Conclusion: Overall, the QoL and PF of adults ≥ 50 years were not affected post-second RZV dose; a transient impact was observed in adults with grade 3 reactogenicity. These results and the observed reactogenicity and safety profile are consistent with first RZV dose results, as well as that of previous studies with the RZV vaccine in adults of similar age.

Funding: GlaxoSmithKline Biologicals SA.

1. Schmader et al., Abstract 2488, IDWeek 2018

Table. Mean SF-36 PF scale scores pre- and post-second RZV dose by day and reactogenicity grade, type of symptom and overall

Day	Grade			Type of symptom			Total N=391
	0 N=63	1 or 2 N=267	3 N=61	No symptoms N=59	Local symptoms N=302	Systemic symptoms N=245	
Pre-vaccination							
Baseline	78.5	82.6	82.8	79.0	82.7	83.5	82.0
61*	79.6	81.9	83.4	79.2	82.3	83.1	81.8
Post-second RZV dose							
62	83.9	78.2	68.0	83.3	76.4	75.6	77.6
63	82.6	81.5	78.9	82.2	81.2	81.7	81.3
64	82.4	82.5	82.2	81.9	82.9	83.3	82.4
65	82.0	82.8	82.8	81.7	83.2	83.8	82.7
66	82.1	83.1	82.3	82.0	83.3	83.9	82.8
67	81.8	83.2	82.6	81.5	83.3	84.3	82.9
68	83.2	82.9	85.5	82.6	83.3	84.1	83.3

Overall SF-36 PF score pre- and post-RZV dose 2	Baseline N=391	Mean score N=389	Change from baseline N=389
Mean (SD)	82.0 (20.50)	81.8 (22.48)	-0.4 (10.38)
Median (min-max)	90.0 (5–100)	90.8 (0–100)	0.0 (-43–43)

SF-36, Short Form health survey; PF, physical functioning; RZV, adjuvanted recombinant zoster vaccine; N, number of participants for each category; SD, standard deviation. Baseline is calculated as the mean of the day -7 (7 days before RZV dose 1), day 1 (pre-dose 1 RZV vaccination) and day 61 (pre-dose 2 RZV vaccination) assessments.
*Day of administration of the second RZV dose.
The following intensity grade was used: grade 0 – participants with no solicited symptom; grade 1 or 2 – participants with at least one grade 1 (mild) or grade 2 (moderate) symptom; grade 3 – participants with at least one grade 3 (severe) symptom.

Disclosures. **All authors:** No reported disclosures.

2779. Efficacy of the Adjuvanted Recombinant Zoster Vaccine According to Sex, Geographic Region, and Geographic Ancestry/Ethnicity: A Post-hoc Analysis

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Background: The risk of herpes zoster (HZ) has been reported to vary by sex and ethnicity. In 2 large-scale clinical trials, ZOE-50 (NCT01165177) and ZOE-70 (NCT01165229), the adjuvanted recombinant zoster vaccine (RZV) demonstrated high vaccine efficacy (VE) against HZ and post-herpetic neuralgia (PHN). We present a post-hoc analysis of RZV efficacy against HZ and PHN in the ZOE-50/70 population stratified by sex, geographic region and geographic ancestry/ethnicity.

Methods: The ZOE-50 and ZOE-70 studies were phase III, observer-blind, placebo-controlled trials conducted across 5 geographic regions. Adults ≥ 50 years of age (YOA; ZOE-50) and ≥ 70 YOA (ZOE-70), randomized 1:1, received 2 doses of RZV or placebo 2 months apart. Here, VE against HZ by sub-population was estimated from the ZOE-50 population (≥ 50 YOA) and the pooled ZOE-50/70 population (pooled ≥ 70 YOA), and VE against PHN by sub-population was evaluated in the pooled ≥ 70 YOA.

Results: VE was evaluated in 7,340 RZV and 7,413 placebo recipients ≥ 50 YOA (mean age: 62.3 [RZV], 62.2 [placebo] YOA) and 8,250 RZV and 8,346 placebo recipients in pooled ≥ 70 YOA (mean age: 75.5 [RZV, placebo] YOA). VE against HZ and PHN was similar for women and men in the ≥ 50 YOA and pooled ≥ 70 YOA (Tables 1 and 2). Point estimates for VE against HZ by geographic region ranged from 95.7% to 97.2% in ≥ 50 YOA and from 87.3% to 95.1% in pooled ≥ 70 YOA (Table 1). Point estimates for VE against PHN by geographic region ranged from 86.8% to 100% in pooled ≥ 70 YOA. VE was similar across geographic ancestry groups in pooled ≥ 70 YOA: VE point estimates against HZ ranged from 89.6% to 100% and VE against PHN ranged from 87.5% to 100% (Tables 1 and 2). VE against HZ was 88.1% and against PHN was 65.9% in Hispanic participants in pooled ≥ 70 YOA (Tables 1 and 2).

