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

Last program update: September 17, 2020

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<tr>
<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>
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<tr>
<td>mRNA-1273</td>
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<td>COVID-19 vaccine</td>
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<td>mRNA-1653</td>
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<td>hMPV/PIV3 vaccine</td>
<td>Phase 1 (healthy volunteers)</td>
<td>Phase 1b (Age de-escalation) Seropositives</td>
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<td>Respiratory syncytial virus (RSV) vaccine</td>
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<td>Merck to pay milestones and royalties</td>
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<td>Influenza H7N9 vaccine</td>
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<td>Worldwide                  Advancing subject to funding</td>
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Prophylactic vaccines
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**

*First mRNA vaccine to be evaluated in children*

**Key objective**
- To evaluate the safety and immunogenicity of mRNA-1652 when administered to adults and to children 12-36 months of age with serologic evidence of prior exposure

**Primary endpoint**
- Safety

**Secondary endpoint**
- Neutralizing antibodies against hMPV and PIV3

**Trial progress**
- Adult cohort is completed; First 10 pediatric participants dosed in trial before COVID-19 related disruptions
- Sites are open and actively recruiting participants

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### Adult Cohort

- Cohort 1 (N=24)
  - mRNA-1653: mRNA-1653: placebo (1:1:1)

### Pediatric Cohorts

- Cohort 2 (N=30)
  - mRNA-1653: placebo (1:1)

- Cohort 3 (N=30)
  - mRNA-1653: placebo (1:1)

- Cohort 4 (N=30)
  - mRNA-1653: placebo (1:1)

**Abbreviations**

SMC = Safety Monitoring Committee
hMPV/PIV3 vaccine (mRNA-1653)

Preclinical data – combo vaccine generates neutralizing titers against each virus

Preclinical 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

<table>
<thead>
<tr>
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<th>total mRNA N=90</th>
<th>Placebo N=28</th>
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<td>hMPV-B</td>
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<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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