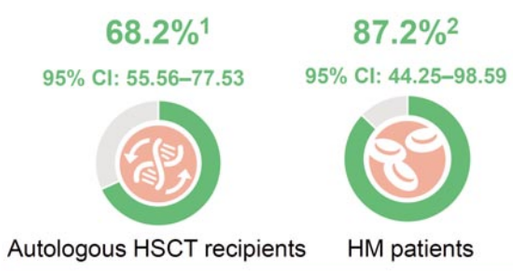
BACKGROUND

Immunocompromised (IC) populations are at increased risk of Herpes Zoster (HZ)



The adjuvanted recombinant zoster vaccine (RZV) demonstrated high efficacy in preventing HZ in IC populations

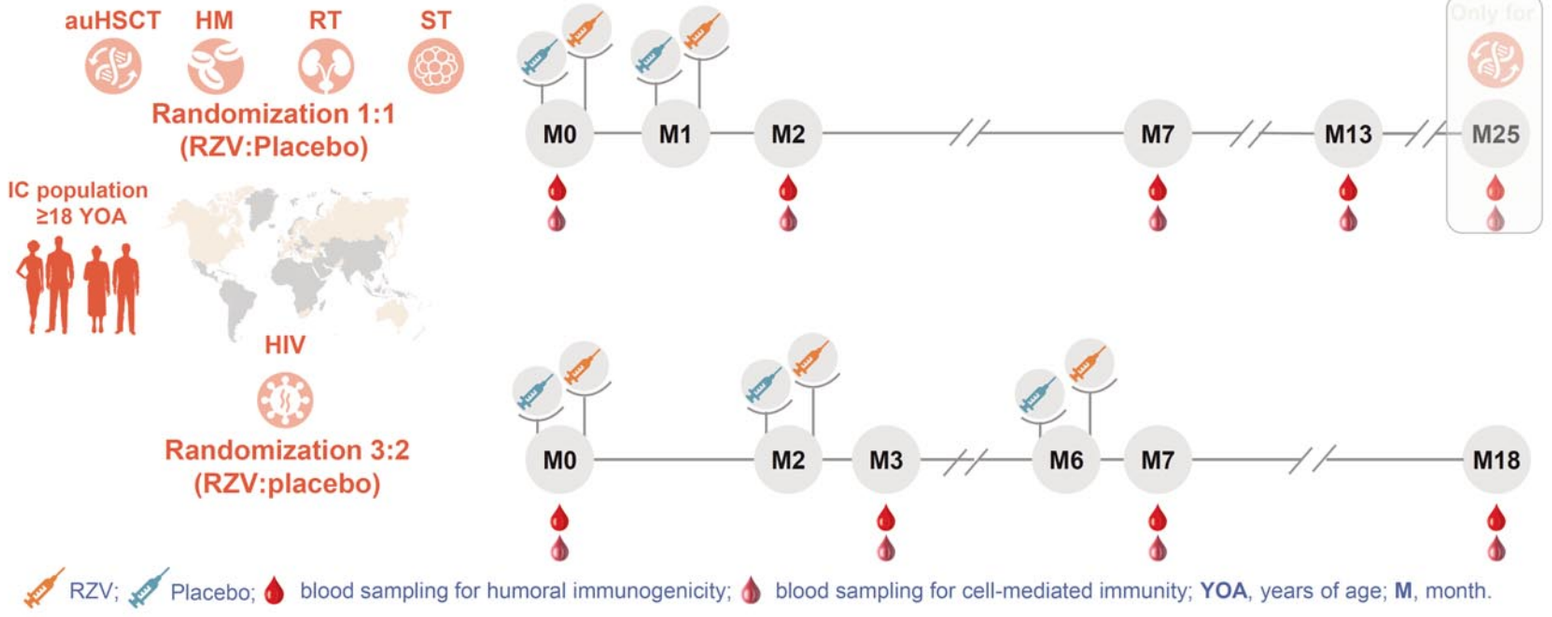


We present the immunogenicity of RZV in five IC populations ≥18 years of age

CI, confidence interval.
*Diseases listed are the ones studied in the IC program of RZV.

