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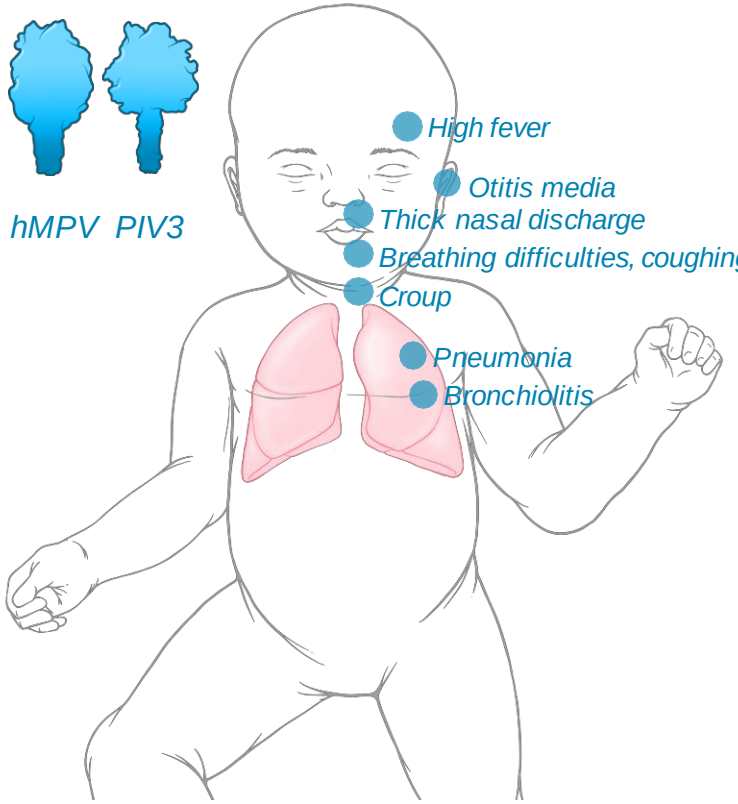
Human metapneumovirus (hMPV) and para-influenza virus 3 (PIV3) vaccine (mRNA-1653)

Last program update: May 7, 2020

Modality	ID #	Program	Preclinical development	Phase 1	Phase 2	Phase 3 and commercial	Moderna rights
Prophylactic vaccines	mRNA-1273	Novel coronavirus (SARS-CoV-2) vaccine					Worldwide *BARDA funded*
	mRNA-1647	Cytomegalovirus (CMV) vaccine					Worldwide
	mRNA-1653	hMPV/PIV3 vaccine		Phase 1 (healthy volunteers)	Phase 1b (Age de-escalation) Seropositives		Worldwide
	mRNA-1172/ Merck V172	Respiratory syncytial virus (RSV) vaccine					Merck to pay milestones and royalties
	mRNA-1777	Respiratory syncytial virus (RSV) vaccine					
	mRNA-1893	Zika vaccine					Worldwide *BARDA funded*
	mRNA-1345	Pediatric respiratory syncytial virus (RSV) vaccine *Future respiratory combo*					Worldwide
	mRNA-1189	Epstein-Barr virus (EBV) vaccine					Worldwide
	mRNA-1851	Influenza H7N9 vaccine					Worldwide *Advancing subject to funding*

