



Prevention of Infant RSV Illness with an RSVpreF Vaccine in Pregnancy



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INTRODUCTION

RSV is the leading cause of lower respiratory tract illnesses worldwide, with a substantial burden of disease borne to young infants, particularly those in lower- and middle-income countries. Rates of severe RSV illness are highest in infants less than 6 months of age, with a peak in hospitalization between 1 and 2 months of life. Treatment of RSV disease for infants consists primarily of supportive care, as there is no vaccine available to prevent RSV disease in infants. Maternal immunization to protect infants early in life offers an attractive strategy for infant disease prevention in this population.

Pfizer’s RSVpreF bivalent vaccine is a prophylactic vaccine that is being investigated for the prevention of medically attended lower respiratory tract disease (MA-LRTI) and severe medically attended lower respiratory tract disease (sMA-LRTI) caused by RSV in infants from birth through 6 months of age by active immunization of pregnant maternal participants in a Phase 3 trial. Here we present results of our primary analysis.

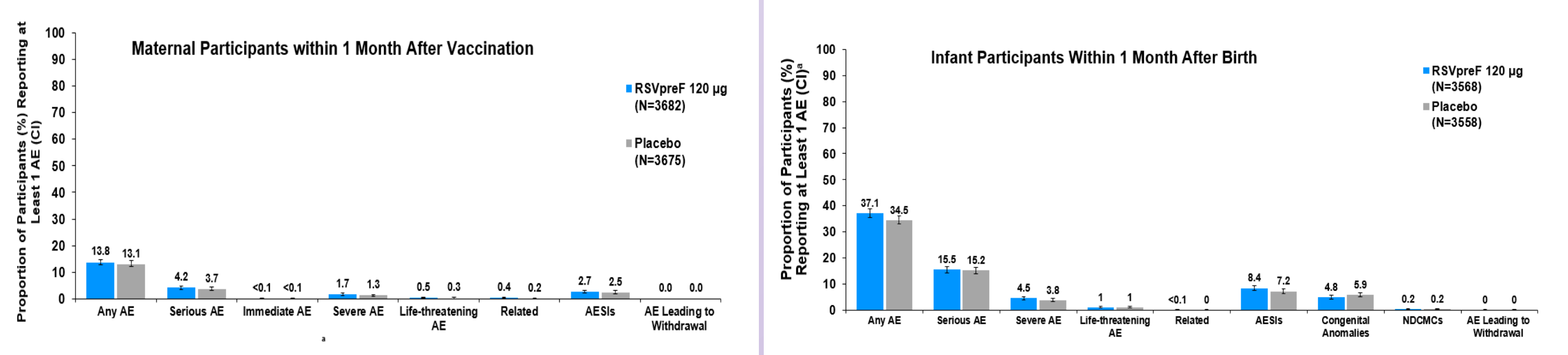
METHODS

- Study C3671008 is an ongoing Phase 3, multicenter, randomized, double-blinded, placebo-controlled study executed in 18 countries.
- 7,392 maternal participants randomized 1:1 RSVpreF 120µg or placebo
 - Pregnant participants ≤49 years of age between ≥24 and ≤36 weeks gestation
 - Follow-up 6 months postpartum
 - 7,128 infants born to vaccinated mothers



RESULTS:

Favorable Safety Profile and Well Tolerated - Adverse Events Comparable Between RSVpreF and Placebo in Maternal and Infant Participants



Primary Efficacy Endpoint

Primary Endpoint: Severe MA-LRTI

	Vaccine Efficacy
First 90 days of life	81.8% (CI: 40.6%, 96.3%)
Six-month follow-up	69.4% (CI: 44.3%, 84.1%)

Primary Endpoint: MA-LRTI

	Vaccine Efficacy
First 90 days of life	57.1% (CI: 14.7%, 79.8%)
Six-month follow-up	51.3% (CI: 29.4%, 66.8%)