METHODS

Multicenter studies in immunocompromised populations were randomized, observer-blinded, placebo-controlled



RZV; Placebo; blood sampling for humoral immunogenicity; blood sampling for cell-mediated immunity; **YOA**, years of age; **M**, month.

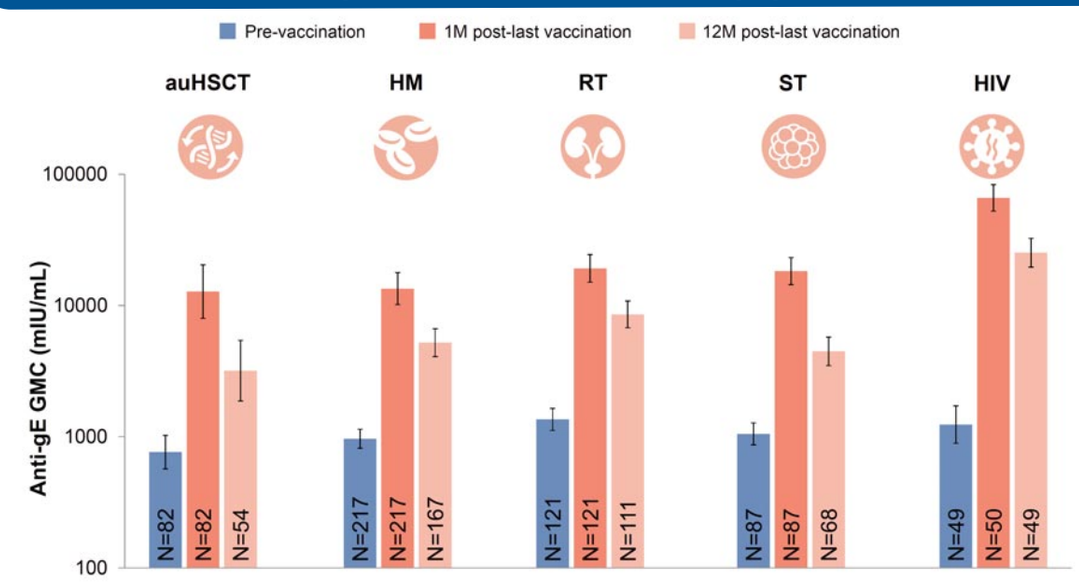
Study identifiers and cohorts

IC populations		auHSCT		HM		RT		ST		HIV	
Study year		2012–2017		2013–2017		2014–2017		2013–2016		2010–2013	
Number		NCT01610414		NCT01767467		NCT02058589		NCT01798056		NCT01165203	
ATP cohort for immunogenicity	N	RZV	Placebo	RZV	Placebo	RZV	Placebo	RZV	Placebo	RZV	Placebo
	Humoral	82	76	217	198	121	119	87	98	54	37
	CMI	59	55	69	63	36	36	27	31	54	37

RZV; Placebo. **ATP**, according to protocol; **IC**, immunocompromised; **N**, participants in ATP cohort for humoral immunogenicity or **CMI** (cell-mediated immunity).

