**Background**

- RSV can cause severe respiratory disease in older adults aged ≥60 years.\(^1\)\(^2\)
- The seasonality of both RSV and influenza are overlapping.\(^2\) 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: 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)

**Results**

- **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=442; 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 groups**

**Co-primary endpoints: Humoral immunogenicity**

- **RSV neutralizing Ab**
  - RSV-A-neutralizing Ab
    - Co-Ad group: 1.17 (1.12–1.44)
    - Control group: 1.17 (1.02–1.35)
  - Flu A/Hong Kong/2671/2019 H3N2 Hi Ab
    - Co-Ad group: 1.17 (1.02–1.35)
    - Control group: 1.22 (1.03–1.44)
  - Flu A/Victoria/2570/2019 H1N1 Hi Ab
    - Co-Ad group: 1.17 (1.04–1.32)
  - Flu B/Phuket/3073/2013 Yamagata Hi Ab
    - Co-Ad group: 1.17 (1.09–1.26)
  - Flu B/Washington/02/2019 Victoria Hi Ab
    - Co-Ad group: 1.17 (1.10–1.26)

**Secondary endpoints: Reactogenicity and safety**

- **Pain** was the most commonly reported solicited systemic 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

**Conclusions**

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

**Abbreviations:**

- RSV: respiratory syncytial virus
- RSVPreF3 OA: RSV prefusion F Older Adult
- SAE: serious adverse event
- pIMD: potential immune-mediated disease
- PPS: per-protocol set
- ES: extended content version
- FLU-QIV: quadrivalent influenza vaccine
- RSV-A neutralizing Ab: geometic mean titer (GMT) of RSV-A neutralizing antibody
- GMT ratio: 1 month post vaccination – PPS
- Error bars represent 95% CI.

**Study initiation (first subject first visit): April 27, 2021**

**Visit 1 (Day 1)**

**Visit 2 (Day 31)**

**Visit 3 (Day 60)**

**Study completion (last subject last contact): February 8, 2022**

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