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Antibody against Chikungunya virus (mRNA-1944)

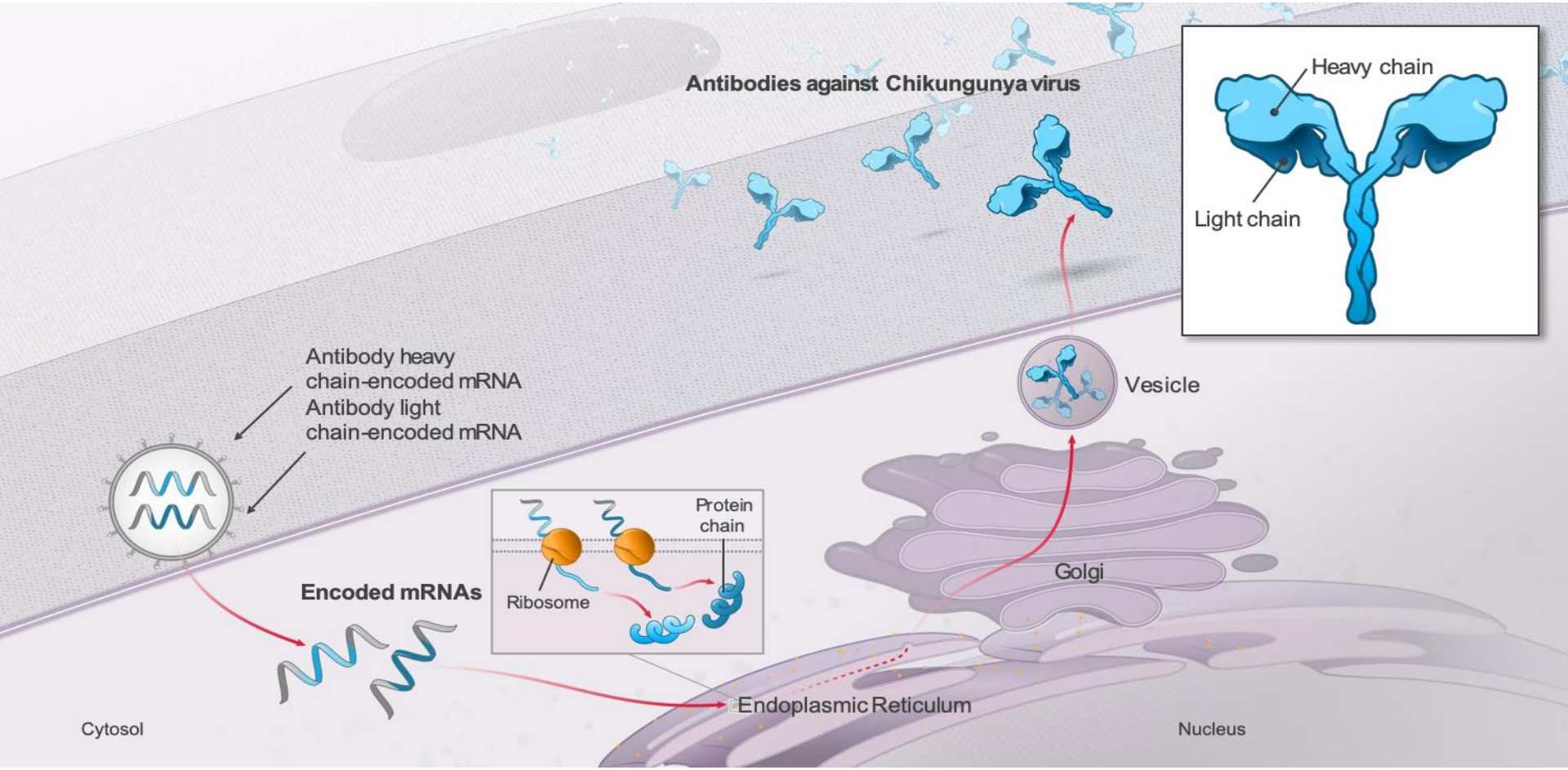
Last program update: May 7, 2020

Modality	ID #	Program *Indication*	Preclinical development	Phase 1	Phase 2	Phase 3 and commercial	Moderna rights
Systemic secreted & cell surface therapeutics	**mRNA-1944**	Antibody against Chikungunya virus					Worldwide *DARPA funded*
	AZD7970	Relaxin *Heart failure*					50-50 U.S. profit sharing; AZ to pay royalties on ex-U.S. sales
	mRNA-6981	PD-L1 *Autoimmune hepatitis*					Worldwide
	mRNA-6231	IL-2 *Autoimmune disorders*					Worldwide

Positive Phase 1 data reported

