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

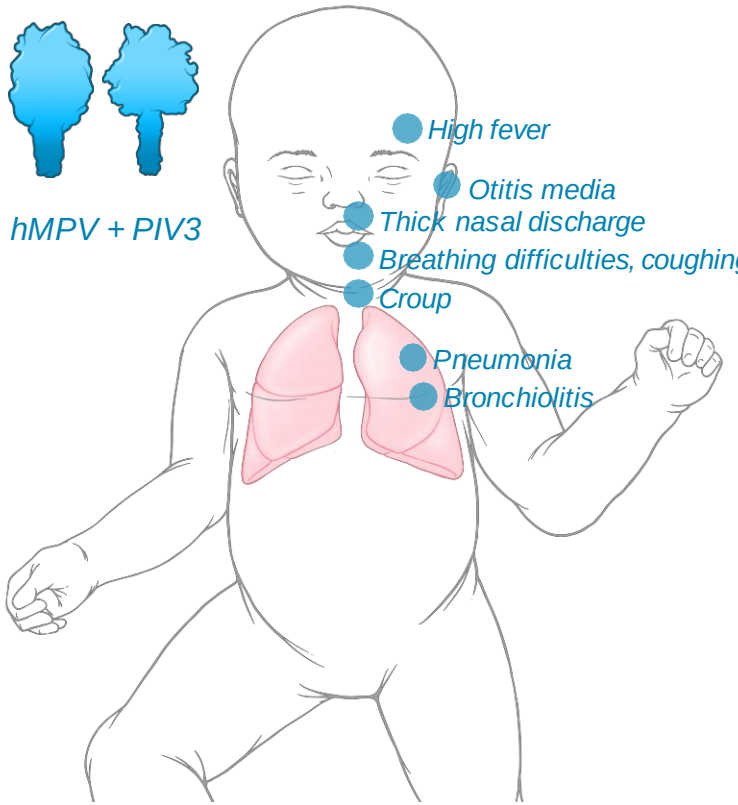
Last program update: October 2, 2019

Modality	Program #	Program	Preclinical dev elopment	Phase 1	Phase 2	Phase 3 and commercial	Moderna rights
Prophylactic Vaccines	m RNA-1172	RSV vaccine					Merck to pay milestones and royalties
	m RNA-1777	RSV vaccine					
	m RNA-1647	CMV vaccine					Worldw ide
	m RNA-1653	hMPV+PIV3 vaccine					Worldw ide
	m RNA-1440	Influenza H10N8 vaccine					Worldw ide *Advancing subject to funding*
	m RNA-1851	Influenza H7N9 vaccine					Worldw ide *Advancing subject to funding*
	m RNA-1893	Zika vaccine					Worldw ide *BARDA funded*
	m RNA-1388	Chikungunya vaccine					Worldw ide *Advancing subject to funding*

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)