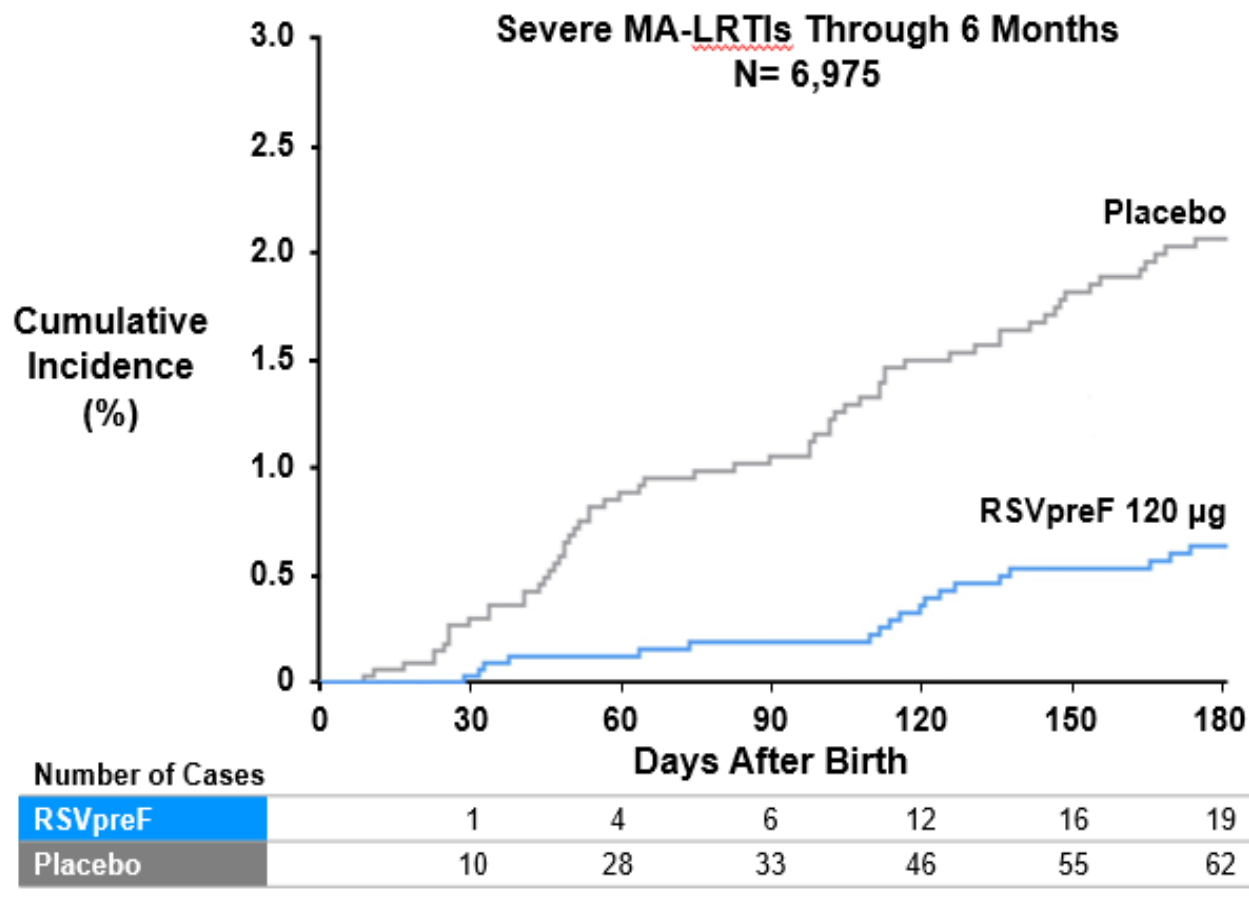


Figure 2: RSVpreF highly efficacious against severe infant MA-LRTI, and this is maintained through 6 months post-birth regardless of RSV seasonality.

Secondary Efficacy Endpoints

Continued Efficacy Against MA-LRTIs Through 1 Year

Time Interval after birth	RSVpreF 120 µg Cases (%)	Placebo Cases (%)	VE% (99.17% CI)
210 Days	70 (2.0)	127 (3.6)	44.9 (17.3, 63.5)
240 Days	76 (2.2)	133 (3.8)	42.9 (16.1, 61.6)
270 Days	82 (2.3)	137 (3.9)	40.1 (13.0, 59.2)
360 Days	92 (2.6)	156 (4.5)	41.0 (16.2, 58.9)

