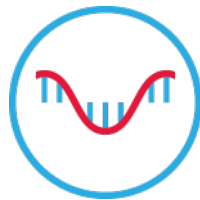


Vaccine & Business Updates

March 27, 2024



moderna®

Forward-looking statements and disclaimer

This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including statements regarding: the advancement of Moderna's programs under clinical development; the timing for anticipated approvals of vaccine candidates; the efficacy, safety and tolerability of vaccine candidates; the total addressable markets for programs under development; the efficiencies and advantages of Moderna's mRNA platform; the potential for AI to assist in dose selection and resultant timing savings; and future capital allocation and financing efforts. In some cases, forward-looking statements can be identified by terminology such as "will," "may," "should," "could," "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 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, those risks and uncertainties described under the heading "Risk Factors" in Moderna's Annual Report on Form 10-K for the fiscal year ended December 31, 2023, 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 of this presentation.

Moderna's infectious disease portfolio

28

vaccines
addressing
respiratory and
latent + other
pathogens

Today's presentations cover the following



Latent + Other vaccines

CMV

mRNA-1647

Norovirus

mRNA-1403/05

VZV

mRNA-1468

HSV

mRNA-1608

EBV (IM/MS)

mRNA-1189/95



Respiratory vaccines

COVID (Spikevax)

mRNA-1273

NextGen COVID

mRNA-1283

RSV

mRNA-1345

Seasonal Flu

mRNA-1010

Flu/COVID

mRNA-1083

Today we are sharing clinical updates from select vaccine programs

28

vaccines
addressing
respiratory and
latent + other
pathogens



Latent + Other vaccines

CMV
mRNA-1647

Norovirus
mRNA-1403/05

VZV
mRNA-1468

HSV
mRNA-1608

EBV (IM/MS)
mRNA-1189/95



Respiratory vaccines

COVID (Spikevax)
mRNA-1273

NextGen COVID
mRNA-1283

RSV
mRNA-1345

Seasonal Flu
mRNA-1010

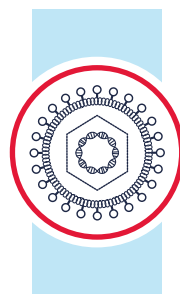
Flu/COVID
mRNA-1083

Expanding our mRNA platform into areas of high unmet need through our latent + other portfolio



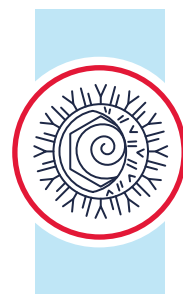
CMV

Most common infectious cause of birth defects in the U.S.; 1 in 200 babies in the U.S. are born with a congenital CMV infection



EBV

Major cause of infectious mononucleosis (IM) in the U.S., accounting for over 90% of the estimated 150,000 cases annually¹, with potential sequelae



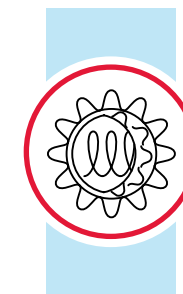
HSV

Herpes Simplex Virus Type 2 (HSV-2) infects ~13% of adults globally and is the primary cause of genital herpes²



VZV

Declining immunity in older adults decreases immunity against VZV, allowing reactivation of the herpes zoster virus

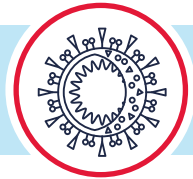


Norovirus

A leading cause of diarrheal deaths globally

Sources: (1) Tying S, Moore AY, Lupi O (2016). Mucocutaneous Manifestations of Viral Diseases: An Illustrated Guide to Diagnosis and Management (2 ed.). CRC Press. p. 123. (2) <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7265941/>

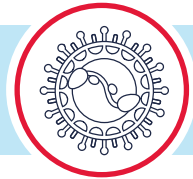
Our platform has allowed us to develop a diverse respiratory pipeline



COVID-19

Updates to address emerging variants

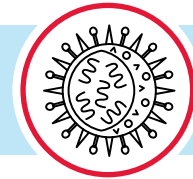
Next generation COVID-19 vaccine designed to be refrigerator stable



RSV

mRNA vaccine targeting pre-fusion F protein in older adults

Indication expansion into additional age cohorts



Flu

First generation mRNA vaccine

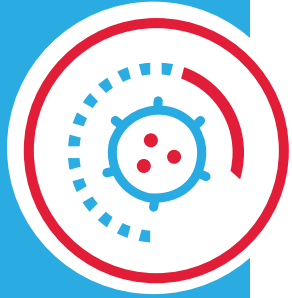
Next generation flu vaccines including additional antigens

Combos

Combination respiratory vaccines to drive value by addressing compliance and convenience

Vaccine and business updates 2024: Agenda

Introduction	Stephen Hoge, M.D., President
Latent + Other vaccine portfolio	
Overview of latent virus vaccine portfolio	Jacqueline Miller, M.D., SVP, Head of Development, Infectious Diseases
CMV	
Spotlight on AI in R&D	
EBV	Sumana Chandramouli, Ph.D., Sr. Director, Infectious Diseases Research
HSV	
VZV	Jacqueline Miller, M.D., SVP, Head of Development, Infectious Diseases
Norovirus	
Coffee Break	
Respiratory vaccine portfolio	
Overview of respiratory portfolio COVID-19	Jacqueline Miller, M.D., SVP, Head of Development, Infectious Diseases
RSV	Christy Shaw, Ph.D., VP, Portfolio Head, Respiratory Vaccines
Influenza and combos	Raffael Nachbagauer, M.D., Ph.D. Program Leader, Infectious Disease
Commercial opportunity	Stéphane Bancel, Chief Executive Officer
Manufacturing	Jerh Collins, Chief Technical Operations and Quality Officer
R&D Investment Strategy	Jamey Mock, Chief Financial Officer
Conclusion	Stéphane Bancel, Chief Executive Officer
General Q&A	Stéphane Bancel, Stephen Hoge, Jamey Mock, Jerh Collins, Jacqueline Miller



Latent + Other Vaccine Portfolio

Jacqueline Miller, M.D.

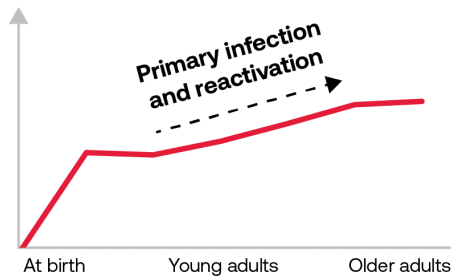
*Senior Vice President, Head of Development,
Infectious Diseases, Moderna*

Latent Viruses Overview

Moderna's mRNA technology is well positioned to address immediate impact and long-term sequelae from latent viruses

Latent virus characteristics

- Immediate impact of infection (e.g., birth defects, mono)
- Long-term sequelae from latent infections (cancer, autoimmune)



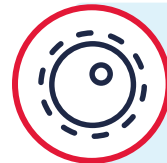
Important features to address latent viruses



Both antibody and T cell responses are important

mRNA vaccine attributes

mRNA vaccines elicit both antibody and T cell immune responses



Multiple cell entry pathways

Can code for multiple antigens and antigen complexes in the same vaccine



Includes complex antigens

Demonstrated ability for mRNA to code for complex antigens

Moderna is currently developing vaccines against latent viruses with unmet or underserved needs

Latent Viruses	Any Approved Vaccine	
<p>Cytomegalovirus (CMV)</p> <ul style="list-style-type: none"> • Leading infectious cause of birth defects (12-20K congenital CMV cases annually in the U.S. alone)¹ • Major cause for graft loss in solid organ transplant patients 	<p>✘</p>	<p>→ mRNA-1647 Phase 3</p>
<p>Epstein-Barr virus (EBV)</p> <ul style="list-style-type: none"> • >160K deaths attributed to EBV-related malignancies (2017)² • Major driver of Multiple Sclerosis risk (>30x increase)³ 	<p>✘</p>	<p>→ mRNA-1189 mRNA-1195</p>
<p>Herpes simplex virus (HSV)</p> <ul style="list-style-type: none"> • HSV-2 establishes life-long latent infections within sensory neurons from which it can reactivate, leading to genital herpes • Globally, ~13% of the population in the 18-49 age range is HSV-2 seropositive⁴ 	<p>✘</p>	<p>→ mRNA-1608</p>
<p>Varicella zoster virus (VZV)</p> <ul style="list-style-type: none"> • Declining immunity in older adults leads to reactivation of the virus from latently infected neurons, causing painful and itchy lesions • Herpes zoster occurs in 1 out of 3 adults in the U.S. in their lifetime⁵ 	<p>✔</p>	<p>→ mRNA-1468</p>

1. Lanzieri, Tatiana, CDC, <https://www.hhs.gov/sites/default/files/2018-9-13-nvac-exploringthepipeline-cmvvaccines.pdf> ; 2. Khan, Gulfaraz et al., *BMJ Open* (2020), <https://doi.org/10.1136/bmjopen-2020-037505> ; 3. Bjornevik et al <https://www.science.org/doi/10.1126/science.abj8222>; 4. Looker et al, *BMJ Global Health* (2020), <https://doi.org/10.1136/bmjgh-2019-001875> ; 5. CDC, Shingles, <https://www.cdc.gov/shingles/about/index.html> ;

Latent Viruses

CMV

Cytomegalovirus (CMV) Overview

CMV is the most common infectious cause of birth defects in the U.S.¹

Several billion dollars in annual healthcare costs²

Sequelae include:

- **At birth:** microcephaly, chorioretinitis, seizures, sensorineural hearing loss
- **Long term:** cognitive impairment, cerebral palsy, seizure disorder, sensorineural hearing loss

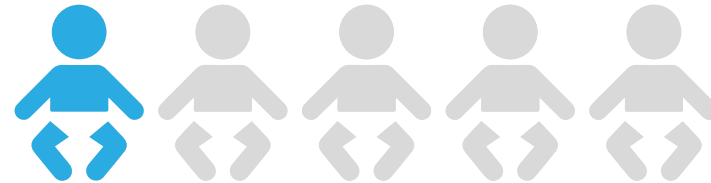
(1) CDC, <https://www.cdc.gov/cmvcongenitalinfection.html>

(2) Grosse, Scott et al. "Economic assessments of the burden of congenital cytomegalovirus infection and the cost-effectiveness of prevention strategies," *Seminars in perinatology*, 2021, <https://doi.org/10.1016/j.semperi.2021.151393>



1 in 200

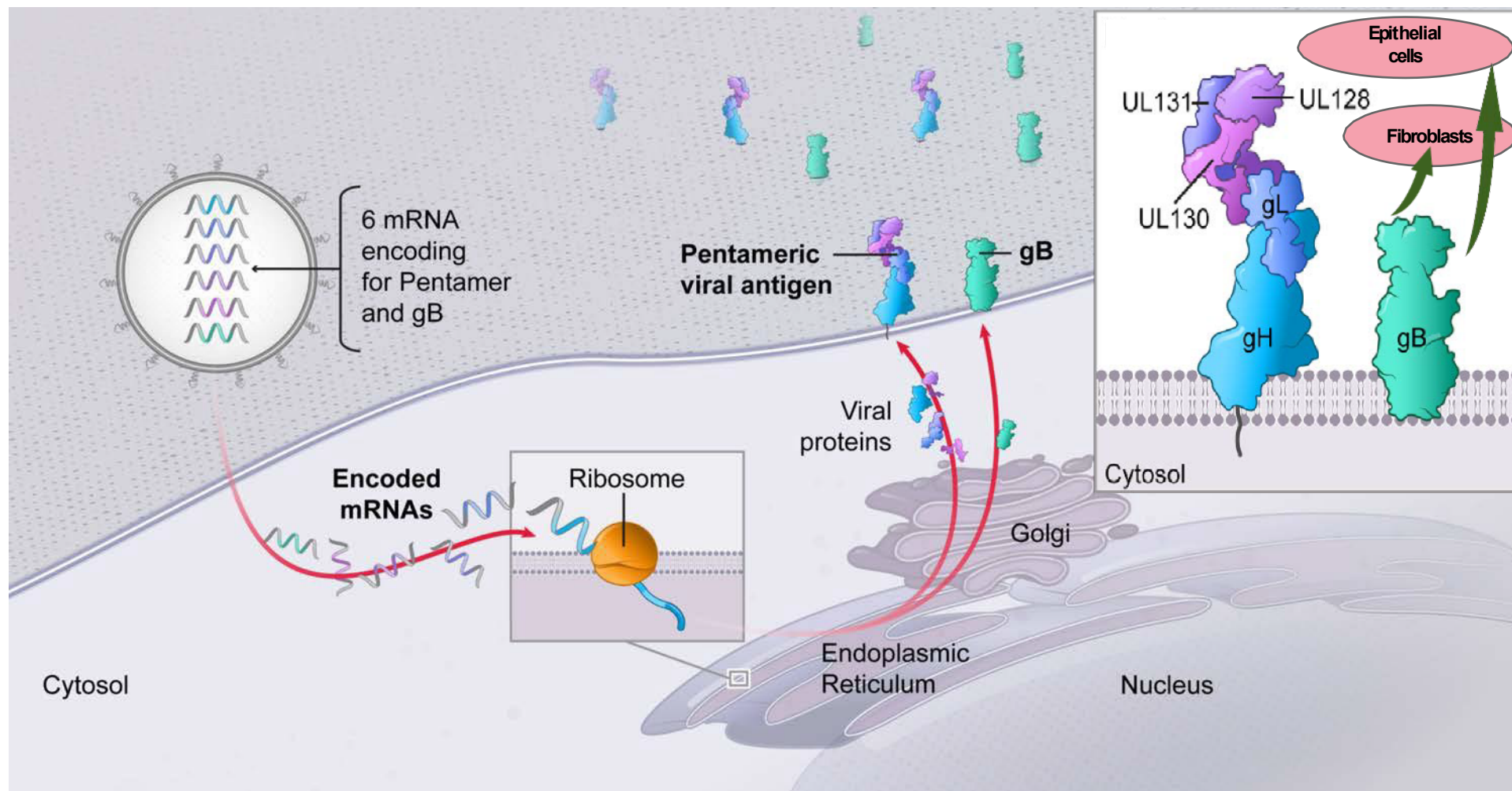
babies in the U.S. are born with a congenital CMV infection (CMV infection is present at birth)



1 in 5

will have severe, life-altering health problems

Our CMV vaccine (mRNA-1647) includes 6 mRNAs (five encode the pentamer, the 6th encodes for the gB antigen)



CMV vaccine (mRNA-1647) Phase 3 trial fully enrolled; 50 cases have accrued and are undergoing confirmation

Randomized, observer-blind, placebo-controlled study to evaluate the **efficacy, safety and immunogenicity of mRNA-1647 to evaluate prevention of primary infection**

Enrollment complete in the U.S. and internationally across 290 sites globally

Participants older than 20 years of age were enrolled only if they had contact with young children

Primary efficacy analysis will be triggered based on accrual of primary infection cases

Phase 3 trial design

mRNA-1647 (100 µg)
N=~3,650

Placebo
N=~3,650

3 dose course: D1, D57, D169

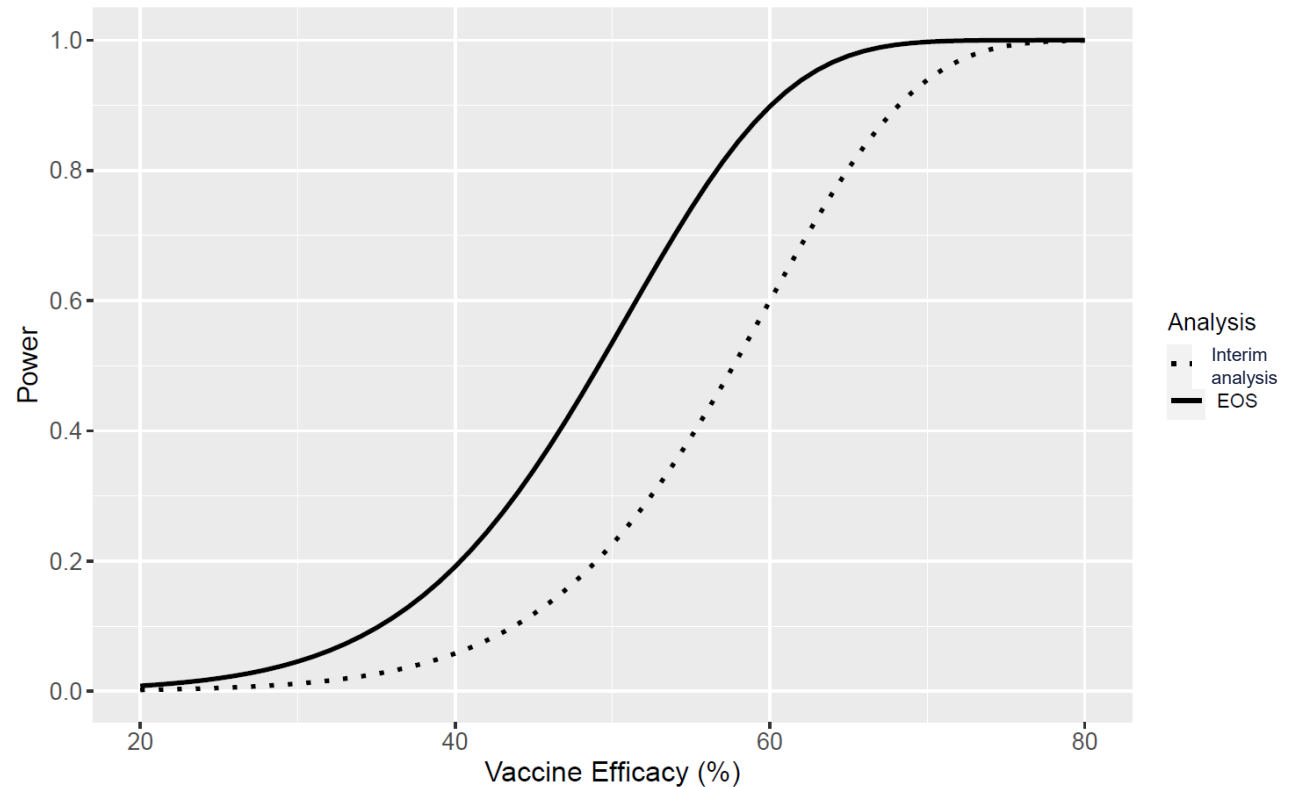


Overview of primary efficacy endpoint



Efficacy Boundaries with Alpha-allocation between 2 Planned Analyses

	Approximate # of Cases	One-sided Alpha	VE: Efficacy Bound
Interim Analysis	81	0.5%	~ 57.7%
End of Study (EOS) Analysis	112	2.0%	~ 49.1%



CMV (mRNA-1647) Phase 3 vaccine summary and next steps

Addressing disease burden

- CMV is the most common cause of congenital infection worldwide¹
- Moderna's CMV vaccine targets two antigens, the pentamer and the glycoprotein B (gB) antigen

Latest updates

- CMV Phase 3 trial is fully enrolled; 50 cases have accrued and are undergoing confirmation

Next steps

- Data Safety Monitoring Board (DSMB) will evaluate vaccine efficacy from the interim analysis when the trial has accrued 81 confirmed cases
- Potential for vaccine efficacy readout in 2024

Sources: (1) <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8453618/>

CMV vaccine (mRNA-1647) indication expansion studies



Adolescents

(9-15 years old)

- Phase 1/2 trial has begun enrollment



Transplant

(Adults)

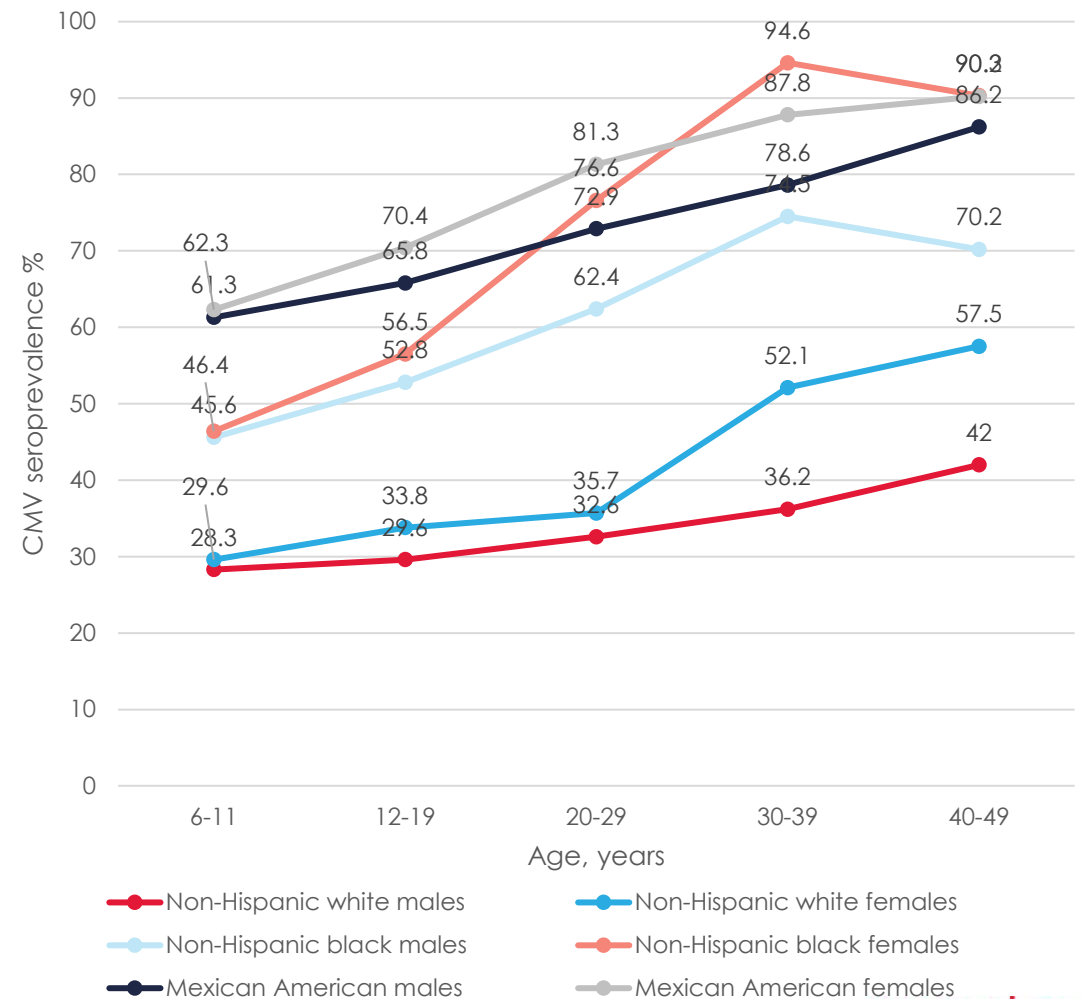
- Trial initiated
- Ongoing enrollment

CMV vaccination in adolescents is aimed at primary prevention

Because infection rates increase with age, **we will prevent a greater number of primary infections if we can vaccinate adolescents**

Ease of implementation into existing (ACIP) vaccination schedule for this age group

CMV Seroprevalences, US NHANES 1999-2004, stratified by age, sex, and race/ethnicity



<https://www.cdc.gov/nchs/products/databriefs/db90.htm>
NHANES (National Health and Nutrition Examination Survey)

CMV vaccine (mRNA-1647) Phase 1/2 study in adolescents has begun enrollment

Phase 1/2 open-label and placebo-controlled study to evaluate safety and immunogenicity in male and female participants at 9 to 15 years of age

The study will include ~770 participants across ~70 sites globally

Immunogenicity will be assessed against both epithelial cell and fibroblast cell infection

Ph 1/2 trial design

Placebo

mRNA-1647
Low dose

mRNA-1647
Medium dose

mRNA-1647
High dose

3 dose course: D1, D57, D169

CMV vaccine (mRNA-1647) indication expansion studies



Adolescents

(9-15 years old)

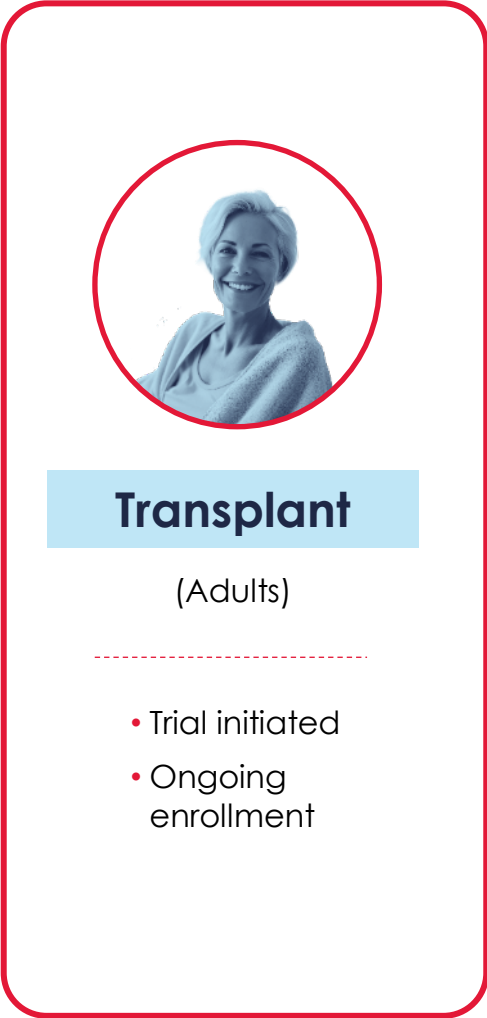
Phase 1/2 trial has begun enrollment



Transplant

(Adults)

- Trial initiated
- Ongoing enrollment



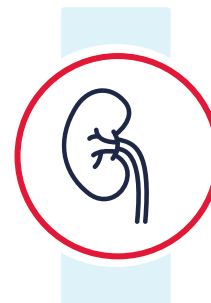
CMV is a major health burden in the transplant population

Risks associated with CMV infection post SOT/HSCT¹

- Graft rejection
- End-organ CMV disease (EOD)

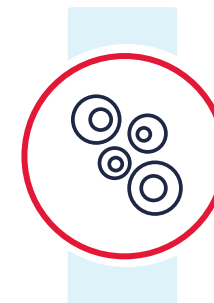
Unmet need:

- No approved vaccines against CMV for post-transplant
- High cost and toxicity of antiviral prophylaxis



47K

Solid Organ
Transplantation
(SOT)²



23K

Hematopoietic Stem Cell
Transplantation (HSCT)³

~70K

transplants in
the US annually

(1) <https://pubmed.ncbi.nlm.nih.gov/32603496/> (2) <https://insights.unos.org/OPTN-metrics/>. Data for year 2023. (3) <https://bloodstemcell.hrsa.gov/data/donation-and-transplantation-statistics> Data for year 2021

CMV vaccine (mRNA-1647) Phase 2 proof-of-concept study in allogeneic hematopoietic cell transplant (HCT) patients; enrollment ongoing

- Phase 2, placebo controlled, single-center proof-of-concept (POC) study evaluating efficacy, safety and immunogenicity of mRNA - 1647 in patients undergoing HCT
- The study will recruit CMV-seropositive patients who have gone high-risk allogeneic HCT
- Primary outcome measure is time to first occurrence of an CS-CMV_i event measures by initiation of antiviral therapy
- The study will recruit approximately 224 patients with a 1:1 randomization
- We are enrolling participants after immune reconstitution with 3 doses over an accelerated schedule and following subjects over 1 year

Ph 2 trial design

Placebo

mRNA-1647

3 dose course: D42, D67 and D92 post-HCT
Booster dose at day 180 post-HCT

Spotlight on AI in R&D

Dose ID GPT: An AI dose-selection assistant to inform advancement to late phase clinical trials

Introducing 'Dose ID' GPT



Dose ID

Analyzes clinical data to make an optimal dose recommendation.