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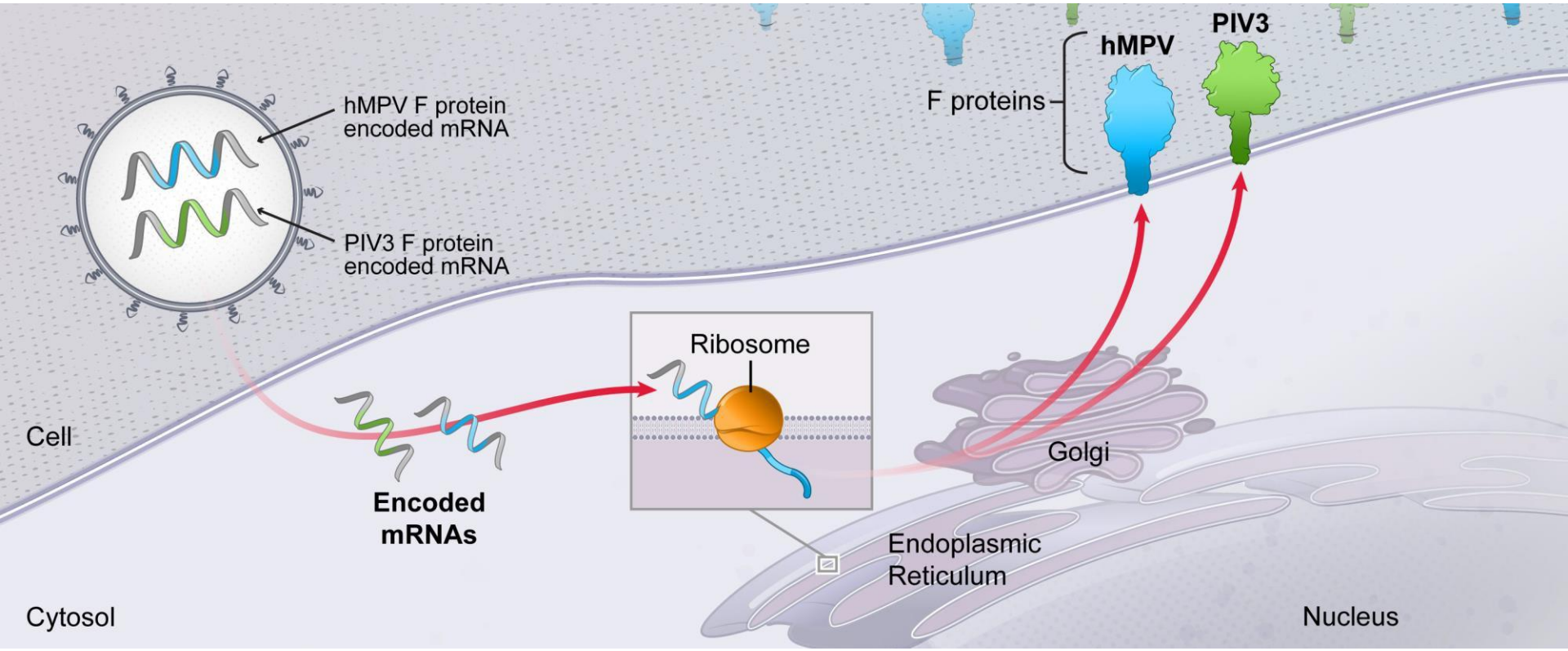
hMPV+PIV3 vaccine combines mRNAs encoding antigens from two different viruses



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

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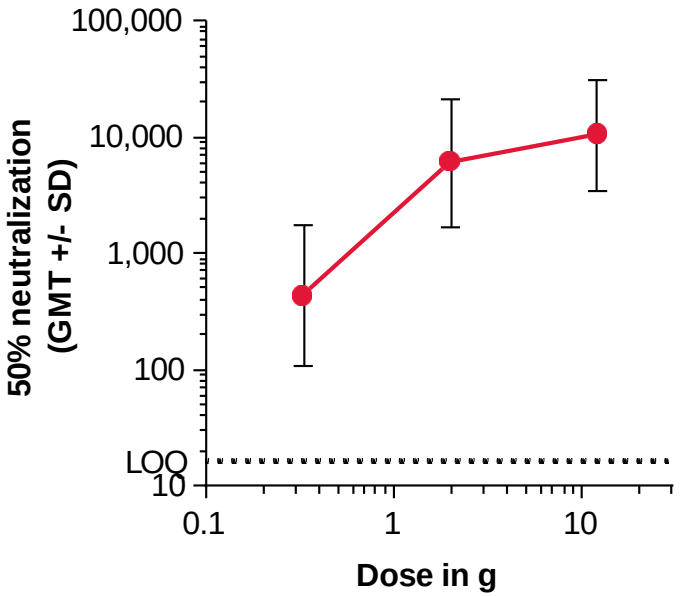
hMPV+PIV3 vaccine (mRNA-1653)

