## Respiratory syncytial virus (RSV) vaccine (mRNA-1345)

### Last program update: May 6, 2021

<table>
<thead>
<tr>
<th>Program</th>
<th>ID #</th>
<th>Preclinical development</th>
<th>Phase 1</th>
<th>Phase 2</th>
<th>Phase 3</th>
<th>Commercial</th>
<th>Moderna rights</th>
</tr>
</thead>
<tbody>
<tr>
<td>COVID-19 vaccine</td>
<td>mRNA-1273, mRNA-1273.351/-211</td>
<td>mRNA-1283, mRNA-1273.351/-211</td>
<td>mRNA-1283</td>
<td>mRNA-1273.351/-211</td>
<td>Worldwide</td>
<td>BARDA funded</td>
<td></td>
</tr>
<tr>
<td>Cytomegalovirus (CMV) vaccine</td>
<td>mRNA-1647</td>
<td>mRNA-1653</td>
<td>Worldwide</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>hMPV/PIV3 vaccine</td>
<td>mRNA-1693</td>
<td>mRNA-1893</td>
<td>Worldwide</td>
<td></td>
<td></td>
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<tr>
<td>Zika vaccine</td>
<td>mRNA-1647</td>
<td></td>
<td>Worldwide</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Respiratory syncytial virus (RSV) vaccine</td>
<td>mRNA-1345</td>
<td>mRNA-1345</td>
<td>Worldwide</td>
<td></td>
<td></td>
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<tr>
<td>Epstein-Barr virus (EBV) vaccine</td>
<td>mRNA-1189</td>
<td></td>
<td>Worldwide</td>
<td></td>
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<tr>
<td>Ru vaccine</td>
<td>mRNA-1010, mRNA-1020, mRNA-1030</td>
<td>mRNA-1215</td>
<td></td>
<td></td>
<td></td>
<td>Worldwide</td>
<td>NIH funded</td>
</tr>
<tr>
<td>Nipah vaccine</td>
<td>mRNA-1644, mRNA-1574</td>
<td></td>
<td>Worldwide</td>
<td></td>
<td></td>
<td>Worldwide</td>
<td>IAVI/BMGF/NIAID and others funded</td>
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<tr>
<td>HIV vaccine</td>
<td>mRNA-1851</td>
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<td></td>
<td></td>
<td></td>
<td>Worldwide</td>
<td>Advancing subject to funding</td>
</tr>
</tbody>
</table>

**Note:** The table above summarizes various vaccine programs, including the RSV vaccine, with their respective IDs, phases of development, and commercial status. The RSV vaccine (mRNA-1345) is highlighted in red.
RSV is the leading cause of respiratory illness in young children and older adults (65+) are at high risk for severe RSV infections

Disease burden in pediatrics

- Hospitalization rate in children <5 years old in the U.S.: ~3:1000¹
- Annually over 2 million medically attended RSV infections in children <5 years old in the U.S., more than 86,000 are hospitalized²
- Pediatric RSV results in an estimated ~$2 billion in annual medical costs in the U.S.
- Almost all children will have had an RSV infection by their second birthday³

Disease burden in older adults

- There are ~177,000 hospitalizations in adults 65+ due to RSV in the U.S. each year, and ~14,000 deaths⁴
- Globally it is estimated that there are ~1.5 million episodes of acute respiratory tract infection and ~336,000 hospitalizations related to RSV each year⁵
- RSV in older adults results in an estimated >$3 billion in annual medical costs in the U.S. each year

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³ Respiratory Syncytial Virus Infection (RSV), CDC, https://www.cdc.gov/rsv/about/symptoms.html
⁴ RSV in Older Adults and Adults with Chronic Medical Conditions, CDC, https://www.cdc.gov/rsv/high-risk/older-adults.html
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
- RSV uses same LNP as Moderna COVID-19 Vaccine
RSV vaccine (mRNA-1345) Phase 1 ongoing in pediatric and adult populations