- Leverages available data to recommend an optimal dose
- Provides study team option to further analyze and probe the data to guide decision-making process

Generative pre-training transformer (GPT) to recommend optimal dose for vaccine development



Consider multiple parameters

Evaluate efficacy, comparator data and any immune correlates if available, along with safety and tolerability data to find the optimal balance



Synthesize data in minutes with human input

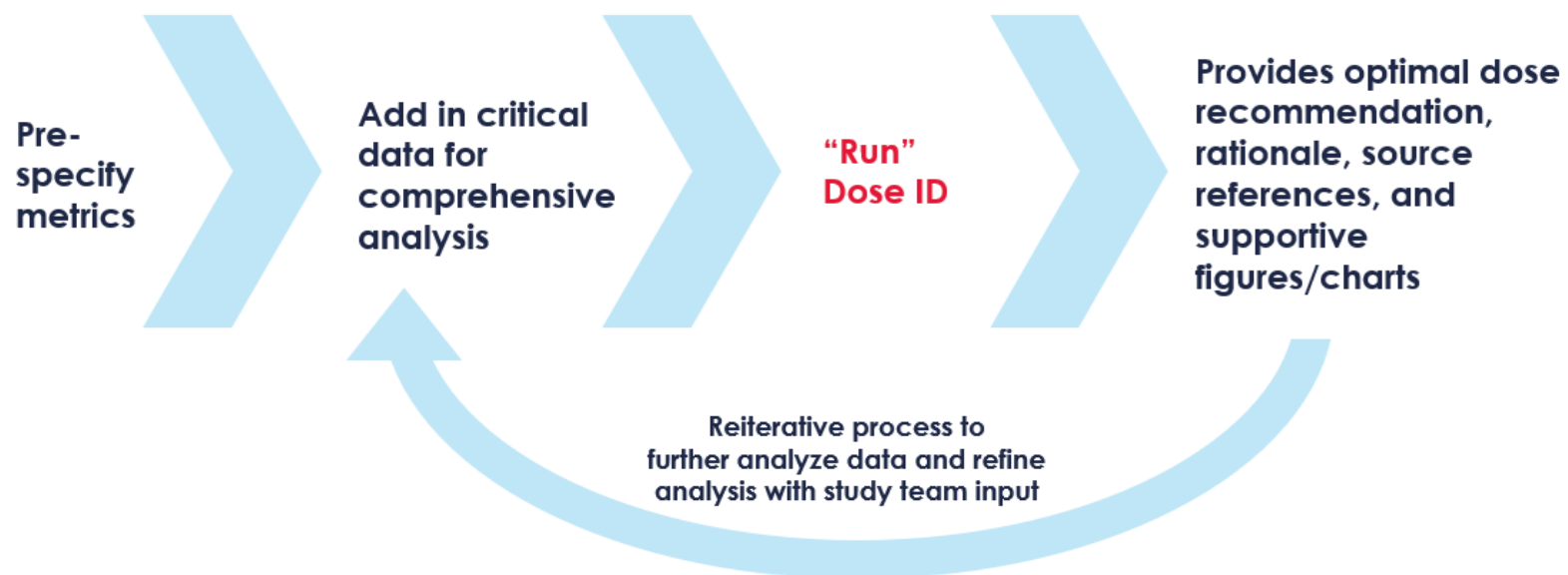
Base recommendation on thorough analysis of all available uploaded data while retaining study team oversight and clinical judgement



Recommend an optimal vaccine dose

Review data to determine the dose that provides maximum immunogenicity while maintaining an acceptable level of reactogenicity and adverse events

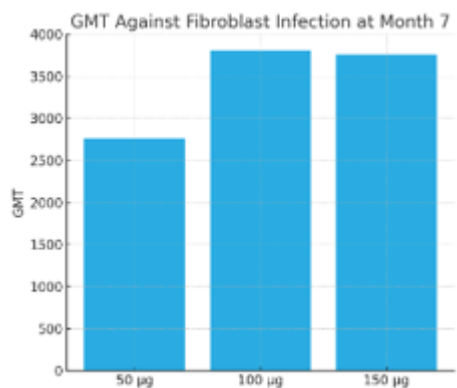
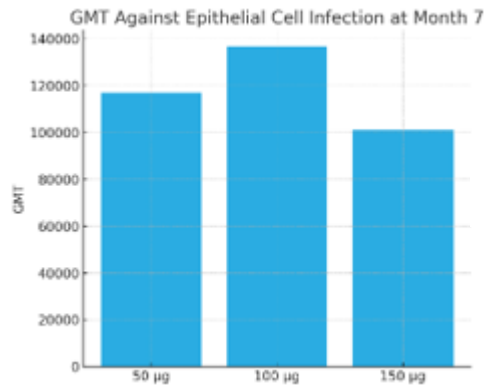
Dose ID GPT process flow



- Works in parallel with human process
- Augments analysis
- Potential to accelerate dose selection timeline

Example: CMV phase 3 dose selection using Dose ID GPT

Back tested Dose ID GPT using CMV data for Phase 3 dose selection



Tested and refined GPT on CMV data; output from Python to English

```

Analysis
python Copy code

import matplotlib.pyplot as plt
import numpy as np

# Data for plotting
doses = ['50 µg', '100 µg', '150 µg']
gmt_epithelial = [117022.3, 136935.3, 101113.5] # CMV Ser
gmt_fibroblast = [2758.2, 3811.4, 3761.2] # CMV Sero
grade_3_ar_post_injection_1 = [6.3, 5.5, 7.9] # Percenta
teae_grade_3_or_higher = [19.0, 20.2, 7.9] # Percenta

# Creating multiple subplots
fig, axs = plt.subplots(2, 2, figsize=(12, 10))

# Plot for GMT against Epithelial Cell Infection
axs[0, 0].bar(doses, gmt_epithelial, color='#2AACE2')
axs[0, 0].set_title('GMT Against Epithelial Cell Infection')
axs[0, 0].set_ylabel('GMT')

# Plot for GMT against Fibroblast Infection
axs[0, 1].bar(doses, gmt_fibroblast, color='#2AACE2')
axs[0, 1].set_title('GMT Against Fibroblast Infection at M')
axs[0, 1].set_ylabel('GMT')

```

In summary, the 100µg dose of mRNA-1647 appears to provide a balance between robust immunogenic responses and a manageable safety profile, aligning with the primary objective of identifying a well-tolerated and highly immunogenic dose. Therefore, based on the data analysis and graphical illustrations, the 100µg dose could be considered as a suitable candidate for further evaluation in clinical development.

Applying Dose ID GPT to trials moving into later stage studies



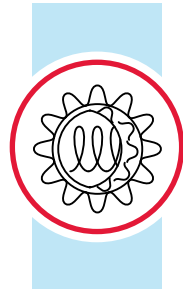
VZV

mRNA-1468



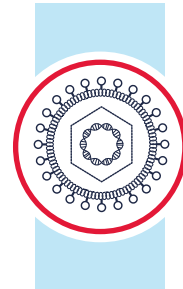
**RSV
pediatric**

mRNA-1345



Norovirus

mRNA-1403/1405



EBV

mRNA-1189

mRNA-1195



**CMV
adolescents**

mRNA-1647

Additional Clinical Development GPTs In Development



Reactogenicity Reviewer

Grade Solicited Adverse Reactions (SARs) from ePRO up to day 7 Diary data or raw eDiary listing



Clinical Literature Review Assistant

Identifies and summarizes clinical literature



Reactogenicity Reporter

Create summary report and visualization using reactogenicity summary data created by Reactogenicity Reviewer



Clinical Biomarker Evaluation Tool

Helps Evaluate Clinical Biomarkers for Specific Target Area of Interest

Latent Viruses

EBV

Sumana Chandramouli, Ph.D.

Senior Director, Infectious Diseases Research

EBV has several serious health impacts

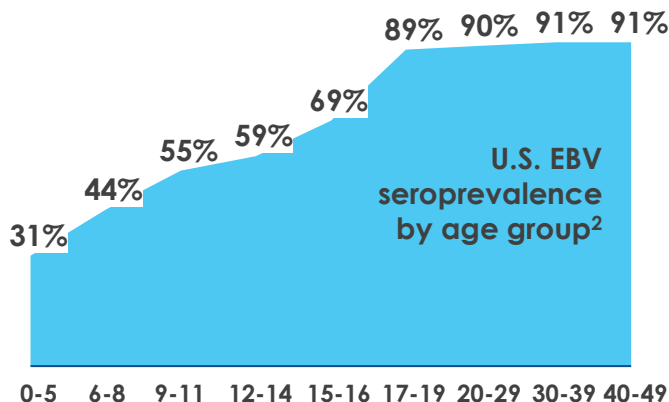
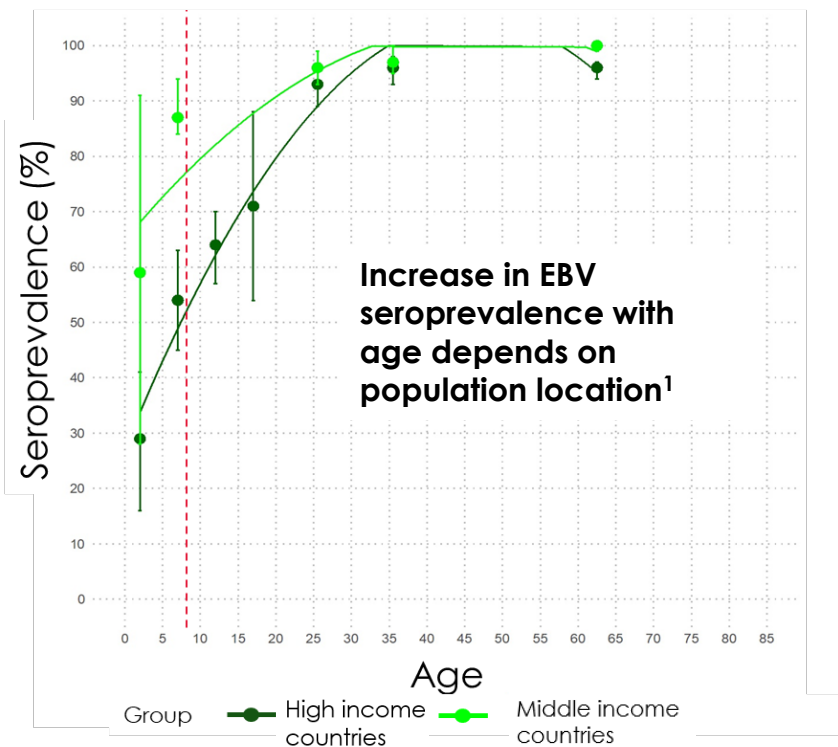
Infectious
mononucleosis

Multiple
sclerosis

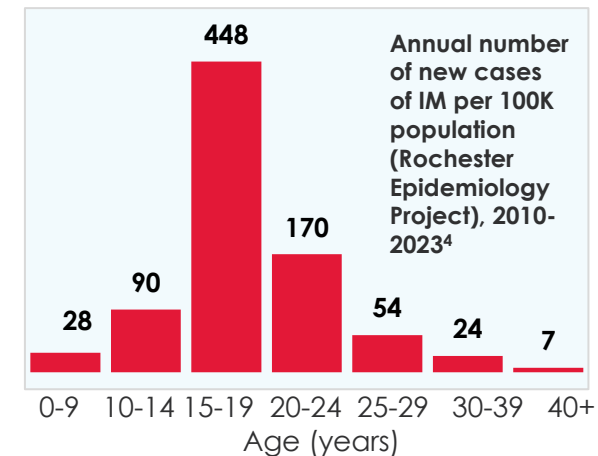
Cancer

Epidemiology of EBV and infectious mononucleosis (IM)

EBV infects the vast majority of the world population by adulthood (~95% seropositivity)



Studies in Europe and North America show a more gradual increase in seroprevalence which did not exceed 90% until age 22³

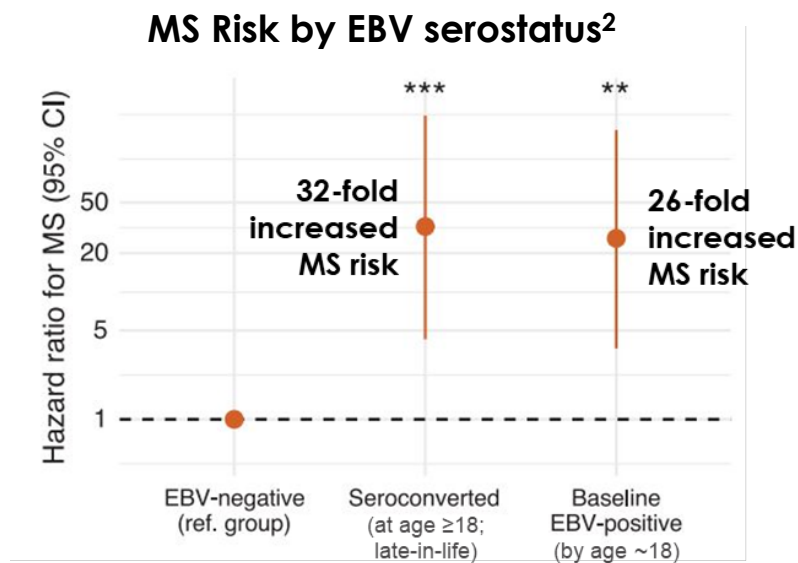


EBV accounts for over 90% of cases of IM⁵. Annual incidence of IM in the general U.S. population is estimated to be at least 45 cases per 100,000⁶, with **peak incidence occurring at ages 15-19y⁷**

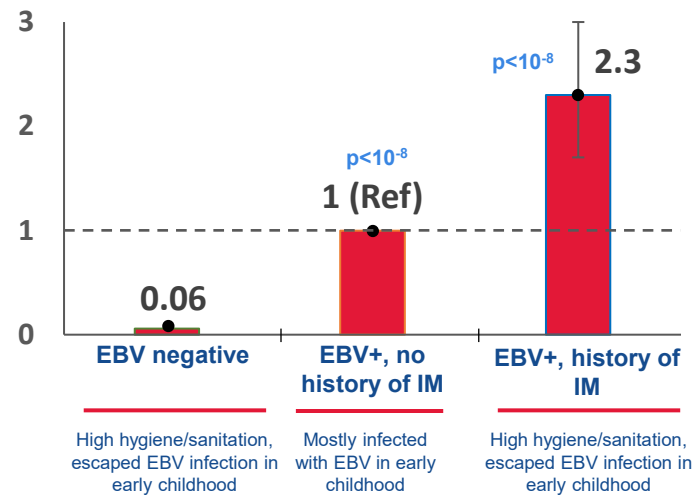
Sources: 1. Gequelin, Lucian, et al. Rev Bras Hematol Hemoter (2011), <https://doi.org/10.5581/1516-8484.20110103> 2. Balfour et al <https://pubmed.ncbi.nlm.nih.gov/23868878/>, Moderna data on file. 3. Winter et al <https://pubmed.ncbi.nlm.nih.gov/32257152/>. 4. Moderna data on file, Rochester Epidemiology Project 5. Fugl et al 2019 <https://bmcpimcare.biomedcentral.com/articles/10.1186/s12875-019-0954-3> 6. Tying S, Moore AY, Lupi O (2016). *Mucocutaneous Manifestations of Viral Diseases: An Illustrated Guide to Diagnosis and Management* (2 ed.). CRC Press. p. 123. 7. Kuri et al 2020 <https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-020-09049-x>

Etiologic link between EBV and multiple sclerosis (MS)

- **Nearly 1M people have MS in the U.S.**¹
- EBV seropositivity is nearly universal in MS and seronegative individuals have a negligible risk of MS
- Recent landmark study established a **~32 fold increased risk of developing MS following EBV seroconversion**²
- It was previously established that **infectious mononucleosis** is an MS risk factor, beyond the contribution of EBV alone; in addition, the epidemiology of IM and MS are similar

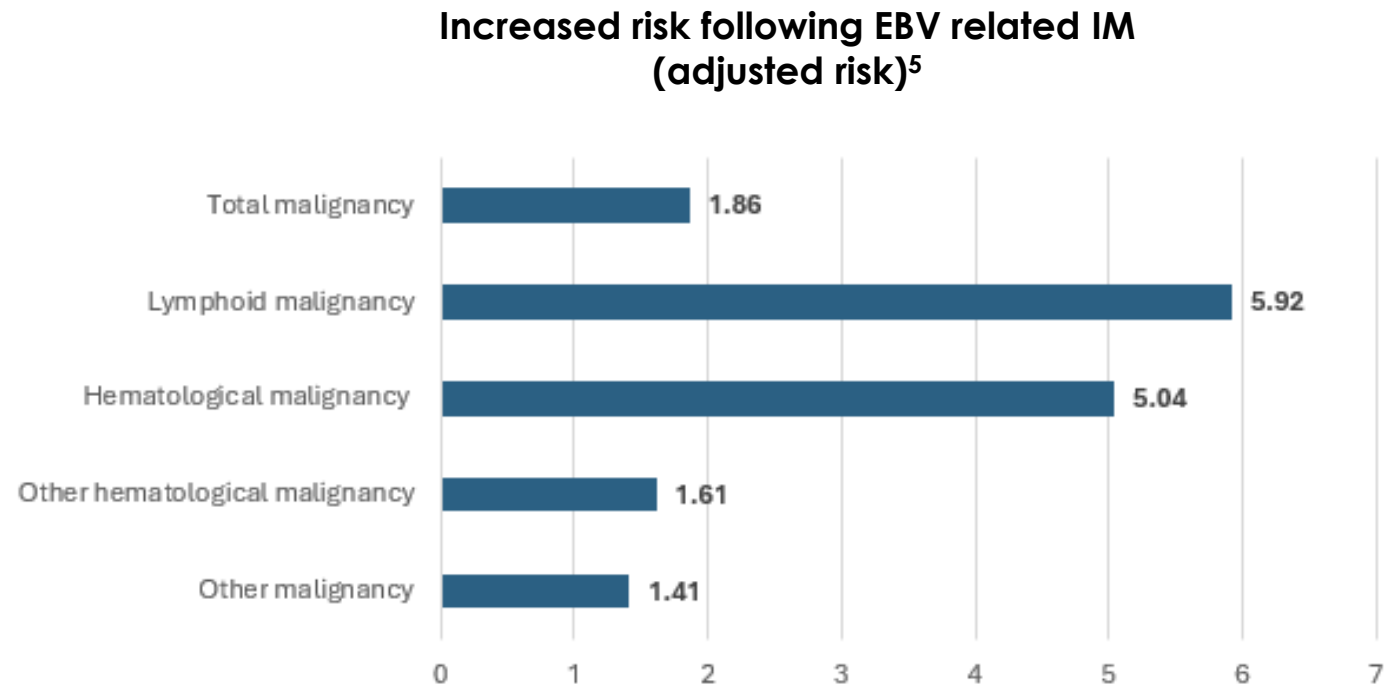
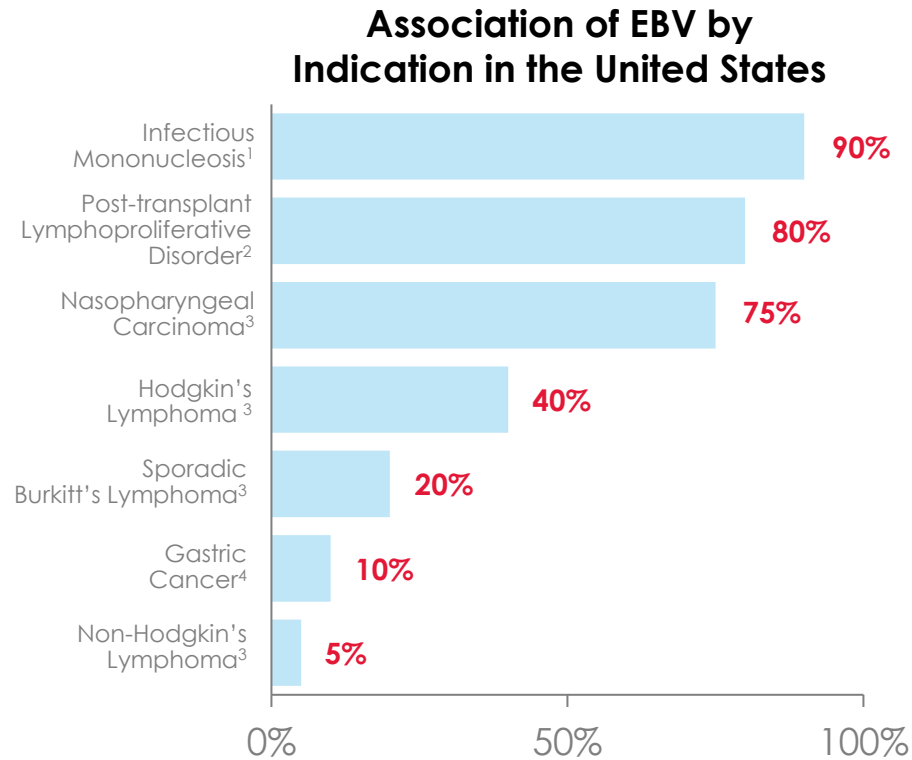


MS Risk by history of IM and EBV serostatus³



Sources: 1. <https://www.nationalmssociety.org/About-the-Society/MS-Prevalence> 2 Bjornevik et al <https://www.science.org/doi/10.1126/science.abj8222>; 3. Ascherio A, Munger KL. Epidemiology of Multiple Sclerosis: From Risk Factors to Prevention-An Update. Semin Neurol. 2016 Apr;36(2):103-14. doi: 10.1055/s-0036-1579693. Epub 2016 Apr 26. PMID: 27116717.