Antibody against Chikungunya virus (mRNA-1944)

mRNA-1944 contains two mRNAs that encode for the heavy and light chains of CHKV-24 antibody, which may confer passive immunity



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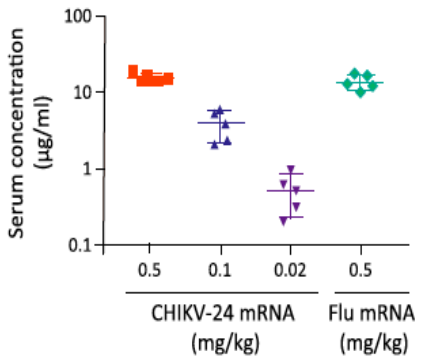
Antibody against Chikungunya virus (mRNA-1944)

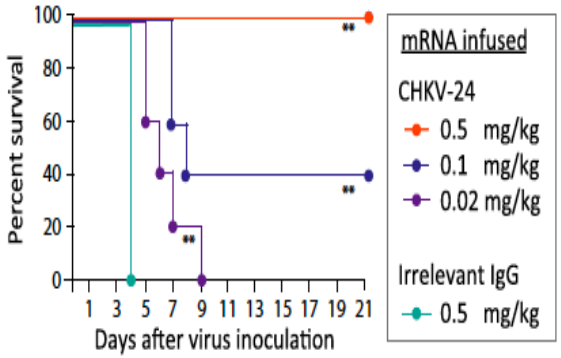
Preclinical evidence that mRNA-1944 encodes for functional antibody against Chikungunya virus

Species: Mouse

Expression of antibody against Chikungunya virus



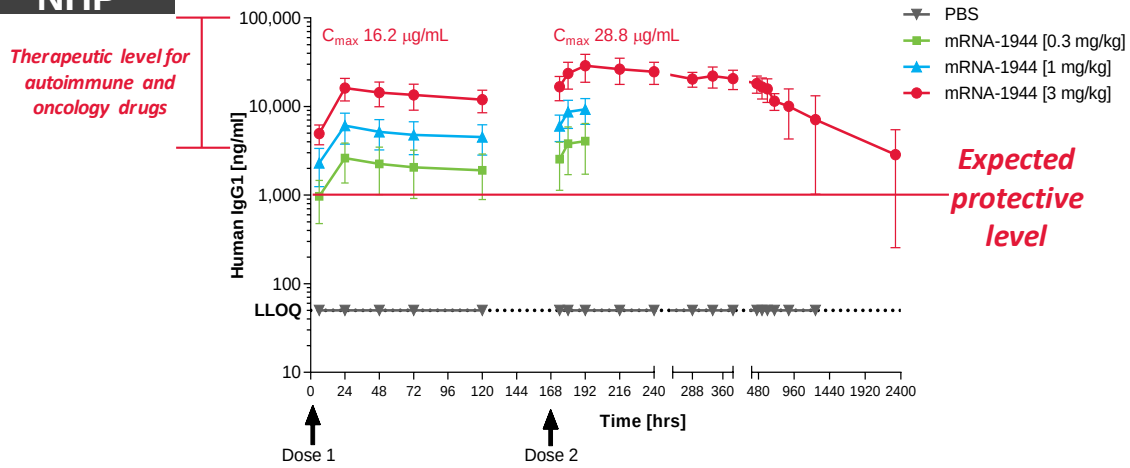
Survival after prophylactic vaccination with mRNA-1944