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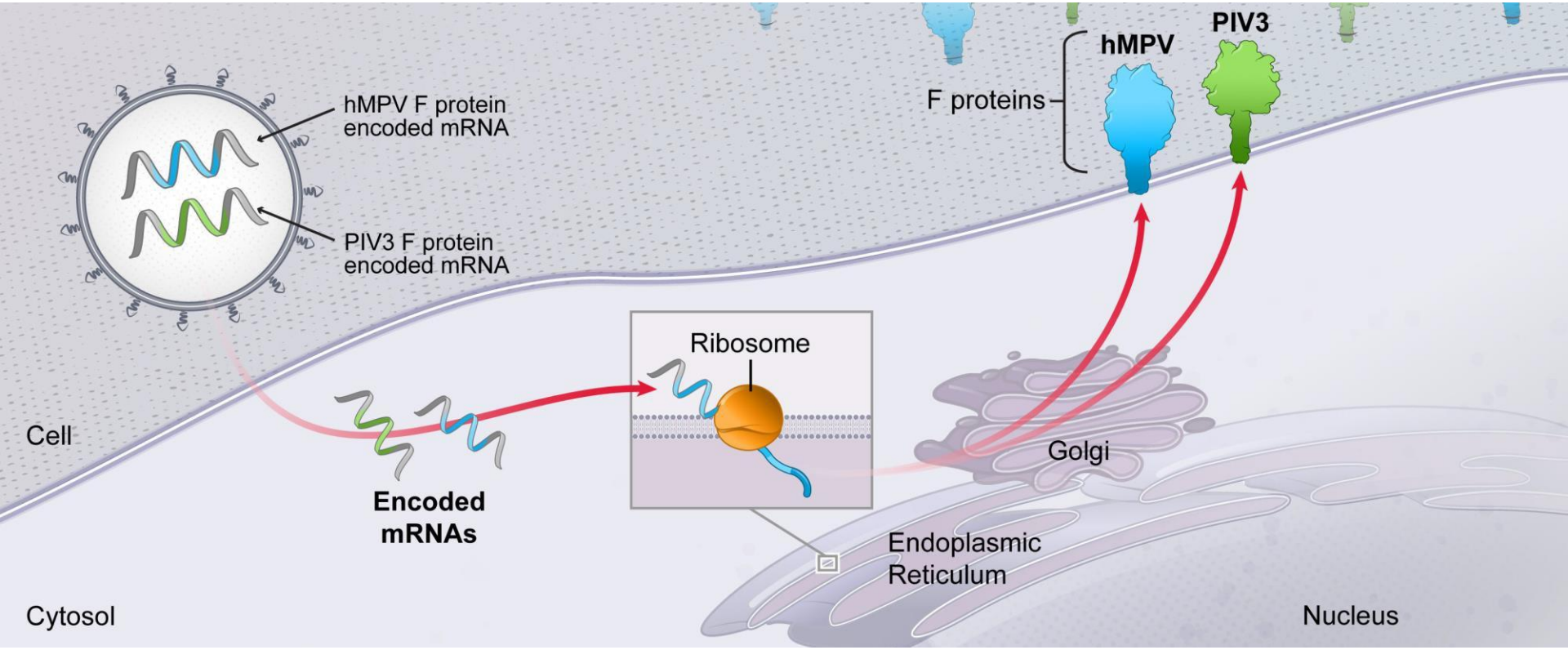
hMPV/PIV3 vaccine combines mRNAs encoding antigens from two different viruses



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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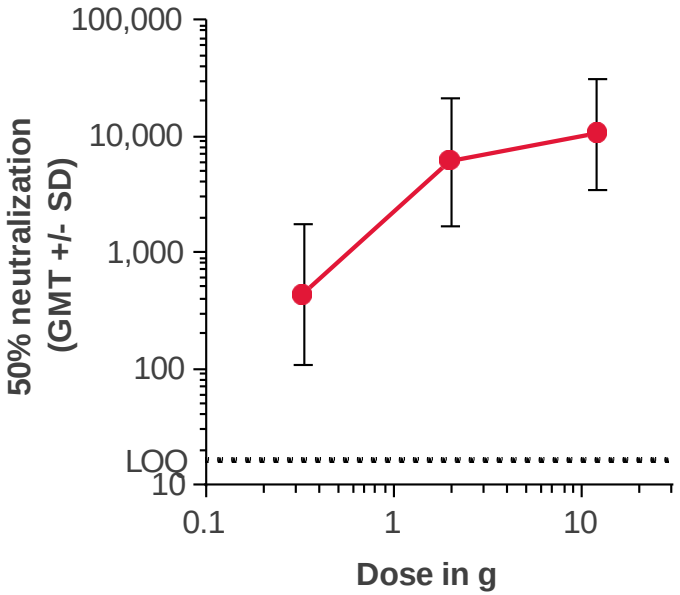
hMPV/PIV3 vaccine (mRNA-1653)