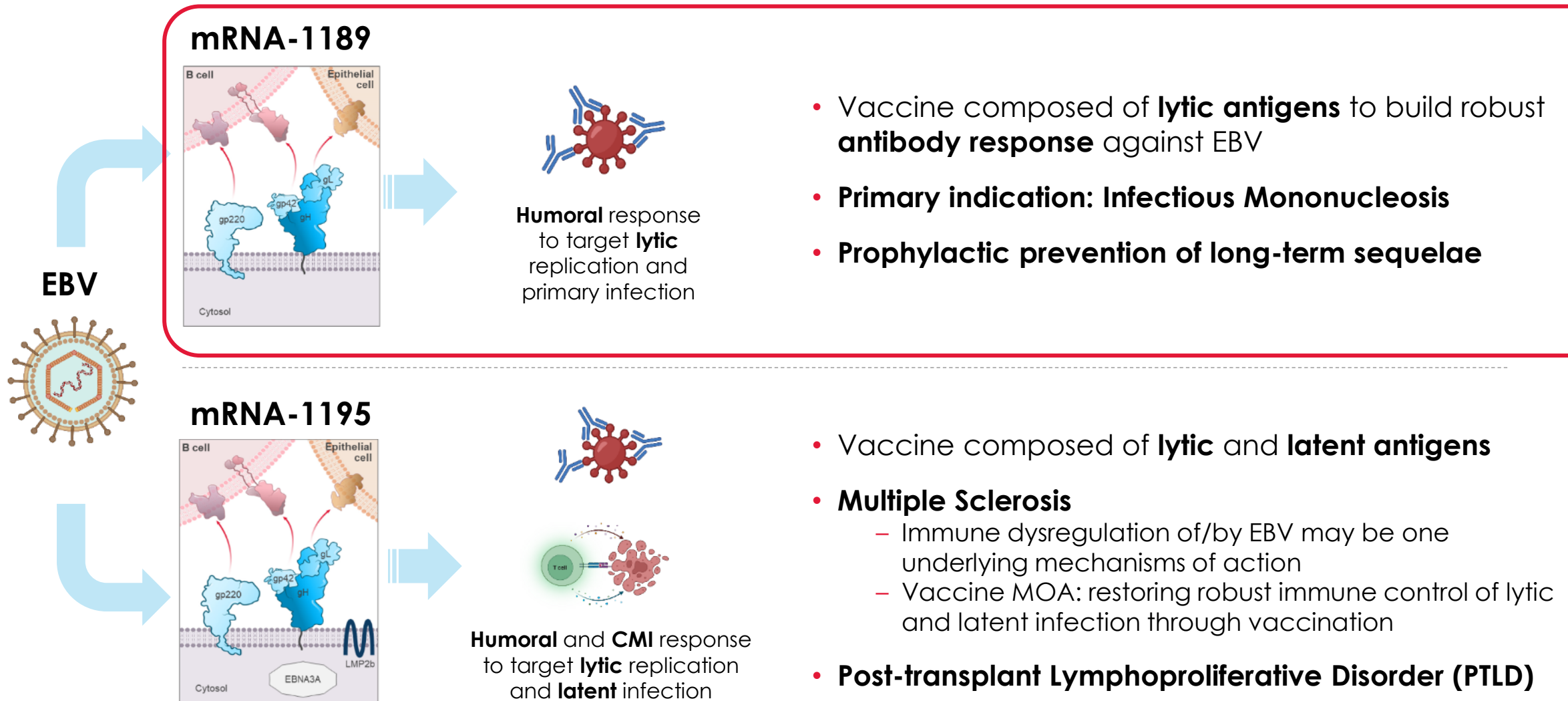
EBV infection is associated with cancer incidence, with increased risk following symptomatic IM



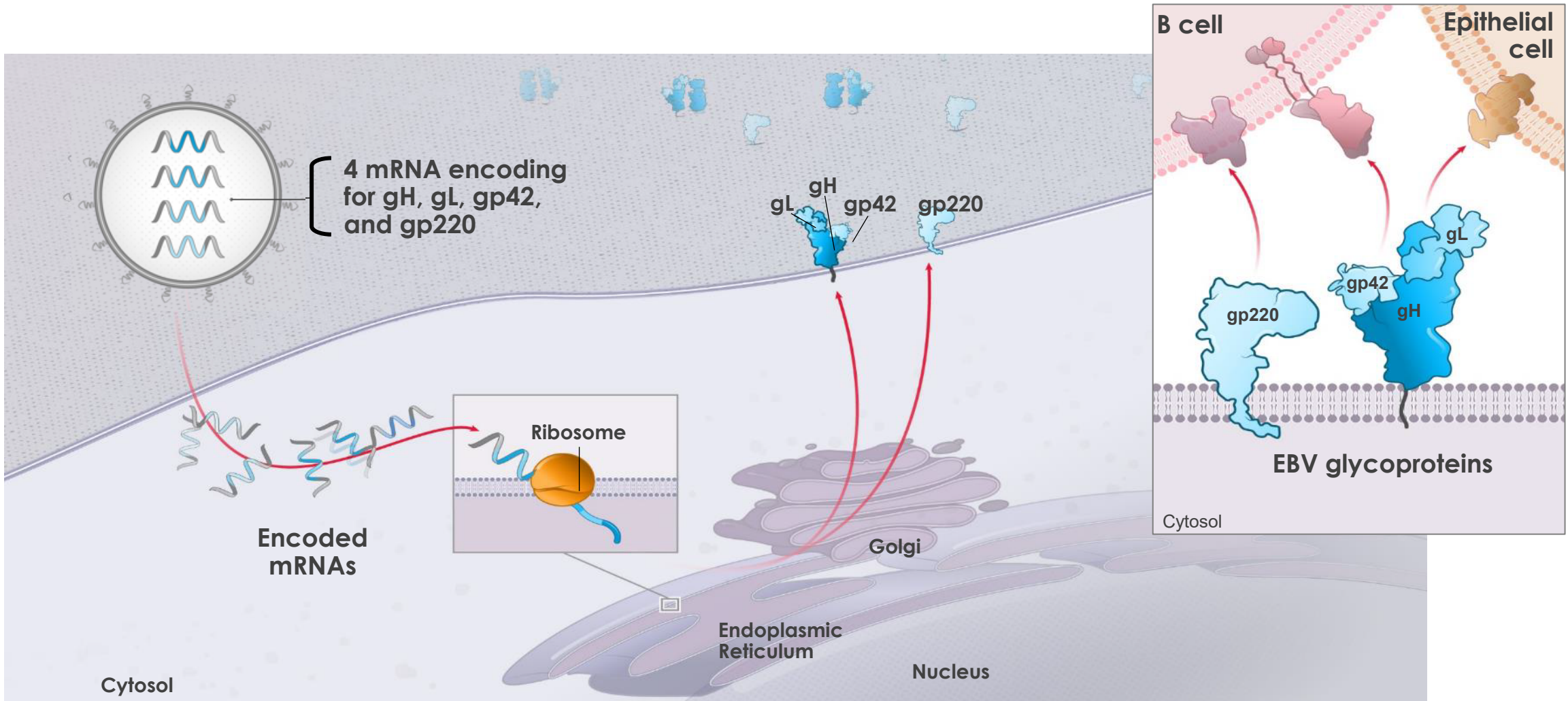
Globally, EBV-associated cancers account for over **200,000** new cases of cancer annually and **150,000** cancer deaths, representing about **1% and 2% of total global cancer incidence and cancer deaths**, respectively⁶

1. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6518816/>; 2. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4946499/>; 3. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3415781/>; 4. <https://dceg.cancer.gov/research/cancer-types/stomach-gastric/ebv-associated-gastric-cancer/>; 5. Risk analyses adjusted for gender, parity, maternal age at delivery, maternal education, maternal residence, and paternal malignancy history. Ref: <https://www.frontiersin.org/journals/oncology/articles/10.3389/fonc.2022.991069/full>; 6. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8532523/>

Moderna's EBV vaccine candidates could tackle multiple EBV-associated conditions



EBV vaccine (mRNA-1189) encodes for four antigens



EBV (IM): mRNA-1189 Phase 1 trial design; sharing data today from Part A

The Phase 1 was designed to test the safety, reactogenicity, and immunogenicity of 4 different dose levels of mRNA-1189 in participants 12-30 years of age



Design

Randomized equally across 4 arms (Part A) and 5 arms (Part B), observer-blind, placebo-controlled study

Number of participants



Part A: 272 EBV seronegative and EBV seropositive healthy adults (18-30 years old)

Part B: 150 healthy EBV seronegative adolescents (12-17 years old)



Vaccination schedule

Three doses of mRNA-1189 (0-2-6 month) or placebo



Duration: 18-months

Enrollment period: December 2021–Oct 2023

Study participants will be followed up for 12 months after study injection



Site location

US

Part A

Cohort 1 (Dose A)

N=68

Cohort 2 (Dose B)

N=68

Cohort 3 (Dose C)

N=68

Cohort 4 (Placebo)

N=68

Part B

Cohort 1 (Dose A)

N=30

Cohort 2 (Dose B)

N=30

Cohort 3 (Dose C)

N=30

Cohort 4 (Dose D)

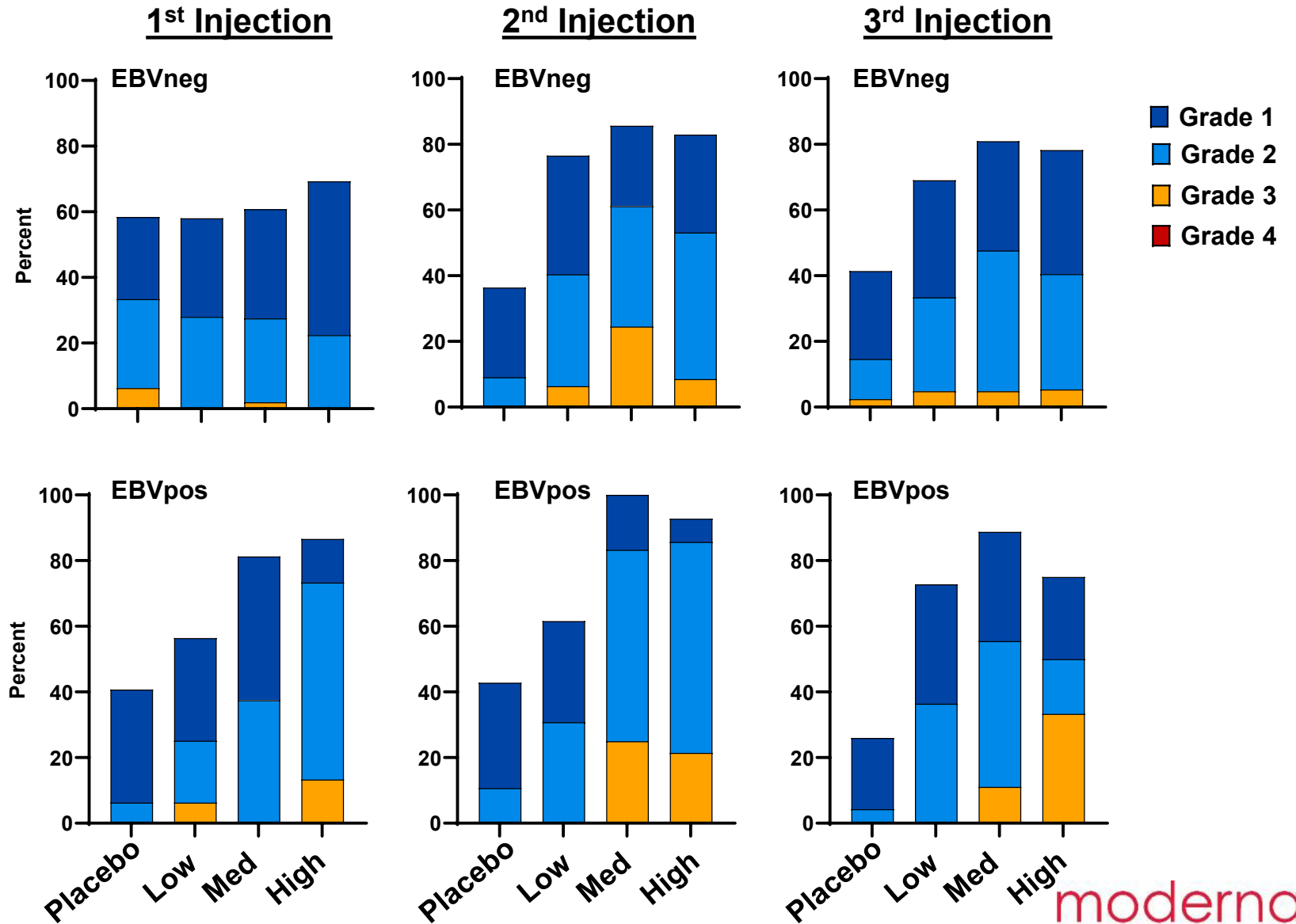
N=30

Cohort 5 (Placebo)

N=30

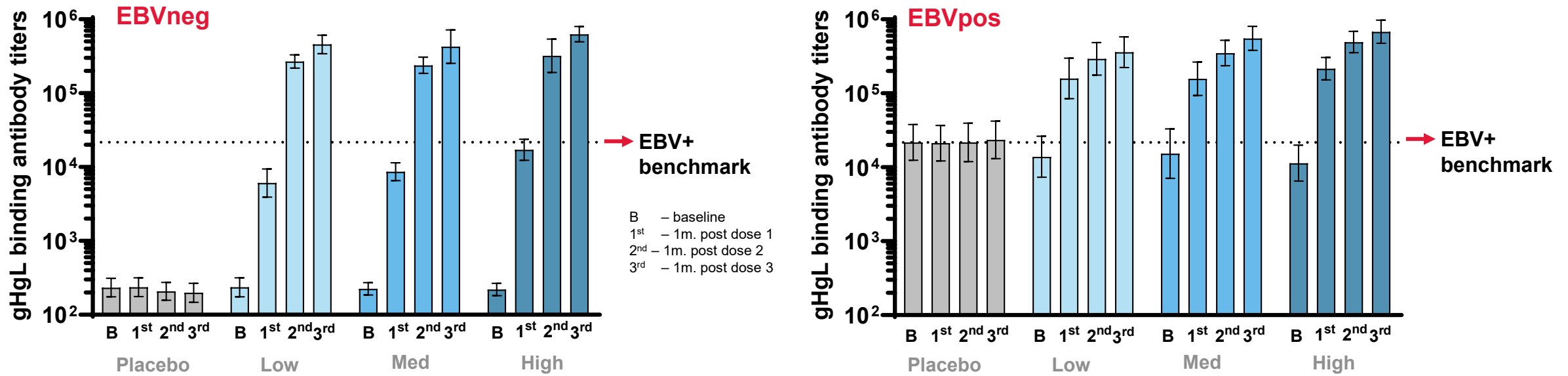
mRNA-1189 was observed to be generally well tolerated following 3 injections

- mRNA-1189 was observed to be generally well tolerated in the Phase 1 study
- The low dose group exhibited the lowest rate of systemic reactogenicity
- The frequency and severity of systemic SARs increased after the second and third injections regardless of EBV serostatus
- **Local reactogenicity:** pain was the most common local reaction at injection site, with frequency similar to other mRNA vaccines



Data from mRNA-1189-P101 Part A (Adults 18-30Y)

gHgL binding antibody titers elicited by mRNA-1189 are numerically higher than those induced by natural infection



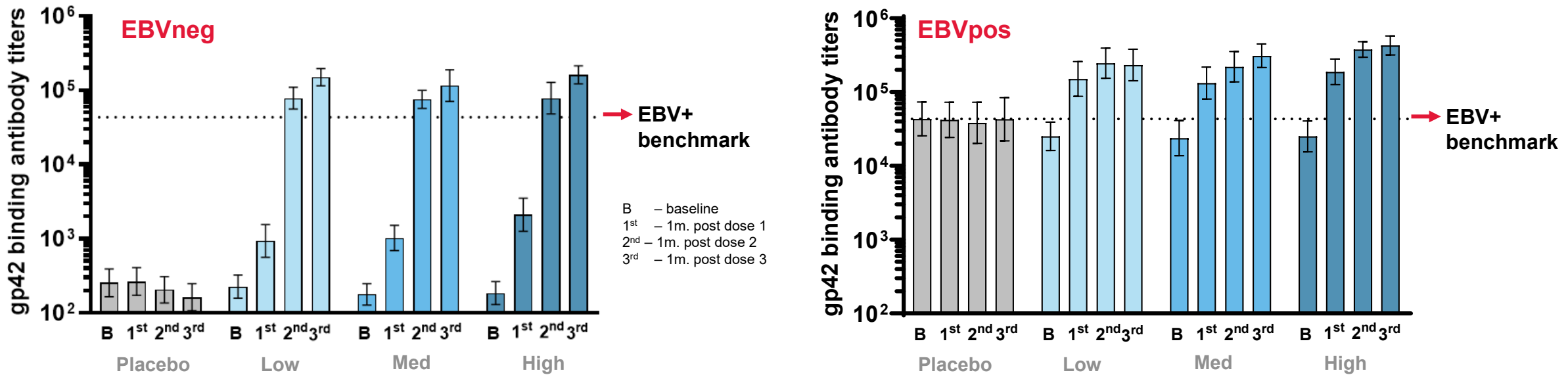
Data from mRNA-1189-P101 Part A (Adults 18-30Y)

Binding antibody titers to gHgL increased after each injection in both EBV seronegatives and EBV seropositives

There was no obvious dose response after 3 injections, regardless of serostatus

After 3 injections, gHgL titers in seronegative recipients were numerically higher than those in EBV seropositives at baseline

gp42 binding antibody titers elicited by mRNA-1189 are numerically higher than those induced by natural infection



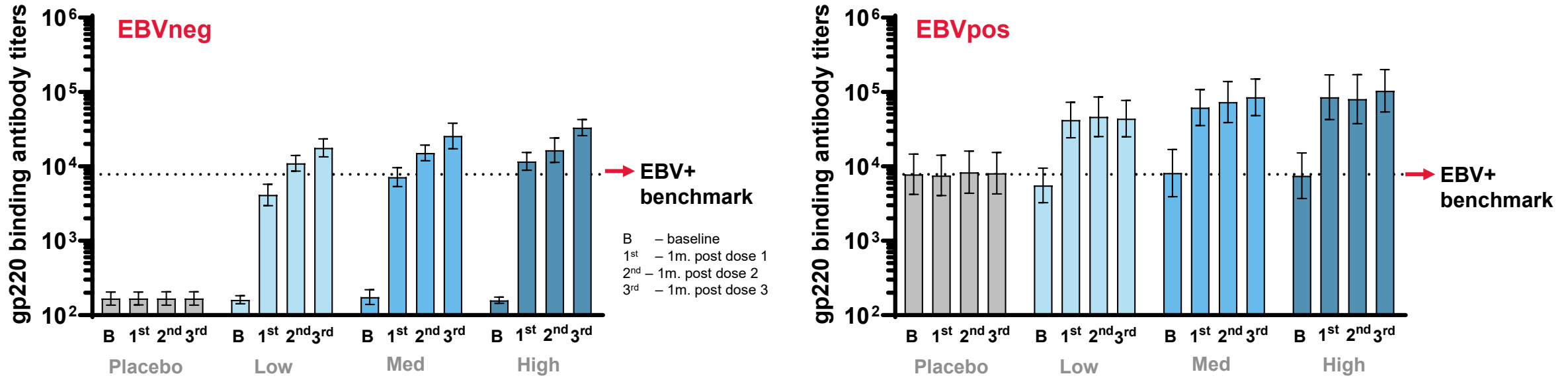
Data from mRNA-1189-P101 Part A (Adults 18-30Y)

Binding antibody titers to gp42 increased after each injection in both EBV seronegatives and EBV seropositives

There was no obvious dose response after 3 injections, regardless of serostatus

After 3 injections, gp42 titers in seronegative recipients were numerically higher than those in EBV seropositives at baseline

gp220 binding antibody titers elicited by mRNA-1189 are numerically higher than those induced by natural infection



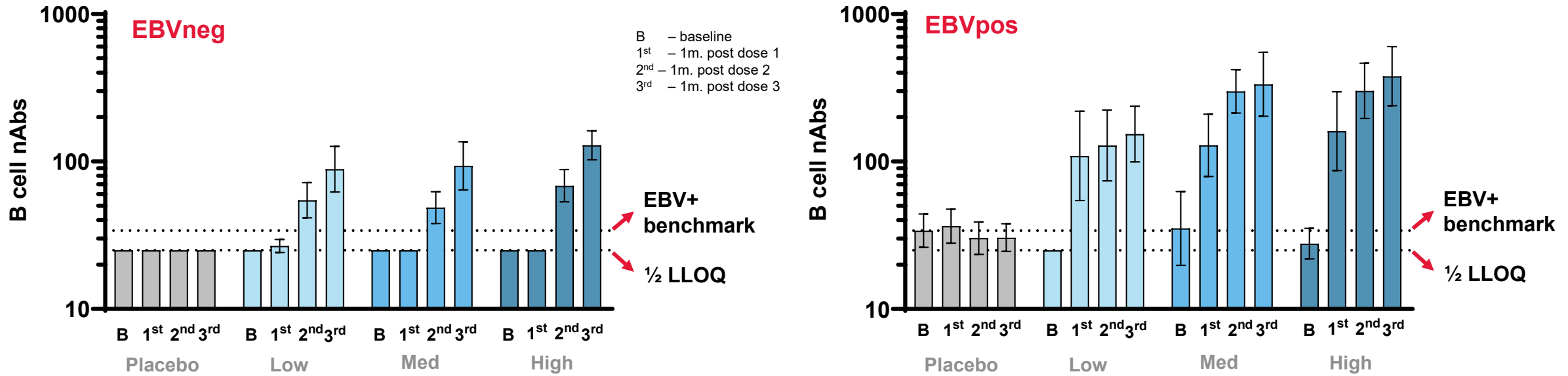
Data from mRNA-1189-P101 Part A (Adults 18-30Y)

Binding antibody titers to gp220 increased after each injection in EBV seronegatives while the fold rise was less obvious in EBV seropositives with the 2nd and 3rd injection

There was no obvious dose response after 3 injections, regardless of serostatus

After 3 injections, gp220 titers in seronegative recipients were numerically higher than those in EBV seropositives at baseline

B cell neutralizing antibody titers elicited by mRNA-1189 are numerically higher than those induced by natural infection



Data from mRNA-1189-P101 Part A (Adults 18-30Y)

B cell nAbs were below detection in all EBV seronegative and most EBV seropositive participants at baseline, indicating a low response even in previously infected healthy individuals

Regardless of serostatus, participants across mRNA-1189 dose groups showed increases in B-cell nAbs from Baseline following 3 injections

Though titers were similar across the 3 dose levels, the highest titers were observed in the highest dose group

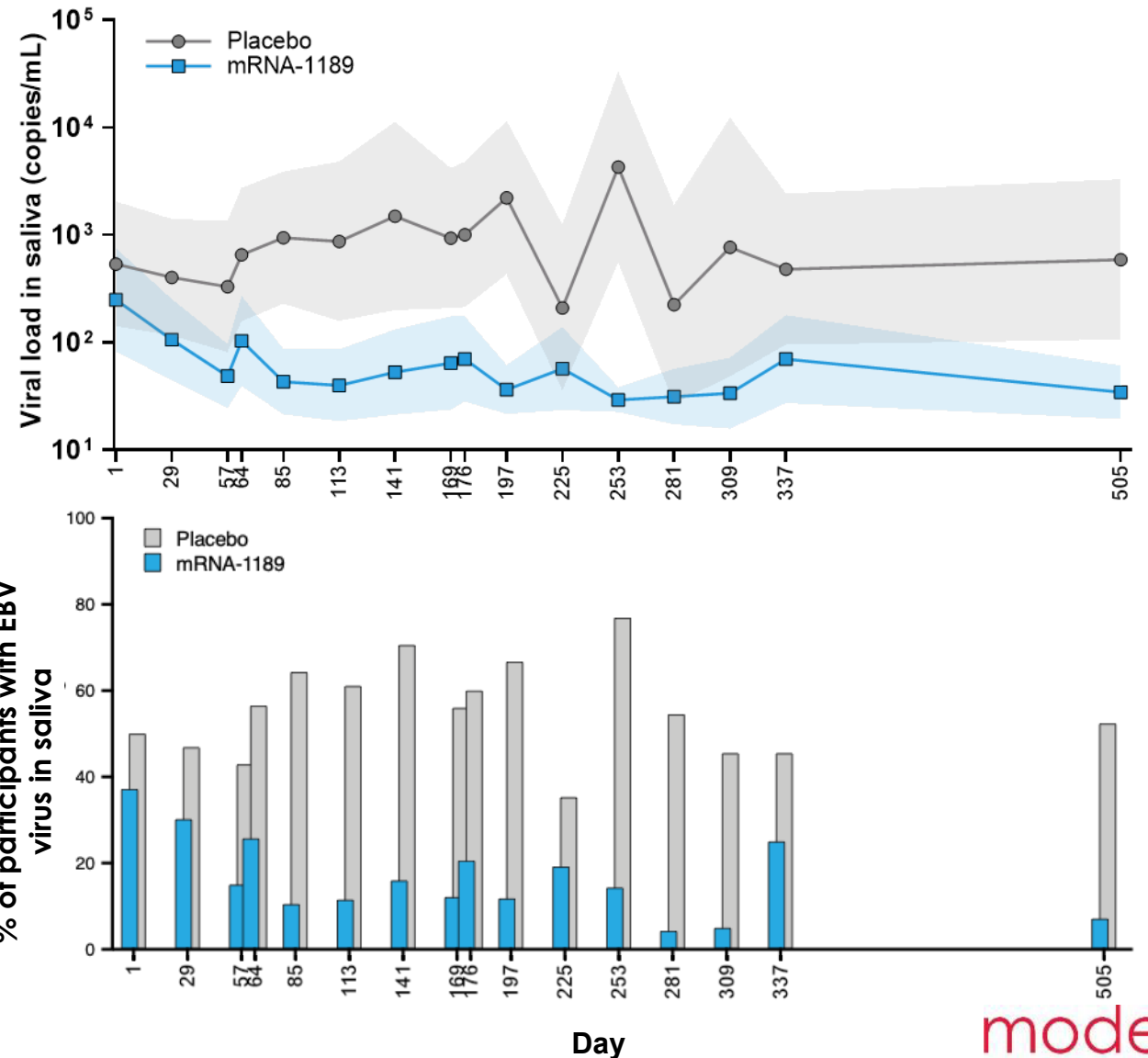
A larger impact of the 3rd injection on B cell nAbs was noted in the EBV seronegative group compared to the EBV seropositive group

Pooled mRNA-1189 dose levels were observed to reduce viral shedding as compared to placebo

Due to small sample size, results across the three mRNA-1189 dose levels were consolidated and analyzed together to provide better qualitative description of the viral shedding data

