






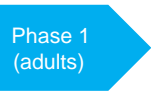






# Human metapneumovirus (hMPV) and para-influenza virus 3 (PIV3) vaccine (mRNA-1653)

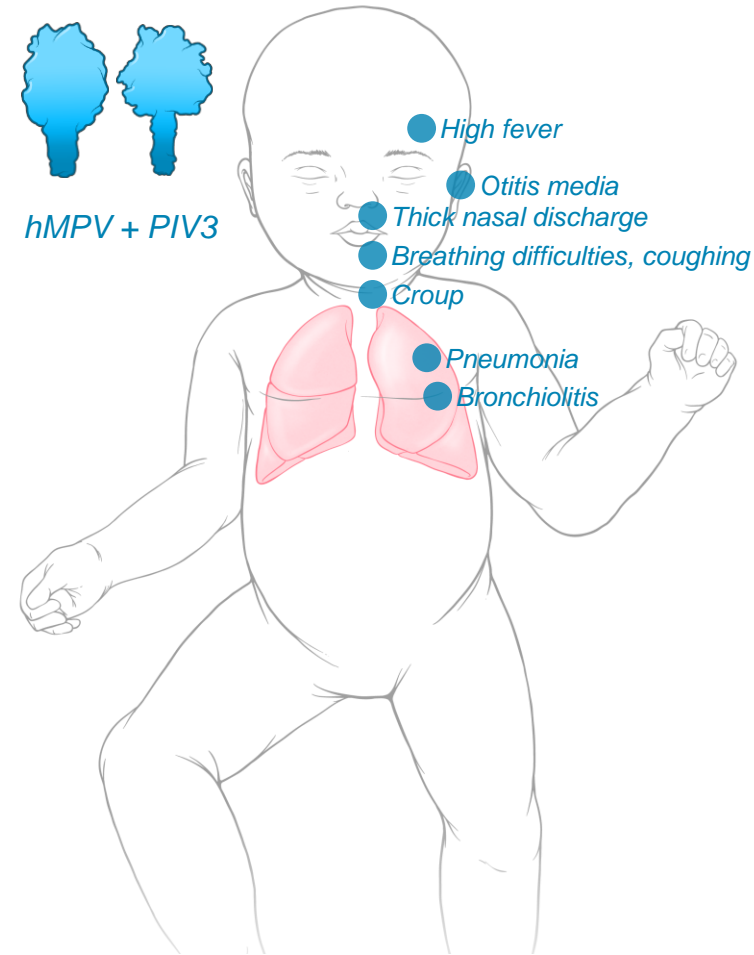
Last updated: February 12, 2019

Modality	Program #	Program	Preclinical development	Phase 1	Phase 2	Phase 3 and commercial	Moderna rights
 Prophylactic Vaccines – Commercial programs	mRNA-1777	RSV vaccine					Merck to pay milestones and royalties
	mRNA-1647	CMV vaccine					Worldwide
	mRNA-1653	hMPV+PIV3 vaccine					Worldwide
	mRNA-1278	VZV vaccine					Merck to pay milestones and royalties

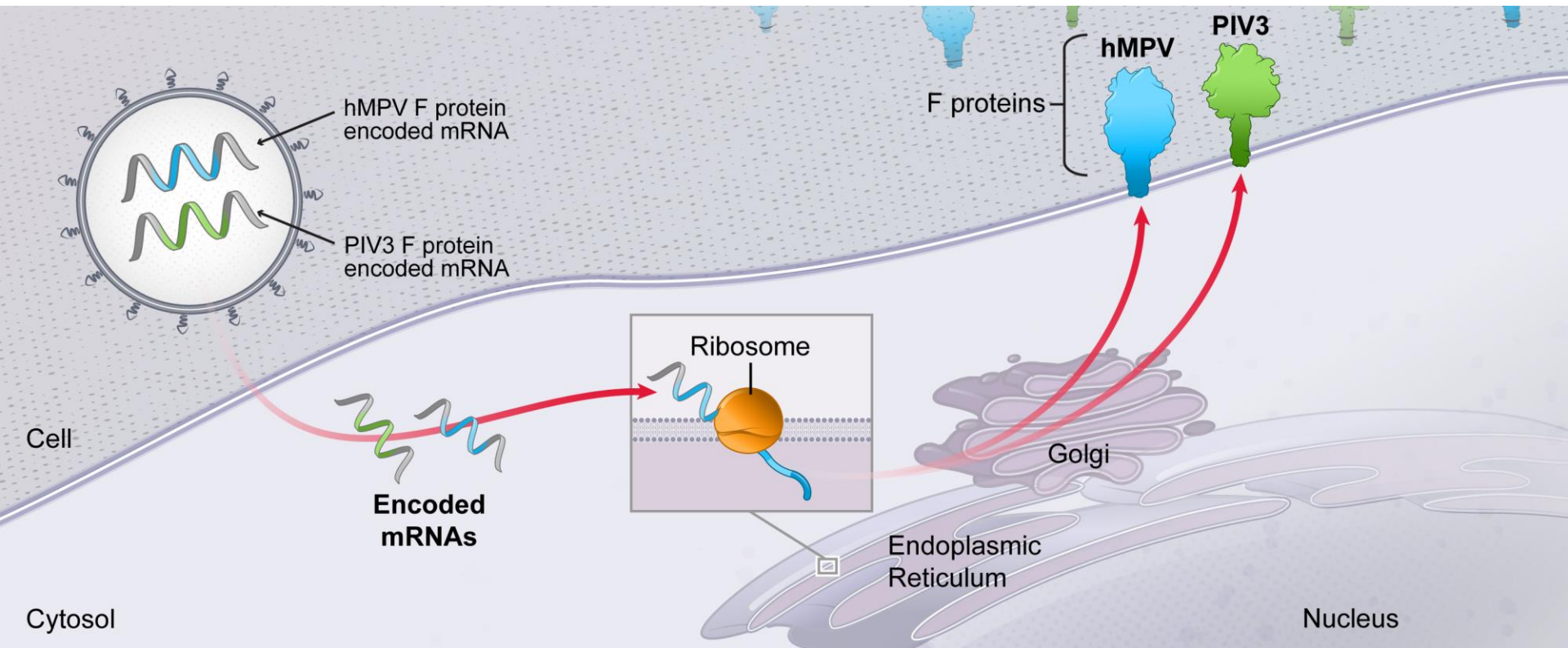
**Positive interim safety & immunogenicity data from mRNA-1653 Phase 1 trial in healthy adults**

