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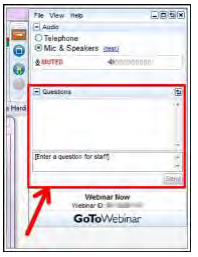


Type them into questions box!

**"Why am I muted?"**
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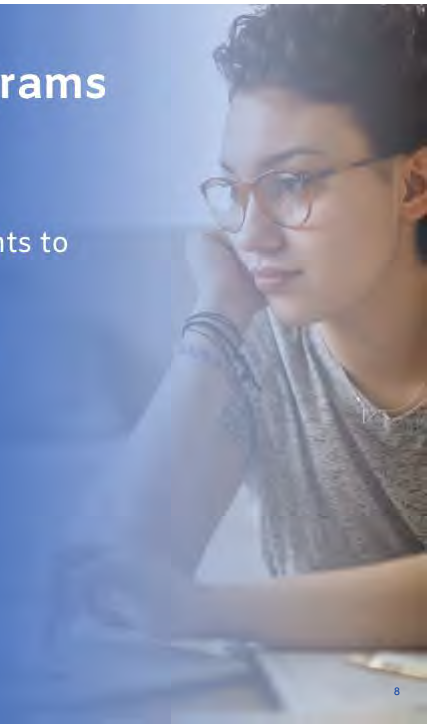

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aaps American Association of Pharmaceutical Scientists

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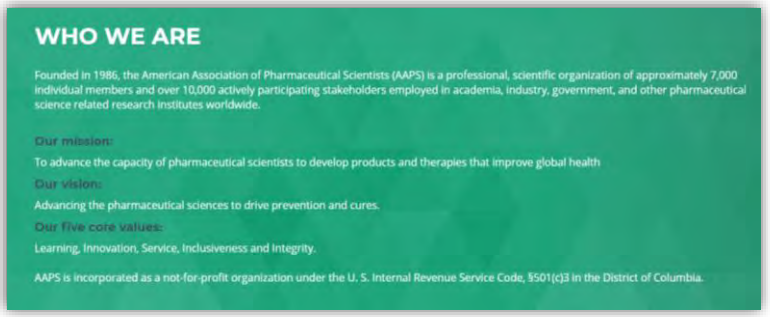


Members of the American Association of Pharmaceutical Scientists (AAPS) gathered during the 2013 AAPS Annual Meeting and Exposition to discuss why they chose a career in pharmaceutical sciences and how AAPS has helped foster their journey. The I Am AAPS video series displays the diversity of AAPS membership while exhibiting one common goal: to impact global health.

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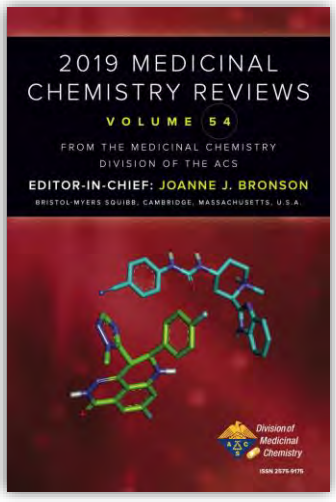


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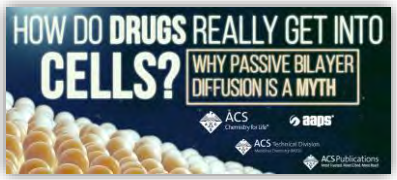
Join Angela Zhou, an Information Scientist at CAS, as she provides an overview of published scientific information relevant to COVID-19 research with an emphasis on patents in the CAS content collection. https://www.acs.org/content/acs/en/acs-webinars/drug-discovery/covid-19.html


Join Research Fellow Li Di of Pfizer as she discusses why design principles that increase passive permeability are effective approaches to increase oral bioavailability, enhance brain penetration, and reduce renal clearance.
https://www.acs.org/content/acs/en/acs-webinars/drug-discovery/passive-permeability.html




Join Douglas Kell, Research Chair in Systems Biology at the University of Liverpool to discover how drugs pass through cell membrane solely by hitchhiking on membrane transporters and why so-called "passive diffusion" through any bilayer in real cells is negligible.
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Tuesday, June 2, 2020 at 2-3pm ET
Speaker: Sandra Lung, Post Road Consulting
Moderator: Tom Halleran, American Chemical Society

Register for Free!

