**Human metapneumovirus (hMPV) and para-influenza virus 3 (PIV3) vaccine (mRNA-1653)**

*Last program update: March 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>
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<tr>
<td>COVID-19 vaccine</td>
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<td>hMPV/PIV3 vaccine</td>
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<td>Zika vaccine</td>
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<td>Ru vaccine</td>
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<td>Nipah vaccine</td>
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<td>HIV vaccine</td>
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<td>Worldwide IAVI/BMGF/NIAID and others funded</td>
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<td>Influenza H7N9 vaccine</td>
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Human metapneumovirus (hMPV) and parainfluenza virus type 3 (PIV3) represent a high unmet need in young children

- hMPV and PIV3 are RNA viruses that are important causes of respiratory tract infections, particularly in children
- Increasing rates of diagnosis and association with hospitalization for respiratory illness
- **Disease burden**: Major cause of hospitalization due to respiratory infection
  - Symptoms range from mild upper respiratory tract infection to life threatening severe bronchiolitis and pneumonia
  - Both viruses cause clinically indistinguishable disease
- **Target population**: Infants
  - Most hMPV or PIV3-associated hospitalizations in children occur under 2 years old
  - Hospitalization rates in children < 5 years old in the U.S.:
    - hMPV: 1.2 per 1,000
    - PIV3: 0.5 per 1,000
- **Unmet need**: No approved hMPV or PIV3 vaccine
  - Other companies’ previous attempts focused only on hMPV or PIV alone (no known attempts at a combination vaccine)

### hMPV and PIV3 infection sequelae
- High fever
- Otitis media
- Thick nasal discharge
- Breathing difficulties, coughing
- Croup
- Pneumonia
- Bronchiolitis
hMPV/PIV3 vaccine (mRNA-1653)
Combines mRNAs encoding antigens from two different viruses
hMPV/PIV3 (mRNA-1653) Phase 1b trial is ongoing in children

Key objective
• To evaluate the safety and immunogenicity of mRNA-1653 when administered to adults and to children 12-59 months of age with serologic evidence of prior exposure to hMPV and PIV3

Primary endpoints
• Safety

Secondary endpoints
• Neutralizing antibodies against hMPV and PIV3

Trial progress
• Positive Phase 1 interim analysis data reported in 2019
• Phase 1b enrolling – Cohort 1 and 2 fully enrolled
hMPV/PIV3 vaccine (mRNA-1653)

Preclinical data – combo vaccine generates neutralizing titers against each virus

Pre-clinical studies of hMPV and PIV3 combination vaccine demonstrated ability to generate robust neutralizing antibody titers. In separate experiments in NHP (not shown) vaccination conferred protection against hMPV or PIV3 viral challenge.
hMPV/PIV3 vaccine (mRNA-1653)

Preclinical data – combo vaccine generates neutralizing titers against each virus

Key Objectives

• Evaluate safety and immunogenicity through 12 months after the second vaccination
• Select optimal dose and vaccination schedule for further clinical development

Dosing schedule: Day 1 and month 1

Dose-escalation Phase A (N=20) Sequential enrollment
Randomization 4:1 for mRNA-1653: placebo, Five subjects per dose cohort

- mRNA-1653 25µg or placebo
- mRNA-1653 75µg or placebo
- mRNA-1653 150µg or placebo
- mRNA-1653 300µg or placebo

All subjects received two doses

Dose-selection Phase A (N=104) Parallel enrollment
Randomization of 1:1:1:1, 26 subjects per dose cohort

- mRNA-1653 75µg
- mRNA-1653 150µg
- mRNA-1653 300µg
- placebo

Within each mRNA-1653 dose level group, subjects randomized 1:1 to receive one or two doses
hMPV/PIV3 vaccine (mRNA-1653)

Phase 1 in healthy adults; Interim results, through 1 month

Safety and tolerability

- mRNA-1653 was found to be generally well tolerated at all dose levels
- No serious adverse events (SAEs), adverse events of special interest, or adverse events leading to withdrawal were reported
- Injection site pain was the most commonly reported solicited adverse event and grade 3 adverse event
hMPV/PIV3 vaccine (mRNA-1653)

Phase 1 in healthy adults; Interim results, through 1 month

- mRNA-1653 tended to induce a greater boost in neutralizing antibody in subjects with lower baseline titers
- 1 month after a single vaccination, hMPV and PIV3 neutralization titers were ~6x and ~3x baseline, respectively

Relationship Between Baseline Titer and Response to First mRNA-1653 Vaccination (Day 28 / Day 1 Titer Ratio)

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Total mRNA N=90</th>
<th>Placebo N=28</th>
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<tbody>
<tr>
<td>hMPV-A</td>
<td>6.04</td>
<td>1.00</td>
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<td>hMPV-B</td>
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<tr>
<td>PIV3</td>
<td>3.24</td>
<td>1.03</td>
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hMPV/PIV3 vaccine (mRNA-1653)
Phase 1 in healthy adults; Interim results, through 7 months

Neutralizing Antibody Titers Through Day 196 by Dose Level and Regimen

**Immunogenicity**

- Single vaccination boosted serum neutralization titers against hMPV and PIV3 at all dose levels tested.

- Second vaccination did not further boost antibody titers, suggesting a single vaccination was sufficient to achieve a plateau in neutralizing antibodies in this pre-exposed population.

- Second interim data show antibody titers remained above baseline at all dose levels at 7 months after vaccination.
hMPV/PIV3 vaccine (mRNA-1653)

Phase 1 in healthy adults; Summary interim results, through 7 months

Safety and tolerability
- mRNA-1653 was found to be generally well tolerated at all dose levels
- No serious adverse events (SAEs), adverse events of special interest, or adverse events leading to withdrawal were reported
- Injection site pain was the most commonly reported solicited adverse event and grade 3 adverse event

Immunogenicity
- Single vaccination boosted serum neutralization titers against hMPV and PIV3 at all dose levels tested. mRNA-1653 was found to be generally well tolerated at all dose levels.
- Neutralizing antibodies against hMPV and PIV3 present at baseline in all subjects, consistent with prior exposure to both viruses.
- 1 month after a single vaccination, hMPV and PIV3 neutralization titers ~6x and ~3x baseline, respectively.
- Second vaccination did not further boost antibody titers, suggesting a single vaccination was sufficient to achieve a plateau in neutralizing antibodies in this pre-exposed population.
- Second interim data show antibody titers remained above baseline at all dose levels at 7 months after vaccination.
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