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| **Efficacy of One Dose of the Respiratory Syncytial Virus (RSV) Prefusion F Protein Vaccine (RSVPreF3 OA) in Adults ≥ 60 Years of Age Persists for 2 RSV Seasons** |
| Michael G. Ison1, Niamh Mangan2, Alberto Papi3, Joanne M. Langley4, Dong- Gun Lee5, Isabel Leroux-Roels6, Federico Martinon-Torres7, Tino F. Schwarz8, Richard N. van Zyl-Smit9, Susanna Cuadripani10, Nancy Dezutter11, Olivier Gruselle11, Laurence Fissette11, Marie-Pierre David11, Aurélie Olivier11, Marie Van der Wielen11, Dominique Descamps11, on behalf of the AReSVi-006 study group |
| *1National Institutes of Allergy and Infectious Diseases, Bethesda, MD, United States**2GSK, Australia**3University of Ferrara, St. Anna University Hospital, Ferrara, Italy**4Canadian Center for Vaccinology (Dalhousie University, IWK Health and Nova Scotia Health), Halifax, Canada**5The Catholic University of Korea, Seoul, South Korea**6Ghent University and Ghent University Hospital, Ghent, Belgium**7Hospital Clínico Universitario de Santiago, Santiago de Compostela, A Coruña, Spain**8Klinikum Würzburg Mitte, Campus Juliusspital, Würzburg, Germany**9University of Cape Town and Groote Schuur Hospital, Cape Town, South Africa**10GSK, Stevenage, Hertfordshire, United Kingdom**11GSK, Wavre, Belgium* |
| **Aim:** We present persistence of vaccine efficacy (VE) of a single RSVPreF3 OA dose, along with VE and safety of annual revaccination dose, over 2 RSV seasons.**Methods:** In this phase 3, placebo-controlled, multi-country study (NCT04886596), adults aged ≥ 60 were randomized 1:1 to receive RSVPreF3 OA or placebo before RSV season 1. RSVPreF3 OA recipients were then re-randomized 1:1 before RSV season 2 to receive a second RSVPreF3 OA dose (RSV\_annual group) or placebo (RSV\_1dose group); participants who received placebo pre-season 1 received an additional placebo dose (placebo group). VE against first occurrence of RSV-LRTD, severe RSV-LRTD, RSV-LRTD by age, baseline comorbidity and frailty status, and RSV-related acute respiratory illness (ARI) was assessed over 2 seasons. Reactogenicity and safety were also evaluated.**Results:** Of 24,973 participants vaccinated before season 1, 24,967 were included in the current VE analyses (RSV\_annual: 6,242; RSV\_1dose: 6,227; placebo: 12,498). The median follow-up over 2 seasons was 17.8 months. VE of a single dose of RSVPreF3 OA against RSV-LRTD over 2 seasons was 67.2% (97.5% confidence interval [CI]: 48.2–80.0); VE of annual revaccination over 2 seasons was 67.1% (97.5% CI: 48.1–80.0). Sustained VE was observed over 2 seasons against severe RSV-LRTD, against RSV-LRTD among participants 60–69 YOA, 70–79 YOA, those with ≥ 1 baseline comorbidity of interest, pre-frail participants and against RSV-ARI (Figure 1). The reactogenicity (Figure 2) and the safety profile of the second RSVPreF3 OA dose was acceptable.**Conclusion:** One dose of RSVPreF3 OA is efficacious against RSV-LRTD in adults ≥ 60 YOA over 2 full RSV seasons, as well as against severe RSV-LRTD, and in adults with advanced ages and underlying comorbidities. Revaccination after 1 year does not appear to confer additional efficacy benefit for the overall population. The clinical program will assess persistence and optimal revaccination timing.**Grant Support:** GSK [212494] |