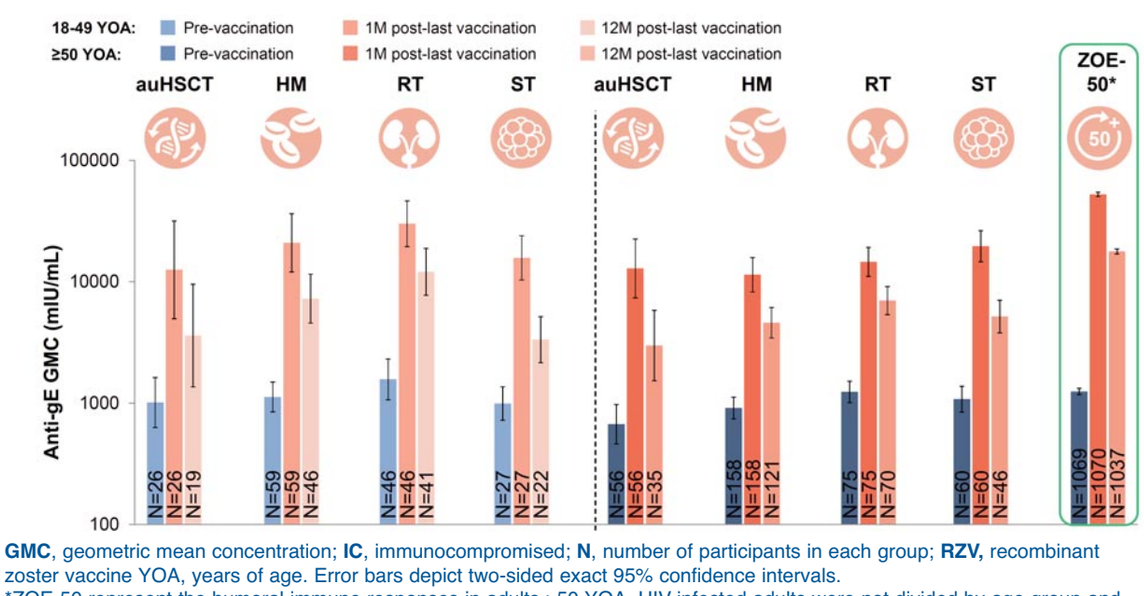
RESULTS

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



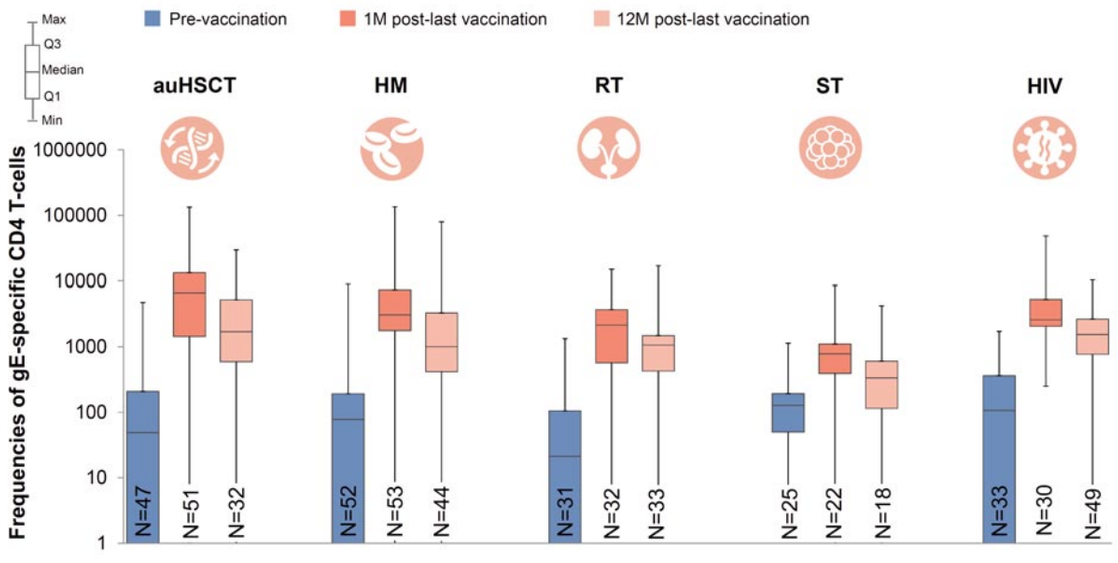
gE, glycoprotein E; **GMC**, geometric mean concentration; **IC**, immunocompromised; **N**, number of participants in each group; **M,** month; **RZV**, recombinant zoster vaccine. Error bars depict two-sided exact 95% confidence intervals.