What You Will Learn

- Best practices for connecting on LinkedIn
- How to find people, companies, and opportunities to help you get referred
- How to take advantage of LinkedIn career features

Co-produced with: ACS Career Navigator


Wednesday, June 3, 2020 at 2-3pm ET
Speaker: Mary Beth Mulcahy, *ACS Chemical Health & Safety*
Moderator: Kali Miller, American Chemical Society

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What You Will Learn

- Strategies to prepare a well-organized, carefully crafted manuscript
- Tips on making compelling graphical elements, selecting a strong title and writing an impactful cover letter
- The chance to have an ACS Editor answer your questions about the publishing process

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Thursday, June 4, 2020 at 2-3pm ET
Speakers: Luis Echegoyen, University of Texas, El Paso / Peter Dorhout, Kansas State University / Davita Camp, Spelman College
Moderator: TBD

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What You Will Learn

- The impact of COVID-19 on researchers
- What the process of restarting research will look like
- What funding agencies and policymakers can do to ease the transition

Co-produced with: ACS External Affairs and Communications


Friday, June 5, 2020 at 2-3pm ET
Speaker: Paul Hodges, International Echem
Moderator: Bill Carroll, Carroll Applied Science

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What You Will Learn

- How developing patterns of consumption, deflation, changes in behavior will affect the market
- Applying Elisabeth Kübler Ross' Paradigm of Loss model in relation to the COVID-19 pandemic and ensuing economic crisis
- Six key questions to determine if your company will survive and prosper

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mRNA Technology for Infectious Diseases: Therapeutic Applications and Vaccine Development

**Jim Thompson**
CMC Therapeutic Area Lead,
Moderna, Inc.

**Venkat Krishnamurthy**
Associate Principal Scientist, Advanced
Drug Delivery Group, AstraZeneca

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# mRNA Technology for Infectious Diseases: Therapeutic Applications and Vaccine Development

James D. Thompson, Ph.D.
CMC Therapeutic Area Lead,
Moderna

## Forward-looking statements and disclaimers

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; the impact of the SARS-CoV-2 pandemic on the Company's clinical trials and operations; the timing and finalization of a dose-confirmation Phase 2 study and planning for a pivotal Phase 3 study for mRNA-1647; the status and outcome of the Phase 1 clinical trial for mRNA-1273 being conducted by NIH; the next steps and ultimate commercial plan for mRNA-1273; the size of the potential market opportunity for mRNA-1273; the size of the potential commercial market for novel vaccines produced by Moderna or others; the potential peak sales for the Company's wholly-owned vaccines; the probability of success of the Company's vaccines individually and as a portfolio; and the ability of the Company to accelerate the research and development timeline for any individual product or the platform as a whole. In some cases, forward-looking statements can be identified by terminology such as "will," "may," "should," "expects," "intends," "plans," "aims," "anticipates," "believes," "estimates," "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 press release 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: whether the interim or final Phase 1 results for mRNA-1647 and mRNA-1893 will be predictive of any future clinical studies for these or other development candidates with the same LNP formulation; preclinical and clinical development is lengthy and uncertain, especially for a new class of medicines such as mRNA, and therefore our 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 potential class of medicines, and may never be approved; mRNA drug development has substantial clinical development and regulatory risks due to the novel and unprecedented nature of this new class of medicines; despite having ongoing interactions with the FDA or other regulatory agencies, the FDA or such other regulatory agencies may not agree with our regulatory approval strategies, components of our or filings, such as clinical trial designs, conduct and methodologies, or the sufficiency of data submitted; the impact of the COVID-19 pandemic on the operation of the Company's clinical trials, pre-clinical work, and overall operations, including delays and inability to progress with certain clinical trials; and those risks and uncertainties described under the heading "Risk Factors" 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 the 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 contained 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. This presentation also contains estimates, projections and other statistical data made by independent parties and by Moderna relating to market size and growth and other data about Moderna's industry. These data involve a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions and estimates of Moderna's future performance and the future performance of the markets in which the Company operates are necessarily subject to a high degree of uncertainty and risk. Certain of the information contained herein is based upon or derived from information provided by third parties and industry sources. While the Company believes that such information is accurate and that the sources from which it has been obtained are reliable, the Company has not independently verified the assumptions on which such information is based. The Company makes no guarantee, express or implied, as to the accuracy and completeness of such information and has neither reviewed nor endorsed the content of third party information.