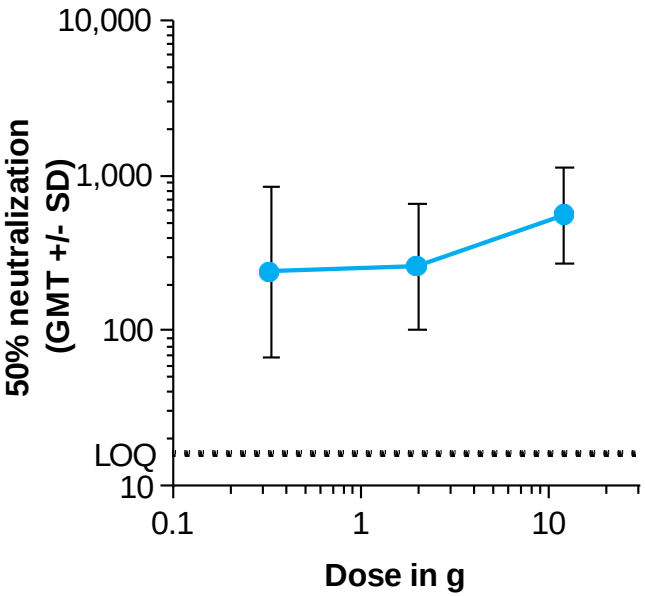
Pre-clinical data – combo vaccine generates neutralizing titers against each virus

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

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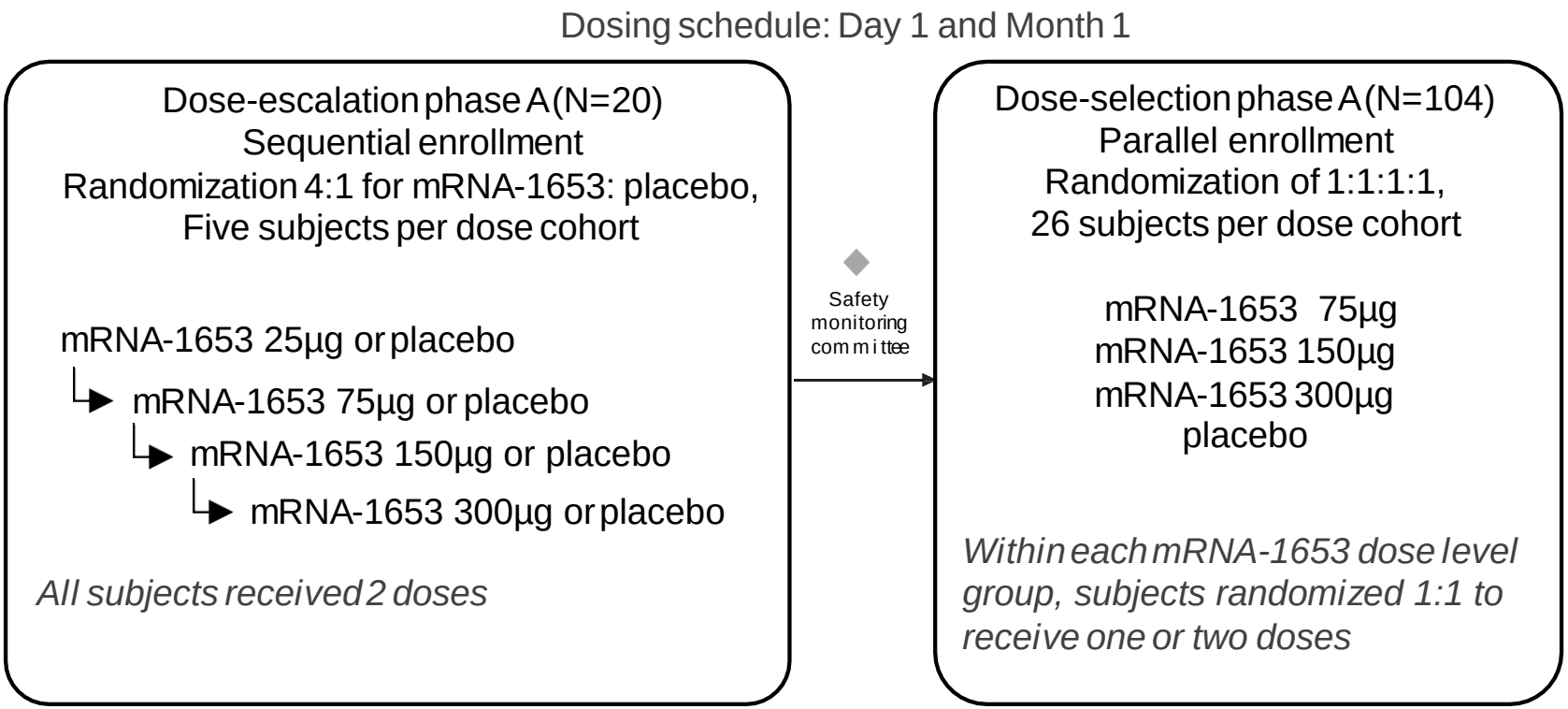
hMPV+PIV3 vaccine (mRNA-1653)