# Human metapneumovirus (hMPV) and parainfluenza virus type 3 (PIV3) overview

- 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+PIV3 vaccine combines mRNAs encoding antigens from two different viruses



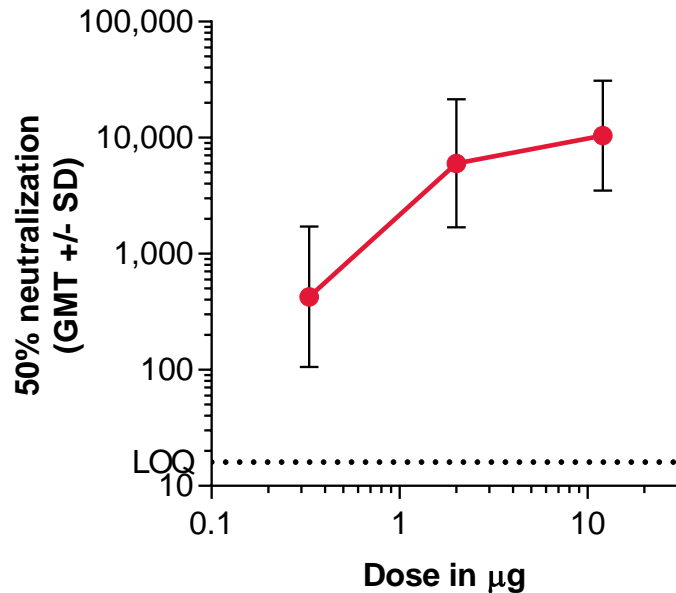
**Moderna concept: mRNA vaccine, IM-administered, consisting of 2 distinct mRNA sequences, co-formulated, that encode the membrane-bound F proteins of hMPV and PIV3**

# hMPV+PIV3 vaccine (mRNA-1653)

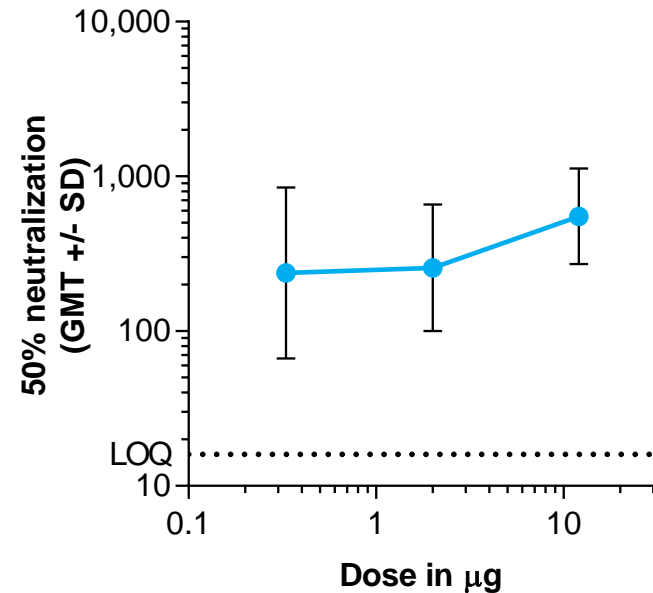
Pre-clinical data – combo vaccine generates neutralizing titers against each virus