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## Agenda

- Company/technology background
- mRNA-based vaccines
  - CMV case history
- mRNA-based therapeutics for viral diseases
  - Chikugunya antibody case history
- Conclusions

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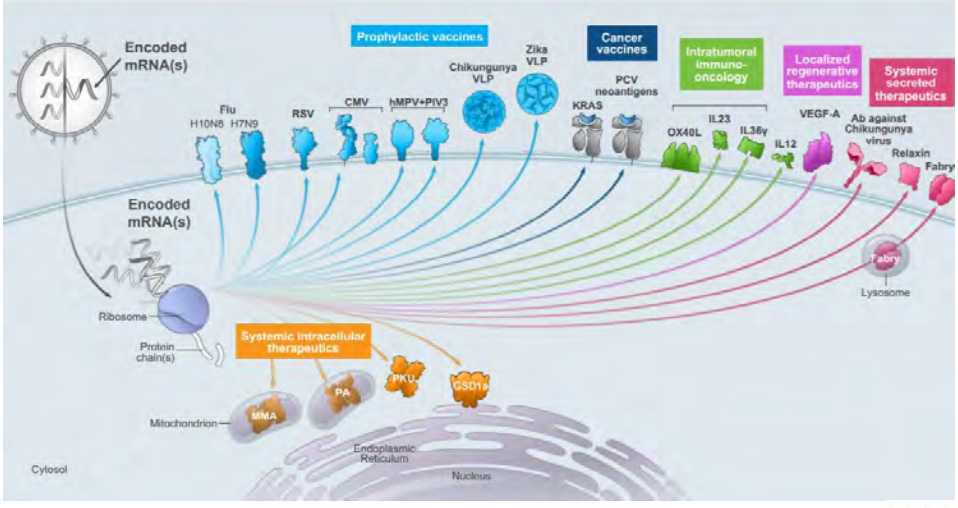
## Moderna Pipeline Beginning 2020

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# Moderna Manufacturing Facility


- 200,000 square foot facility operationalized July 2018
- High throughput, automated research-grade production
  - Can produce up to 1,000 mRNAs & formulations/month to supply Moderna and Partner discovery engines
  - ≤30-day turnaround
- cGMP manufacturing of Plasmid, Drug Substance, Drug Product & Fill/finish to supply early and late phase clinical demand (>100 clinical batches produced to-date)
- Personalized cancer vaccine production through to pack/labeled vials
- Full cGMP QC/release capabilities
- Automation and digital integration from built from ground up, including electronic batch records and real-time data capturing

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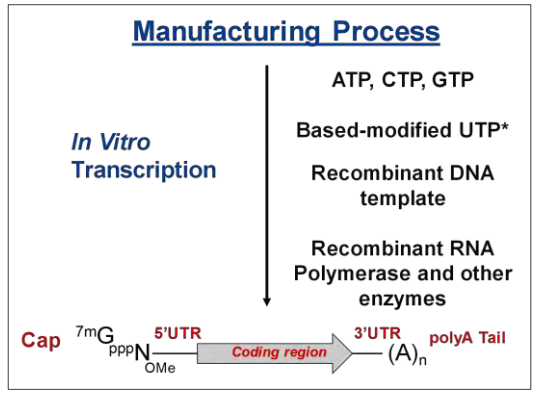
# Overview of mRNA Therapeutics

- mRNAs encode therapeutic proteins/enzymes that are produced by the patient's own body
- mRNAs are produced in a cell-free, *in vitro* transcription reaction
- Properties of mRNA therapies
  - Do not contain vector sequences
  - Do not need to enter the nucleus for activity
  - Do not interact with DNA
  - Do not integrate into the genome
  - Effect is transient and dose-dependent




*Moderna uses naturally-occurring pyrimidine base modifications to minimize indiscriminate recognition by pathogen-associated molecular pattern receptors