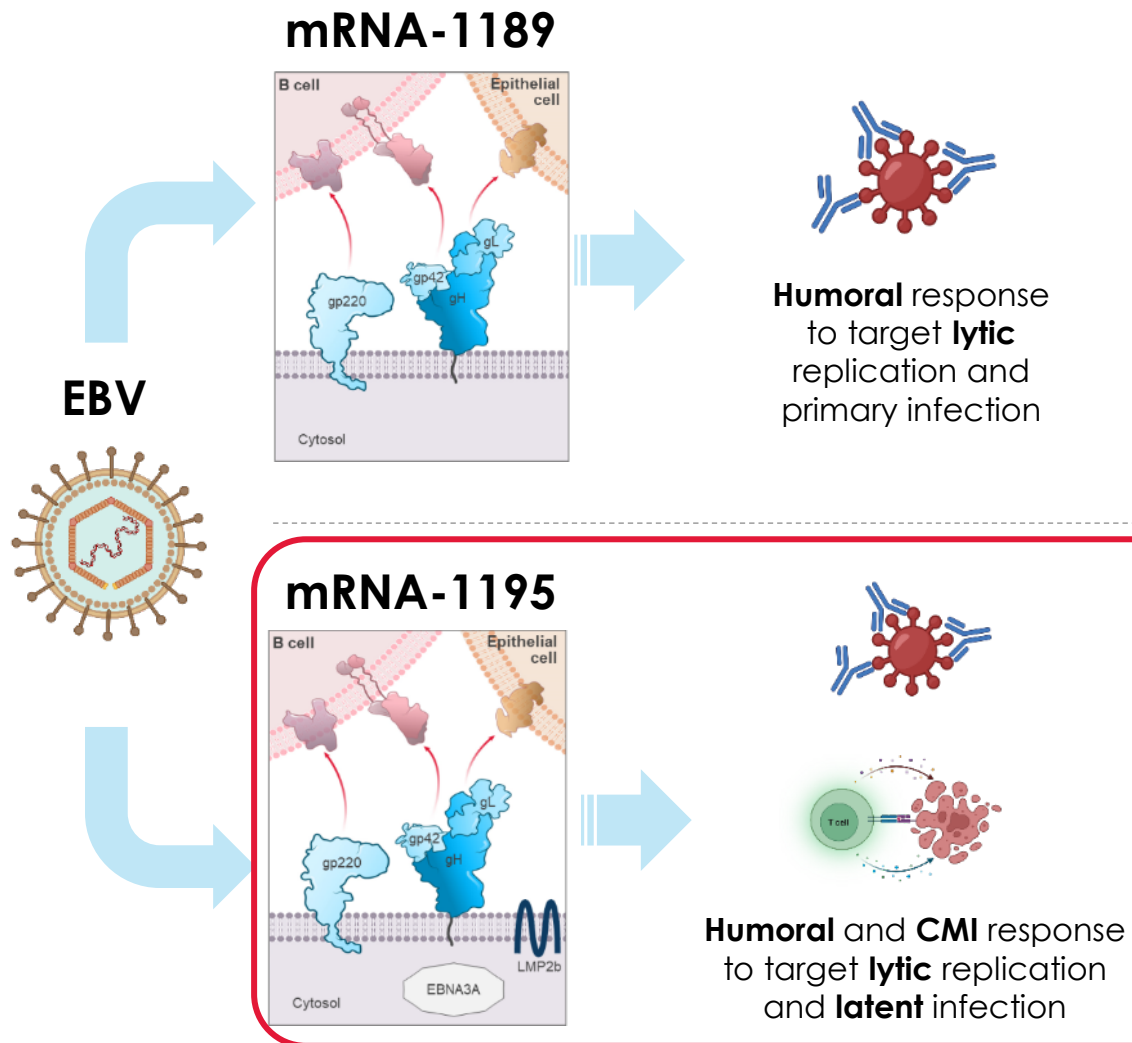
At each timepoint, all dose levels of mRNA-1189 delivered a measurable reduction in detectable EBV viral DNA in saliva sampled at monthly intervals when compared to placebo

Though limited in sample size, this impact continues to be observed at 6 months (D337) and 1 year (D505) after the last injection



Data from mRNA-1189-P101 Part A (Adults 18-30Y)

Moderna's EBV vaccine candidates could tackle multiple EBV-associated conditions



- Vaccine composed of **lytic antigens** to build robust **antibody response** against EBV
- **Primary indication: Infectious Mononucleosis**
- **Prophylactic prevention of long-term sequelae**

- Vaccine composed of **lytic and latent antigens**
- **Multiple Sclerosis**
 - Immune dysregulation of/by EBV may be one underlying mechanisms of action
 - Vaccine MOA: restoring robust immune control of lytic and latent infection through vaccination
- **Post-transplant Lymphoproliferative Disorder (PTLD)**

EBV vaccine (mRNA-1195) Phase 1 part A trial design; fully enrolled

The Phase 1 Part A was designed to test the safety, reactogenicity, and immunogenicity of mRNA-1195 (4 different dose levels) in healthy EBV seropositive participants 18-55 years of age



Design

Randomized equally across 10 arms, observer-blind, placebo-controlled study



Number of participants

350 healthy EBV seropositive adults (18-55 years old)



Vaccination schedule

Three doses of mRNA-1195 (0-2-6 month) or placebo



Duration: 12-months

Enrollment period: Apr – Jul 2023

Study participants will be followed up for 6 months after study injection



Site location

US

Part A (18-55 Y)

Total N = 350

Randomization Ratio = 1:1:1:1:1:1:1:1:1:1

Cohort 1(1195.1; Dose A)	Cohort 2(1195.2; Dose A)
N=35	N=35
Cohort 3(1195.1; Dose B)	Cohort 4(1195.2; Dose B)
N=35	N=35
Cohort 5(1195.1; Dose C)	Cohort 6(1195.2; Dose C)
N=35	N=35
Cohort 7(1195.1; Dose D)	Cohort 8(1195.2; Dose D)
N=35	N=35
Cohort 9(1189; Dose E)	Cohort 10(Placebo)
N=35	N=35

EBV vaccine summary and next steps

Disease burden

- EBV infects more than 90% of the world's adult population; it causes serious health conditions including infectious mononucleosis, several cancers and autoimmune disorders like multiple sclerosis

Safety

- mRNA-1189 is generally well tolerated in adults 18-30 yrs

Immunogenicity

- Phase 1 interim analysis data from mRNA-1189 demonstrate binding antibody titers for glycoproteins (gHgL, gp42, gp220) were boosted regardless of serostatus
- Regardless of serostatus, participants across mRNA-1189 dose groups showed increases in B-cell nAbs from Baseline following 3 injections
- Following 3 injections, titers in mRNA-1189 recipients crossed baseline EBV seropositive threshold
- mRNA-1189 reduced measurable viral shedding in saliva of EBV seropositive recipients

Next steps

- mRNA-1189: advancing toward pivotal development
- mRNA-1195: ongoing Phase 1 study in healthy volunteers

Latent Viruses

HSV

Herpes Simplex Virus Type 2 (HSV-2) infects ~13% of adults globally and is the primary cause of genital herpes

There are an estimated 4 billion people globally infected with HSV, of which 491 million cases are HSV-2¹

Significant unmet medical need

- Globally: ~13% of the population aged 15-49 years has acquired HSV-2²
- US: ~18.6 million people aged 15-49 years living with HSV-2, with ~572,000 new infections/ year³

HSV-2 is the leading cause of genital herpes

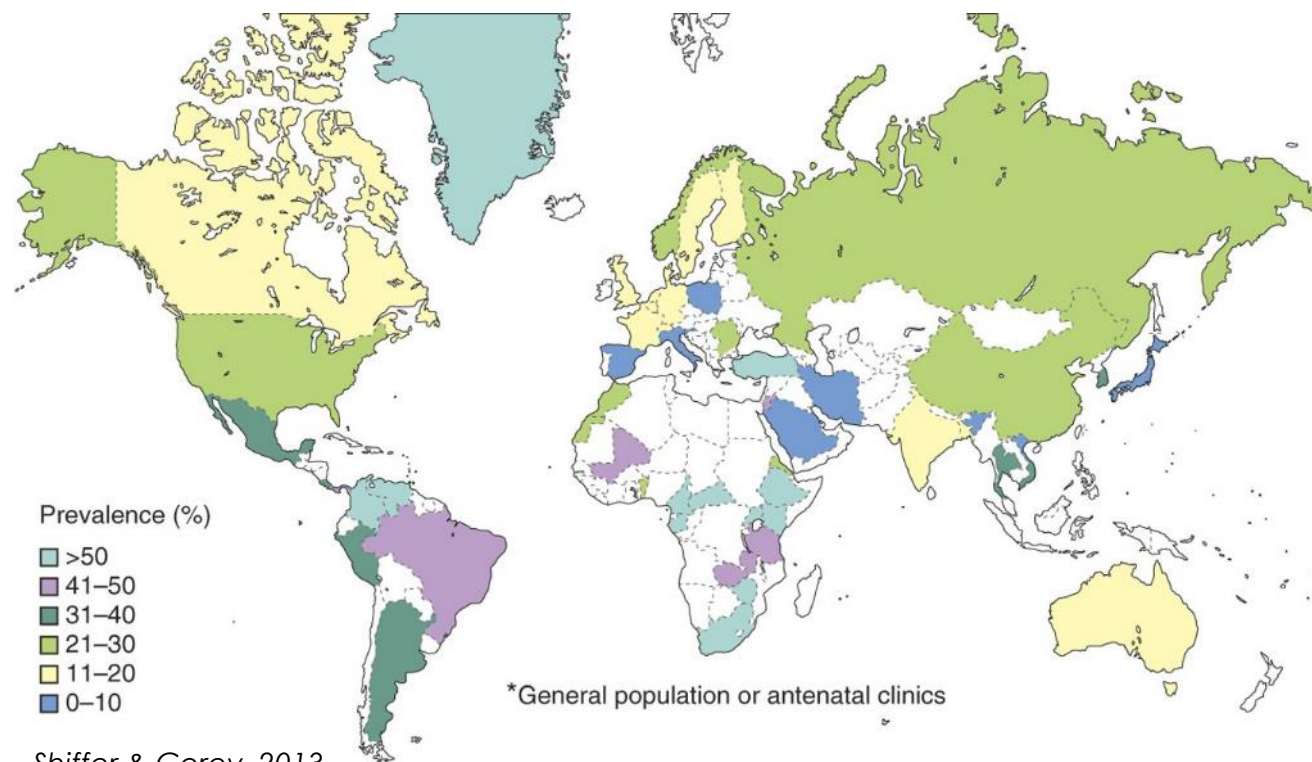
- Globally: ~ 178 million cases (95%) of genital herpes attributable to HSV-2⁴

Disease disparities: women, racial and sexual minority populations at highest risk⁵

- Women almost twice as likely to have HSV-2 infection as men
- Seroprevalence highest in non-Hispanic Black persons in the US⁶

1. James et al, 2020: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7265941/>; 2. James et al, 2016: <https://pubmed.ncbi.nlm.nih.gov/32514197/>; 3. Kreisel et al, 2021: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10245608/>; 4. Looker et al, 2020: <https://gh.bmj.com/content/5/3/e001875>; 5. Looker et al, 2020: <https://gh.bmj.com/content/5/3/e001875>; Spicknall et al, 2021: https://journals.lww.com/stajournal/fulltext/2021/04000/estimates_of_the_prevalence_and_incidence_of.9.aspx; McQuillan et al, 2018 (NCHS Data Brief): <https://www.cdc.gov/nchs/data/databriefs/db304.pdf>; 6. McQuillan et al, 2018 (NCHS Data Brief): <https://www.cdc.gov/nchs/data/databriefs/db304.pdf>

Prevalence of HSV-2 infection in women globally



HSV: mRNA-1608 Phase 1/2 trial design of a therapeutic vaccine against HSV-2; fully enrolled

The Phase 1/2 was designed to test safety and immunogenicity and establish a proof-of-concept of clinical benefit of mRNA-1608 in adults 18-55 years of age with recurrent HSV-2 genital herpes



Design

Randomized 1:1:1:1, observer-blind, controlled study



Number of participants

300 healthy adults 18-55 years of age with a history of HSV-2 infection > 1 year and 3-9 HSV genital recurrences in the prior 12 months

At least 35% participants male in each study arm



Vaccination schedule

1 of 3 dose levels of mRNA-1608 or control (BEXSERO) given at 0 and 2 months



Duration: Approximately 15-months

Study participants will be followed up for 12 months after study injection



Site location

US

Total N = 300
Randomization = 1:1:1:1

mRNA-1608 (Low dose)	N=75
mRNA-1608 (Medium dose)	N=75
mRNA-1608 (High dose)	N=75
Control (BEXSERO)	N=75

Latent Viruses

VZV

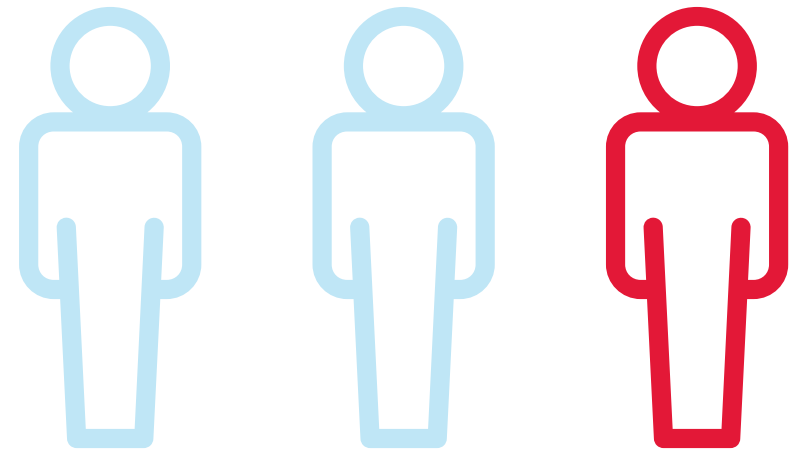
Jacqueline Miller, M.D.

SVP, Head of Development, Infectious Diseases

Herpes zoster (shingles) disease overview

Herpes zoster is caused by **reactivation of latent varicella-zoster virus (VZV)**

Declining immunity in older adults decreases immunity against VZV, allowing reactivation of the virus from latently infected neurons, causing painful and itchy lesions



Herpes zoster occurs in **1 out of 3 adults in the U.S. in their lifetime** and incidence increases at approximately 50 years of age¹

1. <https://www.cdc.gov/shingles/about/index.html>

VZV vaccine mRNA-1468 Phase 1/2 trial design; presenting data today

The Phase 1/2 was designed to test the safety and immunogenicity of mRNA-1468 in healthy adults ≥ 50



Design

Randomized 1:1:1:1:1, observer-blind, active-controlled study



Number of participants

500 medically stable adults ≥ 50 years of age without previous immunization against HZ or history of HZ in previous 10 years

At least 35% participants ≥ 70 years of age in each study arm



Vaccination schedule

2 doses of mRNA-1468 at 1 of 3 dose levels (Low, Medium, High) given at 0, 2 months, or

Single dose of mRNA-1468, given as placebo at month 0 and 1 dose of mRNA-1468 at month 2, or

2 doses of SHINGRIX given at 0, 2 months



Duration: 12-months

Study participants will be followed up for 12 months after study injection



Site location

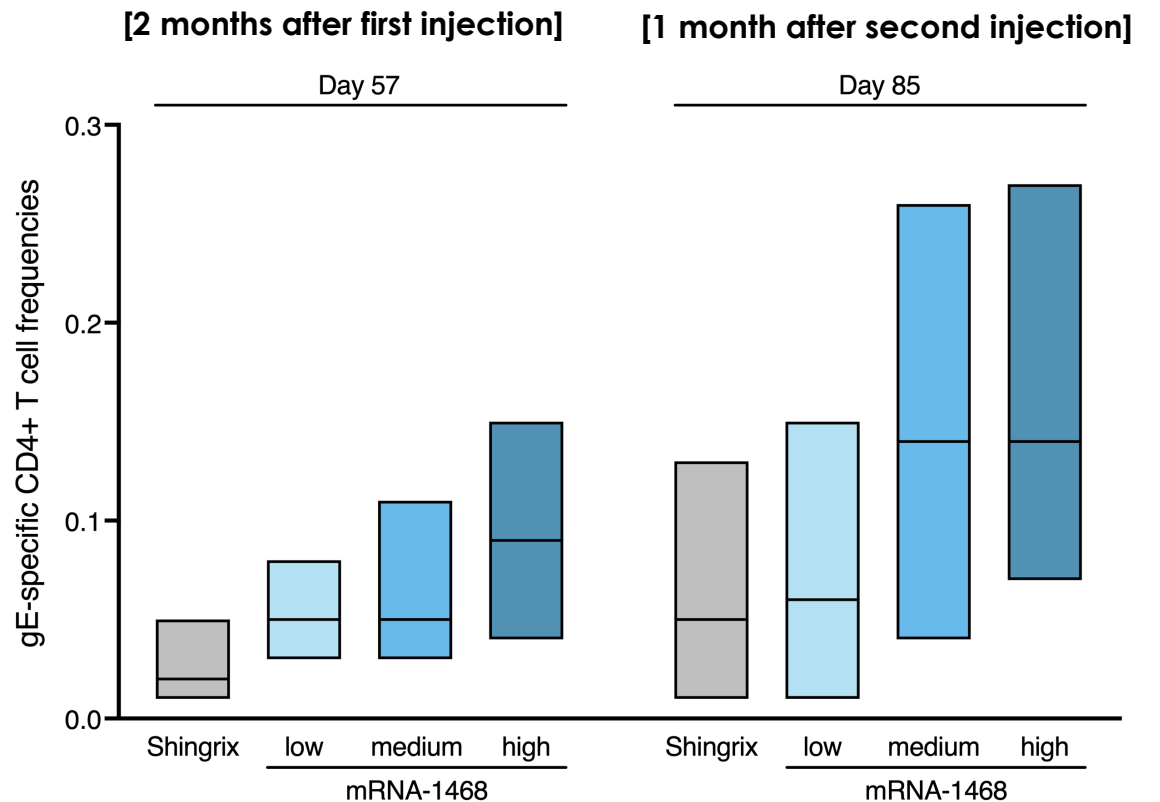
US

Total N = 500
Randomization = 1:1:1:1:1

Active comparator (SHINGRIX)	N=100
mRNA-1468 (2 doses, Low)	N=100
mRNA-1468 (2 doses, Medium)	N=100
mRNA-1468 (2 doses, High)	N=100
mRNA-1468 (1 dose, High)	N=100

2 doses of mRNA-1468 elicited strong antigen-specific CD4+ T cell responses

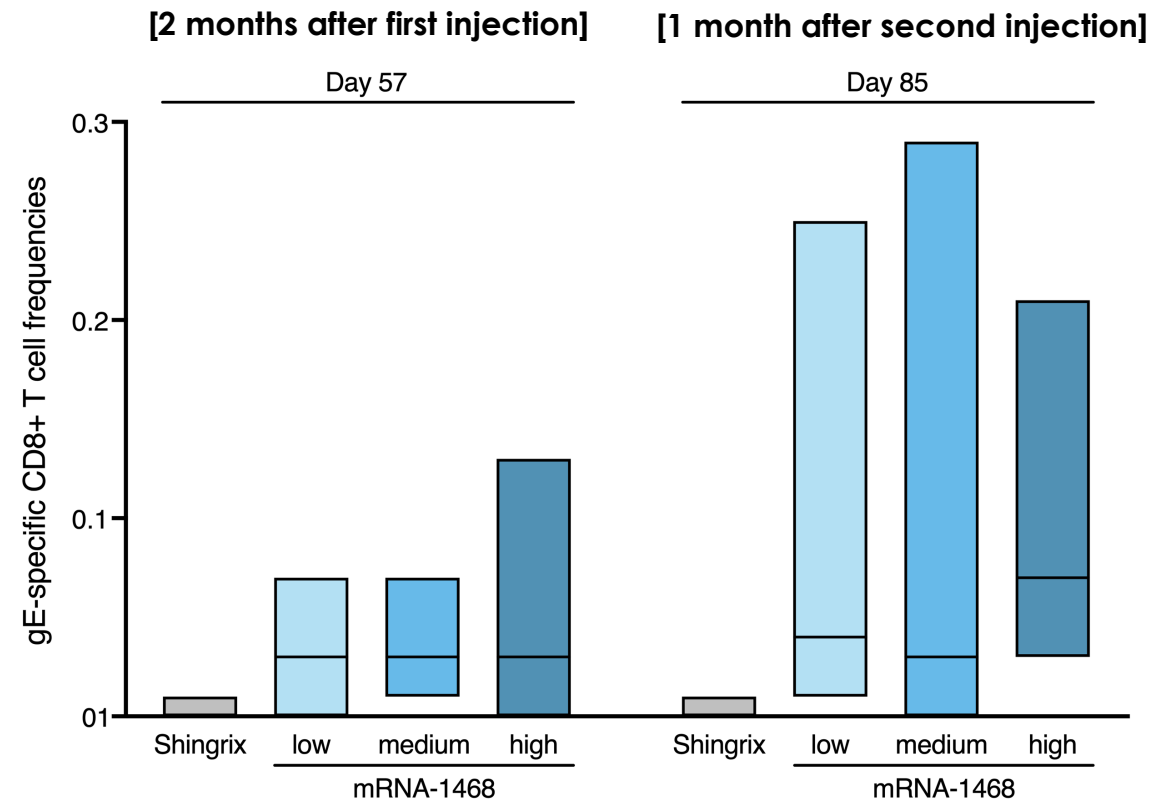
- CD4+ T cells defined as non-naïve gE-specific CD4+ T cells expressing 2 or more of the following markers: IFN γ , TNF α , IL-2, CD40L.
- Approximately 25 participants represented in each study arm at IA1.
- mRNA-1468 elicited comparable or higher CD4+ T cell responses relative to Shingrix after the first and second injection.



Box plots show interquartile range (Q1-Q3) with lines indicating median.

2 doses of mRNA-1468 elicited strong antigen-specific CD8+ T cell responses

- CD8+ T cells defined as non-naïve gE-specific CD8+ T cells expressing any of the following markers: IFN γ , TNF α , or IL-2.
- Approximately 25 participants represented in each study arm at IA1.
- mRNA-1468 elicited comparable or higher CD8+ T cell responses relative to Shingrix after the first and second injection.

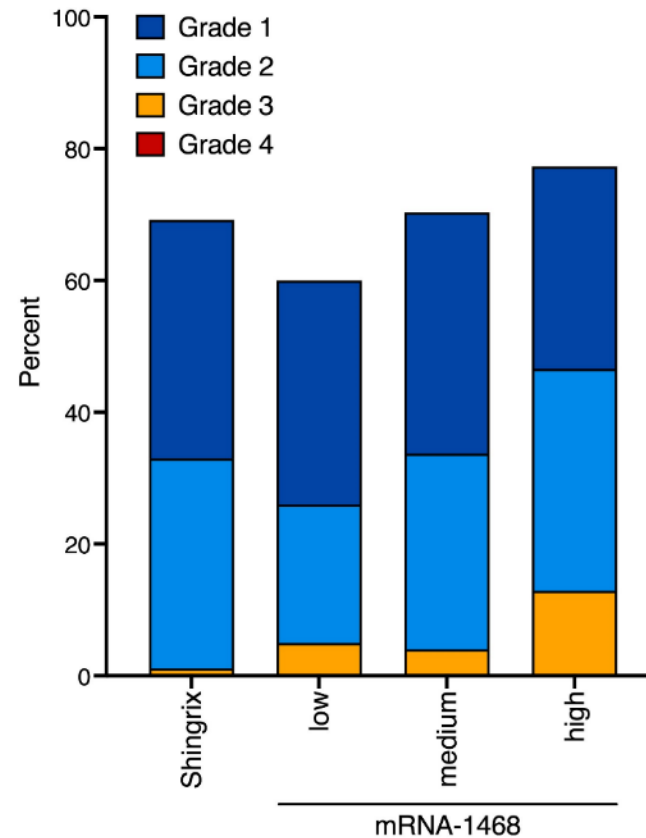


Box plots show interquartile range (Q1-Q3) with lines indicating median.

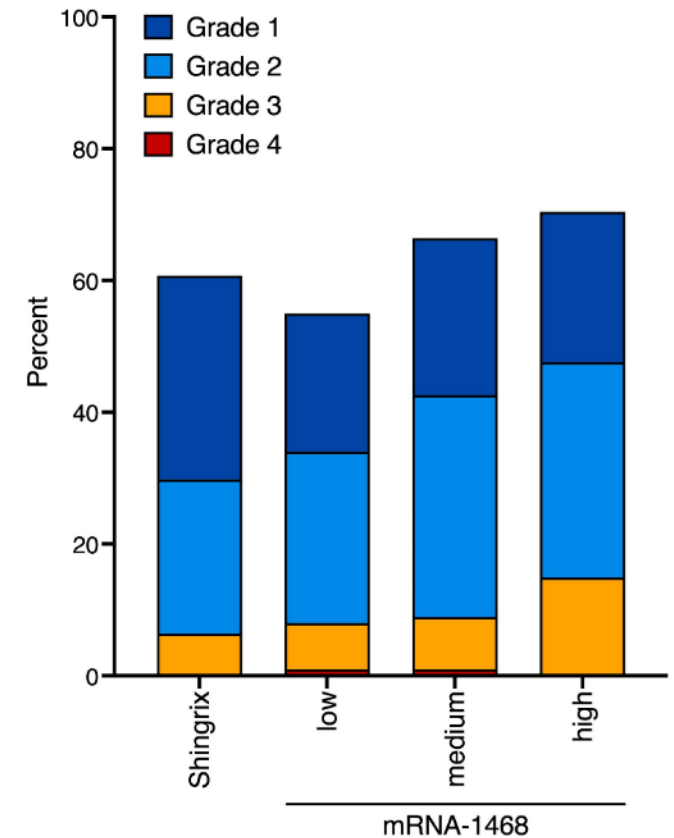
Reactogenicity profile of mRNA-1468 was comparable to Shingrix after any dose

- Reactogenicity of 2 doses of mRNA-1468 after any dose was comparable to Shingrix.
- 94-101 participants in each study arm.