Key Objectives
- The primary objectives of this study are to evaluate the tolerability and reactogenicity of mRNA-1345 in younger adults, older adults and children

Primary endpoints
- Safety

Secondary endpoints
- Neutralizing antibody titers against RSV

Trial progress
- All 4 younger adult cohorts are fully enrolled
- Older adult dosing is ongoing

Interim data
- Safety and immunogenicity of Cohorts 1 and 2 through Month 1 post vaccination

Today sharing first interim analysis of the younger adult cohorts

Phase 1 Trial Design

Younger Adults (18-49 years)
- Cohort 1 (50 µg)
- Cohort 2 (100 µg)
- Cohort 3 (100 µg)
- Cohort 4
- Cohort 5
- Cohort 6

Older adults (65-79 years)
- Cohort 7
- Cohort 8
- Cohort 9

DSMB: Data Safety and Monitoring Board

RSV Seropositive Children (12-59 months)
- mRNA-1345
- DSMB: Data Safety and Monitoring Board
Solicited local adverse reactions after vaccination

A single mRNA-1345 vaccination of 50 or 100 µg was generally well-tolerated in adults 18-49 years of age

- The most common local solicited adverse reaction was injection site pain, reported by at least 73.7% of participants in mRNA-1345 groups
- The most common systemic solicited adverse reaction were headache, fatigue and myalgia
- The majority of solicited adverse reactions occurred within 1-3 days after vaccination and resolved after 1-4 days
- There were no deaths, no SAEs, no study discontinuations due to AEs, and no AEs that led to a study pause

Solicited Local Adverse Reactions after Vaccination
mRNA-1345-P101, Cohort 1 and 2

Interim data through 1 month post vaccination, Solicited Safety set
N = 10 for placebo, 19 for 50 µg and 20 for 100 µg
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Solicited systemic adverse reactions after vaccination
A single mRNA-1345 vaccination of 50 or 100 µg was generally well-tolerated in adults 18-49 years of age
mRNA-1345 boosts RSV neutralizing antibodies in younger adults

- Neutralizing antibodies were confirmed to be present at baseline in all subjects, as expected.
- A single mRNA-1345 vaccination of 50 or 100 µg boosted neutralizing antibody titers against RSV with no apparent dose response.
- At Month 1, the geometric mean fold rise in neutralizing antibody relative to baseline was at least 20.5 for RSV-A and at least 11.7 for RSV-B.

Interim data, Per-Protocol analysis set
N = 10 for placebo, 18 for 50 µg and 19 for 100 µg
Increased immunogenicity of RSV mRNA vaccines achieved through technology advances

Geometric Mean Fold Rise (95% CI) in RSV-A Neutralizing Antibody Titer at Month 1 Relative to Baseline;
Younger Adults 18-49 Years

<table>
<thead>
<tr>
<th>Treatment</th>
<th>mRNA-1777&lt;sup&gt;1&lt;/sup&gt;</th>
<th>mRNA-1345&lt;sup&gt;2&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo</td>
<td>1.2 (0.9, 1.6)</td>
<td>1.0 (0.9, 1.1)</td>
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<tr>
<td>25 µg mRNA</td>
<td>1.6 (1.3, 1.9)</td>
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<tr>
<td>50 µg mRNA</td>
<td></td>
<td>20.5 (13.6, 30.9)</td>
</tr>
<tr>
<td>100 µg mRNA</td>
<td>2.7 (2.1, 3.4)</td>
<td>21.0 (13.9, 31.8)</td>
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<tr>
<td>200 µg mRNA</td>
<td>3.9 (3.1, 4.9)</td>
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- mRNA-1777 and mRNA-1345 both encode prefusion RSV-F
- Changes include:
  - Optimization of the protein sequence
  - Optimization of the codon usage
  - Same LNP technology as mRNA-1273

(2) mRNA-1345 Phase 1 interim analysis, Cohorts 1 and 2, Per Protocol set
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