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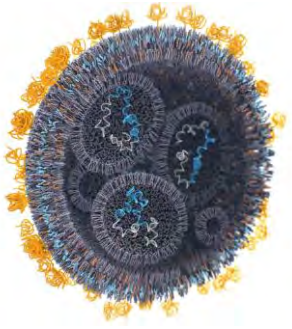
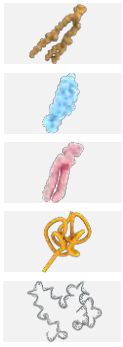
## mRNA-LNP formulations





Amino lipid '*ionizable*' → Drives potency/endosomal release

Cholesterol, Phospholipid → '*Structural lipids*' Stabilize/form membrane

PEG lipid '*hydrolyzable*' → Stabilize/shield LNP Shed in serum

mRNA → Encodes protein

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# Case History
# mRNA-1647 Cytomegalovirus (CMV) vaccine

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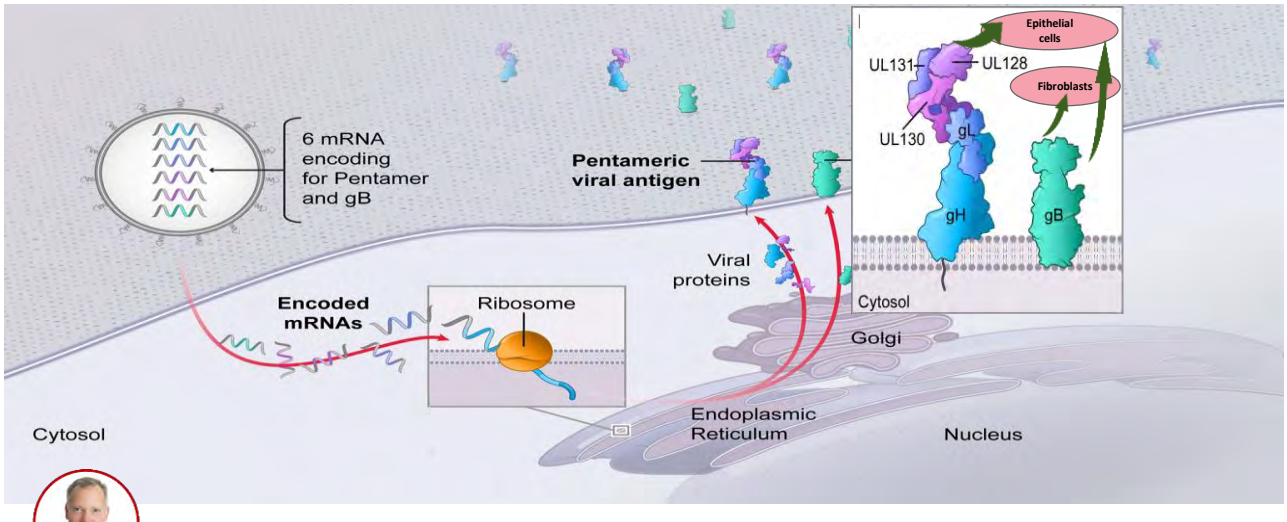
## Congenital CMV vaccine includes 6 mRNAs

*5 encode the Pentamer, 6th encodes gB antigen*

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# mRNA-1647 CMV Vaccine Phase 1 Interim Analysis

*Immunogenicity in CMV-seronegative participants, per-protocol set*

| Variable | Neutralizing Antibodies Against Epithelial Cell Infection | | | |
|---|---|---|---|---|
| | Placebo | 30 µg | 90 µg | 180 µg |
| Baseline GMT | 8 | 8 | 8 | 8 |
| GMT post 1st vaccination | 8 | 37 | 708 | 1,387 |
| GMT post 2nd vaccination | 12 | 3,263 | 15,305 | 30,743 |
| GMT/benchmark ratio | --- | 0.6 | 2.7 | 5.5 |
| | CMV-seropositive GMT benchmark = 5,588 | | | |
| **Variable** | **Neutralizing Antibodies Against Fibroblast Infection** | | | |
| | Placebo | 30 µg | 90 µg | 180 µg |
| Baseline GMT | 8 | 8 | 8 | 8 |
| GMT post 1st vaccination | 8 | 8 | 24 | 10 |
| GMT post 2nd vaccination | 10 | 305 | 1,141 | 1,264 |
| GMT/benchmark ratio | --- | 0.2 | 0.9 | 1.0 |
| | CMV-seropositive GMT benchmark = 1,295 | | | |