Local Reactogenicity After Any Dose



Systemic Reactogenicity After Any Dose



*Reported grade 4 fever in mRNA-1468 25 µg and 50 µg arms verified as a reporting error and confirmed with subjects

VZV summary and next steps

Immunogenicity

- mRNA-1468 elicited comparable or higher CD4+ and CD8+ T cell responses relative to Shingrix

Safety

- mRNA-1468 was generally well tolerated across all dose levels tested

Next steps

- Additional results from the ongoing Phase 1/2 study will be available later this year, including persistence data
- Advancing toward a pivotal Phase 3 trial

Enteric Viruses

Norovirus

Among enteric viruses, norovirus is a leading cause of diarrheal disease globally resulting in substantial health care burden

Norovirus is associated with 18% of all acute gastroenteritis worldwide¹

The **highest incidence is in children**; morbidity and mortality greatest in children in low-income countries

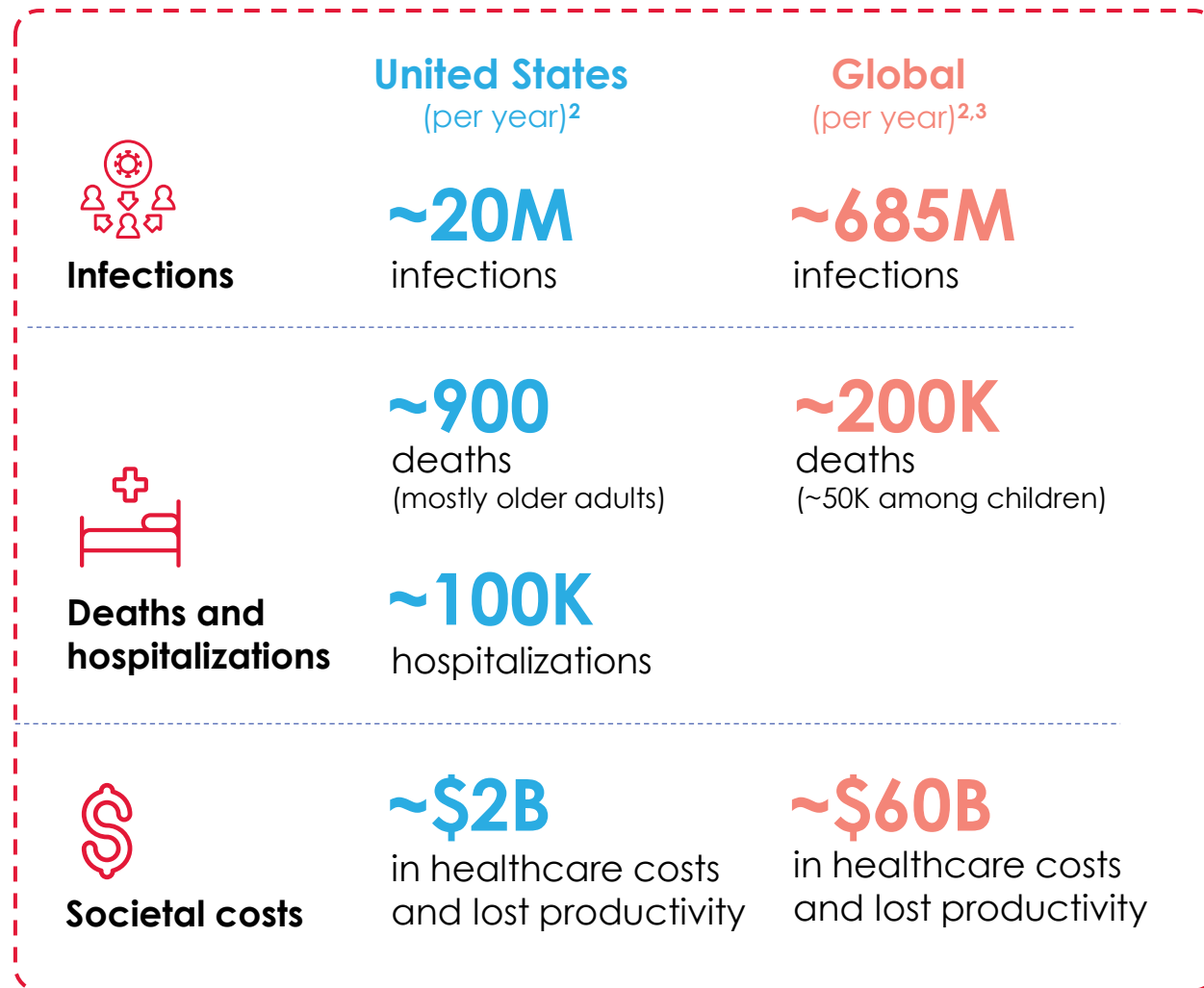
In high-income countries, **older adults and immunocompromised patients are at highest risk of severe outcomes**, including death

The **burden of norovirus among older adults is expected to rise** along with societal aging and an increased need for institutionalized care

1. Ahmed, S.M., et al., Global prevalence of norovirus in cases of gastroenteritis: a systematic review and meta-analysis. *Lancet Infect Dis*, 2014.

2. <https://www.cdc.gov/norovirus/burden.html>

3. <https://www.who.int/teams/immunization-vaccines-and-biologicals/diseases/norovirus>



mRNA-1403/1405 Phase 1 trial design; presenting data today

The Phase 1 was designed to evaluate the safety, reactogenicity and immunogenicity of mRNA-1403 and mRNA-1405 in participants 18-49 and 60-80 years of age



Design

Randomized, observer-blind, placebo-controlled study



Number of participants

664 healthy volunteers 18-49 or 60-80 years old*



Vaccination schedule

1-2 doses of mRNA-1403, mRNA-1405 or placebo in 0,1 month schedule



Duration:

Participants will be followed up for 12 months after last study injection



Site location

US

Total N = 664
11 arms, n~60 per arm



*>40% of participants enrolled were 60-80 years old

Norovirus vaccine development is challenging due to genotypic diversity and variability over time

Norovirus has broad variant variability;
The virus is classified into 10 genogroups and 49 genotypes

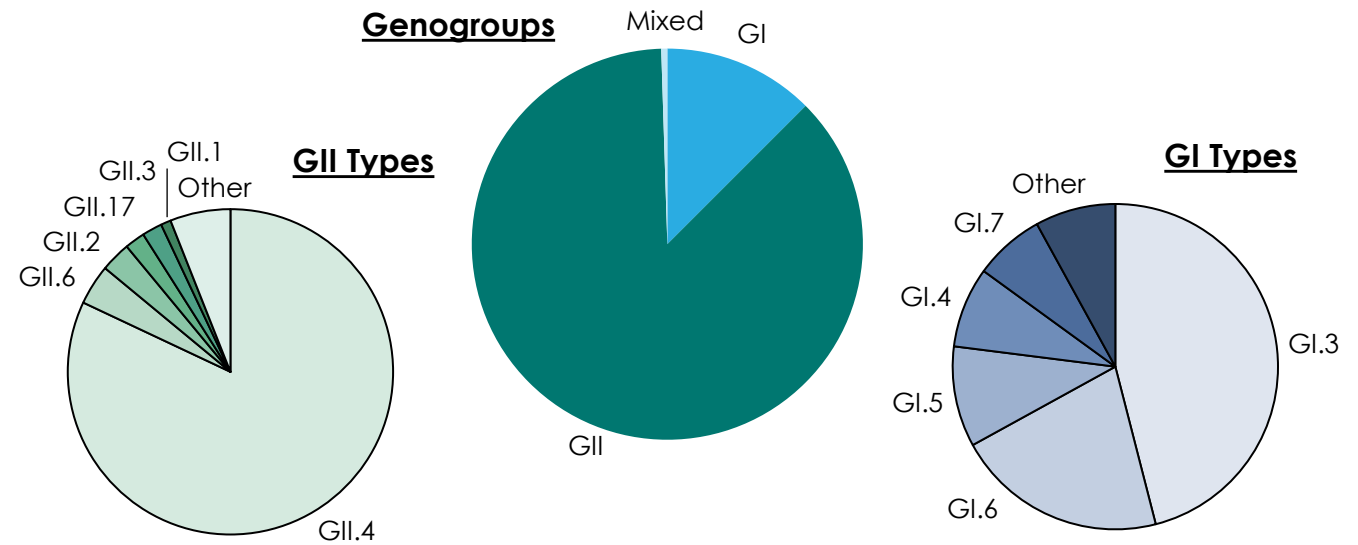
Vaccine development has been challenging to date due to the broad and shifting diversity of genotypes which requires frequent vaccine updates

To protect against >70-80% of noro-AGE in young children and older adults, a multivalent vaccine design is required

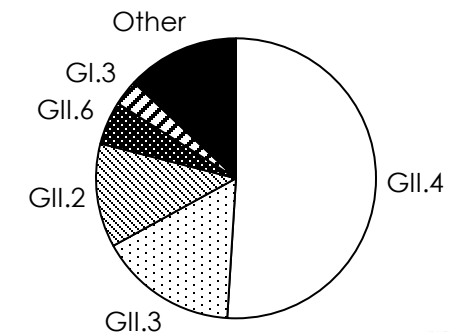
Norovirus genogroups and genotypes in long term care facility outbreaks in the US

2009-2018

Adapted from Calderwood et al, 2022



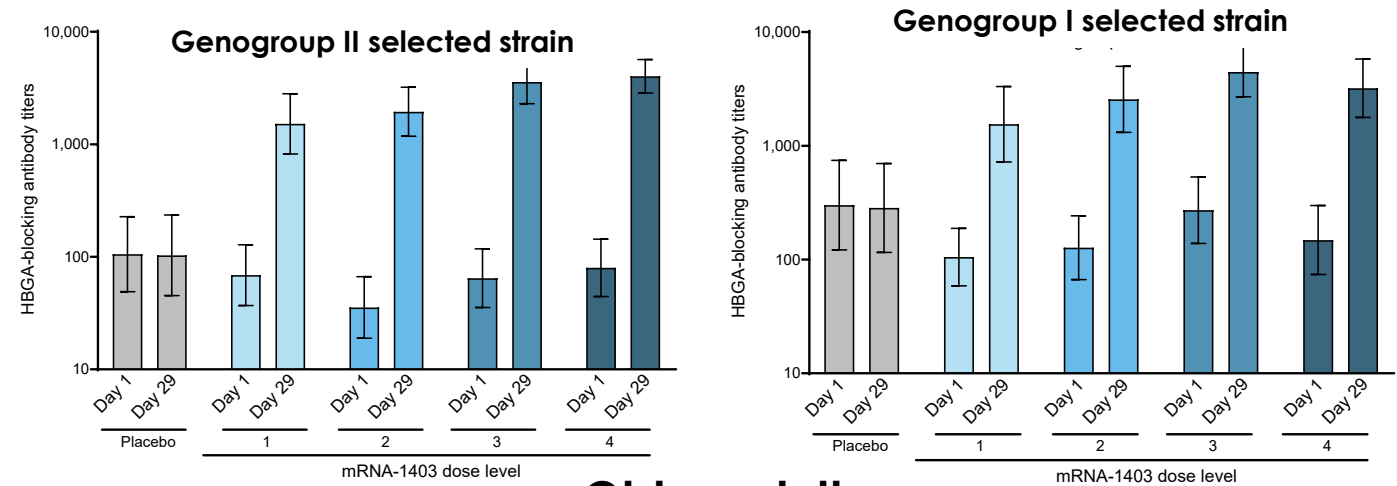
Global distribution of norovirus genotypes among hospitalized children <5, NoroSurv 2015-20122



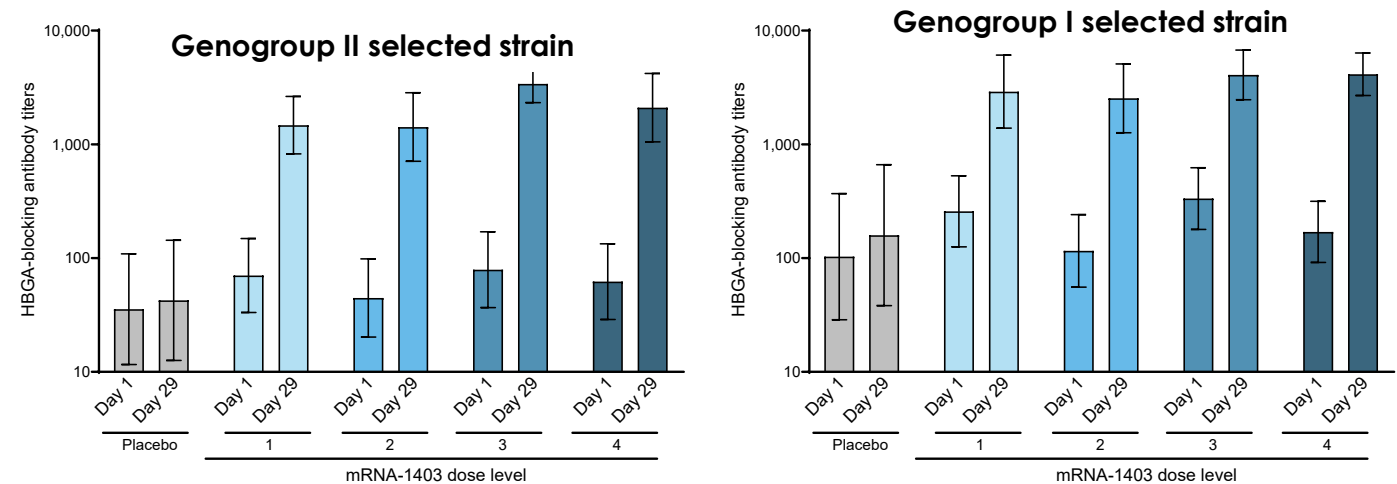
Single dose of mRNA-1403 elicited robust antibody titers against vaccine-matched norovirus genogroup I & II selected strains

- Serum histo-blood group antigen (HBGA) blocking antibody titers measured at Day 1 (pre-dose) and Day 29 (1 month post dose 1) for mRNA-1403 vs. placebo
- Robust boosting of HBGA-blocking antibody titers observed against vaccine-matched norovirus genogroup I and II selected strains across all dose levels evaluated
- Similar mRNA-1403 induced HBGA-blocking antibody titers observed in younger adult and older adult age groups

Younger adults



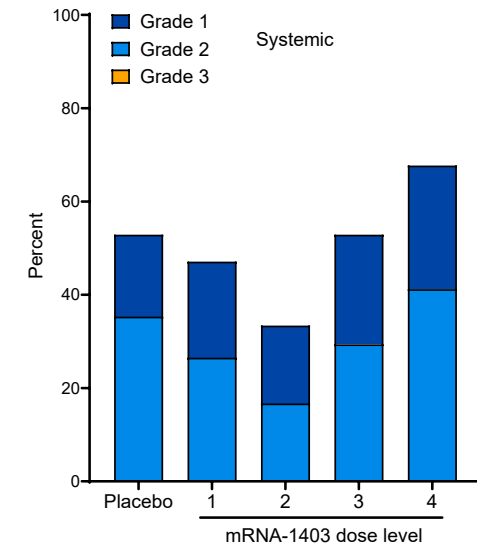
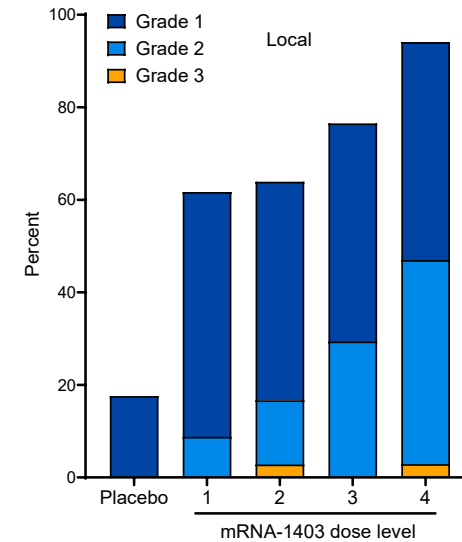
Older adults



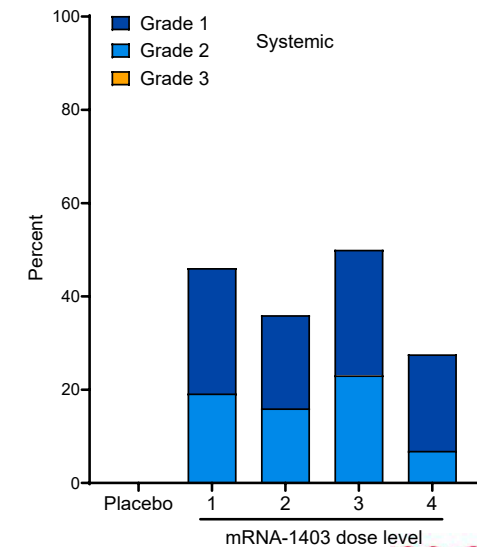
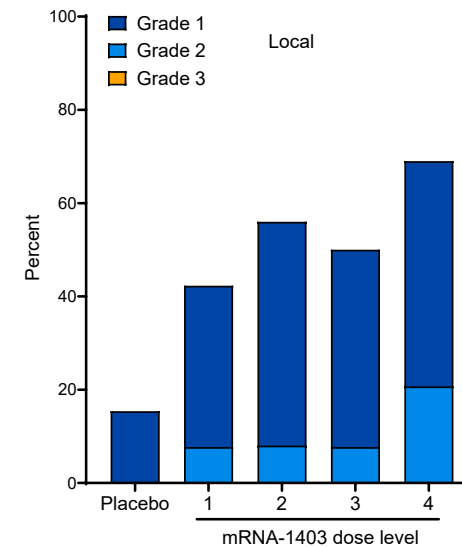
Single dose of mRNA-1403 was well-tolerated across all dose levels evaluated

- Data from interim analysis on mRNA-1403 candidate through completion of Day 29 visits
- No mRNA-1403 related safety concerns identified through interim analysis data cut-off
- Single dose of mRNA-1403 showed a favorable reactogenicity profile across dose levels evaluated with most solicited adverse reactions reported as grade 1 or 2 and few grade 3 reactions

Younger adults



Older adults



Norovirus summary

Burden of disease

- Norovirus is a leading cause of diarrheal disease globally resulting in substantial health care burden

Immunogenicity

- Robust HGBA-blocking antibody titers observed against vaccine-matched norovirus genogroup I and II selected strains across all dose levels evaluated
- Similar mRNA-1403 induced HGBA-blocking antibody titers observed in younger adult and older adult age groups

Safety

- No mRNA-1403 related safety concerns identified through interim analysis data cut-off
- Single dose of mRNA-1403 was well tolerated and showed a favorable reactogenicity profile across dose levels

Next steps

- Advancing toward a pivotal Phase 3 trial



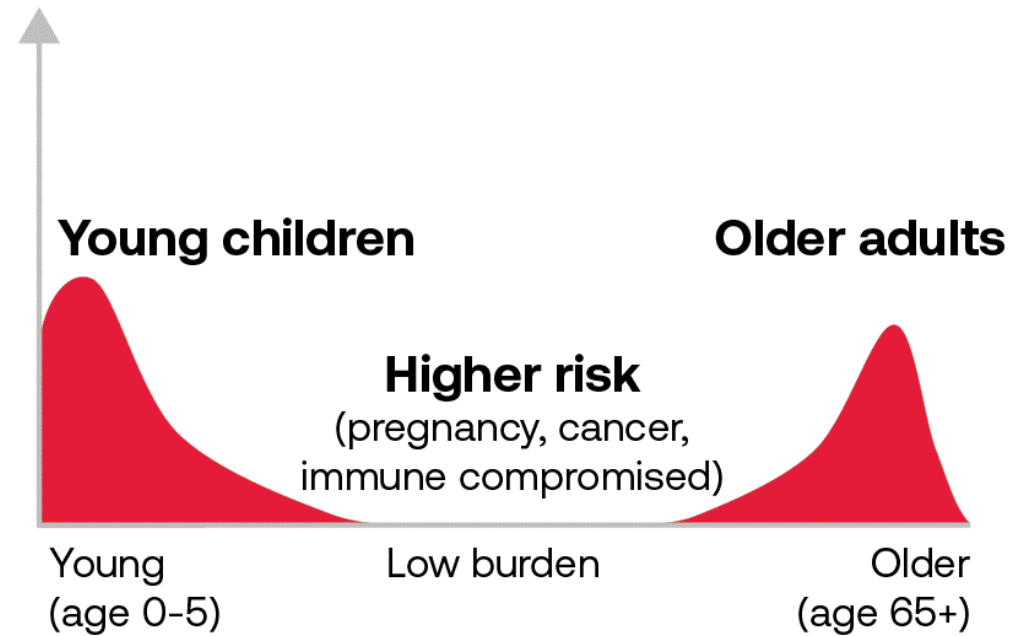
Respiratory Vaccine Portfolio

Jacqueline Miller, M.D.

*Senior Vice President, Head of Development,
Infectious Diseases, Moderna*

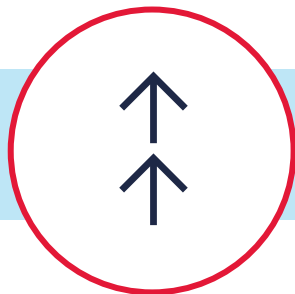
Respiratory virus disease burden is greatest in the young and the old

Burden of respiratory viruses
(illustrative)



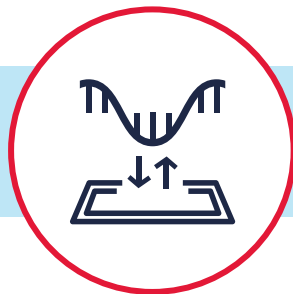
COVID-19

Moderna's SARS-CoV-2 variant monitoring and seasonal update process for mRNA-1273



Preparation for strain selection

- Moderna performs continuous epidemiological monitoring and risk assessment of variants throughout the year
- Updated variant vaccine candidates are prepared and assessed in animals; after strain selection new variant vaccine clinical study is conducted



Seasonal strain selection

- VRBPAC meeting on **May 16 to select strain for 2024/25 season**
- Moderna is well-positioned to serve the 2024/25 fall vaccination campaign because of our ability to use our mRNA platform to rapidly adapt to emerging strains



Continued monitoring / assessment

- Assessment of new variant vaccine clinical participants against new variants as they emerge
- Ongoing epidemiological monitoring and risk assessment of variants throughout the season

Our next generation COVID-19 vaccine mRNA-1283 is a significant leap forward in our respiratory vaccine strategy



mRNA-1283 encodes specifically for the Receptor Binding Domain (RBD) and N-Terminal Domain (NTD) of the spike protein

Enables combination vaccines and enhances overall respiratory portfolio

Offers a more competitive standalone COVID-19 vaccine, designed to be refrigerator-stable and will be in pre-filled syringes (PFS)

mRNA-1283 pivotal Phase 3 trial design; presenting data today

The Phase 3 was designed to test the immunogenicity, safety and relative vaccine efficacy of mRNA-1283.222 against mRNA-1273.222 in participants 12+ years of age



Design

Randomized 1:1, observer-blind, active-controlled study



Number of participants

11,500 medically stable adults \geq 12 years old



Vaccination schedule

Single dose of mRNA-1283.222 or mRNA-1273.222

Bivalent vaccine encoding the ancestral and BA.4/5



Duration:

Study participants will be followed up for 12 months after study injection



Site location

US, UK and Canada

Total N = 11,500
Randomization Ratio = 1:1

mRNA-1283.222
N~5750
mRNA-1273.222
N~5750

mRNA-1283.222 elicited higher titers against both BA.4/5 and original SARS-CoV-2 compared to mRNA-1273.222

Geometric mean titer (GMT) ratio of mRNA-1283.222 was compared to mRNA-1273.222 against BA.4/BA.5 and original SARS-CoV-2 in a Phase 3 study

Approximately 600 participants in each study arm

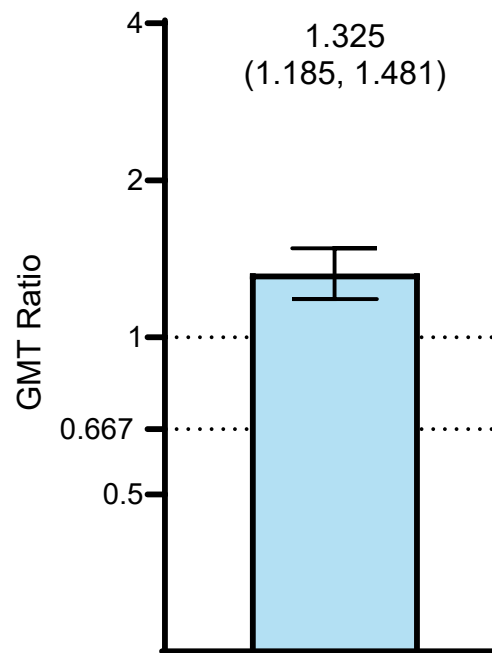
- N=623 mRNA-1283 arm, n=567 mRNA-1273 arm

GMTs, GMFR, and seroresponse rate higher for mRNA-1283.222 versus mRNA-1273.222 (all ages)

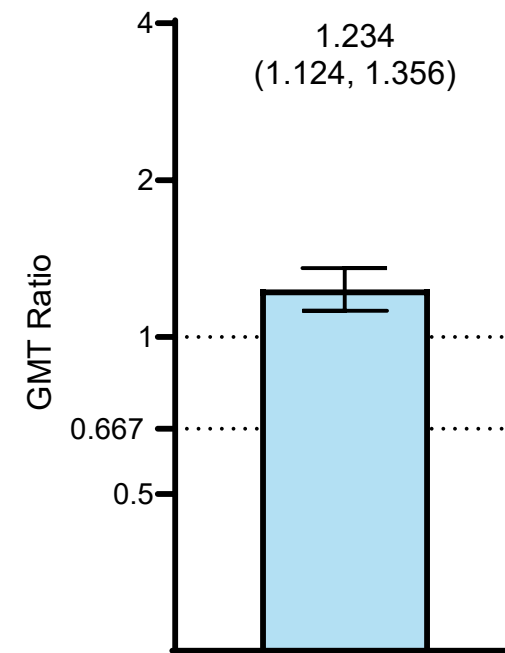
Success Criteria Met

- GMT Ratio¹ non inferiority:
Lower 95% CI of GMT Ratio >0.667
- Seroresponse rate² difference non-inferiority:
Lower 95% CI of difference > -10%

BA.4/BA.5
12 years of age and up



Original SARS-CoV-2
12 years of age and up



¹ ANCOVA model adjusting for SARS-CoV-2 infection status pre-vaccination, randomization age group, number of prior doses and type of last COVID-19 vaccine (mRNA Omicron bivalent, mRNA original monovalent, non-mRNA vaccine). Coefficients for Least Square Means use margins.

