A candidate respiratory syncytial virus (RSV) prefusion F protein investigational vaccine (RSVPreF3 OA) is immunogenic when administered in adults ≥ 60 years of age: results at 6 months after vaccination

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Background

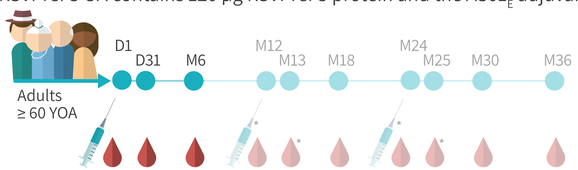
- RSV disease presents a significant burden in older adults (OA) ≥ 60 years of age (YOA).[1–4]
- In 2015, ~1.5 million RSV-associated acute respiratory infection cases were reported in OA from industrialized countries, and of these ~14.5% were admitted to hospitals.[5]
- RSV can cause severe respiratory infections in adult population, particularly in the elderly, immunocompromised, and those with underlying pulmonary or cardiac diseases.[3,6–8]

Objectives

We present immunogenicity results up to M6 after vaccination with the investigational RSVPreF3 OA.

Methods

- Phase 3, randomized, multi-country, ongoing study (NCT04732871)
- RSVPreF3 OA contains 120 µg RSVPreF3 protein and the AS01$_E$ adjuvant system



Current analysis Objectives

HI subset
RSV subtype A/B (RSV-A/B) NAb GMTs - neutralization assay (ED60)
RSVPreF3-specific immunoglobulin (Ig) G GMCs - ELISA (EU/mL)

CMI subset
Frequency of RSVPreF3-specific polypositive CD4+/CD8+ T cells expressing ≥ 2 activation markers including ≥ 1 cytokine among cluster of differentiation 40 ligand, 4-1BB, interleukin (IL)-2, tumor necrosis factor-α, interferon-γ, IL-13, IL-17 (events/10^6 cells)

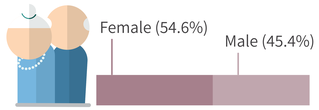
RSVPreF3 OA investigational vaccine blood sample for HI and CMI

AS01$_E$, adjuvant system containing 25 µg 3-O-desacyl-4-monophosphoryl lipid, 25 µg *Quillaja saponaria* Molina fraction 21 and liposomes. **D**, day; **M**, month; **HI**, humoral immunogenicity; **CMI**, cell-mediated immunity; **NAb**, neutralizing antibody; **ED60**, serum dilution inducing 60% inhibition in plaque-forming units; **ELISA**, enzyme-linked immunosorbent assay; **EU/mL**, ELISA units per milliliter. *Applicable only for the group receiving vaccine dose at M12 and M24.

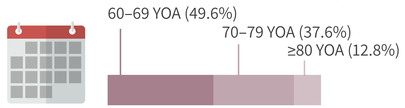
Results

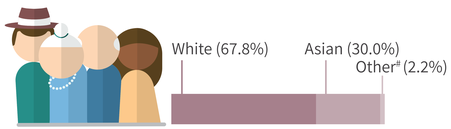
Demographic characteristics of the participants

- 1653 participants vaccinated with RSVPreF3 OA
- PPS at D1:
  - HI subset: 987 participants
  - CMI subset: 566 participants



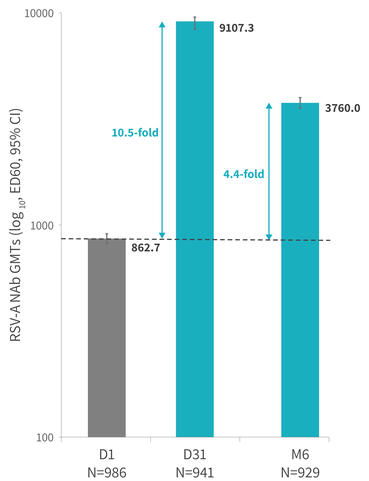
Mean age at study entry: 70.0 (±6.6) years

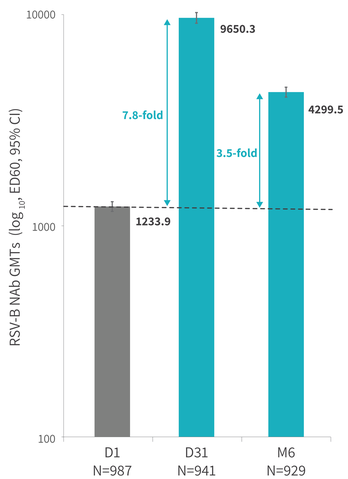


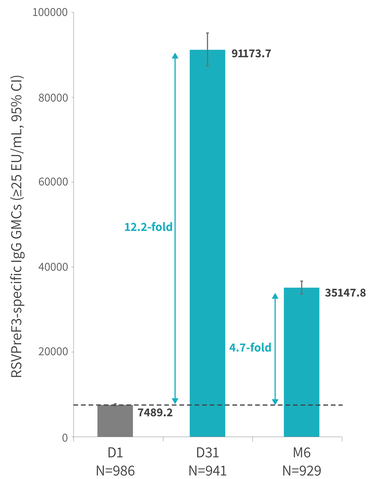


PPS, per-protocol set includes all participants who received 1 dose of the study intervention to which they were randomized, were not excluded due to deviations and have post-vaccination data. #Includes Black or African American, American Indian or Alaska native or native Hawaiian or other Pacific Islander.

The RSV-A and RSV-B NAb GMTs and RSVPreF3-specific IgG GMC increased between D1 and D31 and declined between D31 and M6, but remained above pre-vaccination levels (PPS for HI).



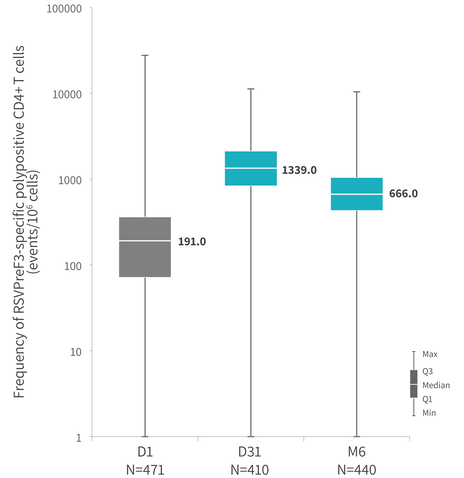




Pre-vaccination Post-vaccination

GMT, geometric mean titer; **GMC**, geometric mean concentration; **N**, number of participants with available results; **CI**, confidence interval; **Q1/Q3**, first/third quartiles.
Note: RSV-A/RSV-B immunogenicity results and RSVPreF3-specific CD4+ T cells results by age category are available *via* the QR code.

The RSVPreF3-specific polypositive CD4+ T cells median frequency increased after vaccination from D1 to D31 and declined between D31 and M6, but remained above the assay quantification limit (PPS for CMI).



At the time points assessed, no RSVPreF3-specific CD8+ T cell response was detected after RSVPreF3 OA vaccination.

One dose of RSVPreF3 OA had an acceptable safety profile in adults ≥ 60 YOA

Conclusions

Interactive version available

Both humoral immunity and specific cell-mediated immune responses increased by D31 post-vaccination (fold increase of NAb RSV-A and RSV-B of 10.5 and 7.8, respectively) and remained 3.5–4.7-fold above pre-vaccination levels at M6.

In adults ≥ 60 YOA, 1 dose of RSVPreF3 OA was shown to be immunogenic.
This study will continue to monitor the immunogenicity of RSVPreF3 OA up to 3 years.

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