- Seronegative subjects successfully immunized to generate neutralizing titers against CMV
- Dose-related increase in neutralizing antibodies
- After the 2nd vaccination, GMTs of the 90 µg and 180 µg dose levels achieved or exceeded the CMV-seropositive benchmark

GMT = geometric mean titer; CMV-seropositive benchmark values derived from baseline values of all CMV-seropositive participants

Subject n at each timepoint

| | Placebo | 30 µg | 90 µg | 180 µg |
|---|---|---|---|---|
| Baseline | 13 | 17 | 13 | 15 |
| Post 1st vaccination | 12 | 17 | 10 | 15 |
| Post 2nd vaccination | 11 | 14 | 12 | 12 |



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# mRNA-1647 CMV Vaccine Phase 1 Interim Analysis

*Immunogenicity in CMV-seropositive participants, per-protocol set*

| Variable | Neutralizing Antibodies Against Epithelial Cell Infection | | | |
|---|---|---|---|---|
| | Placebo | 30 µg | 90 µg | 180 µg |
| Baseline GMT (Benchmark = 5,588) | 8,169 | 3,614 | 5,634 | 5,700 |
| GMT post 1st vaccination | 7,890 | 24,752 | 39,020 | 52,775 |
| GMT post 2nd vaccination | 7,490 | 47,435 | 62,400 | 119,829 |
| GMR post 2nd vaccination | 0.9 | 13.2 | 9.9 | 19.4 |
| **Variable** | **Neutralizing Antibodies Against Fibroblast Infection** | | | |
| | Placebo | 30 µg | 90 µg | 180 µg |
| Baseline GMT (Benchmark = 1,295) | 1,298 | 1,094 | 1,458 | 1,371 |
| GMT post 1st vaccination | 1,278 | 2,654 | 3,885 | 3,879 |
| GMT post 2nd vaccination | 1,451 | 2,935 | 3,891 | 5,578 |
| GMR post 2nd vaccination | 1.1 | 2.3 | 3.0 | 4.1 |

- Seropositive subjects effectively boosted beyond levels seen in natural infection
- Dose-related increase in neutralizing antibody titers
- mRNA-1647 boosted neutralizing antibody titers against epithelial cells to 10-fold or higher in all treatment groups

GMT = geometric mean titer; GMR = geometric mean ratio, defined here as the average of the ratio between Baseline/post 2nd vaccination for each participant

Subject n at each timepoint

| | Placebo | 30 µg | 90 µg | 180 µg |
|---|---|---|---|---|
| Baseline | 14 | 13 | 12 | 13 |
| Post 1st vaccination | 14 | 13 | 12 | 13 |
| Post 2nd vaccination | 12 | 10 | 9 | 9 |



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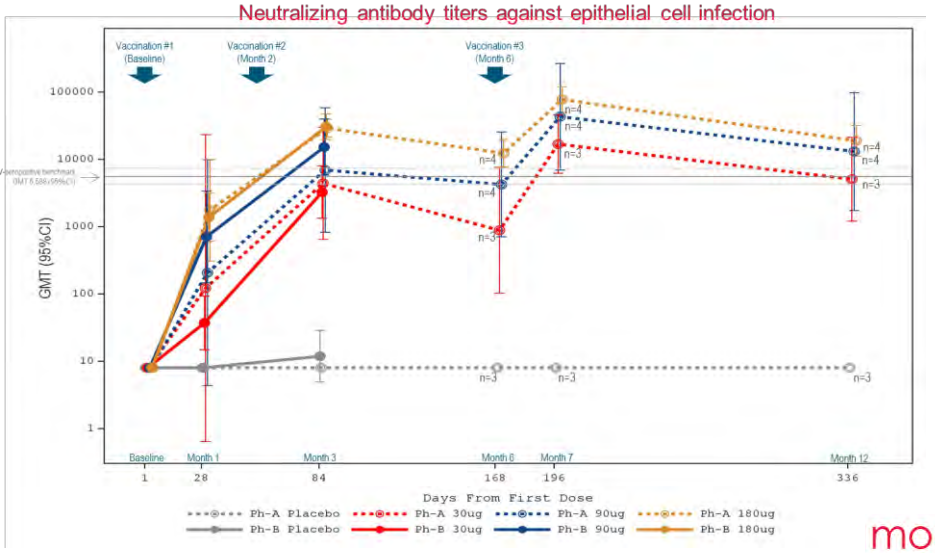
# mRNA-1647 CMV Vaccine Phase 1 Interim Analysis

