Pediatric respiratory syncytial virus (RSV) vaccine (mRNA-1345)

Last program update: September 17, 2020

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<th>Modality</th>
<th>ID #</th>
<th>Program</th>
<th>Preclinical development</th>
<th>Phase 1</th>
<th>Phase 2</th>
<th>Phase 3 and commercial</th>
<th>Moderna rights</th>
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<td>mRNA-1172/Merck V172</td>
<td>Respiratory syncytial virus (RSV) vaccine</td>
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<td>Phase 1 (healthy volunteers)</td>
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<td>Phase 1b (Age de-escalation) Seropositives</td>
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<td>Merck to pay milestones and royalties</td>
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Pediatric respiratory syncytial virus (RSV) overview

- **RSV is the leading cause of unaddressed severe lower respiratory tract disease and hospitalization in infants and young children worldwide**
- **Disease burden:** Major cause of hospitalization due to respiratory infection
  - Hospitalization rate in children <5 years old in the U.S.: ~3:1000
  - Annually over 2 million medically attended RSV infections in children <5 years old in the U.S., more than 86,000 are hospitalized
  - Globally it is estimated over ~33 million episodes of acute lower-respiratory tract infection, 3.2 million hospitalizations and as many as 118,000 deaths per year
  - We estimate pediatric RSV results in ~$2 billion in annual medical costs in the U.S.
- **Target population:** Young children
- **Unmet need:** No approved RSV vaccine

### RSV infection

<table>
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<tr>
<th>Infancy, childhood, adulthood</th>
<th>Fevers</th>
<th>Nasal congestion</th>
<th>Breathing difficulties</th>
<th>Wheezing</th>
<th>Chest congestion</th>
<th>Bronchiolitis</th>
<th>Pneumonia</th>
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Pediatric RSV vaccine (mRNA-1345)

*Encodes for a stabilized prefusion F glycoprotein*

- Prefusion F elicits a superior neutralizing antibody response compared to the post-fusion protein.
- mRNA-1345 will use the same LNP as our hMPV/PIV3 (mRNA-1653), CMV (mRNA-1647) and COVID-19 (mRNA-1273) vaccines.
Pediatric RSV vaccine (mRNA-1345)

IND opened and actively screening participants

Key objective
• To evaluate the safety and immunogenicity of mRNA-1345 when administered to adults and to children 12-36 months of age with serologic evidence of prior exposure

Primary endpoints
• Safety

Secondary endpoint
• Neutralizing antibodies against RSV

Trial progress
• IND opened in August 2020
• Sites are open and actively screening participants

Adult Cohorts

Cohort 1 (N=25)
- mRNA-1345: placebo (4:1)

Cohort 2 (N=25)
- mRNA-1345: placebo (4:1)

Cohort 3 (N=25)
- mRNA-1345: placebo (4:1)

Cohort 4 (N=25)
- mRNA-1345: placebo (4:1)

DSMB

Pediatric Cohorts (12-36 months)

Cohort 5 (N=30)
- mRNA-1345: placebo (1:1)

Cohort 6 (N=30)
- mRNA-1345: placebo (1:1)

DSMB

Abbreviations
D = Day, M = Month, DSMB = Data Safety Monitoring Board
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