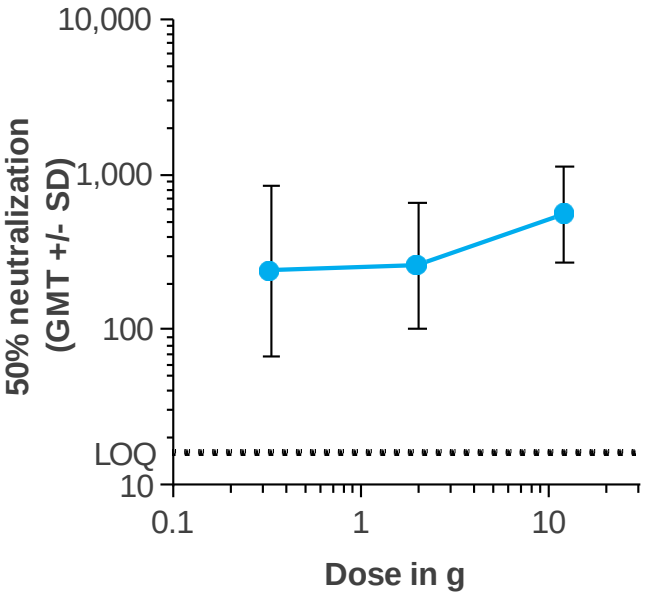
Preclinical data – combo vaccine generates neutralizing titers against each virus

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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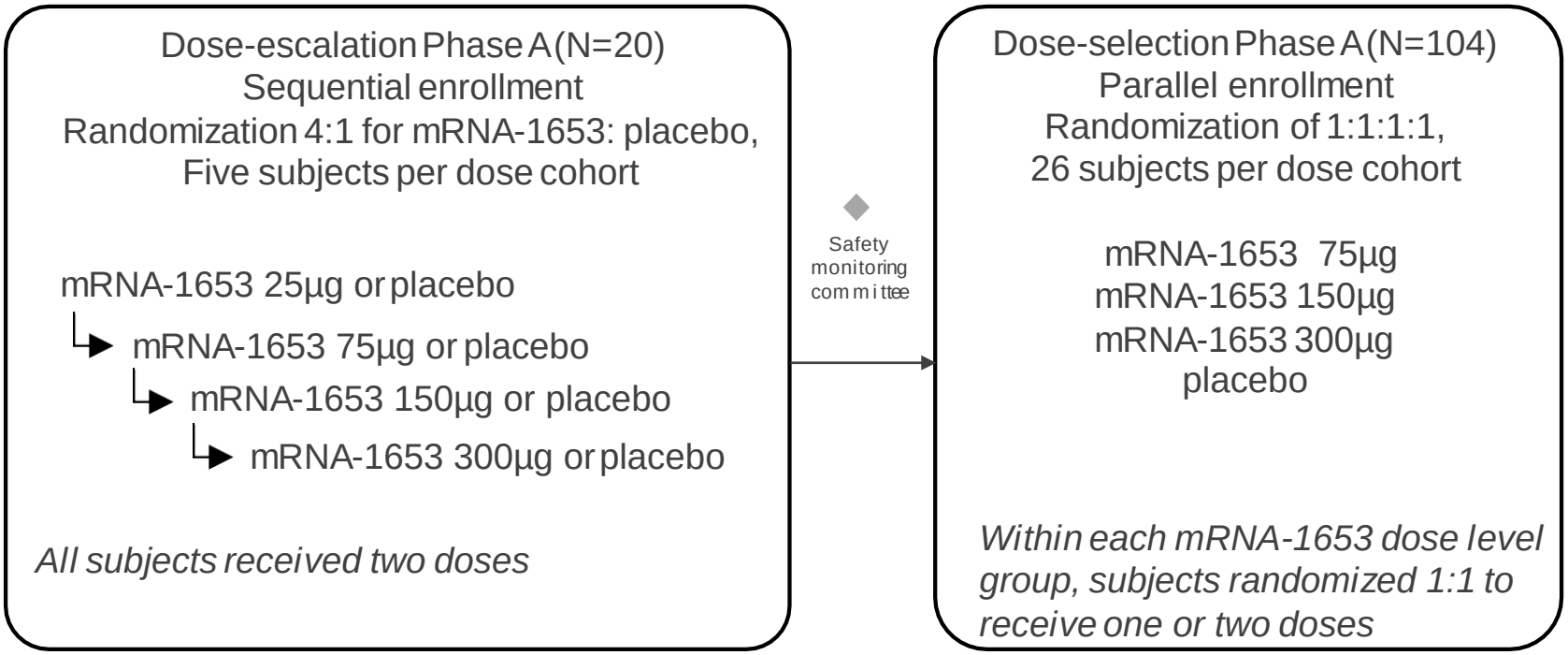
hMPV/PIV3 vaccine (mRNA-1653)