² Seroresponse primary definition = an antibody value change from baseline below the LLOQ to $\geq 4 \times$ LLOQ, or at least a 4-fold rise if baseline is \geq LLOQ and $< 4 \times$ LLOQ, or at least a 2-fold rise if baseline is $\geq 4 \times$ LLOQ; 3 95% CI is calculated using the Miettinen-Nurminen (score) confidence limits

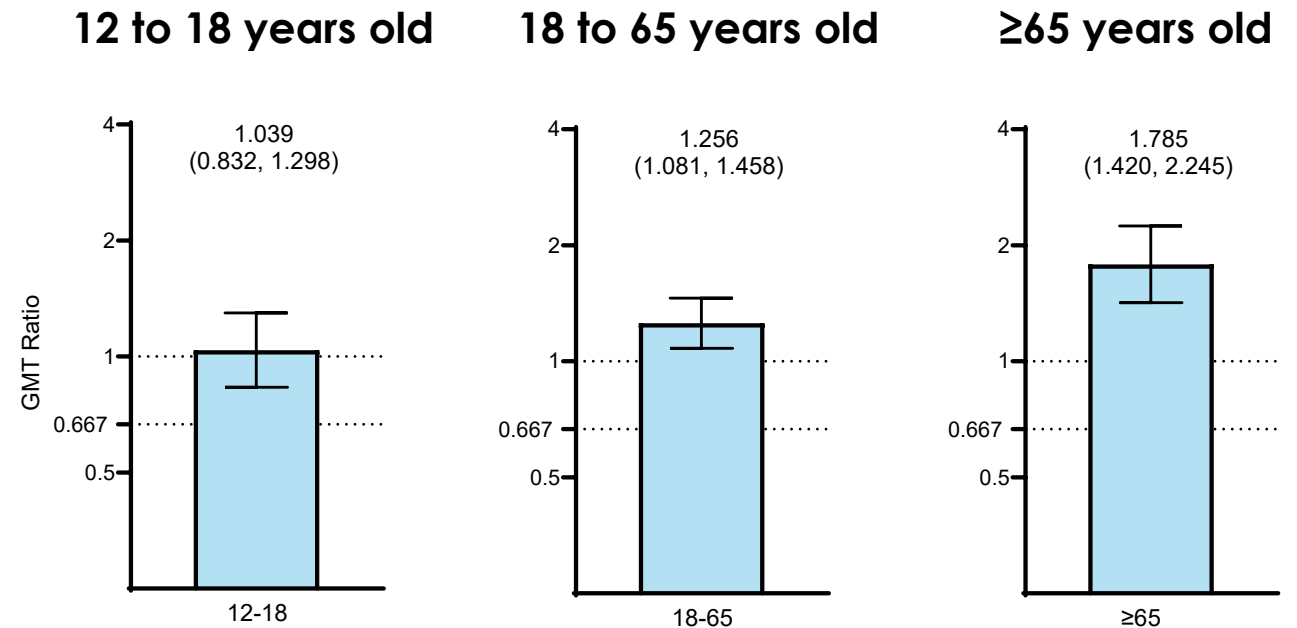
mRNA-1283.222 elicited numerically higher titers against BA.4/5 compared to mRNA-1273.222 in adults

Geometric mean titer (GMT) ratio of mRNA-1283.222 was compared to mRNA-1273.222 against BA.4/BA.5 in a Phase 3 study

GMTs, GMFR, and seroresponse rate higher for mRNA-1283.222 versus mRNA-1273.222 (all ages)

Success Criteria Met

- GMT Ratio¹ non inferiority: Lower 95% CI of GMT Ratio >0.667
- Seroresponse Rate² difference non-inferiority: Lower 95% CI of difference > -10%



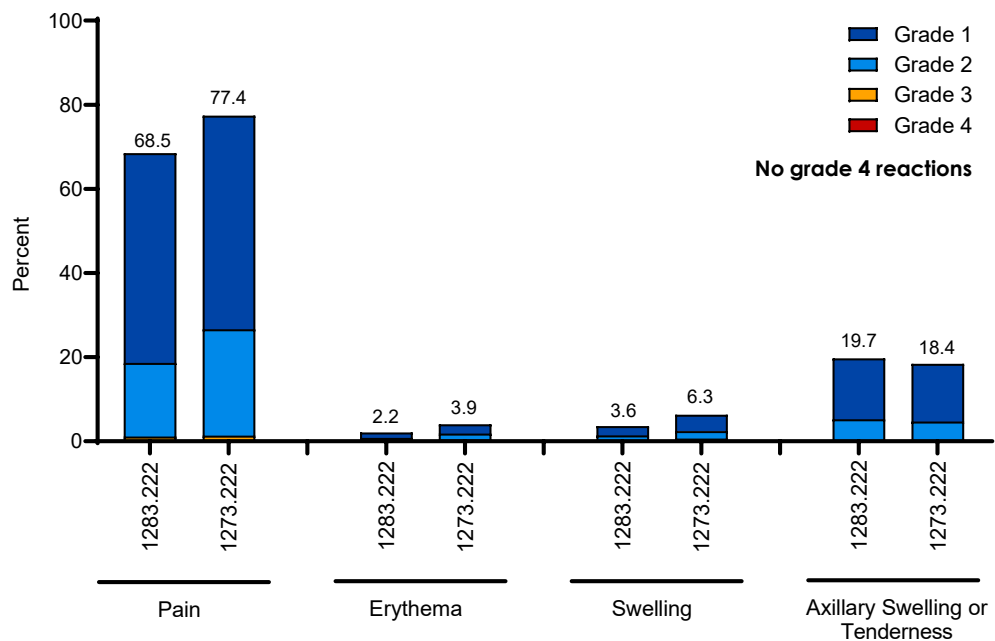
¹ ANCOVA model adjusting for SARS-CoV-2 infection status pre-vaccination, randomization age group, number of prior doses and type of last COVID-19 vaccine (mRNA Omicron bivalent, mRNA original monovalent, non-mRNA vaccine). Coefficients for Least Square Means use margins.

² Seroresponse primary definition = an antibody value change from baseline below the LLOQ to $\geq 4 \times$ LLOQ, or at least a 4-fold rise if baseline is \geq LLOQ and $< 4 \times$ LLOQ, or at least a 2-fold rise if baseline is $\geq 4 \times$ LLOQ; 3 95% CI is calculated using the Miettinen-Nurminen (score) confidence limits

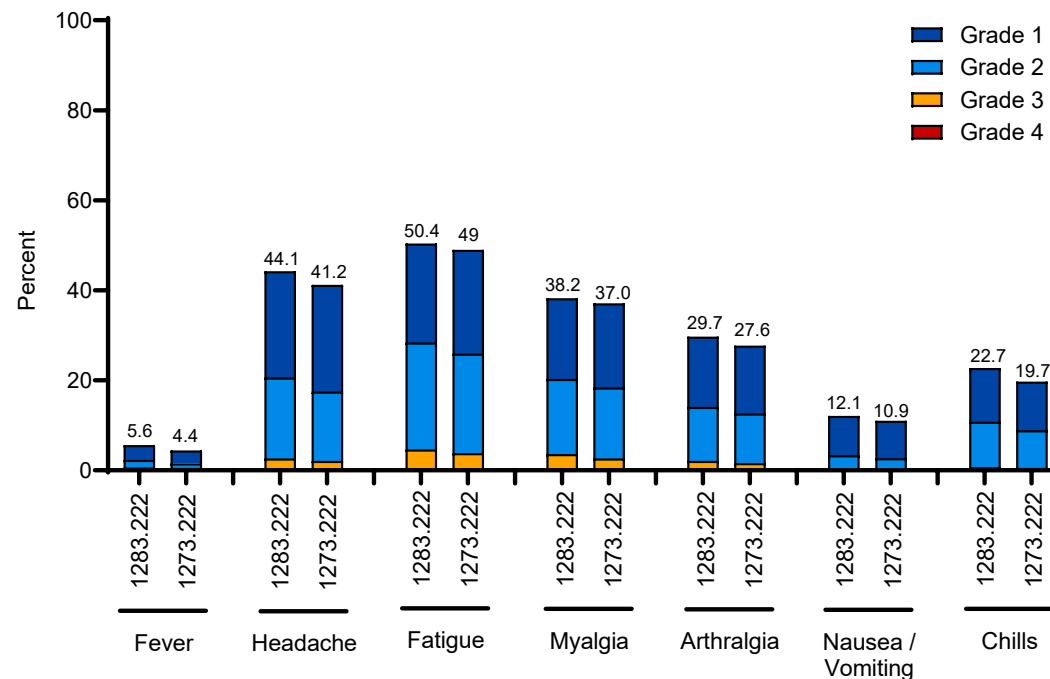
Tolerability profile of mRNA-1283.222 similar to mRNA-1273.222

Overall Local Reactogenicity: 70.3% mRNA-1283.222 vs. 78.4% mRNA-1273.222

Overall Systemic Reactogenicity: 64.4% mRNA-1283.222 vs. 64.2% mRNA-1273.222



Solicited Safety Set: 1283.222 N=5707, 1273.222 N=5711



Solicited Safety Set: 1283.222 N=5707, 1273.222 N=5711

COVID-19 vaccines summary and next steps

Immunogenicity

- mRNA-1283.222 elicited higher titers against both BA.4/5 and original SARS-CoV-2 compared to mRNA-1273.222

Safety

- Tolerability profile of mRNA-1283.222 similar to mRNA-1273.222

Next steps

- mRNA-1273: immunogenicity study after 2024/2025 variant selection
- mRNA-1283: engaging with regulators

RSV

Christy Shaw, Ph.D.

*Vice President, Portfolio Head, Respiratory
Vaccines*

RSV (mRNA-1345) development program in adults >50 years old



Adults (Ages: 60+)

Phase 3
P301 Part A

- Pivotal Phase 3 efficacy and safety
- Awaiting regulatory approvals; preparing for 2024 U.S. launch
- Presenting data today



Adults (Ages: 60+)

Phase 3
P301 Part B

- 24-month revaccination
- Trial ongoing



Adults (Ages: 50+)

Phase 3
P302 Part A

- Standard dose influenza vaccine co-administration
- Presenting data today



Adults (Ages: 50+)

Phase 3
P302 Part B

- COVID-19 vaccine co-administration
- Presenting data today



Adults (Ages: 50+)

Phase 3
P302 Part C

- 12-month revaccination



Adults (Ages: 65+)

Phase 3
P304

- High dose influenza vaccine co-administration;
- Trial fully enrolled

RSV (mRNA-1345) P301 Part A older adult pivotal safety and efficacy

Phase 2/3 pivotal vaccine efficacy and safety trial designed to evaluate the safety, tolerability, and efficacy of mRNA-1345 (50 µg) in adults ≥ 60 years of age



Design

Randomized 1:1, observer-blind, placebo-controlled study



Number of participants

~37,000 adults ≥ 60 years of age (Phase 2: ~2000; Phase 3: ~35,000)



Vaccination schedule

Single dose of mRNA-1345 (50 µg) or placebo



Duration

Participants followed up for 24 months after study injection



Site location

22 countries

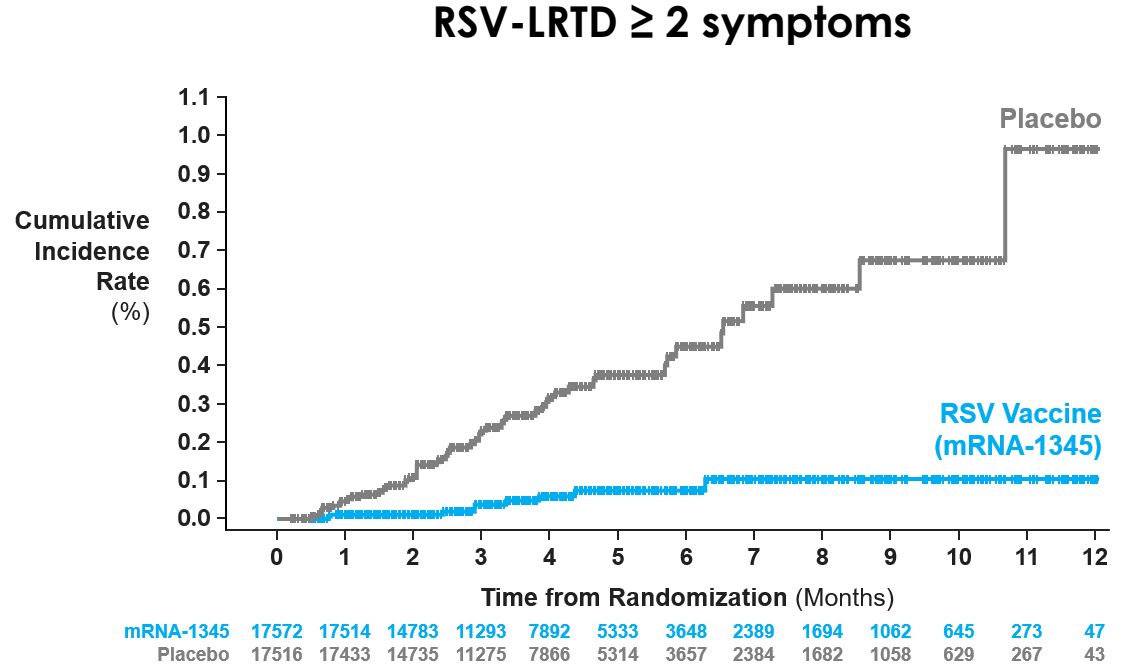
Phase 2/3 pivotal efficacy
≥ 60 years of age
Total N ~ 37,000

mRNA-1345	Placebo
N~18,500	N~18,500

RSV vaccine efficacy met primary and key secondary endpoints in primary analysis

Study 301 per protocol analysis, median follow up of 3.7 months (maximum of 12.6 months) after vaccine/placebo

	Cases, n (%)		Vaccine Efficacy (%) Based on Hazard Ratios ¹
	mRNA-1345 (N = 17,572)	Placebo (N = 17,516)	
RSV LRTD ≥ 2 symptoms	9 (0.05%)	55 (0.31%)	83.7% (66.0%, 92.2%)
RSV LRTD ≥ 3 symptoms	3 (0.02%)	17 (0.10%)	82.4% (34.8%, 95.3%)
RSV ARD	26 (0.15%)	82 (0.47%)	68.4% (50.9%, 79.7%)



The results of the primary efficacy and safety analysis of this Phase 2/3 efficacy study were recently published in the NEJM¹

1. https://www.nejm.org/doi/full/10.1056/NEJMoa2307079?query=featured_home

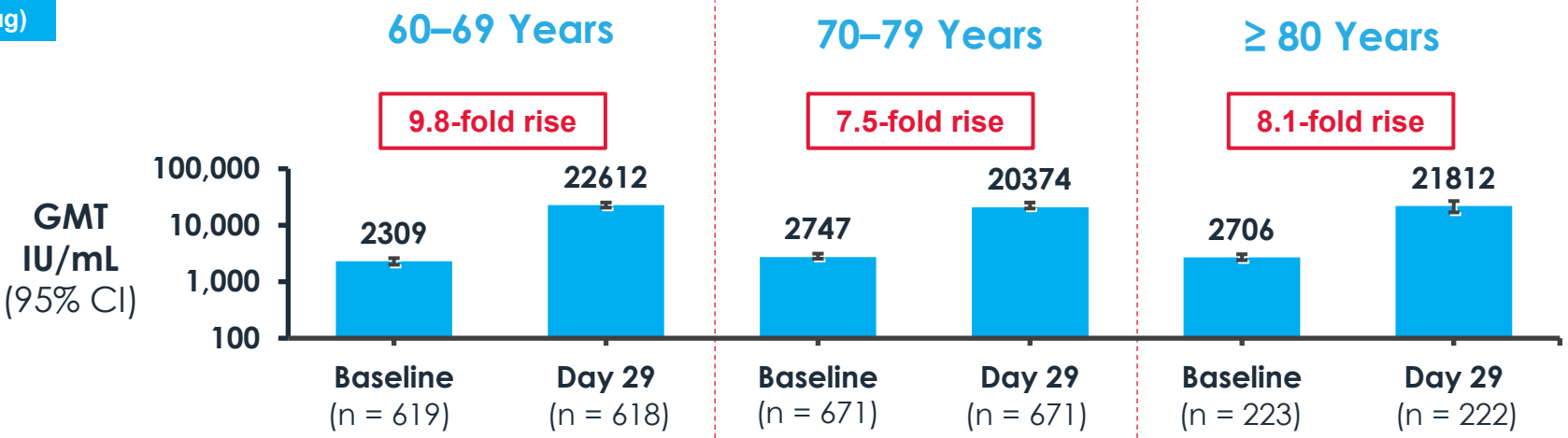
RSV neutralizing antibody responses are similar across age groups, including ≥ 80 years old

Study 301 – RSV neutralizing antibody (IU/mL)

Per Protocol Immunogenicity Set

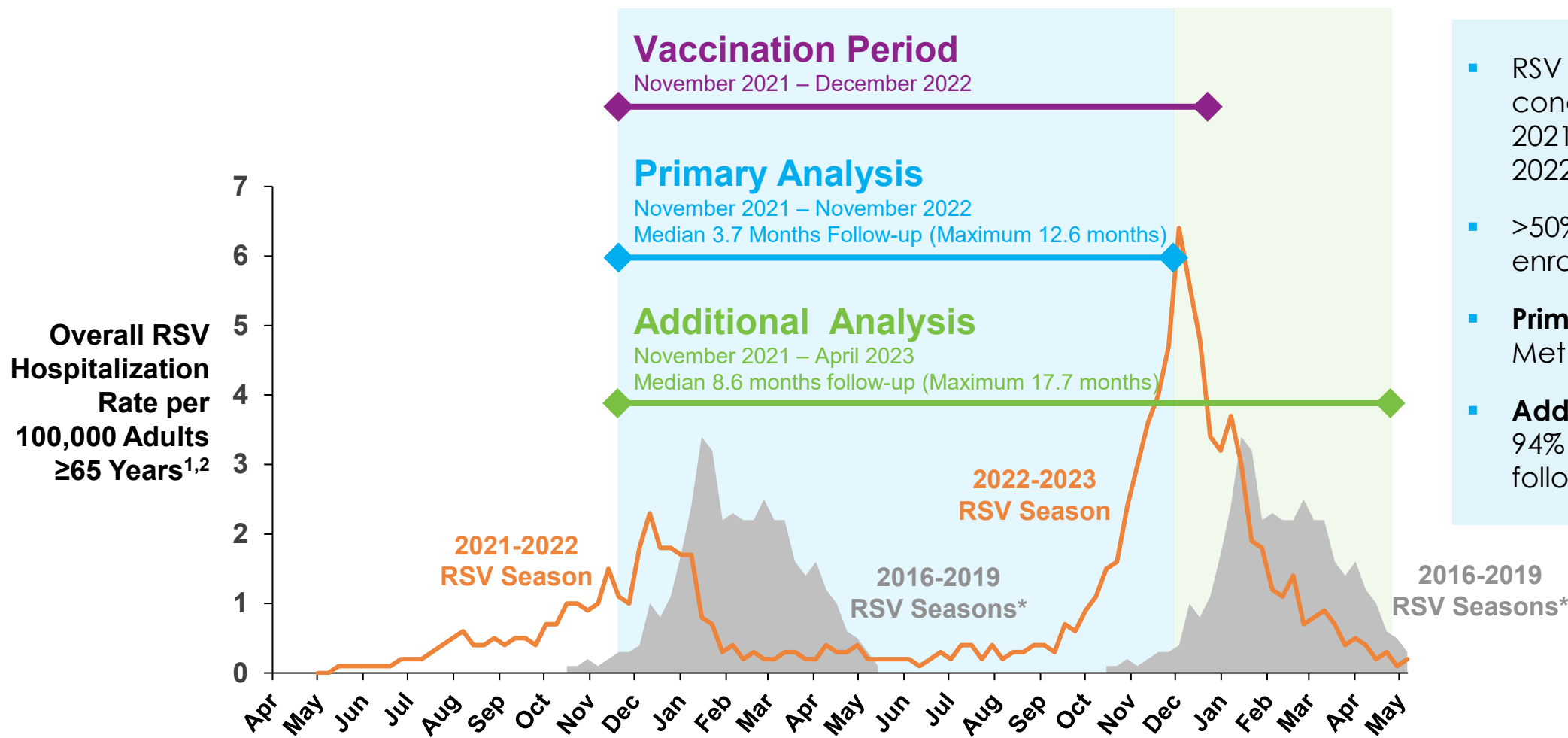
mRNA-1345 (50 µg)

RSV-A Assay



- Baseline titers similar across age groups
- Day 29 titers and fold rise are similar across age groups

Primary and additional analyses confirm durable protection through full 2022-2023 RSV season for mRNA-1345



- RSV efficacy study conducted across 2021 – 2022 and 2022 – 2023 seasons
- >50% of participants enrolled in US
- **Primary Analysis:** Met success criteria²
- **Additional Analysis:** 94% of participants followed for ≥6 months

*Median RSV hospitalization rate for 2016 – 2019. Data only collected from October to April each year.
 1. CDC. Respiratory Syncytial Virus Hospitalization Surveillance Network (RSV-NET). https://data.cdc.gov/Public-Health-Surveillance/Weekly-Rates-of-Laboratory-Confirmed-RSV-Hospitali/29hc-w46k/data_preview. 2. Wilson E, et al. NEJM. 2023;389:2233-2244.

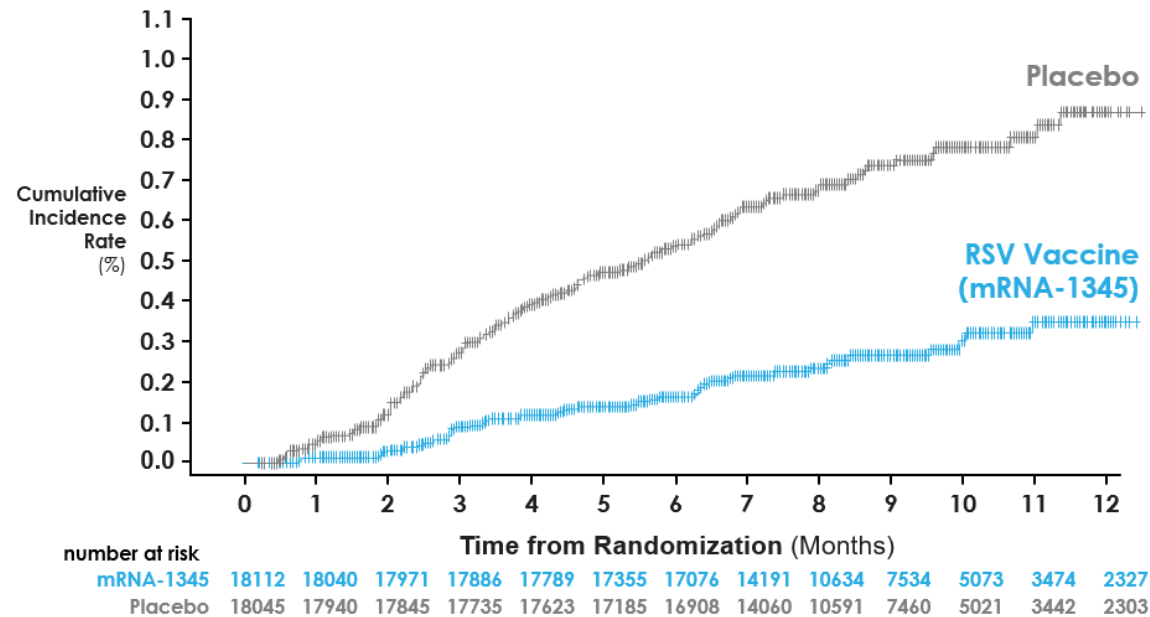
Additional analysis: efficacy of mRNA-1345 against RSV LRTD among adults ≥ 60 Years

Unblinded analysis, median follow-up of 8.6 months (maximum of 17.7 months) after vaccine/placebo

Cases, n (%)

	RSV Vaccine (mRNA-1345) (N = 18,112)	Placebo (N = 18,045)	Vaccine Efficacy (%) Based on Hazard Ratios (95% CI)
RSV LRTD ≥ 2 symptoms	47 (0.26%)	127 (0.70%)	63.3% (48.7%, 73.7%)
RSV LRTD ≥ 3 symptoms	19 (0.10%)	51 (0.28%)	63.0% (37.3%, 78.2%)
RSV ARD	86 (0.47%)	185 (1.03%)	53.9% (40.5%, 64.3%)
RSV-LRTD Associated Shortness of Breath¹	11/18,101 (0.06%)	43/18,002 (0.24%)	74.6% (50.7%, 86.9%)

RSV-LRTD ≥ 2 symptoms



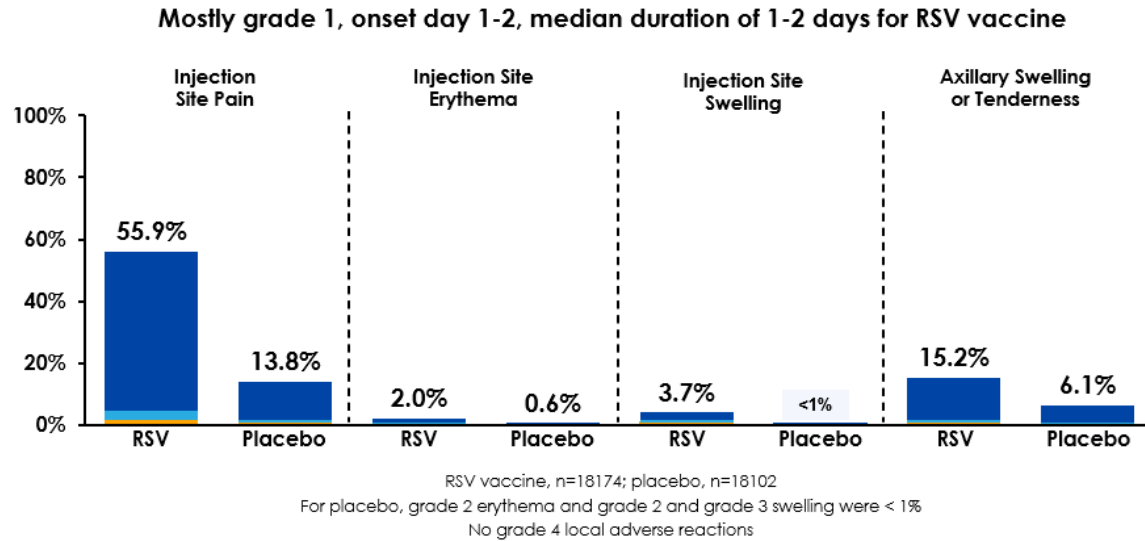
- Vaccine protection continues over a longer period (median 8.6 months) through high-transmission 2022/2023 RSV season
- Lower bound of the confidence interval continued to exceed 20%

