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Recombinant zoster vaccine (RZV) confers persistent immune responses with no safety concerns 4 to 8 years after vaccination of adults with renal transplant

M. HUTTON [1], A. KUXHAUSEN [1], F. ATIG [1], M. TSANG [2], A. SANCHEZ FRUCTUOSO [3], T. ROBBERECHTS [4], R. PEREZ [5], J.B. PARK [6], F. ORTIZ [7], D. KUMAR [8], Y.-J. CHIANG [9], and A. MWAKINGWE-OMARI [1]

[1]GSK, Rockville, USA [2]GSK, London, UK [3]Hospital Clínico San Carlos, Madrid, Spain [4]Department of Nephrology and Arterial Hypertension, Vrije Universiteit Brussel (VUB), Universitair Ziekenhuis Brussel (UZ Brussel), Brussels, Belgium [5]Centro Especializado San Fernando, Panama City, Panama [6]Samsung Medical Center, Seoul, South Korea [7]Helsinki University Hospital, Helsinki, Finland [8]Ajmera Transplant Centre, Toronto, Canada [9]Linkou Chang Gung Memorial Hospital, Taoyuan City, Taiwan

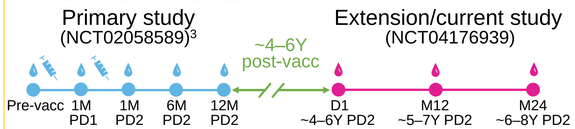
INTRODUCTION

- In immunocompromised populations, vaccination remains an important tool for the prevention of herpes zoster (HZ).
- RZV is immunogenic and is approved for vaccination of adults 18 years and older who are at increased risk of HZ including those who are immunocompromised due to their underlying diseases or therapy.[1,2]
- To understand the durability of the immune response, long-term data are necessary.

AIM

We evaluated the persistence of immunogenicity of 2 doses of RZV 4–8 years after vaccination, as well as long-term safety in renal transplant recipients.

STUDY DESIGN



Pre-/post-vacc, pre-/post-vaccination; **M**, month; **D**, day; **PD**, post-dose; **Y**, year.
Blood sample RZV

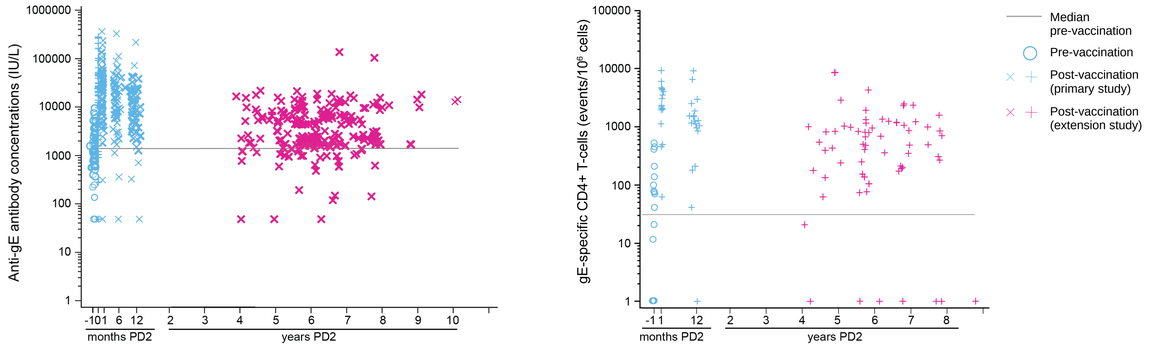
Humoral immunity:
- anti-gE antibody GMC

Cell-mediated immunity (CMI):
- frequencies of gE-specific CD4+ T-cells*(sub-set)

Safety (end of primary study up to M24 in current study):
- HZ episodes, transplant rejections, (related) SAEs, fatal outcomes

RESULTS

- A total of 68 participants who received the 2-dose RZV vaccination primary series in the primary study were enrolled in the current extension study.
- In the current extension study, anti-gE antibody GMC remained at a stable plateau at least until 8 years post-dose 2 and above pre-vaccination levels at all timepoints. CMI showed the same pattern as humoral immunity.



Mean geometric increases (MGIs, 95% CI)[#] of anti-gE antibodies

Primary study			Extension/current study					
1M PD1	N=68	6.20 (4.38–8.76)	D1 (~4–6Y PD2)	N=56	**2.93** (2.13–4.03)	4Y PD2	N=17	**2.92** (1.30–6.56)
1M PD2	N=68	13.86 (9.91–19.40)	M12 (~5–7Y PD2)	N=60	**2.75** (2.00–3.78)	5Y PD2	N=37	**2.65** (1.78–3.96)
6M PD2	N=68	9.90 (7.20–13.62)	M24 (~6–8Y PD2)	N=49	**2.44** (1.60–3.70)	6Y PD2	N=59	**2.71** (1.88–3.90)
12M PD2	N=68	6.33 (4.69–8.53)				7Y PD2	N=40	**2.82** (1.95–4.08)
						8Y PD2	N=17	**3.29** (1.86–5.82)

[#]MGIs reported over pre-vaccination in the primary study; **N**, number of participants with available results.

- There were 2 (2.9%) cases of rejection[¤]: 1 acute antibody-mediated rejection and 1 acute T-cell-mediated rejection. Both started >2000 days post-dose 2 and were considered unrelated to RZV vaccination. Both participants recovered with treatment, and graft function was preserved.

HZ cases	n (%)
Suspected HZ episodes[§]	3 (4.4)
Confirmed HZ episodes[¤]	3 (4.4)

Other safety outcomes	n (%)
Related SAEs[‡]	0 (0.0)
Fatal outcomes[¤] (all unrelated)	6 (8.8)

[¤]from D1 up to M24 in the current study; [§]from end of primary study up to D1 in the current study; [‡]from end of primary study up to M24 in the current study.
Suspected HZ episode, a new HZ rash clinically diagnosed as per standard of care with no alternative diagnosis; **confirmed HZ episode**, HZ case confirmed by polymerase chain reaction test on HZ lesion sample or by HZ Ascertainment Committee.

CONCLUSIONS

- RZV induced a persistent long-term immune response in renal transplant recipients on chronic immunosuppression.
- At 4–8 years after RZV vaccination, humoral immunity and CMI remained at stable levels above pre-vaccination.
- No safety signals were identified during the long-term follow-up after RZV vaccination.

ABBREVIATIONS

gE, glycoprotein E; **GMC**, geometric mean concentration; **SAE**, serious adverse event; **IU**, international unit; **CI**, confidence interval; **n (%)**, number (percentage) of participants in a category; ***expressing ≥2 markers among interferon gamma (IFN-γ), interleukin 2 (IL-2), tumor necrosis factor alpha (TNF-α), cluster of differentiation 40 ligand (CD40L).

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CONTACT INFORMATION

Melinda Hutton, melinda.m.hutton@gsk.com