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



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hMPV+PIV3 vaccine (mRNA-1653)

Phase 1 in healthy adults

Interim results, through 1 month

Unsolicited Adverse Events, Through 28 Days After Each Vaccination Exposed Set

Dose Level (µg)	25	75		150		300		Placebo
Dose Schedule	2-dose	1-dose	2-dose	1-dose	2-dose	1-dose	2-dose	
N	4	13	17	13	17	13	17	30
≥ 1 event	3 (75.0)	3 (23.1)	5 (29.4)	4 (30.8)	5 (29.4)	6 (46.2)	7 (41.2)	5 (16.7)
≥ 1 *related* event	0	0	1 (5.9)	1 (7.7)	3 (17.6)	3 (23.1)	3 (17.6)	0
≥ 1 Grade 3+ event	0	0	0	0	0	1 (7.7)	2 (11.8)	0
≥ 1 *related* Grade 3+ event	0	0	0	0	0	1 (7.7)	2 (11.8)	0
≥ 1 SAE	0	0	0	0	0	0	0	0
≥ 1 medically-attended event	0	1 (7.7)	1 (5.9)	0	0	5 (38.5)	3 (17.6)	0
≥ 1 AESI	0	0	0	0	0	0	0	0
≥ 1 AE leading to withdrawal	0	0	0	0	0	0	0	0

Reported as number of subjects reporting event (% of subjects reporting event)
N = number of subjects enrolled in the specified treatment group; SAE = serious adverse events; AESI = adverse events of special interest

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

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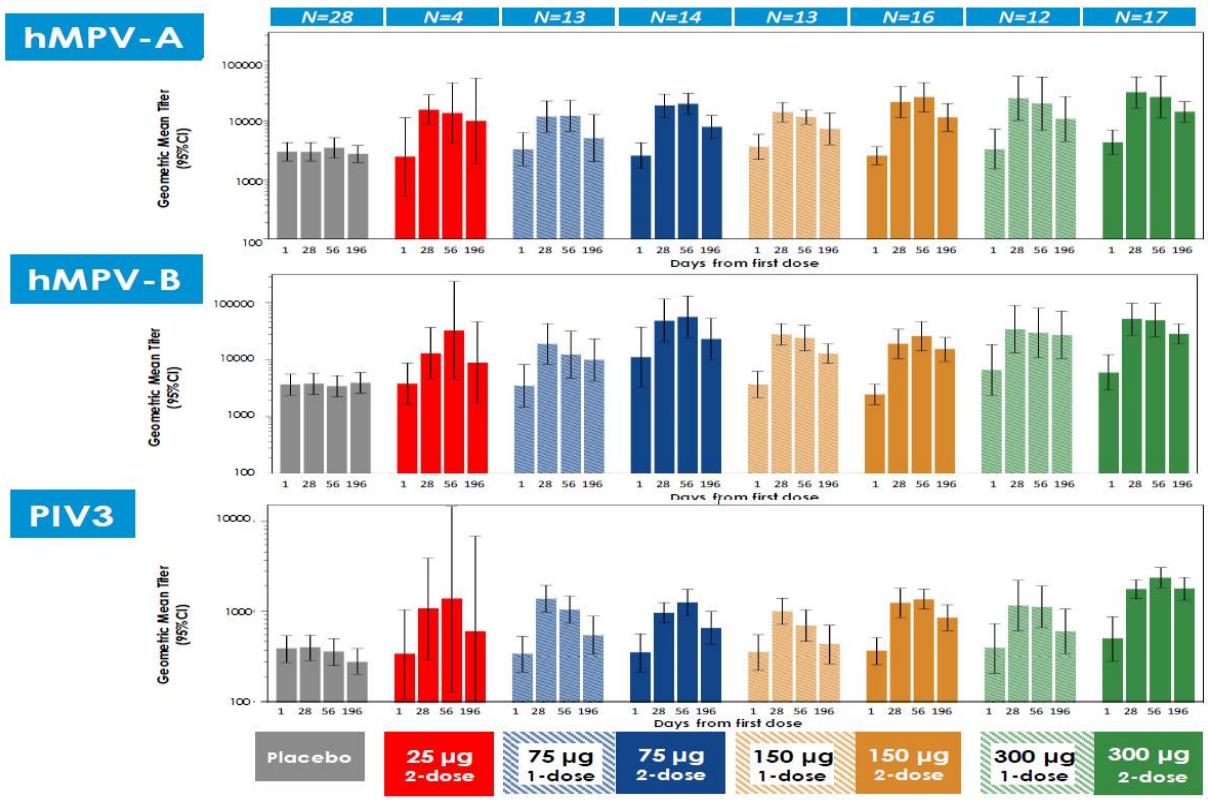
hMPV+PIV3 vaccine (mRNA-1653)