1. Shortness of breath was a post hoc analysis
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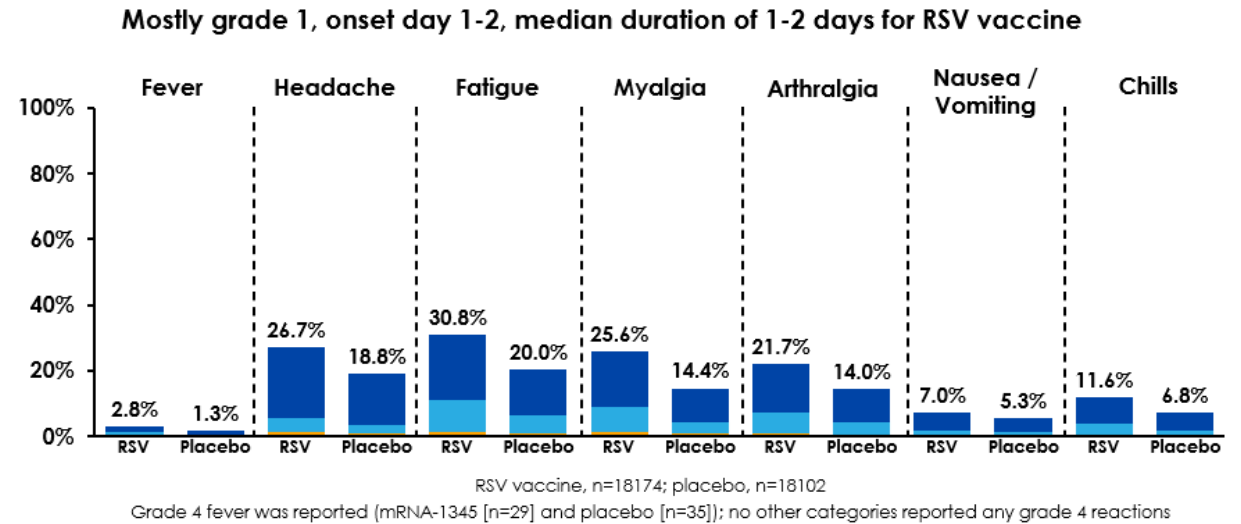
mRNA-1345 reactogenicity

Study 301 - Solicited Safety Set

Solicited Local Reactions within 7 Days After RSV Vaccine vs Placebo



Solicited Systemic Reactions within 7 Days After RSV Vaccine vs Placebo



RSV P301 summary and next steps

Efficacy

- 83.7% and 82.4% against RSV LRTD with ≥ 2 and ≥ 3 , respectively, lower respiratory signs/symptoms in primary analysis of adults 60 and over
- RSV-A & RSV-B nAb responses similar across age groups, including those ≥ 80 years old

Safety

- Well tolerated; solicited adverse reactions were mostly grade 1 or 2
- No safety concerns identified

Next steps

- Awaiting regulatory approvals in multiple countries
- Expecting to launch in the U.S. in 2024 after ACIP recommendation

RSV (mRNA-1345) development program in adults >50 years old



Adults (Ages: 60+)

Phase 3
P301 Part A

- Pivotal Phase 3 efficacy and safety
- Awaiting regulatory approvals; preparing for 2024 U.S. launch
- Presenting data today



Adults (Ages: 60+)

Phase 3
P301 Part B

- 24-month revaccination
- Trial ongoing



Adults (Ages: 50+)

Phase 3
P302 Part A

- Standard dose influenza vaccine co-administration
- Presenting data today



Adults (Ages: 50+)

Phase 3
P302 Part B

- COVID-19 vaccine co-administration
- Presenting data today



Adults (Ages: 50+)

Phase 3
P302 Part C

- 12-month revaccination



Adults (Ages: 65+)

Phase 3
P304

- High dose influenza vaccine co-administration;
- Trial fully enrolled

mRNA-1345 P302 Part A co-administration of RSV vaccine with standard dose quadrivalent influenza vaccine (Afluria®)

Safety and immunogenicity study



Design

Randomized, observer-blind study



Number of participants

~1,600 adults ≥ 50 years of age



Vaccination schedule

Co-administration study of mRNA-1345 and Afluria;

Study arms: mRNA-1345; Afluria; mRNA-1345+Afluria



Duration

Enrollment initiation: Apr 2022

Participants followed up for 6 months after study injection



Site location

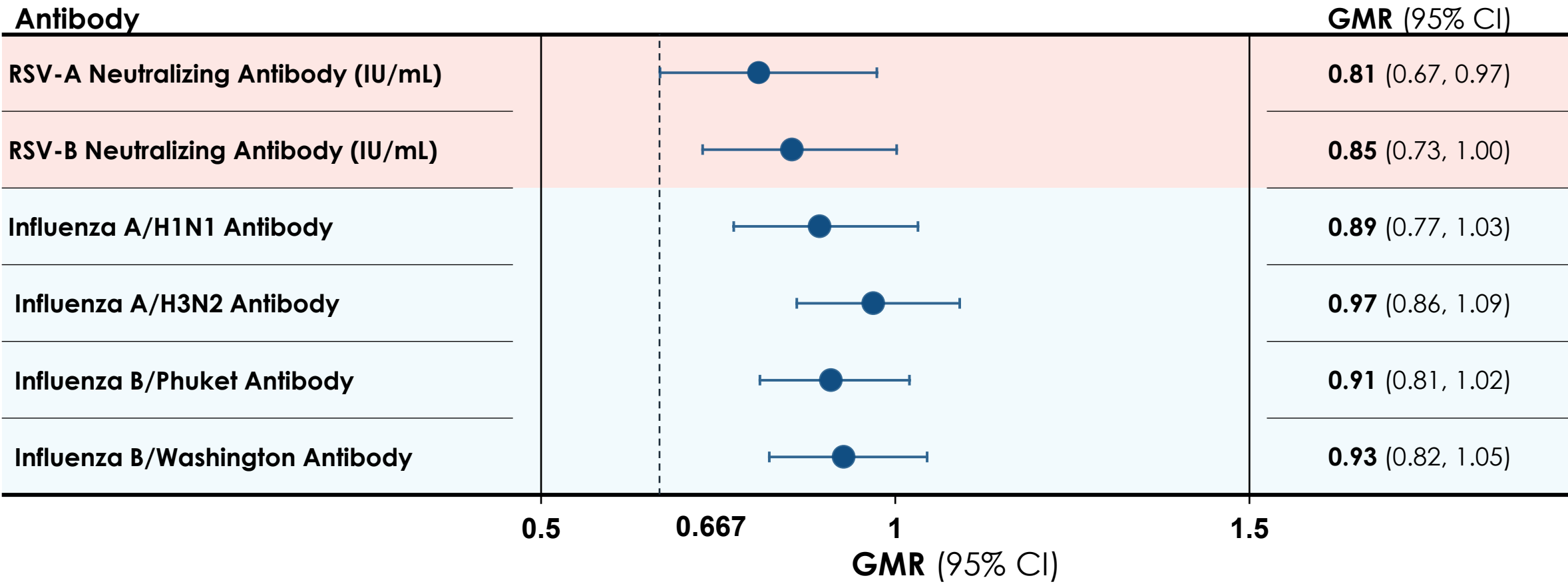
United States

Phase 3
≥ 50 years of age
Total N ~ 1,600

mRNA-1345 + Afluria Quadrivalent	mRNA-1345 + placebo	Afluria Quadrivalent + placebo
N~700	N~200	N~700

Comparison of day 29 geometric mean titer ratio (GMR) – concomitant vs nonconcomitant administration of mRNA-1345 and quadrivalent influenza vaccine

Study 302, Part A



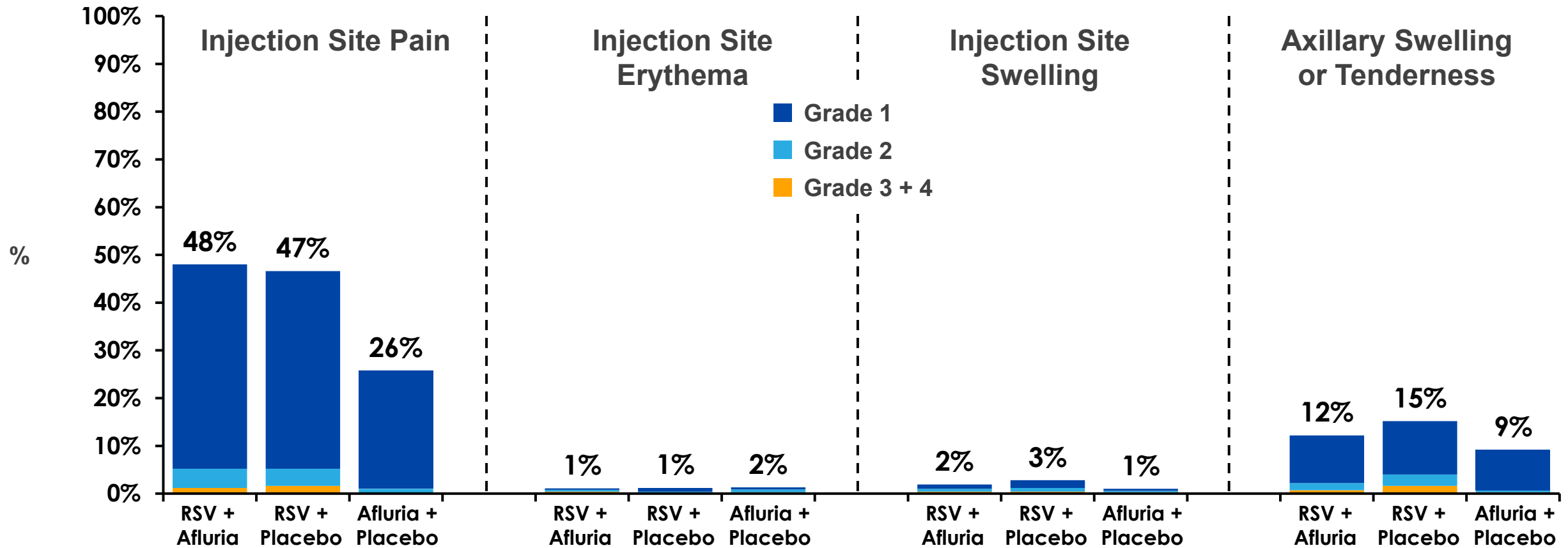
All GMR non-inferiority criteria met (LB of the 2-sided 95% CI of GMR > 0.667)



Solicited local reactions within 7 days after mRNA-1345 alone or co-administered with quadrivalent influenza vaccine (Afluria) in adults ≥ 50

Study 302, Part A - Solicited Safety Set

Mostly grade 1, onset day 1-2, median duration of 2 days for RSV + Flu

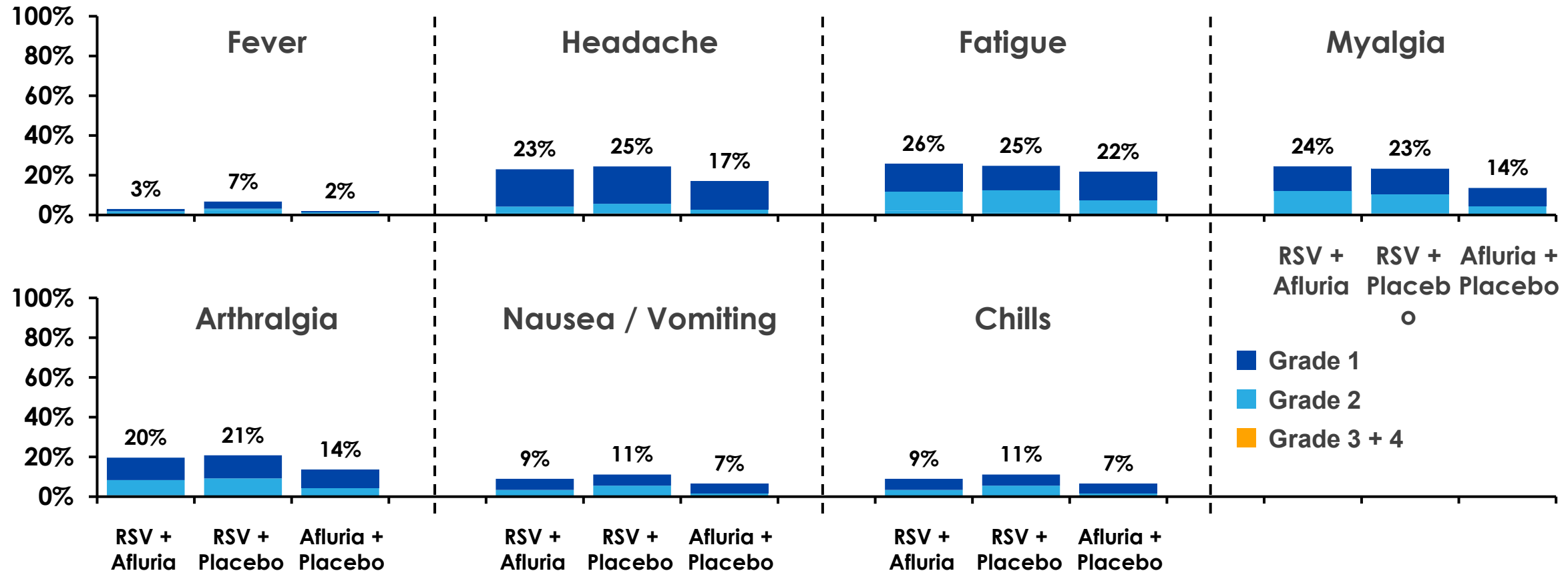


mRNA-1345 + Afluria, n= 678; mRNA-1345 + placebo, n= 249; Afluria + placebo; n= 683
 One grade 4 event (0.4%) of axillary swelling or tenderness in mRNA-1345 + placebo group

Solicited systemic reactions within 7 days after mRNA-1345 alone or co-administered with quadrivalent influenza vaccine in adults ≥ 50

Study 302, Part A - Solicited Safety Set

Mostly grade 1, onset day 1-2, median duration of 2 days for RSV + Flu



mRNA-1345 + Afluria, n= 678; mRNA-1345 + placebo, n= 249; Afluria + placebo; n= 683
 Grade 4 fever reported in 1 recipient of mRNA 1345+ placebo

mRNA-1345 P302 Part B co-administration of RSV vaccine with Spikevax bivalent

Safety and immunogenicity study of concomitant administration of mRNA-1345 with Spikevax bivalent in adults ≥ 50



Design

Randomized, observer-blind study



Number of participants

~1,700 adults ≥ 50 years of age randomized



Vaccination schedule

Co-administration study of mRNA-1345 & Spikevax Bivalent

Study arms: mRNA-1345; Spikevax Bivalent, m-RNA 1345+Spikevax bivalent



Duration

Enrollment initiation: Jul 2022

Participants followed up for 6 months after study injection



Site location

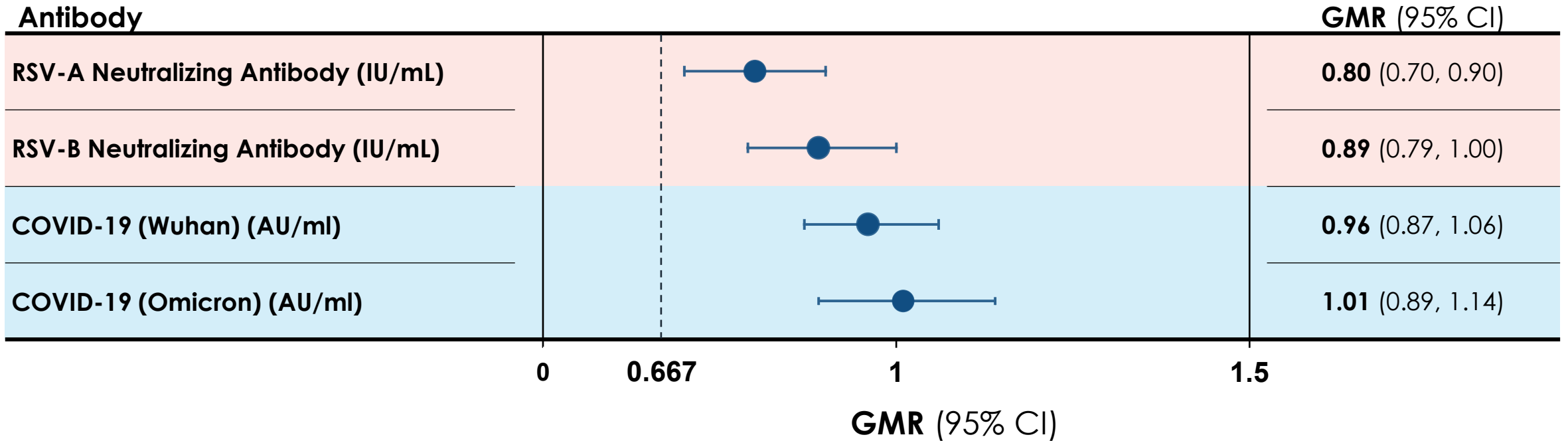
United States

Phase 3
 ≥ 50 years of age
Total N ~ 1,700

mRNA-1345 + Spikevax Bivalent	mRNA-1345 + placebo	Spikevax Bivalent + placebo
N~600	N~600	N~600

Comparison of day 29 GMR – concomitant vs nonconcomitant administration of mRNA-1345 and COVID-19 bivalent vaccine

Study 302, Part B

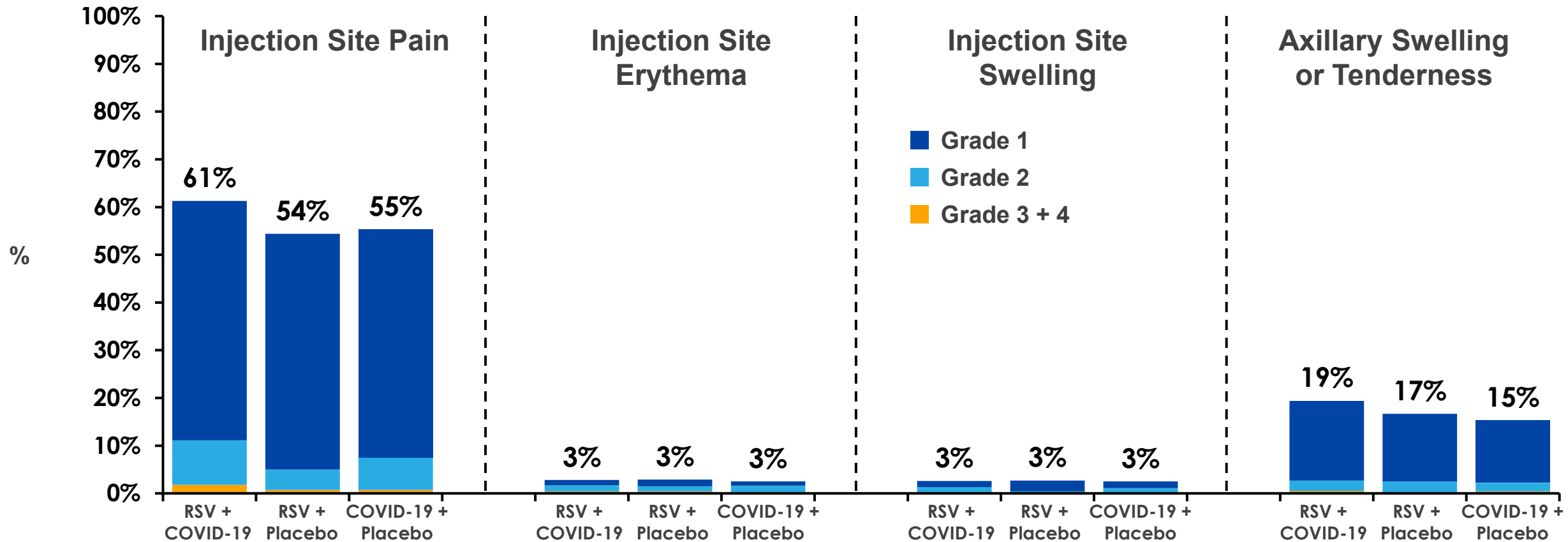


All GMR non-inferiority criteria met (LB of the 2-sided 95% CI of GMR > 0.667)

Solicited local reactions within 7 days after mRNA-1345 alone or co-administered with COVID-19 bivalent vaccine in adults ≥ 50

Study 302, Part B - Solicited Safety Set

Mostly grade 1, onset day 1-2, median duration of 2 days for RSV + COVID-19



mRNA-1345 + COVID-19, n= 558; mRNA-1345 + placebo, n= 555; COVID-19 + placebo; n= 557

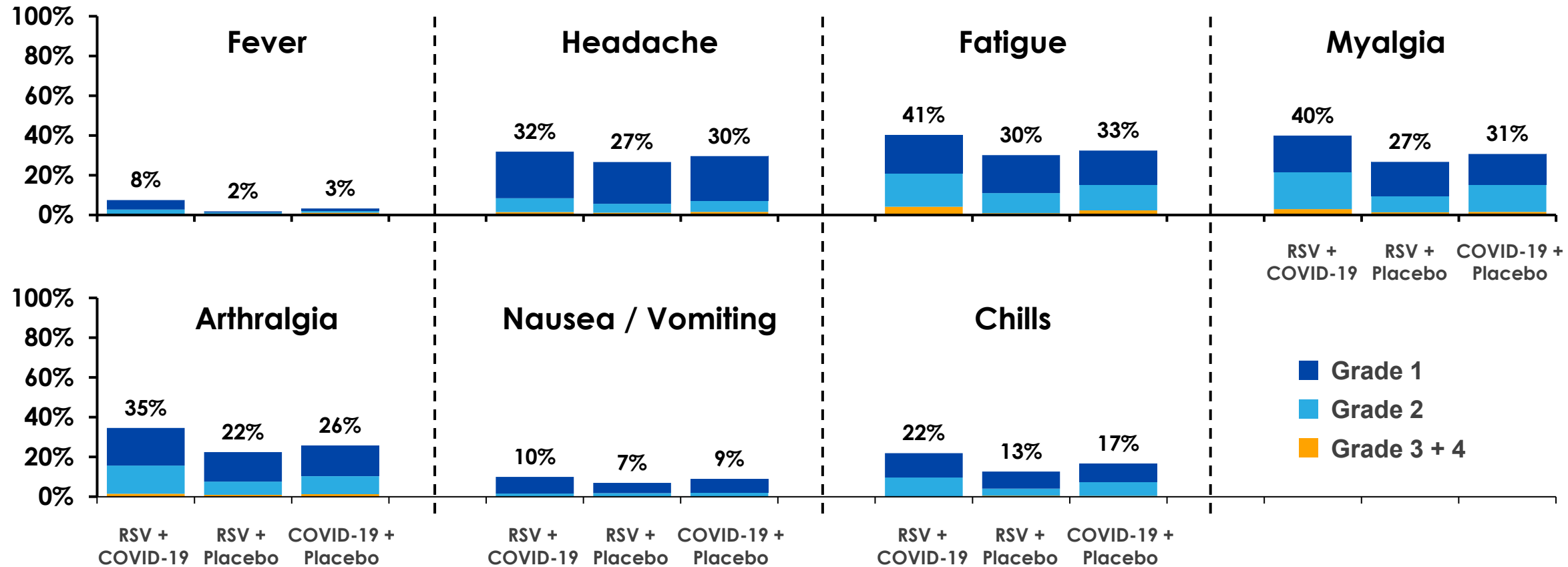
No grade 4 events



Solicited systemic reactions within 7 days after mRNA-1345 alone or co-administered with COVID-19 bivalent vaccine in adults ≥ 50

Study 302, Part B - Solicited Safety Set

Mostly grade 1, onset day 1-2, median duration of 2 days for RSV + COVID-19



mRNA-1345 + COVID-19 vaccine, n= 558; mRNA-1345 + placebo, n= 555; COVID-19 vaccine + placebo; n= 557

Grade 4 fever reported in 1 recipient of COVID-19 + placebo

No reports of safety events of interest from P302 co-administration study of mRNA-1345 with influenza or COVID-19 vaccine

Study 302 A and B – based on 6 months follow-up

No reports of

- Deaths, SAEs, or AESIs as assessed as related by the investigator
- Anaphylaxis
- Guillain Barre Syndrome
- Acute disseminated encephalomyelitis (ADEM)
- Bell's palsy/facial paralysis
- Acute myocarditis or acute pericarditis

RSV P302 summary

Immunogenicity

- Met pre-specified immunogenicity criteria for concomitant administration of mRNA-1345 with influenza vaccine or mRNA COVID-19 vaccine

Safety

- No new safety signals observed with concomitant administration of mRNA-1345 with influenza vaccine or mRNA-COVID-19 vaccine
- No GBS, no ADEM, or other safety concerns

mRNA-1345 has the potential to protect all vulnerable populations from RSV



High risk adults
(ages: 18+)

Phase 3
P303

- Trial initiated



Maternal
(ages 18+)

Phase 2
P201

- Trial ongoing in women who are pregnant



Pediatrics
(2-<5, high risk 5-<18)

Phase 2
P202

- Trial initiated



Phase 1 studies
(5m - <24m)
(12m - <60m)

Phase 1
P101

- 5m-<24m: trial initiated
- 12m-<60m: Fully enrolled and ongoing

Interim data from these studies could be available as early as 2024

Flu & Combinations

Raffael Nachbagauer, M.D., Ph.D.