Science Immunology MAY 2019

Species: NHP

Expression of antibody against Chikungunya virus with repeat dosing of mRNA-1944 in non-human primate study



mRNA-1944 produces an antibody against Chikungunya virus that is

- Functional
- Protective
- Translates between pre-clinical species

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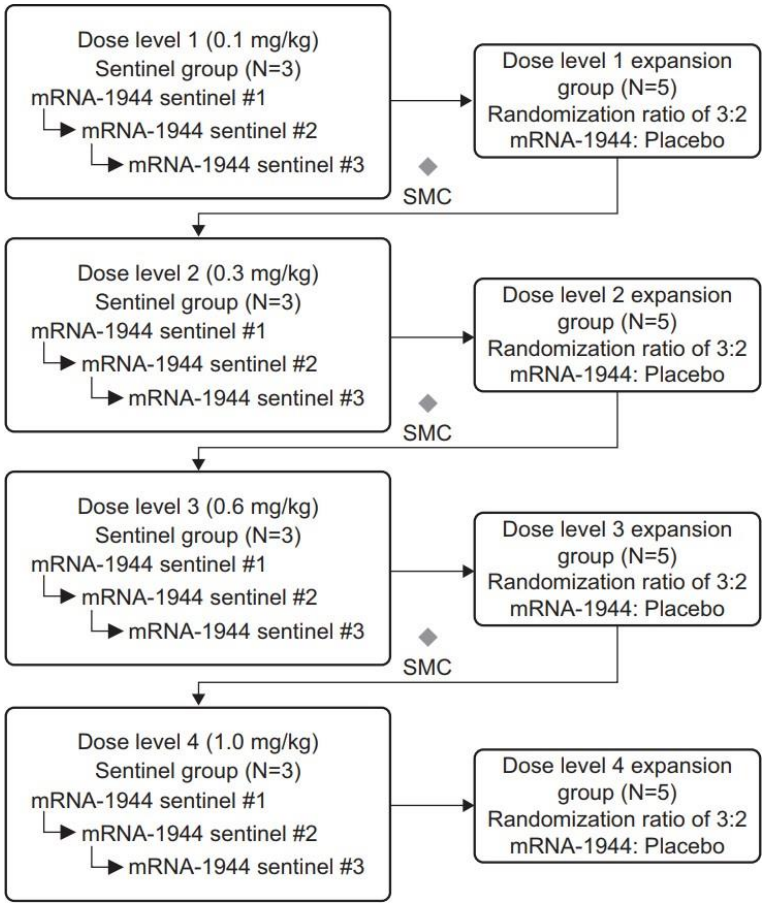
Antibody against Chikungunya virus (mRNA-1944)

Trial design

- Randomized, placebo-controlled, single ascending dose study in healthy adults
- All subjects received premedication with antihistamines
- No subjects received corticosteroids (permitted by protocol)



Key Objectives

- **Safety:** Evaluate safety and tolerability of escalating doses of mRNA-1944 administered via intravenous infusion
- **Translation of protein:** Evaluate pharmacology of mRNA-1944
- **Activity:** Determine ability of antibody to neutralize viral infection