Conclusion: Acknowledging the limitations including the post-hoc character of these analyses and the small number of participants and cases available, our data suggest that RZV is efficacious against HZ and PHN irrespective of sex, geographic region, geographic ancestry, and ethnicity.

Funding: GlaxoSmithKline Biologicals SA.

Table 1. RZV efficacy against HZ in ≥50 YOA and pooled ≥70 YOA populations

	RZV (N)	Placebo (N)	VE (%, 95% CIs)
RZV efficacy against HZ by region and sex in ≥50 YOA population from ZOE-50 study			
Sex			
Female	4,480	4,542	97.0 (93.0–99.1)
Male	2,860	2,871	95.4 (87.8–98.8)
Geographic region			
Europe	3,785	3,828	97.2 (91.5–99.4)
Asia/Australia	1,555	1,574	96.1 (88.3–99.2)
North America	1,291	1,287	95.7 (83.7–99.5)
Latin America	709	724	96.3 (77.3–99.9)
RZV efficacy against HZ by region, sex, ancestry and ethnicity in pooled ≥70 YOA population from ZOE-50/70 studies			
Sex			
Female	4,514	4,593	90.7 (84.3–94.9)
Male	3,736	3,753	92.0 (84.8–96.3)
Geographic region			
Europe	4,501	4,543	90.1 (82.1–95.0)
North America	1,626	1,631	90.1 (77.0–96.5)
Asia/Australia	1,526	1,559	95.1 (87.0–98.7)
Latin America	597	613	87.3 (58.2–97.6)
Geographic ancestry			
European ancestry	6,423	6,475	89.6 (83.5–93.8)
Asian ancestry	1,410	1,434	95.0 (86.6–98.7)
African ancestry	85	81	100 (<0–100)
Other ancestry	332	356	92.6 (51.2–99.8)
Ethnicity			
Hispanic ethnicity	648	655	88.1 (61.2–97.7)
Published studies of overall RZV efficacy against HZ			
ZOE-50[1]	7,344	7,415	97.2 (93.7–99.0)
ZOE-50/70[2]	8,250	8,346	91.3 (86.8–94.5)

N, number of participants in each group; CI, confidence interval. European = Caucasian/European or Arabic/North African heritage; Asian = Central/South Asian, East Asian Japanese or South East Asian heritage; African = African heritage/African American; Other = included all categories with low number of participants: American Indian, Alaskan Native, Native Hawaiian or Other Pacific Islander or a person with several different heritages; Hispanic = American Hispanic or Latino, majority of participants were from Mexico or Brazil. [1]Lal et al., N Engl J Med. 2015, 372:2087–96; [2]Cunningham et al., N Engl J Med. 2016, 375:1019–32.

Table 2. RZV efficacy against PHN in pooled ≥70 YOA population

	RZV (N)	Placebo (N)	VE (%, 95% CIs)
RZV efficacy against PHN by region, sex, ancestry and ethnicity in pooled ≥70 YOA population from ZOE 50/70 studies			
Sex			
Female	4,514	4,593	91.5 (65.7–99.1)
Male	3,736	3,753	83.3 (24.8–98.2)
Geographic region			
Europe	4,501	4,543	86.8 (42.2–98.6)
Asia/Australia	1,526	1,559	90.8 (36.4–99.8)
North America	1,626	1,631	100 (31.2–100)
Latin America	597	613	NC
Geographic ancestry			
European ancestry	6,423	6,475	87.5 (58.7–97.6)
Asian ancestry	1,410	1,434	89.8 (28.5–99.8)
African ancestry	85	81	NC
Other ancestry	332	356	100 (<0–100)
Ethnicity			
Hispanic ethnicity	648	655	65.9 (<0–99.4)
Published study of overall RZV efficacy against PHN			
ZOE-50/70[1]	8,250	8,346	88.8 (68.7–97.1)

N, number of participants in each group; CI, confidence interval; NC, not calculated due to a low number of PHN cases. European = Caucasian/European or Arabic/North African heritage; Asian = Central/South Asian, East Asian, Japanese or South East Asian heritage; African = African heritage/African American; Other = included all categories with low number of participants: American Indian, Alaskan Native; Native Hawaiian or Other Pacific Islander or a person with several different heritages; Hispanic = American Hispanic or Latino, majority of participants were from Mexico or Brazil. [1]Cunningham et al., N Engl J Med. 2016, 375:1019–32.
Note: Due to a lower number of PHN cases, VE against PHN has much wider CIs than VE against HZ.