*Durable immunogenicity demonstrated in initial cohort followed to one year*

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# Audience Challenge Question

ANSWER THE QUESTION ON BLUE SCREEN IN ONE MOMENT


## Neutralizing antibodies are:

- **A)** Antibodies already present in a subject that can inactivate the vaccine.
- **B)** Antibodies generated in a subject following vaccination that inhibit measuring the effect of the vaccine.
- **C)** Antibodies generated in a subject following vaccination that inhibit the ability of the targeted virus to infect either cells or animals.
- **D)** Test reagents in a method to determine the antibody titer in a subject following vaccination.
- **E)** Antibodies that lack an opinion and are therefore neutral.

** If your answer differs greatly from the choices above tell us in the chat!*

# Agenda

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  - Chikungunya antibody case history
- Conclusions



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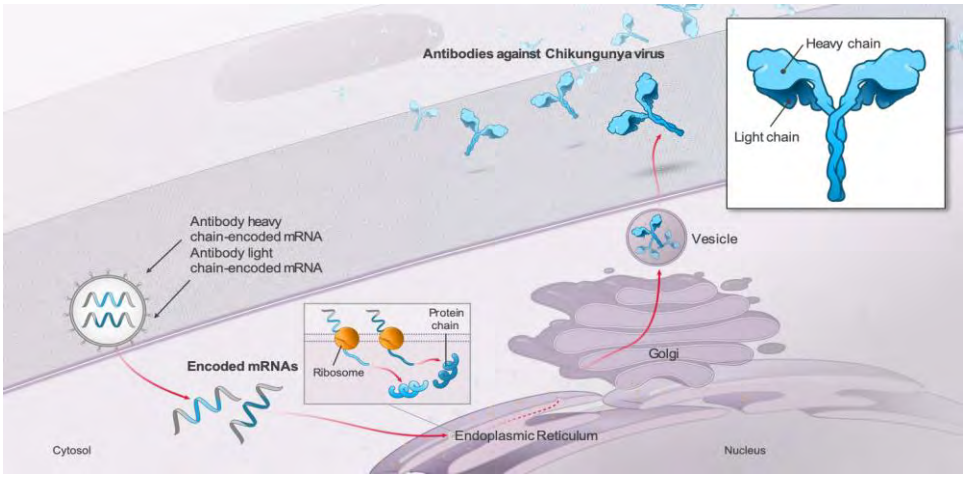
# Antibody against Chikungunya virus (mRNA-1944)

DARPA

*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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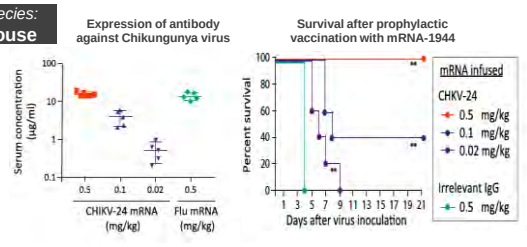
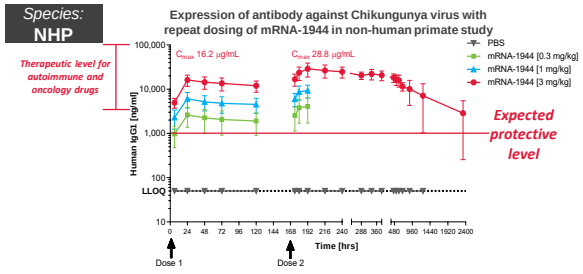
# Preclinical Data mRNA-1944

Species: **Mouse**




Species: **NHP**




Science Immunology

**mRNA-1944 produces an antibody against Chikungunya virus that is**

- Functional
- Protective
- Translates between pre-clinical species

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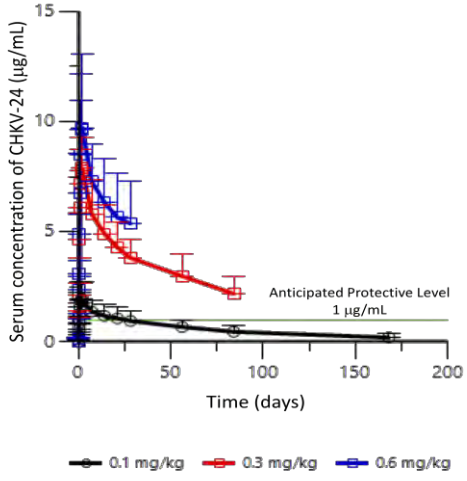
# Preliminary Clinical Data mRNA-1944