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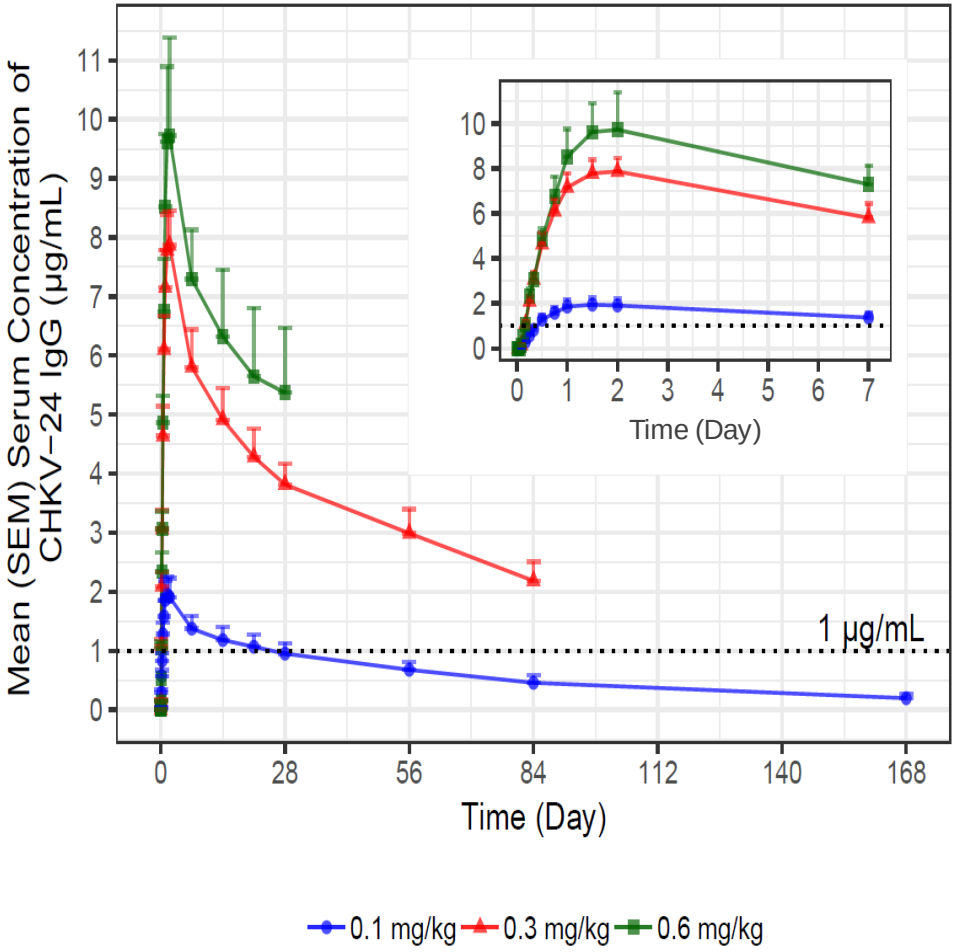
Antibody against Chikungunya virus (mRNA-1944)

Protective antibody levels of >1µg/mL expected to endure at least 16 weeks at the middle dose of 0.3 mg/kg



Cohort	0.1 mg/kg (N=6)	0.3 mg/kg (N=6)	0.6 mg/kg (N=4)
C_{max} (µg/mL)	2.0	7.9	10.2
C_{max} range (µg/mL)	1.1-3.1	6.3-10.0	7.0-14.2
C_{max} % CV	40.6%	18.2%	29.7%

Pharmacology

- Administration of mRNA-1944 resulted in dose-related increase in levels of CHKV-24
- Half life ($t_{1/2}$) of antibody was 62 days
- Middle and high dose (0.3 and 0.6 mg/kg) projected to exceed 1 µg/mL target for at least 16 weeks