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

Dosing schedule: Day 1 and month 1



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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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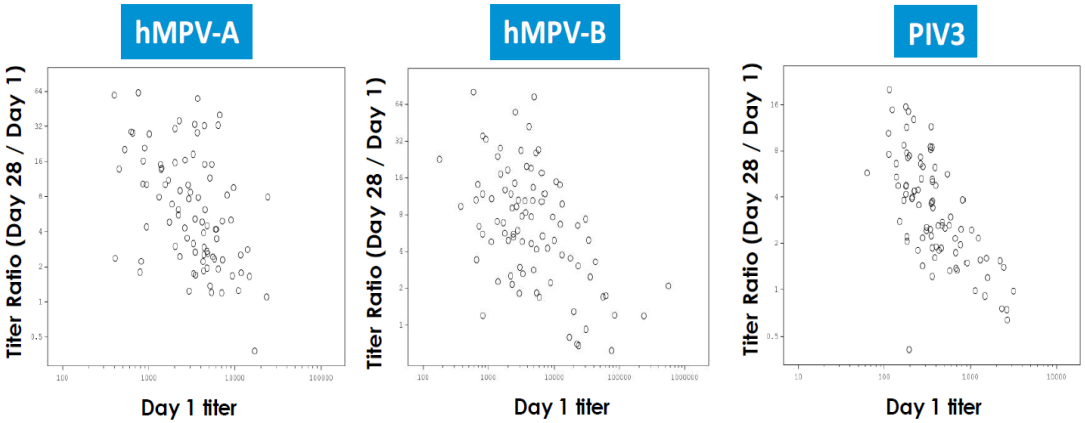
hMPV/PIV3 vaccine (mRNA-1653)