Disclosures. **All authors:** No reported disclosures.

2780. Reactogenicity Profile of Adjuvanted Recombinant Zoster Vaccine after Dose 2 According to the Intensity of the Same Event Experienced after Dose 1

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Background: In the pivotal clinical trials, ZOE-50 (NCT01165177) and ZOE-70 (NCT01165229), the adjuvanted recombinant zoster vaccine (RZV) showed high efficacy against herpes zoster and postherpetic neuralgia. The incidence of reported solicited events was higher in RZV compared with placebo recipients.

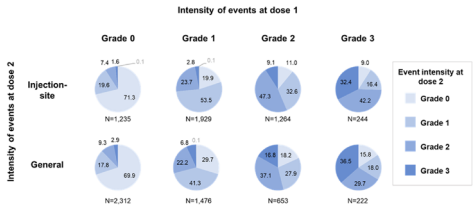
Methods: In these phase III, observer-blind, placebo-controlled trials conducted in 18 countries, adults ≥50 years of age (YOA, ZOE-50) and ≥70 YOA (ZOE-70), randomized 1:1, received 2 doses of RZV or placebo 2 months apart. Injection-site and general events were solicited for 7 days after each dose via diary cards in a participant subset. For this post-hoc analysis, ZOE-50 and ZOE-70 data from participants having completed the diary cards for both RZV doses were pooled. The intensity of each solicited event after dose 2 was stratified by the intensity of the same event after dose 1.

Results: Solicited injection-site and general events were recorded for both RZV doses by 4,676 and 4,668 vaccinees, respectively (Figure 1). Of 1,235 vaccinees with no injection-site event at dose 1, 881 (71.3%) reported no injection-site event and 20 (1.6%) reported a grade 3 event after dose 2. A total of 433 (9.3%) vaccinees reported a grade 3 injection-site event, either after dose 1 or dose 2. Of 244 vaccinees with grade 3 injection-site events at dose 1, 79 (32.4%) also reported a grade 3 event after dose 2. Of 2,312 vaccinees with no general event at dose 1, 1,617 (69.9%) reported no general event and 67 (2.9%) reported a grade 3 event after dose 2. A total of 499 (10.7%) vaccinees reported a grade 3 general event, either after dose 1 or dose 2. Of 222 vaccinees with grade 3 general events at dose 1, 81 (36.5%) also reported a grade 3 general event after dose 2. In general, vaccinees who did not experience a certain event after dose 1, did not experience this event after dose 2 either. Most vaccinees reporting a specific event at high intensity after dose 1, reported the same event at a lower intensity (or not at all) after dose 2 (Figures 2 and 3).

Conclusion: While not powered to predict event intensity of the second RZV dose, our data provides an overview of event intensity after RZV dose 2 according to the intensity of the same event experienced after dose 1.

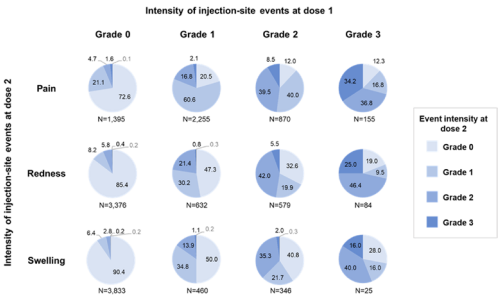
Funding: GlaxoSmithKline Biologicals SA.

Figure 1. Intensity of solicited events (injection-site and general) reported after RZV dose 2 stratified by the intensity reported after RZV dose 1



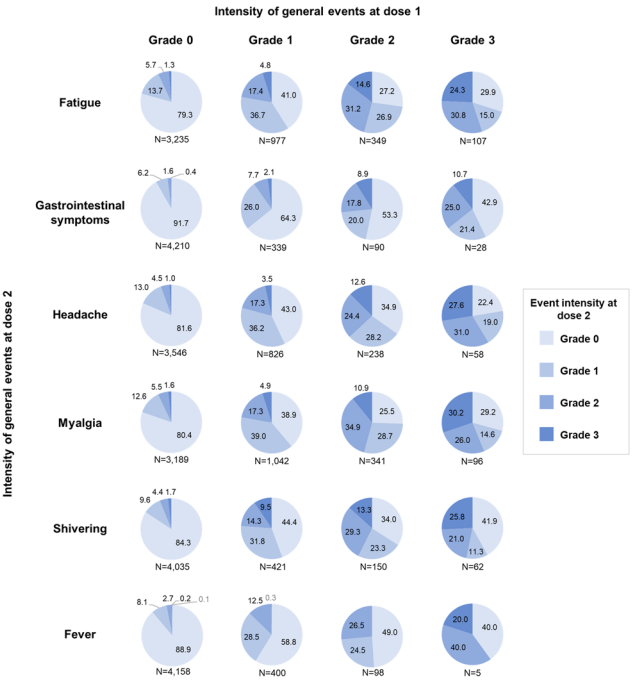
The cohort included in this analysis was a pooled subset of the total vaccinated cohorts in the ZOE-50 and ZOE-70 studies, including participants who completed a diary card after each vaccination.
Injection-site events included: pain at injection site, redness at injection site and swelling at injection site. General events included any experiences which did not occur at the site of injection of the RZV vaccine: fatigue, gastrointestinal symptoms (nausea, vomiting, diarrhea and/or abdominal pain), headache, myalgia, shivering and fever.
RZV, adjuvanted recombinant zoster vaccine; N, number of RZV vaccinees with both doses administered and corresponding event intensity following dose 1. Grey numbers represent missing values. There were 4 injection-site events and 5 general events with missing grading at dose 1 and 6 events (3 for each injection site and general) with missing grading at dose 2.

