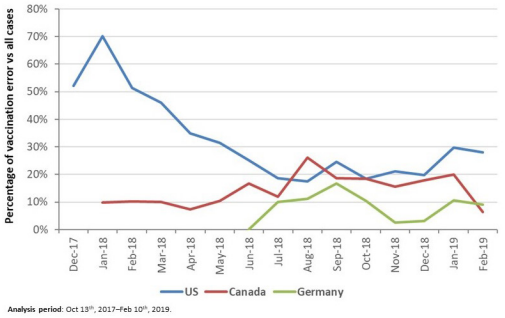
Table 1. Most commonly reported* sign/symptoms events involving RZV vaccination

Sign/Symptoms**	Reporting rate***
Injection-site pain	18.2
Pyrexia	17.8
Pain in extremity	15.7
Pain	14.2
Chills	13.3
Injection-site erythema	13.1
Fatigue	11.6
Headache	11.5
Influenza like illness	9.3
Herpes zoster	9.0
Myalgia	8.6
Injection-site swelling	8.4
Erythema	7.0
Malaise	6.9
Nausea	6.0
Rash	5.8
Injection-site warmth	4.3
Pruritus	3.4
Arthralgia	3.3
Peripheral swelling	3.2
Asthenia	2.6
Dizziness	2.6
Swelling	2.6
Injection-site pruritus	2.5
Feeling abnormal	2.4
Injection-site rash	2.2

Analysis period: Oct 13th, 2017–Feb 10th, 2019. *Only adverse events with a reporting rate >2.0 per 100,000 distributed doses are shown. Vaccination errors were not included in the list. **Based on Medical Dictionary for Regulatory Activities (MedDRA, version 21.1) preferred term; a single report may contain more than 1 MedDRA preferred term. ***Reports per 100,000 RZV doses distributed worldwide during the analytic period.

Figure 2. Evolution of the percentage of vaccination error reports versus all reports with RZV, by country



Analysis period: Oct 13th, 2017–Feb 10th, 2019.

Table 2. Number (%) of reports* of vaccination errors involving RZV

Vaccination error group** (description)	Number (%) of reports* (N=3,579)
Product preparation/reconstitution errors	1,062 (29.7)
Inappropriate/incomplete course of administration	956 (26.7)
Incorrect route of administration	585 (16.4)
Product storage error	463 (12.9)
Other errors	513 (14.3)

Analysis period: Oct 13th, 2017–Feb 10th, 2019. *A report may describe more than 1 error. **A group contains multiple MedDRA preferred terms.

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

2777. Live-Attenuated Vaccine Against RSV Generates Robust Cellular and Humoral Immune Responses

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Background: In people over 65, there are on average 177,000 hospitalizations and 14,000 deaths because of respiratory syncytial virus (RSV) each year. Elderly patients infected with RSV can suffer serious infections leading to pneumonia and congestive heart failure. RSV vaccines have failed in the elderly in part because they have been unable to mount a robust cellular immune response.

Methods: RSV-MinL4.0 is a live-attenuated intranasal vaccine candidate that was generated by codon pair deoptimization of the L gene followed by the addition of four stabilizing mutations found via stress passaging. Four African Green Monkeys (AGMs) per group were vaccinated with RSV-MinL4.0 or wild-type (WT) RSV at 2×10^6 PFU, boosted on day 28 and challenged with wild-type (WT) RSV on day 104. Oropharyngeal swabs and tracheal lavage were collected daily and every other day, respectively, to evaluate virus shedding (qPCR) and blood was drawn on days 1, 14, 21, 28, and 49 for antibody titers ($PRNT_{50}$), and PBMC activation (IFNγ ELISPOT with whole inactivated virus).

Results: MinL4.0 was 2 to 3 $\log_{10}$ attenuated when compared with WT RSV in AGMs. Despite the presence of antibodies on day 28, there was a "take" of the boost indicating the potential for this vaccine to be immunogenic in the elderly with pre-existing circulating antibodies (Figure 1A). MinL4.0 led to robust activation of PBMCs comparable to WT RSV (> 2,000 spots per 10^6 total cells, Figure 1B). Shedding of the vaccine and challenge viruses was minimal (data not shown).

Conclusion: MinL4.0 led to robust activation of cellular and humoral immune responses, which are critical for induction of protective immunity in the elderly. Animals were protected from WT challenge. Preliminary data in AGMs with pre-existing antibodies to RSV indicate that circulating antibodies do not prevent vaccine "take," critical for a vaccine targeting sero-positive elderly individuals.

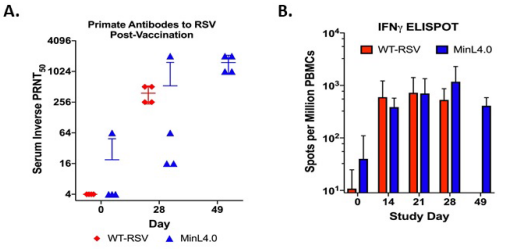

Figure 1: RSV-MinL4.0 generates robust activation of humoral (A) and cellular (B) immunity against RSV

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

2778. Impact of Reactogenicity on Quality of Life and Physical Functioning in Adults ≥50 Years Receiving Both Doses of the Adjuvanted Recombinant Zoster Vaccine

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Background: The adjuvanted recombinant zoster vaccine (RZV) is efficacious in preventing herpes zoster in adults ≥ 50 years. The current study investigates whether the vaccinees' quality of life (QoL) and physical functioning (PF) are impacted by local and systemic reactions due to RZV. In a previous report of this phase III, open-label, multicenter study (NCT02979639), overall PF and QoL were not significantly affected by a first RZV dose. [1] Here we report the results from the same study after a second RZV dose and safety results from dose 1 up to study end.

Methods: Adults aged ≥ 50 years were to receive 2 doses of RZV 2 months apart. Changes in mean Short Form health survey (SF-36) PF score between pre- and post-each RZV dose for 7 days, QoL, reactogenicity and safety were assessed.

Results: 401 adults received dose 1 and 391 received dose 2 of RZV. Post-second RZV dose, the reported solicited local symptoms were pain (75.1%), erythema (22.4%) and swelling (13.9%), and the most frequent solicited systemic symptoms were fatigue (46.3%), headache (37.5%) and myalgia (32.9%). Grade 3 solicited symptoms were reported by 7.2% (local) and 11.1% (general) of participants, and 5 (1.2%) participants reported reactogenicity triggering medical attention post-second RZV dose. From first dose up to study end, 14 (3.5%) participants reported 21 serious adverse events, none related to RZV. In days 1–2, post-second RZV dose, a transient, clinically-important decrease in SF-36 PF score (table) was seen in those reporting grade 3 solicited symptoms, which impacted activities such as walking and climbing stairs. Overall, during the 7 days post-second RZV dose, a mean change of –0.4 points was observed from the mean baseline score, indicating the PF was not clinically meaningfully impacted. No overall quality-adjusted-life-year loss was recorded.

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.

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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