Species:  
Mouse

hMPV neutralizing titers with hMPV+PIV3 mRNA vaccine



PIV3 neutralizing titers with hMPV+PIV3 mRNA vaccine



*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.*

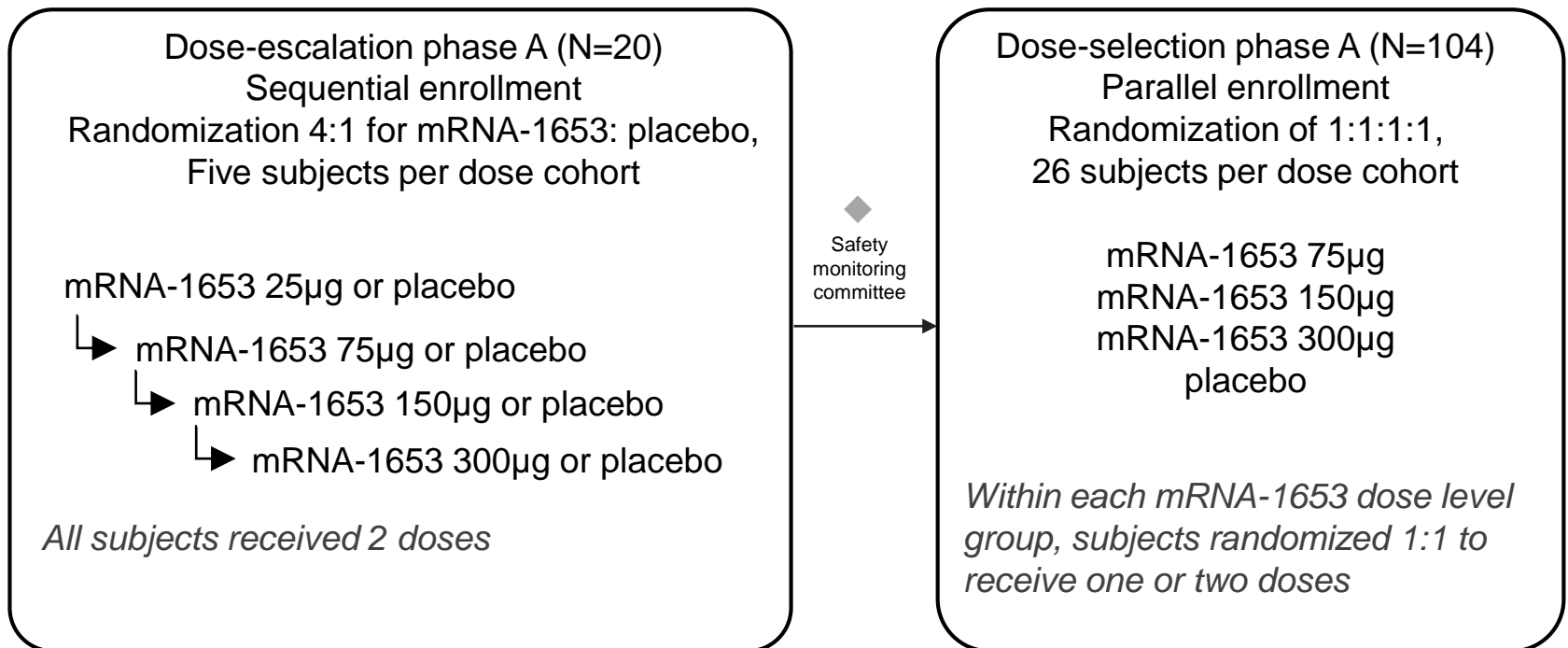
# hMPV+PIV3 vaccine (mRNA-1653)

## Phase 1 design – healthy adults

### 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



# **hMPV+PIV3 vaccine (mRNA-1653)**

*Phase 1 in healthy adults*

*Interim results, through study Month 2 (1 month after second vaccination)*

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## **Safety and tolerability**

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

## **Immunogenicity**

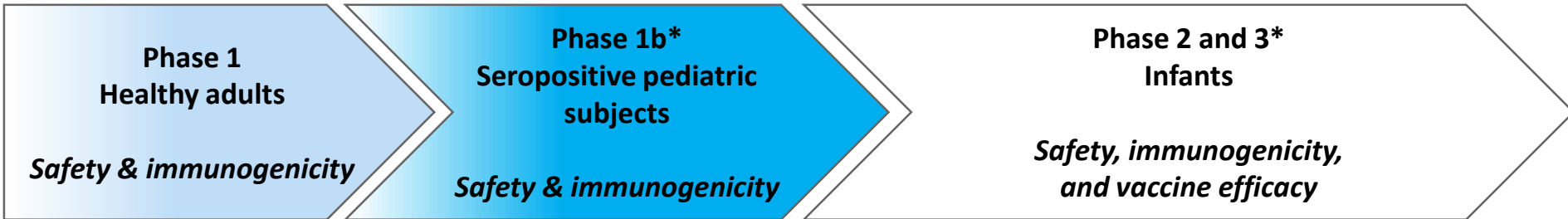
- Single vaccination boosted serum neutralization titers against hMPV and PIV3 at all dose levels tested
- Neutralizing antibodies against hMPV and PIV3 present at baseline in all subjects, consistent with prior exposure to both viruses
- 1 month after a single vaccination, hMPV and PIV3 neutralization 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

*Full data to be presented at future medical meeting*

# hMPV+PIV3 vaccine (mRNA-1653)

Next step: Phase 1b in pediatric population

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\*Clinical development plan contingent on regulatory feedback

*Pediatric Phase 1b planning in progress*

# Special note regarding forward-looking statements

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