P2139

IMMUNOGENICITY, REACTOGENICITY, AND SAFETY OF A RESPIRATORY SYNCYTIAL VIRUS PREFUSION F (RSVPREF3) CANDIDATE VACCINE CO-ADMINISTERED WITH THE SEASONAL QUADRIVALENT INFLUENZA VACCINE IN OLDER ADULTS

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Background

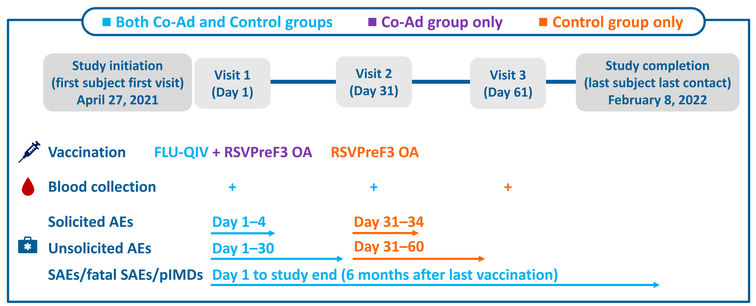
- RSV can cause **severe respiratory disease in older adults aged ≥60 years**[1,2]
- **The seasonality of both RSV and influenza are overlapping**[3]; vaccine co-administration could allow higher flexibility in administration, supporting vaccine coverage, while helping to protect against both infections with reduced healthcare visits[4]

Objective

- **We assessed the humoral immunogenicity, reactogenicity, and safety of an RSVPreF3 OA investigational vaccine when co-administered with a seasonal FLU-QIV in older adults aged ≥60 years**

Methods

- **Phase 3, open-label, randomized controlled study (NCT04841577) in 14 centers:**
  - 7 in New Zealand
  - 5 in Panama
  - 2 in South Africa
- **Randomized (1:1) to two parallel groups**:
  - **Co-Ad group (co-administration):** RSVPreF3 OA and FLU-QIV at visit 1 (Day 1)
  - **Control group (sequential administration):** FLU-QIV at visit 1 (Day 1), followed by RSVPreF3 OA at visit 2 (Day 31)



Co-primary endpoints: 1 month post vaccination, non-inferiority of:

- RSVPreF3 OA: **RSV-A neutralizing Ab GMT ratio**
- FLU-QIV: **HI Ab GMT ratio** for each Flu strain

when co-administered versus when administered sequentially
Non-inferiority: UL of the 95% CI of the group GMT ratio (Control/Co-Ad) **≤1.5**

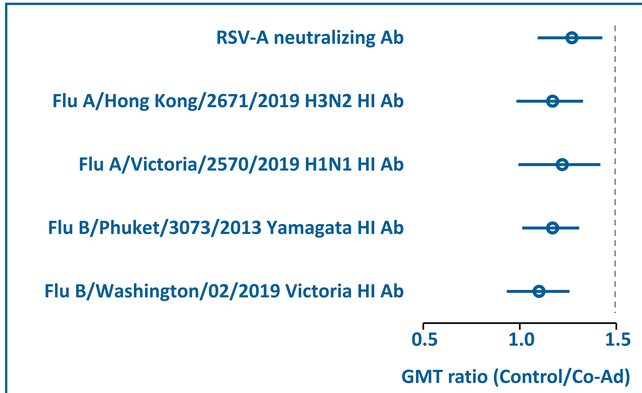
Results

ENROLLMENT AND BASELINE PARTICIPANT CHARACTERISTICS

- Of **890** randomized participants, **885 received ≥1 dose** of the study interventions and were included in the ES* (Co-Ad, n=442; Control, n=443)
- **837 participants (94.6%)** were included in the PPS† for Visit 2 (Co-Ad, n=427; Control, n=410) and **397 (89.6%; Control only)** were included in the PPS for Visit 3

➥ **Characteristics were similar** between **Co-Ad** and **Control** groups, and between the ES and PPS

CO-PRIMARY ENDPOINTS: Humoral immunogenicity

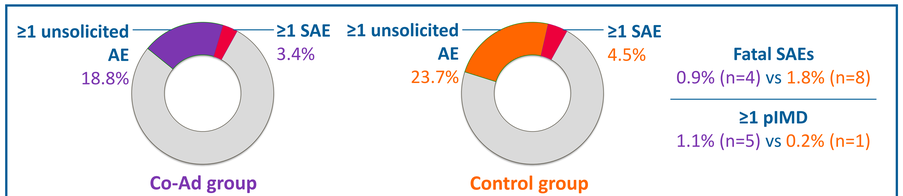


Ab GMT ratio 1 month post vaccination – PPS
Error bars represent 95% CI.