Hospitalizations Due to RSV Demonstrate Efficacy Through 6 Months

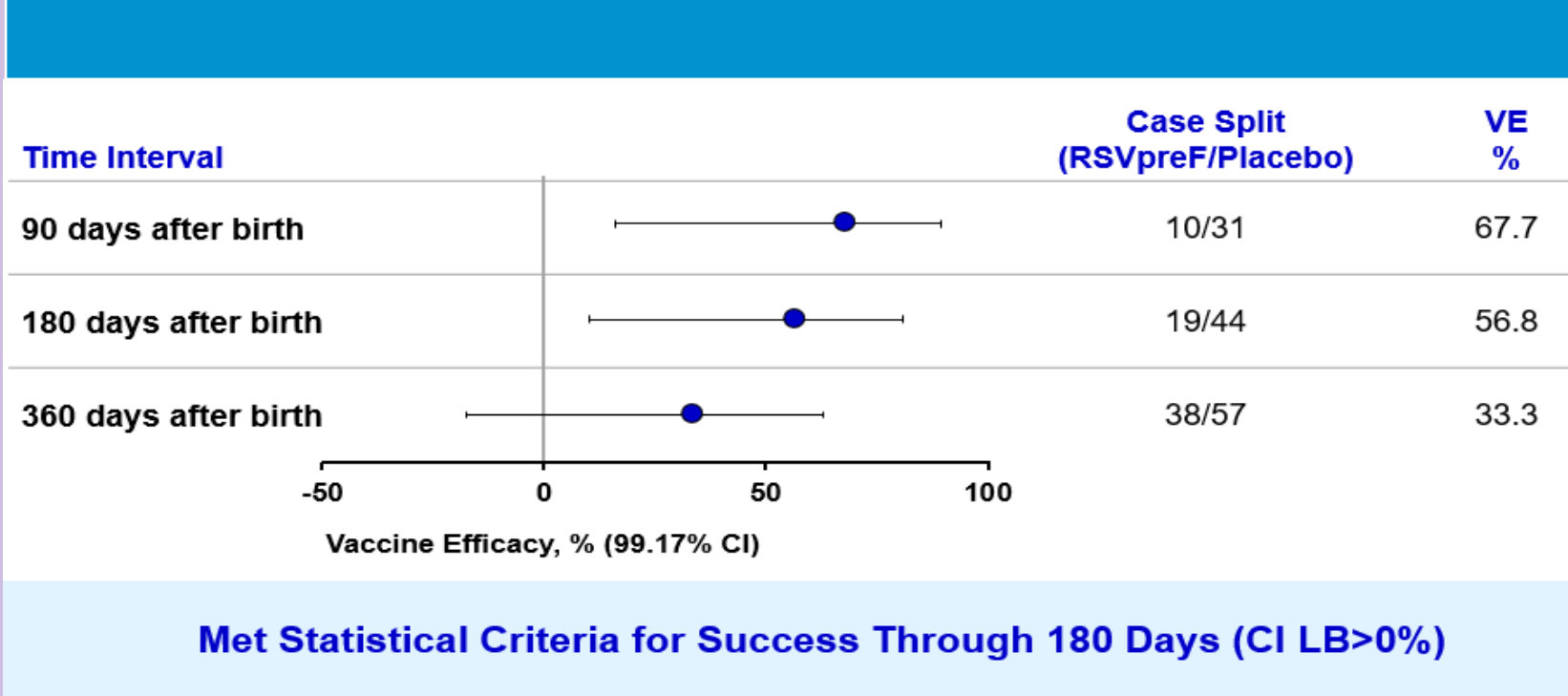


Figure 3: Vaccine efficacy still meaningful post 180 days, as infants are still seeing a benefit to vaccination in the period when maternal antibody is waning.

CONCLUSION

- RSVpreF maternal immunization demonstrated a satisfactory safety profile in mothers and their infants.
- RSVpreF vaccine elicited high and consistent vaccine efficacy (VE) against severe infant MA-LRTI of 81.8% at 90 days and 69.4% at 180.
- Success criterion was not met for MA-LRTI endpoint (57.1% VE at 90 days), however clinically meaningful efficacy was observed with VE of 51.3% out to 180 days.
- Our secondary endpoint of persistent VE against severe RSV to 360 days was met (40-45%).
- Protection against hospitalizations due to RSV after 6-months post-birth was also demonstrated at 67.7 at 90 days and 56.8% at 180 days.

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