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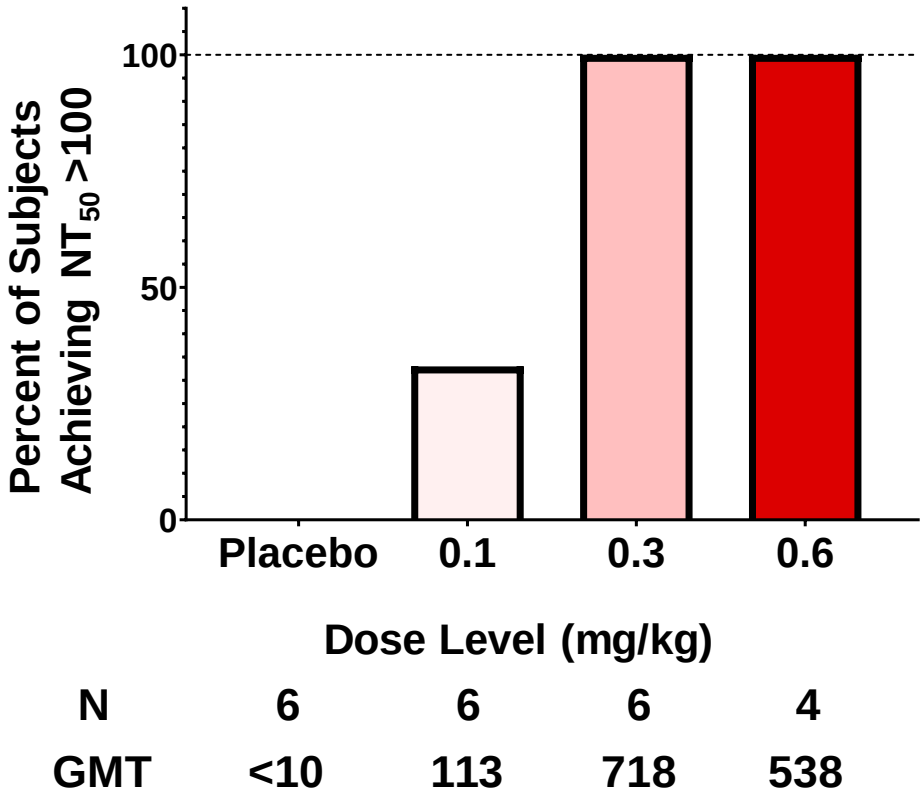
Antibody against Chikungunya virus (mRNA-1944)

mRNA-1944 driven protein expression results in functional antibody (CHKV-24)

Serum neutralization activity 48 hr after mRNA-1944 administration



- Neutralizing antibody titers observed at all dose levels, indicating functional antibody production by mRNA-1944
- All placebo subjects below the lower limit of detection
- 100% of subjects administered 0.3 and 0.6 mg/ kg had titers >100

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Antibody against Chikungunya virus (mRNA-1944)

Summary of related adverse events

Cohort		Grade 1	Grade 2	Grade 3
Placebo (N=6)		None	None	None
mRNA-1944 0.1 mg/kg (N=6)		Feeling of warmth, transient (1)	None	None
mRNA-1944 0.3 mg/kg (N=6)		None	None	None
mRNA-1944 0.6 mg/kg (N=4)	*Subject 1*	Sinus tachycardia, fever, infusion associated shivering, lightheadedness, hypotension	None	None
	Subject 2	None	Nausea, emesis	None
	Subject 3	None	None	None
	Subject 4	Chills, headache, lightheadedness, gaseousness	EKG abnormal (T w ave inversion), emesis, nausea, fever	Sinus tachycardia, elevated WBC

- All AEs were transient and resolved spontaneously without treatment
- No serious AEs in the study
- No meaningful changes in liver or kidney laboratory results