Co-primary endpoints met: RSV-A neutralizing Ab titers (ED60) and HI Ab titers (1/DIL) for each of the Flu vaccine strains in the **Co-Ad group** were shown to be **non-inferior** compared with the **Control group** (UL of 95% CI ≤1.5)

SECONDARY ENDPOINTS: Reactogenicity and safety

- **Pain** was the **most commonly reported** solicited administration site event following any vaccine administration in both groups:
  - ➥ **Following FLU-QIV vaccination, 28.3%** and **20.5%** of participants in the **Co-Ad** and **Control** groups, respectively, reported pain
  - ➥ **Following RSVPreF3 OA vaccination, 47.9%** and **39.1%** of participants in the **Co-Ad** and **Control** groups, respectively, reported pain
- The **most commonly reported** solicited systemic events following any vaccine administration in both groups were **fatigue, headache, and myalgia**
- The observed percentages of **unsolicited AEs/SAEs/pIMDs** were **balanced** between the **Co-Ad** and **Control** groups



Unsolicited AEs, SAEs, fatal SAEs, and pIMDs reported (per participant)
Unsolicited AEs: within 30 days of any dose; SAEs, fatal SAEs, pIMDs: up to study end.

Conclusions

- **Non-inferior immunogenicity of co-administration** versus sequential administration
- **Co-administration** was **well tolerated**, with an acceptable safety profile
- **Simultaneous vaccination is supported** by our data

*ES: All participants who received ≥1 study intervention; analysis per group was based on the study intervention administered.
†PPS: All eligible participants who received ≥1 study intervention as per protocol, had immunogenicity results pre-post-dose for ≥1 antigen, complied with blood draw intervals; contribution of participants to PPS at specific time point was defined by time point, without intercurrent medical conditions that may interfere with immunogenicity and without prohibited concomitant medication/vaccination.

RSVPreF3 OA: Single dose (0.5 mL): 120 µg of recombinant RSVPreF3 antigen and $AS01_E$ adjuvant; intramuscular injection (non-dominant arm).
FLU-QIV: Single dose (0.5 mL): 15 µg of hemagglutinin per strain; intramuscular injection (Co-Ad group: dominant arm; Control: non-dominant arm).
Strains: Flu A/Hong Kong/2671/2019 H3N2, Flu A/Victoria/2570/2019 H1N1, Flu B/Phuket/3073/2013 Yamagata, and Flu B/Washington/02/2019 Victoria.

Funding: GSK Biologicals SA.
Acknowledgments: Medical writing support was provided by Stavroula Bitsi, PhD, of OPEN Health Communications (London, UK), funded by GSK Biologicals SA.

References: 1. Falsey AR et al. *N Engl J Med* 2005;352(17):1749–1759; **2.** Walsh EE et al. *J Infect Dis* 2004;189(2):233–238; **3.** Chadha M et al. *Influenza Other Respir Viruses* 2020;14(6):638–646; **4.** Dolhain J et al. Expert Rev Vaccines 2020;19(5):419–443.

Abbreviations: Ab, antibody; AE, adverse event; CI, confidence interval; DIL, dilution; ED60, estimated dilution 60; ES, exposed set; FLU-QIV, quadrivalent influenza vaccine; GMT, geometric mean titer; HI, hemagglutinin inhibition; pIMD, potential immune-mediated disease; PPS, per-protocol set; RSV, respiratory syncytial virus; RSVPreF3 OA, RSV prefusion F Older Adult; SAE, serious adverse event; UL, upper limit.

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