Safety and reactogenicity of an investigational respiratory syncytial virus (RSV) prefusion F protein vaccine for adults ≥ 60 years of age (RSVPreF3 OA): an interim analysis at 6 months after vaccination

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Background

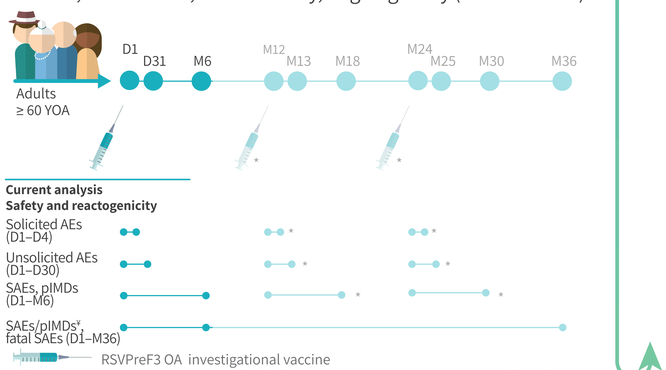
- RSV respiratory infections can lead to serious complications in older adults (OA) ≥ 60 years of age (YOA).[1,2]
- There is no licensed vaccine to prevent RSV infections. An investigational vaccine is currently being tested.

Objectives

We present safety and reactogenicity results up to M6 after vaccination with the investigational RSVPreF3 OA.

Methods

Phase 3, randomized, multi-country, ongoing study (NCT04732871)



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; **AE**, adverse event; **SAE**, serious AE; **pIMD**, potential immune-mediated disease. †Related to vaccination. *Applicable only for the group receiving vaccine dose at M12 and M24.

Results

Demographic characteristics of the participants

- 1653 participants vaccinated with RSVPreF3 OA (exposed set)
- 1618 participants completed M6 follow-up

Female (54.6%)
Male (45.4%)

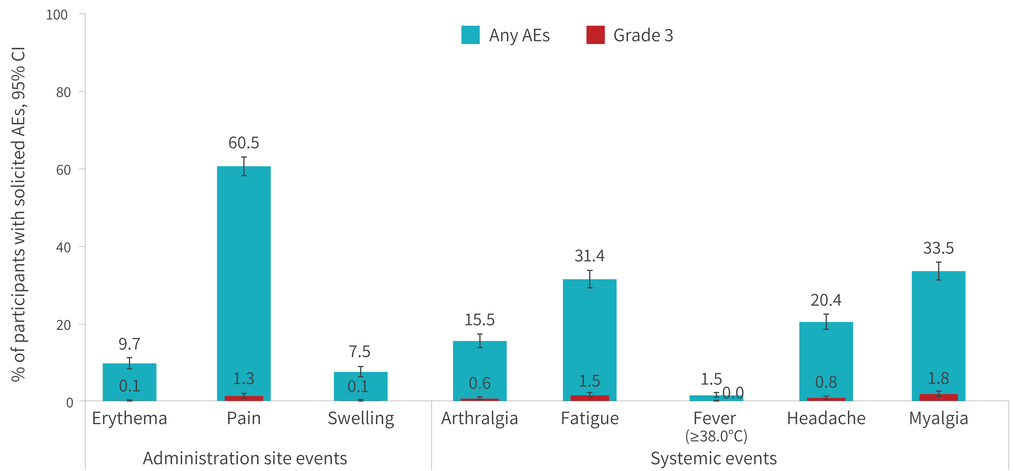
Mean age at study entry: 70.0 (±6.6) years

60–69 YOA (49.6%)
70–79 YOA (37.6%)
≥80 YOA (12.8%)

White (67.8%)
Asian (30.0%)
Other[#] (2.2%)

[#]Includes Black or African American, American Indian or Alaska native or native Hawaiian or other Pacific Islander.

Pain was the most frequently reported solicited administration site event. Myalgia and fatigue were the most frequently reported systemic events. Most solicited AEs lasted ~2 days and were of mild to moderate intensity.



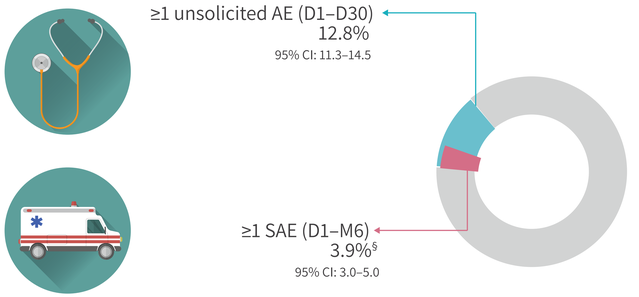
CI, confidence interval. **Grade 3**, significant pain at rest that prevents normal everyday activities, diameter >100 mm (erythema and swelling), preventing normal activities (headache, fatigue, myalgia, arthralgia), >39°C (fever).

Conclusion

Interactive version available

One dose of investigational RSVPreF3 OA was well tolerated and had an acceptable safety profile in adults ≥ 60 YOA.

Overall, 12.8% of participants reported at least 1 unsolicited AE post-vaccination and 3.9% of these participants reported at least 1 SAE.



§One SAE/pIMD (Guillain-Barre syndrome) was considered by the investigator as related to vaccination. This event was resolved.

- 0.4% (95% CI: 0.2–0.9) of participants reported at least 1 pIMD.
- Fatal SAEs were reported for 6 participants (0.4%, 95% CI: 0.1–0.8). None was considered related to vaccination.
- The observed safety profile is similar to the profile expected in the population ≥ 60 YOA.

One dose of RSVPreF3 OA was shown to be immunogenic in adults ≥ 60 YOA.

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