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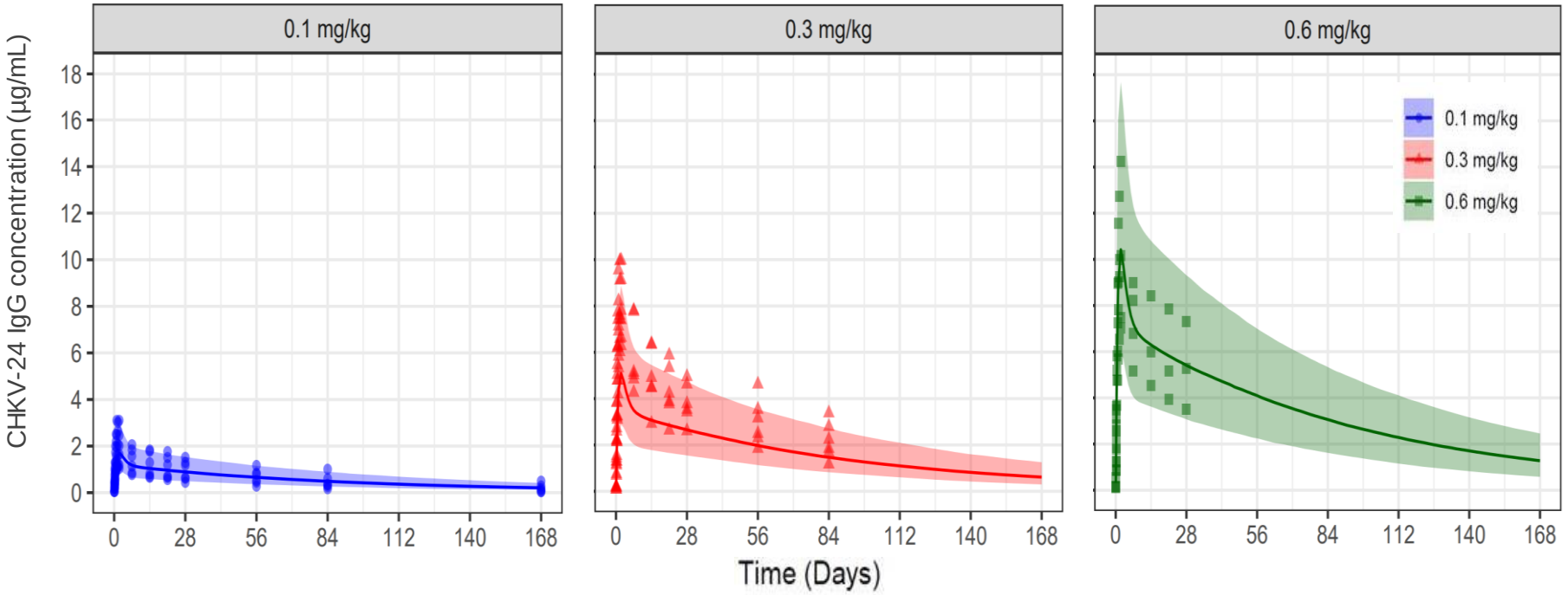
Antibody against Chikungunya virus (mRNA-1944)

Translation from preclinical species to humans



Solid line = Median predicted
Shaded area = 90% prediction interval
Symbols = Individual participant observations

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Summary

- Administration of mRNA-1944 resulted in dose-dependent increases in levels of antibody against Chikungunya (CHKV-24)
- Neutralizing antibodies were observed at all dose levels, indicating functional antibody production by mRNA-1944
- None of the participants treated with mRNA-1944 at the low (0.1 mg/kg) or middle (0.3 mg/kg) doses experienced significant AEs. Three of the four participants at the high (0.6 mg/kg) dose had infusion related AEs, with the highest grade by subject being Grade 1 (n=1), Grade 2 (n=1) and Grade 3 (n=1)
- mRNA-1944 at 0.3 mg/kg and 0.6 mg/kg provides antibody levels that are expected to be protective against Chikungunya infection (>1 µg/mL) for at least 16 weeks, supporting further development
- mRNA to protein translation in human was predicted by preclinical data
- **Next steps**: Moderna has been notified that the enrollment of further subjects in the Phase 1 study of mRNA-1944 has been paused by the site due to the impact of COVID-19. Moderna owns worldwide commercial rights to mRNA-1944.

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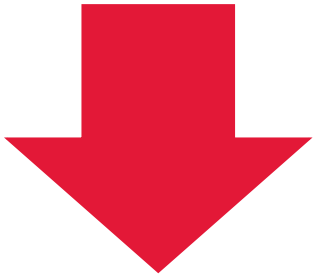
mRNA-1944 enables Moderna's systemic therapeutics

- For the first time, the systemic administration of an mRNA containing LNP has been demonstrated to produce a fully functional complex protein in humans
- Dose dependent pharmacology has been fully predicted from preclinical species with no loss of potency
- Target therapeutic concentrations have been achieved at a well tolerated dose in a healthy volunteer population



- We believe these data strongly support the continued development of our systemic rare disease therapeutic modality that targets both secreted and intracellular proteins

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