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




Serum concentrations plotted as mean (+SD)
1 µg/mL indicates minimum concentration target

| 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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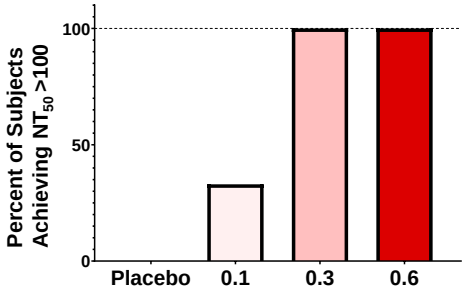
# Preliminary Clinical Data mRNA-1944

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

**Serum neutralization activity 48 hr after mRNA-1944 administration**




| | | | | |
|---|---|---|---|---|
| N | 6 | 6 | 6 | 4 |
| GMT | <10 | 113 | 718 | 538 |

- 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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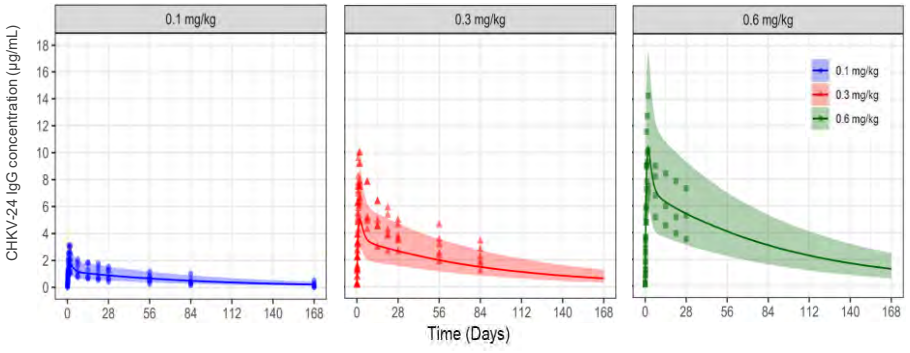
# Preliminary Clinical Data mRNA-1944

*Translation from preclinical species to humans*




**Solid line** = Median predicted

**Shaded area** = 90% prediction interval

**Symbols** = Individual participant observations

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# Audience Challenge Question

ANSWER THE QUESTION ON BLUE SCREEN IN ONE MOMENT

**mRNAs encoding neutralizing antibodies can potentially be used to:**

(Select all that apply)

- Protect a subject from infection prior to potential virus exposure.
- Protect a subject from disease shortly following potential virus exposure.
- Treat disease during infection.
- None of the above.

** If your answer differs greatly from the choices above tell us in the chat!*

## Conclusions

- mRNAs encode proteins that are produced by the patient's own body
- Effect of mRNA therapy is transient and dose-dependent
- Proof of concept of mRNA-based prophylactic vaccines provided for CMV
- Proof of concept of mRNA therapies to produce neutralizing antibodies provided for Chikungunya virus



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# Questions

**Our mission**

*To deliver on the promise of mRNA science to create a new generation of transformative medicines for patients.*

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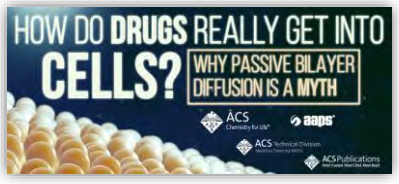
Join Angela Zhou, an Information Scientist at CAS, as she provides an overview of published scientific information relevant to COVID-19 research with an emphasis on patents in the CAS content collection. https://www.acs.org/content/acs/en/acs-webinars/drug-discovery/covid-19.html


Join Research Fellow Li Di of Pfizer as she discusses why design principles that increase passive permeability are effective approaches to increase oral bioavailability, enhance brain penetration, and reduce renal clearance.
https://www.acs.org/content/acs/en/acs-webinars/drug-discovery/passive-permeability.html




Join Douglas Kell, Research Chair in Systems Biology at the University of Liverpool to discover how drugs pass through cell membrane solely by hitchhiking on membrane transporters and why so-called "passive diffusion" through any bilayer in real cells is negligible.
https://www.acs.org/content/acs/en/acs-webinars/drug-discovery/so-lute-carriers.html

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## Free ACS Webinars Every Weekday!