Anti-gE GMCs peaked at 1M post-last RZV vaccination and were maintained above baseline at 12M post-last RZV dose, in both age groups of IC populations



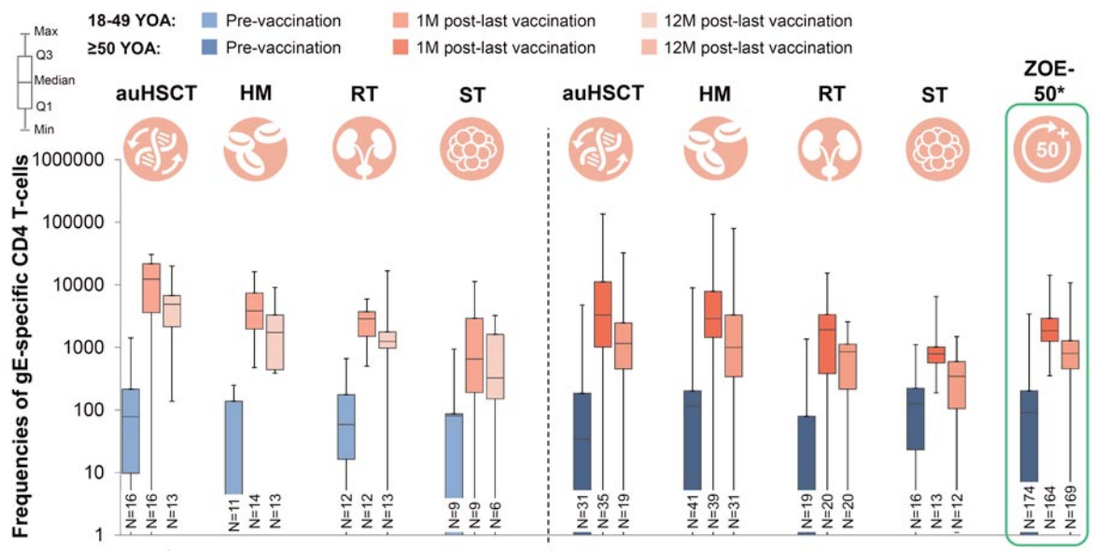
GMC, geometric mean concentration; **IC**, immunocompromised; **N**, number of participants in each group; **RZV,** recombinant zoster vaccine YOA, years of age. Error bars depict two-sided exact 95% confidence intervals.
*ZOE-50 represent the humoral immune responses in adults ≥50 YOA. HIV-infected 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, and persisted up to 12M post-last RZV dose



gE, glycoprotein E; **IC**, immunocompromised; **N**, number of participants in each group; **M**, month; **RZV**, recombinant zoster vaccine. **Q1**, **Q3**, first and third quartiles

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



gE, glycoprotein E; **IC**, immunocompromised; **N**, number of participants in each group; **M**, month; **RZV**, recombinant zoster vaccine; **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.

Plain Language Summary

Recombinant zoster vaccine (RZV immunogenicity and safety data (see poster entitled "Safety profile of the adjuvanted recombinant zoster vaccine in immunocompromised populations: an overview of 6 trials") support a favorable benefit-risk profile of RZV vaccination in immunocompromised adults ≥18 years of age, who are at an increased risk of herpes zoster

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CONCLUSIONS

- **At 1 month post-last vaccination, the recombinant zoster vaccine (RZV) induced robust humoral and cell-mediated immunity (CMI) responses, that lasted up to at least 12M post-last vaccination in all immunocompromised (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 of similar magnitude across IC populations and adults ≥50 years of age, with a potent response occurring even in solid tumors patients vaccinated before chemotherapy**
- **We demonstrated that RZV is immunogenic in severely IC populations, of which efficacy was demonstrated in 2 populations: autologous hematopoietic stem cell transplant recipients and hematologic malignancy patients**

References:
1. Bastidas et al, JAMA, 2019 (primary analysis);
2. Dagnew et al, Lancet, 2019 (post-hoc analysis)

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