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

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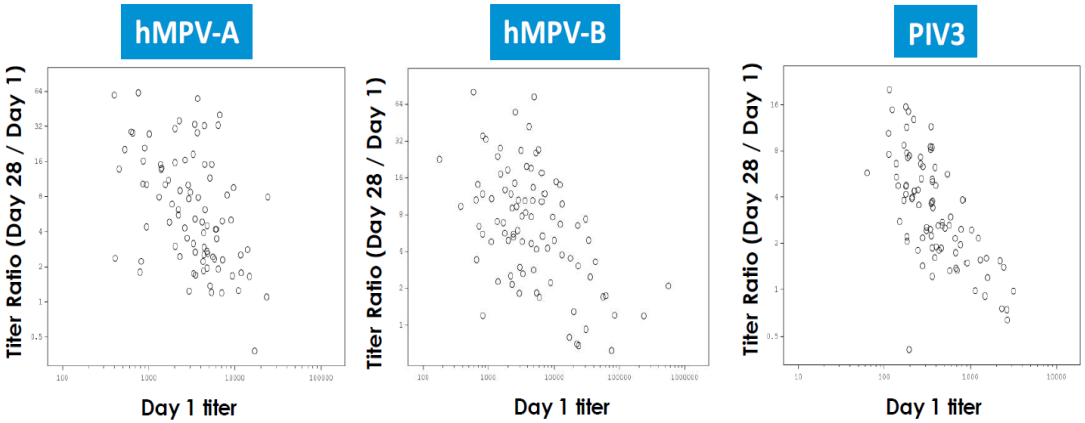
hMPV+PIV3 vaccine (mRNA-1653)

Phase 1 in healthy adults

Interim results, through 1 month

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



- 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

Geometric Mean Titer Ratio Day 28 / Day 1

	total mRNA N=90	Placebo N= 28
hMPV-A	6.04	1.00
hMPV-B	6.33	1.04
PIV3	3.24	1.03

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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
- 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

Interim results through 7 months presented at IDWeek Conference, 2019

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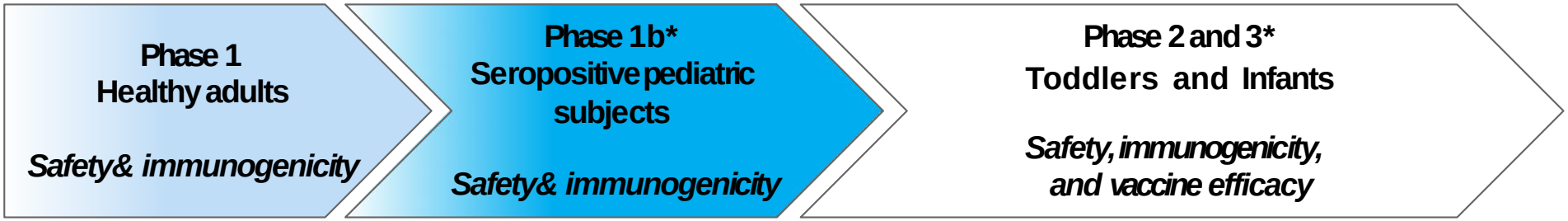
hMPV+PIV3 vaccine (mRNA-1653)

Next step: Phase 1b in pediatric population



*Clinical development plan contingent on regulatory feedback

Pediatric Phase 1b in seropositive toddlers preparing to start

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