*Upcoming Broadcasts*


Tuesday, June 2, 2020 at 2:3pm ET
Speaker: Sandra Long, Post Road Consulting
Moderator: Tom Halleran, American Chemical Society

Register for Free!

What You Will Learn

- Best practices for connecting on LinkedIn
- How to find people, companies, and opportunities to help you get referred
- How to take advantage of LinkedIn career features

Co-produced with: ACS Career Navigator


Wednesday, June 3, 2020 at 2:3pm ET
Speaker: Mary Beth Mulcahy, *ACS Chemical Health & Safety*
Moderator: Kali Miller, American Chemical Society

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What You Will Learn

- Strategies to prepare a well-organized, carefully crafted manuscript
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Co-produced with: ACS on Campus


Thursday, June 4, 2020 at 2:3pm ET
Speakers: Luis Echegoyen, University of Texas, El Paso / Peter Dornhout, Kansas State University / Davita Camp, Spelman College
Moderator: TBD

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What You Will Learn

- The impact of COVID-19 on researchers
- What the process of restarting research will look like
- What funding agencies and policymakers can do to ease the transition

Co-produced with: ACS External Affairs and Communications


Friday, June 5, 2020 at 2:3pm ET
Speaker: Paul Hodges, International Echem
Moderator: Bill Carroll, Carroll Applied Science

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What You Will Learn

- How developing patterns of consumption, deflation, changes in behavior will affect the market
- Applying Elisabeth Kübler Ross' Paradigm of Loss model in relation to the COVID-19 pandemic and ensuing economic crisis
- Six key questions to determine if your company will survive and prosper

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mRNA Technology for Infectious Diseases: Therapeutic Applications and Vaccine Development

**Jim Thompson**
CMC Therapeutic Area Lead,
Moderna, Inc.

**Venkat Krishnamurthy**
Associate Principal Scientist, Advanced Drug Delivery Group, AstraZeneca

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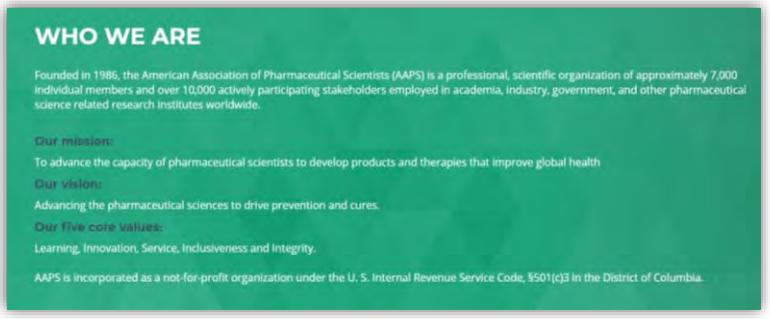


Members of the American Association of Pharmaceutical Scientists (AAPS) gathered during the 2013 AAPS Annual Meeting and Exposition to discuss why they chose a career in pharmaceutical sciences and how AAPS has helped foster their journey. The I Am AAPS video series displays the diversity of AAPS membership while exhibiting one common goal: to impact global health.

https://www.aaps.org

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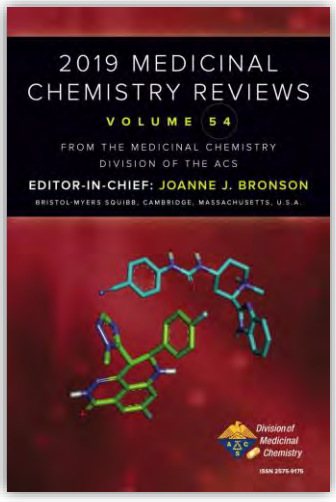


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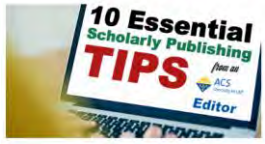


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