Figure 2. Intensity of solicited injection-site events reported after RZV dose 2 stratified by the intensity reported after RZV dose 1



The cohort included in this analysis was a pooled subset of the total vaccinated cohorts in the ZOE-50 and ZOE-70 studies, including participants who completed a diary card after each vaccination.
RZV, adjuvanted recombinant zoster vaccine; N, number of RZV vaccinees with both doses administered and corresponding event intensity following dose 1. Grey numbers represent missing values. Pain: grade 0, none; grade 1, mild, any pain neither interfering with nor preventing normal every day activities; grade 2, moderate, painful when limb was moved and interfered with every day activities; grade 3, severe, significant pain at rest, prevented normal every day activities. Swelling, redness: grade 0, <20 mm diameter; grade 1, ≥20 mm to ≤50 mm diameter; grade 2, >50 mm to ≤100 mm diameter; grade 3, >100 mm diameter.

Figure 3. Intensity of general events reported after RZV dose 2 stratified by the intensity reported after RZV dose 1



The cohort included in this analysis was a pooled subset of the total vaccinated cohorts in the ZOE-50 and ZOE-70 studies, including participants who completed a diary card after each vaccination.
RZV, adjuvanted recombinant zoster vaccine; N, number of RZV vaccinees with both doses administered and corresponding event intensity following dose 1. Grey numbers represent missing values. Gastrointestinal symptoms, nausea, vomiting, diarrhea and/or abdominal pain; fever, body temperature ≥37.5 °C measured by oral, axillary or tympanic route. Fatigue, gastrointestinal symptoms, headache, myalgia, shivering: grade 0, normal or none; grade 1, easily tolerated; grade 2, interfered with normal activity; grade 3, prevented normal activity. Fever: grade 0, <37.5 °C; grade 1, 37.5–38.0 °C; grade 2, 38.1–39.0 °C; grade 3, >39.0 °C.

Disclosures. **All authors:** No reported disclosures.

2781. Statistical Modeling to Predict Maternal RSV Vaccine Efficacy from Neutralizing Titers

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Session: 279. Vaccines: Viral Non Influenza
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Background: In the United States, respiratory syncytial virus (RSV) is the leading cause of respiratory-related hospitalization in infants. The well-studied efficacy of the prophylactic monoclonal antibody, palivizumab, at preventing RSV disease in the highest risk infants provides proof of mechanism that serum neutralizing antibody protects against RSV. The expense and burden of monthly antibody injections limit the utility of palivizumab, leaving a large unmet medical need. Maternal immunization, with transplacental transfer of antibodies to the fetus, is an alternative, highly practical approach to protect many more infants.

Methods: Levels of protection by known palivizumab serum concentrations provide a basis for predicting maternal RSV vaccine efficacy in infants based on serum neutralizing antibody titers elicited in vaccine clinical trials, using statistical modeling to compensate for differences between palivizumab prophylaxis and maternal immunization. The model adjusts for the dependency of maternal vaccine responses on pre-immunization RSV neutralizing titers, exponential decay of maternal antibodies in infants, and exponentially decreasing airway resistance (reducing RSV disease risk) as infants grow.

Results: The rates of severe RSV disease by age projected from the model match the pattern of US infant hospitalization for RSV, with a peak at 1.5 months of age. The model relates vaccine-elicited increases in maternal RSV neutralizing titers to predicted reductions in severe RSV disease in infants from 0 to 6 months of age.

Conclusion: Statistical modeling of maternal RSV vaccine efficacy based on elicited RSV neutralizing titers provides a rational basis for decision-making during RSV vaccine development.

Disclosures. **All authors:** No reported disclosures.

2782. Host Immune Response to *Enterovirus* and *Parechovirus* Systemic Infections in Children

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