Phase 1 in healthy adults; Interim results, through 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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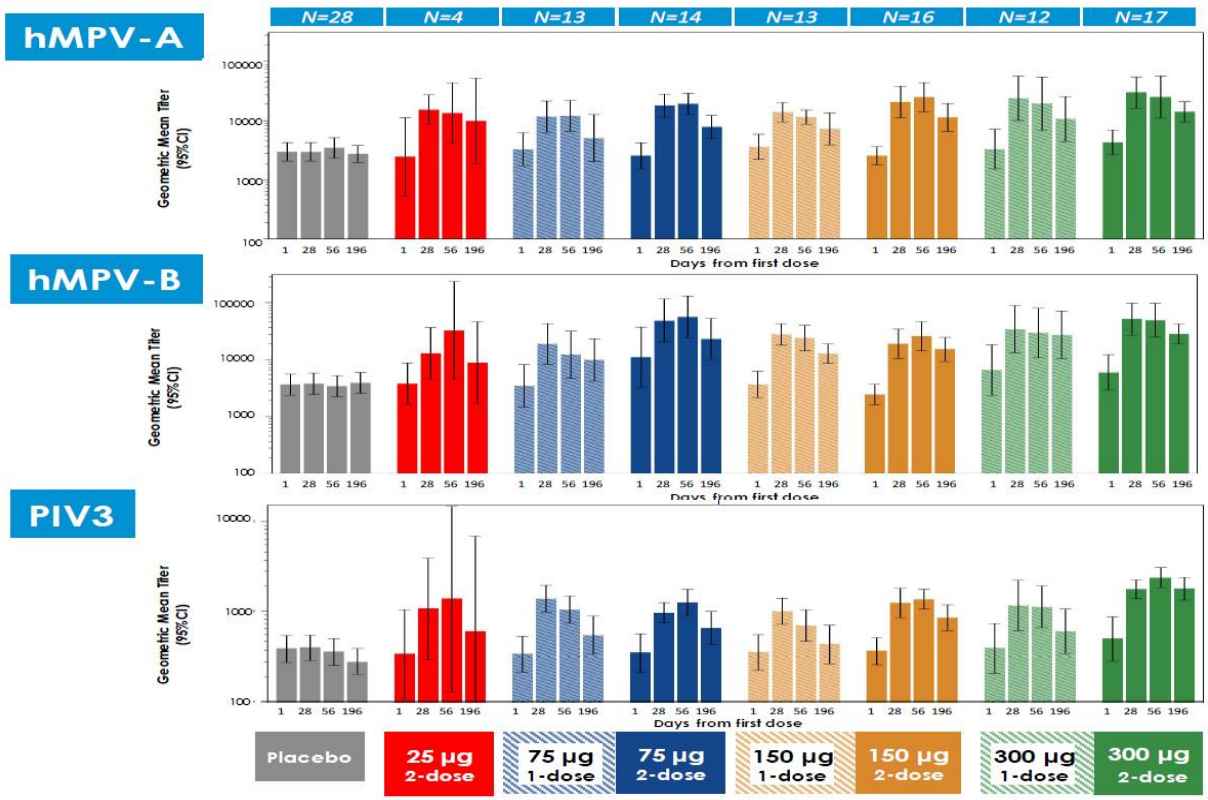
hMPV/PIV3 vaccine (mRNA-1653)

Phase 1 in healthy adults; 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; 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 testedmRNA-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

Interim results through 7 months presented at IDWeek Conference, 2019

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hMPV/PIV3 vaccine (mRNA-1653)

Phase 1b age de-escalation study suspended due to COVID-19 impact

*Clinical development plan contingent on regulatory feedback

Due to the pandemic, enrollment of participants in the on-going hMPV/PIV3 study (mRNA-1653) has been suspended. The study had had been actively enrolling seropositive pediatric participants (12-36 months of age)[1]

1. Intend to work with appropriate medical and site personnel to determine when to resume new enrollment

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Forward-looking statements

This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended including, but not limited to, statements concerning potential development candidate applications, development candid ate activities, preclinical and clinical studies, regulatory submissions and approvals, risk management and estimates and forward -looking projections with respect to Moderna or its anticipated future performance or events. In some cases, forward -looking statements can be identified by terminology such as “may,” “should,” “expects,” “intends,” “plans,” “aims,” “anticipates,” “believes,” “estimat es,” “predicts,” “potential,” “continue,” or the negative of these terms or other comparable terminology, although not all forward -looking statements contain these words. The forward-looking statements in this presentation are neither promises nor guarantees, and you should not place undue reliance on these forward-looking statements because they involve known and unknown risks, uncertainties and other factors, many of which are beyond Moderna’s control and which could cause actual results to differ materially from those expressed or implied by these forward -looking statements. These risks, uncertainties and other factors include, among others: preclinical and clinical development is lengthy and uncertain, especially for a new category of medicines such as mRNA, and therefore Moderna’s preclinical programs or development candidates may be delayed, terminated, or may never advance to or in the clinic; no mRNA drug has been approved in this new p otential category of medicines, and may never be approved; mRNA drug development has substantial clinical development and regulatory r isks due to the novel and unprecedented nature of this new category of medicines; and those described in Moderna’s most recent Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (SEC) and in subsequent filings made by Moderna with SEC, which are available on the SEC's website at www.sec.gov. Except as required by law, Moderna disclaims any intention or responsibility for updating or revising any forward-looking statements in this presentation in the event of new information, future developments or otherwise. These forward-looking statements are based on Moderna’s current expectations and speak only as of the date hereof.

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