

## OP35.2

### **Efficacy and safety of an adjuvanted herpes zoster subunit vaccine candidate in adults $\geq 70$ years of age**

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**Background & Aim:** Herpes Zoster (HZ) is not uncommonly seen in daily clinical practice of family physicians/general practitioners. In the PhIII ZOE-50 trial (NCT01165177), the herpes zoster subunit (HZ/su) vaccine candidate, containing recombinant varicella-zoster virus glycoprotein E and the AS01B Adjuvant System, reduced the risk of HZ by 97.2% in  $\geq 50$  years of age (YO). We present results of the parallel ZOE-70 trial in adults  $\geq 70$  YO, and from a pre-specified pooled analysis over both studies.

**Method:** ZOE-70 (NCT01165229, GlaxoSmithKline Biologicals SA) was a randomized, observer-blind, placebo-controlled, multicountry trial to evaluate HZ/su efficacy and safety in  $\geq 70$  YO. Subjects received 2 intramuscular doses of HZ/su or saline 2 months apart. Vaccine efficacy (VE) was assessed in subjects who received both doses and did not develop confirmed HZ within 1 month post-dose 2. Safety was assessed in all subjects over the study and reactogenicity in a subset of subjects within 7 days after each vaccination. VE against postherpetic neuralgia (PHN) and HZ was assessed in  $\geq 70$  YO pooled from both studies.

**Results:** 13,900 subjects received  $\geq 1$  dose and were evaluated for safety. 13,163 were included in the primary VE analysis; 1,025 in the reactogenicity analysis. After a mean follow-up of 3.7 (SD:0.8) years, VE against HZ in ZOE-70 was 89.8% (95% CI, 84.2–93.7%). HZ/su was more reactogenic than saline (79.0% and 29.5% of subjects reported any reaction, respectively). No imbalances in serious adverse events, deaths, potential immune-mediated diseases were identified between groups. In the pooled analyses (N=16596), VE was 88.8% (68.7–97.1%) against PHN and 91.3% (86.8–94.5%) against HZ.

**Conclusions:** HZ/su vaccine candidate demonstrated high efficacy in reducing risk of HZ and PHN in  $\geq 70$  YO, and has an acceptable safety profile. This highlights its potential to improve prevention in ageing population, most at risk of HZ and its complications.