Influenza Portfolio Lead

mRNA-1010 Phase 3 P303 study overview

P303 was designed to test the immunogenicity and safety of an optimized composition of mRNA-1010



Design

Randomized, observer-blind, active-controlled study



Number of participants

2,416 medically stable adults \geq 18 years old



Vaccination schedule

Single dose of mRNA-1010 or Fluarix



Duration

Study participants will be followed for 6 months after study injection



Site location

Northern Hemisphere (United States)

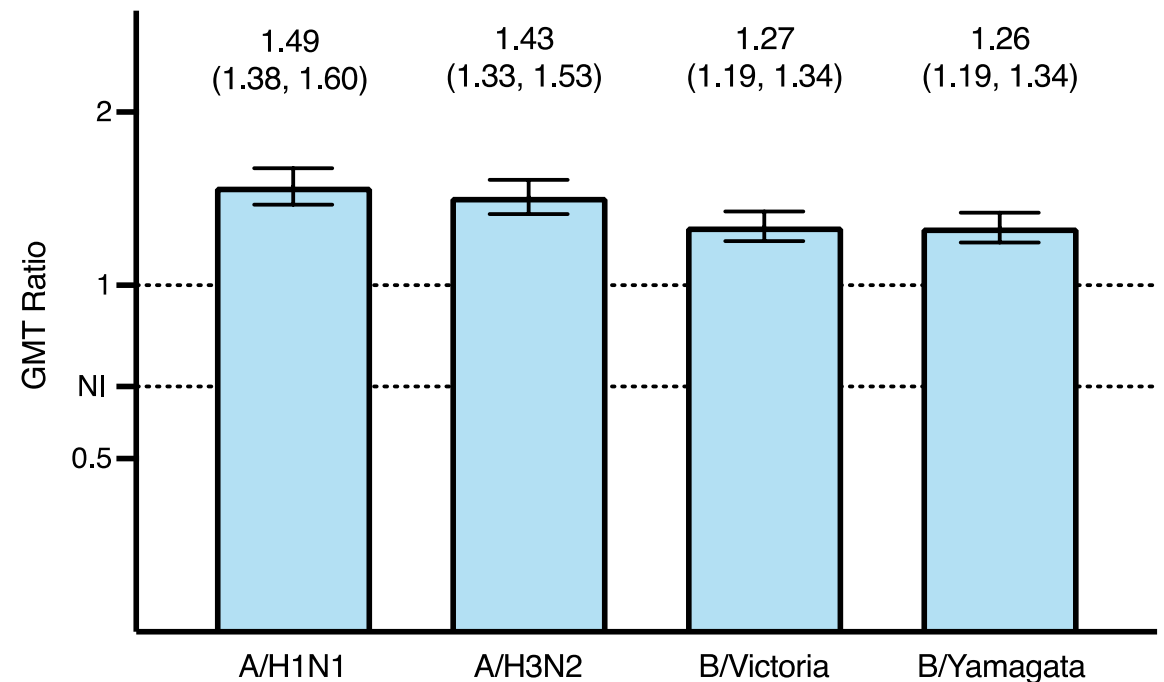
Total N = 2,416
Randomization Ratio = 1:1

mRNA-1010 (50 μg)
N=1227
Fluarix
N=1189

mRNA-1010 met all primary immunogenicity endpoints in P303

- Immunogenicity criteria were met for all 8 co-primary endpoints
 - GMT ratios
 - Seroconversion rates
- Higher GMTs and seroconversion rates compared to standard dose influenza vaccine were observed for mRNA-1010 for all four strains in P303 study
- Higher immunogenicity relative to standard dose influenza vaccine was consistently observed across age groups

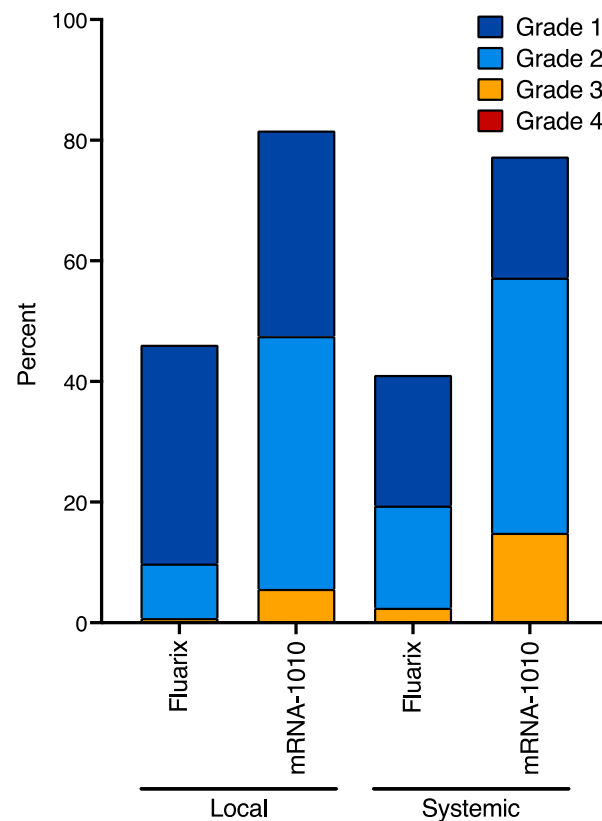
Adults 18 years and older



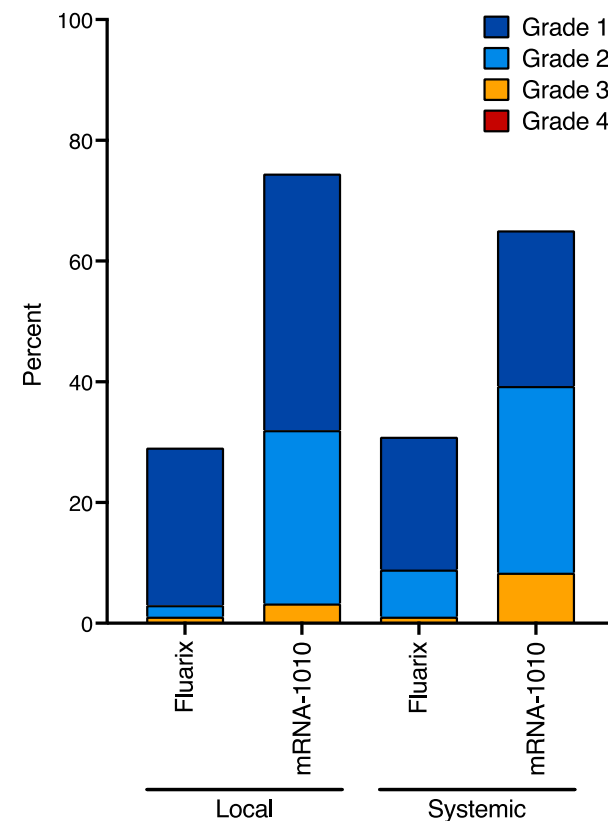
Reported rates of local and systemic reactogenicity after mRNA-1010 compared to standard dose influenza vaccine

- Safety profile was in line with prior clinical studies for mRNA-1010
- mRNA-1010 showed an acceptable reactogenicity profile, with the majority of solicited adverse reactions reported as grade 1 or 2 in severity
- Reactogenicity was higher in mRNA-1010 recipients compared to standard dose influenza vaccine recipients
- Reactogenicity in older adults was lower compared to younger age groups

Adult 18 years and older



Adults 65 years and older



mRNA-1010 Phase 3 P303 older adult extension study; fully enrolled

Study was designed to test the immunogenicity and safety of an optimized composition of mRNA-1010



Design

Randomized, observer-blind, active control study of optimized mRNA-1010



Participants

3,000 medically stable adults ≥ 65 years old



Vaccination schedule

Single dose of mRNA-1010 or Fluzone HD



Duration: 6 months

Participants will be followed up for 6 months



Site locations

Northern hemisphere (United States)

**P303 Older
adult extension**
 ≥ 65 years
N=3,000

Randomization Ratio= 1:1

1 mRNA-1010 (50 μ g)
N=1,500

2 Fluzone HD
N=1,500

8 primary endpoints: GMT
and SCR across 4 strains
mRNA-1010 vs Fluzone HD

Flu (mRNA-1010) summary and next steps

Immunogenicity

- Immunogenicity criteria were met for all 8 co-primary endpoints for GMT ratio and seroconversion rates

Safety

- Showed an acceptable reactogenicity profile, with the majority of solicited adverse reactions reported as grade 1 or 2 in severity

Next steps

- In discussions with regulators; intend to file in 2024

mRNA-1083: Influenza and COVID-19 combination vaccine

mRNA-1010

Flu

- Improvements made to mRNA-1010 to increase immune responses
- In a recent Phase 3 trial, P303, mRNA-1010 met all immunogenicity endpoints, demonstrating higher titers compared to a licensed influenza vaccine

mRNA-1083

Flu + COVID-19

**mRNA-1083 Phase 3 trial
is ongoing**

mRNA-1283

COVID-19

- mRNA-1283 is designed to be refrigerator stable
- In a recent Phase 3 study, P301, mRNA-1283 met immunogenicity primary endpoints, demonstrating higher titers compared to mRNA-1273

Recent interim results from a mRNA-1083 Phase 1/2 study showed strong immunogenicity against influenza and SARS-CoV-2¹

1. <https://investors.modernatx.com/news/news-details/2023/Moderna-Announces-Positive-Phase-1-2-Data-from-mRNA-1083-the-Company-s-Combination-Vaccine-Against-Influenza-and-COVID-19/default.aspx>

mRNA-1083-P301 Phase 3 study ongoing; fully enrolled with data expected in 2024

Study was designed to test the immunogenicity and safety of mRNA-1083



Design

Randomized, observer-blind, active control study



Participants

~8000 adults \geq 50 years of age



Vaccination schedule

2 injections on Day 1 (mRNA-1083 + placebo or licensed influenza vaccine + COVID-19 vaccine)



Duration: 6 months

Participants will be followed up for 6 months



Site locations

US

Phase 3 clinical study

Cohort A:
Ages 50 to < 65 years

mRNA-1083
+ placebo

Influenza vaccine +
COVID-19 vaccine

Cohort B:
Ages \geq 65 years

mRNA-1083
+ placebo

Influenza vaccine +
COVID-19 vaccine

mRNA-1083 summary and next steps

Immunogenicity

- Influenza and COVID-19 combination vaccine showed strong immunogenicity against influenza and COVID-19 in a Phase 1/2 study

Addressing disease burden

- Moderna's combination vaccine candidates aim to cover respiratory viruses associated with the largest disease burden in the category

Leveraging data and clinical experience

- Flu vaccine (mRNA-1010) met all immunogenicity primary endpoints and showed acceptable tolerability in Phase 3 P303 study
- Next generation COVID vaccine (mRNA-1283) met immunogenicity primary endpoints, demonstrating higher titers compared to mRNA-1273 in Phase 3

Next steps

- Data expected from flu/COVID-19 combination vaccine (mRNA-1083) Phase 3 study in 2024

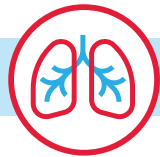


Commercial Opportunity

Stéphane Bancel

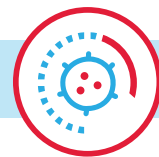
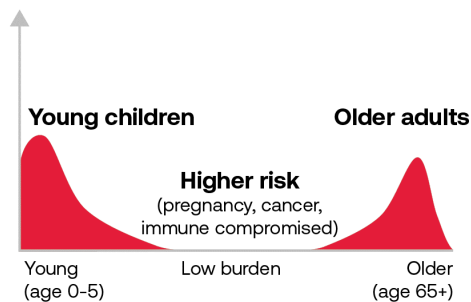
Chief Executive Officer

Respiratory and latent + other viruses represent large unmet or underserved medical needs



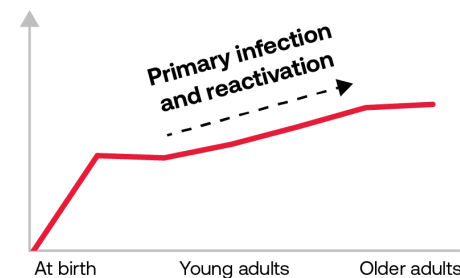
Respiratory viruses

- Highest burden in the young, old and immunocompromised
- Respiratory infections are a top cause of death globally



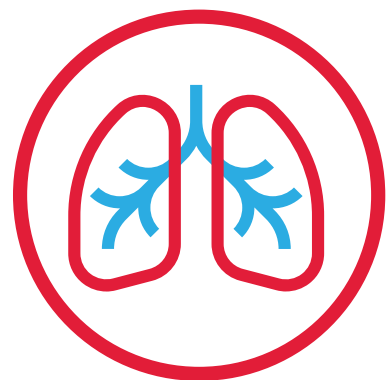
Latent viruses

- Immediate impact of infection (e.g., birth defects, mono)
- Long-term sequelae from latent infections (cancer, autoimmune)



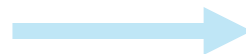
Human and economic costs from infectious diseases highlight the need for effective vaccines

Moderna's respiratory vaccine pipeline is targeting large addressable markets



Respiratory

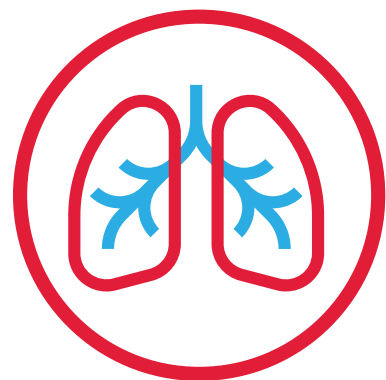
COVID, RSV, Flu,
Combinations



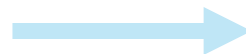
\$27B+

Estimate of peak annual
market¹

1. Evaluate Pharma and internal estimates



COVID-19
vaccines



~\$10B

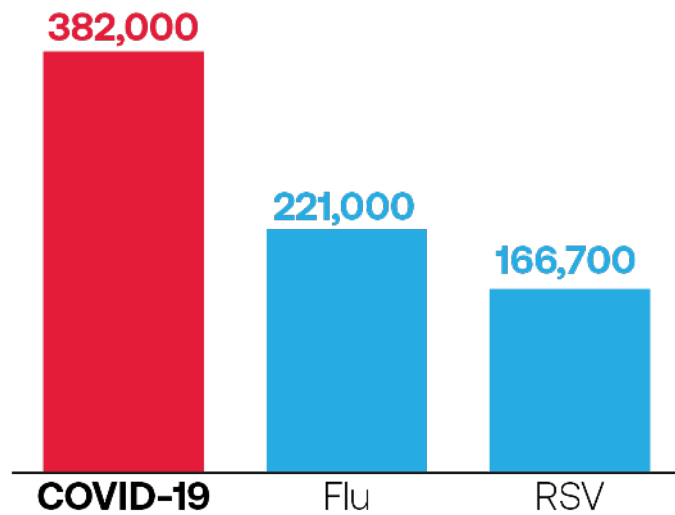
2024 market estimate¹

1. Based upon Pfizer and Novavax earnings reports and internal estimates.

COVID-19 continues to show a high burden of disease

COVID-19 hospitalizations remain high

Total hospitalizations from October '23 through March 2, 2024



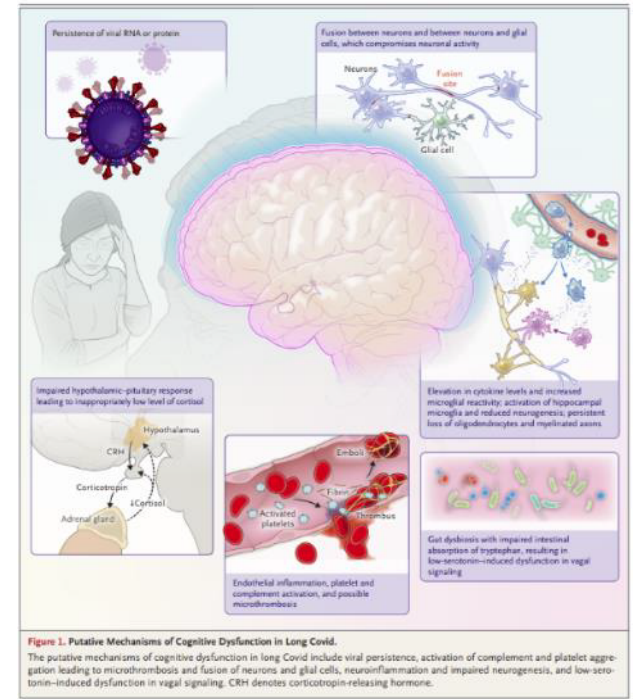
SOURCE: RESP-NET – Respiratory Virus Hospitalizations Surveillance Network – CDC

Risks of long COVID are better understood

New England Journal of Medicine

Long COVID and Impaired Cognition — More Evidence and More Work to Do

<https://www.nejm.org/doi/full/10.1056/NEJMe2400189>



We are focused on education and awareness to increase vaccination rates

Long COVID data suggests even traditionally low risk groups should be vaccinated



COVID-19 Vaccine Reduces Long COVID in Children

TIME

Getting Vaccinated May Be Your Best Protection from Long COVID

Forbes

65 Million People Suffer From Long Covid. Our Experts Say New Vaccines Are The Best Defense

Long COVID awareness



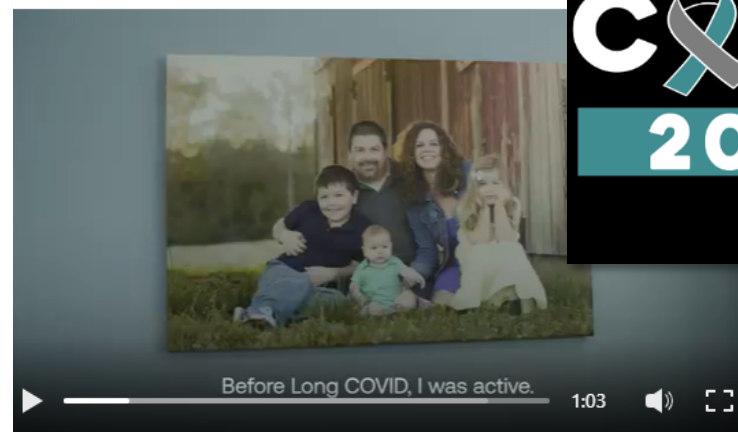
Moderna
556,336 followers
48m •

It's been four years since #COVID19 was declared a national emergency, and while we've learned to live with the virus as an endemic, millions continue to suffer from long-term effects of a COVID-19 infection.

One such patient is Rachel, a wife and mother to three children, who was diagnosed with #LongCOVID in May 2021 after a COVID-19 infection prior that unbeknownst to her, would turn her life upside down.

Learn more about Rachel's story: <https://lnkd.in/e8-sKSb3>

#LongCOIDAwarenessDay

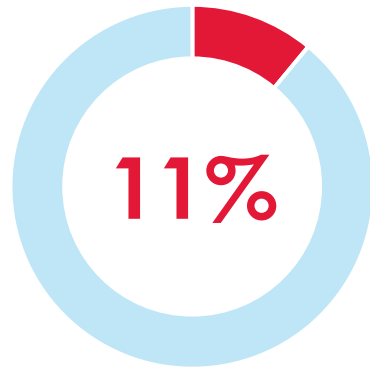


CONFRONT
LONG
COVID
2024

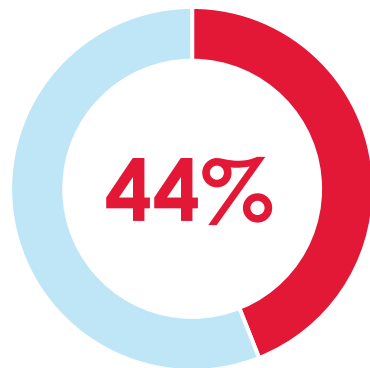
Long COVID video link

<https://player.vimeo.com/video/923429102>

Despite a higher burden of disease, COVID-19 U.S. vaccination rates are lower than flu



2023 COVID-19 vaccination rate¹



2023 flu vaccination rate²

Health officials see need to increase coverage rates

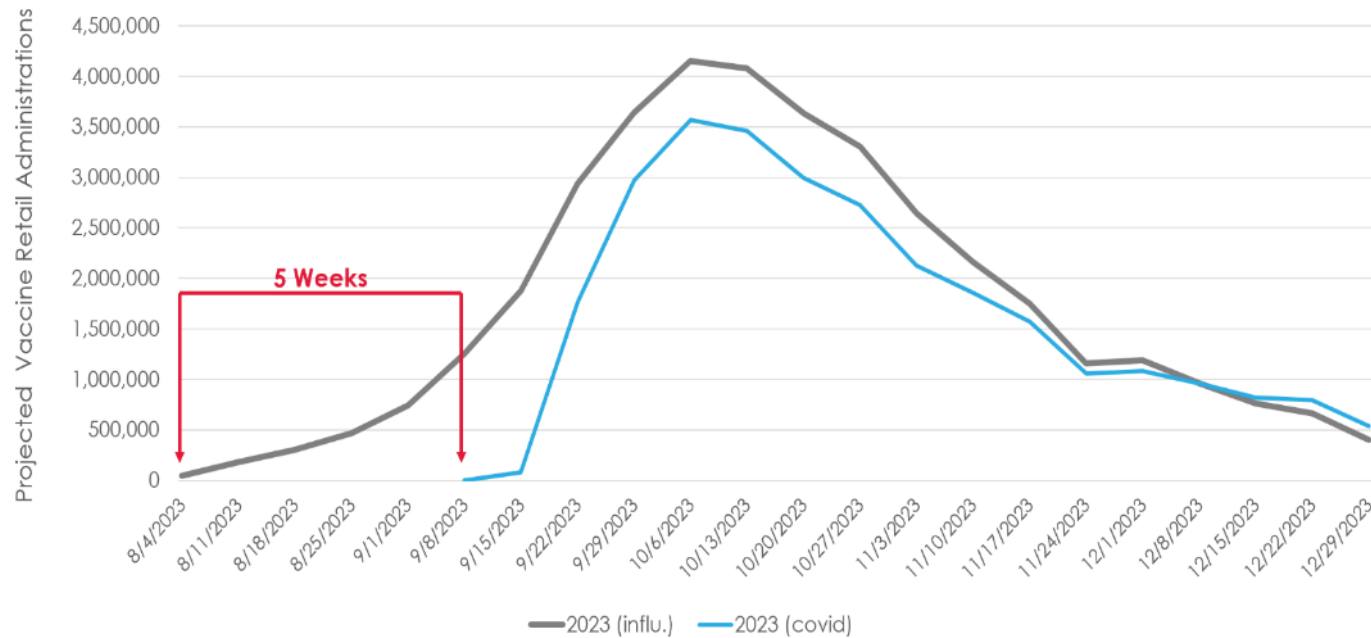
A collage of news articles and health advisories. The top article is a CDC Health Alert Network (HAN) advisory titled "Urgent Need to Increase Immunization Coverage for Influenza, COVID-19, and RSV and Use of Authorized/Approved Therapeutics in the Setting of Increased Respiratory Disease Activity During the 2023 – 2024 Winter Season". It includes logos for HAN, NWH, and CDC. Below it is a Reuters article titled "WHO sees 'incredibly low' COVID, flu vaccination rates as cases surge". To the right is a TODAY article titled "The US is starting 2024 in its second-largest COVID surge ever, experts say". At the bottom right is a CNN health article titled "Covid-19 vaccination rate is 'lower than we'd like to see,' CDC says".

1. IQVIA and Moderna internal estimates

2 <https://www.cdc.gov/flu/fluview/dashboard/vaccination-doses-distributed.html> Assumes normal industry return rate from doses distributed.

Improve public health impact by aligning timing of COVID-19 and flu vaccine launches

Time aligned Flu & COVID-19 vaccine administrations (retail pharmacy) - 2023



In 2023, COVID-19 vaccines were not on the market until 5 weeks after Flu

3M Flu shots provided prior to COVID-19 launch

Vaccinations in August are predominately in the retail pharmacy channel

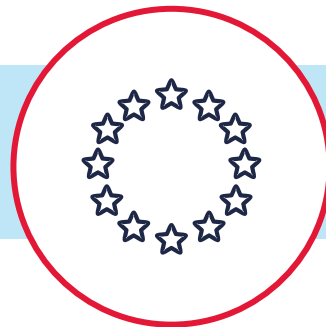
We expect higher vaccination uptake if vaccines are available sooner, and if they are offered at the same time as the flu shot

Our COVID-19 commercial strategy is focused on the needs of each region



United States

Our focus is working with public health officials to increase vaccination coverage rates for the 2024/2025 season to reduce the substantial burden of COVID-19



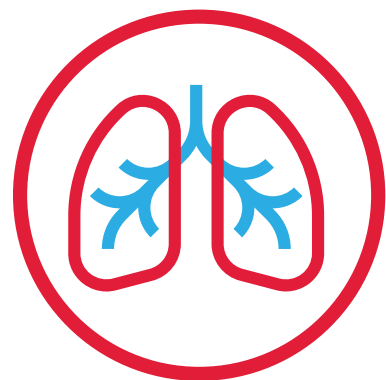
European Union

New tender published in January 2024 for up to 36M doses per year for up to 4 years

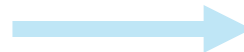


Rest of World

Prioritizing markets for greater commercial focus



**RSV
vaccines**



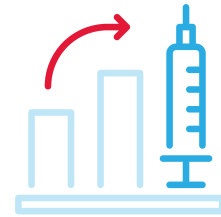
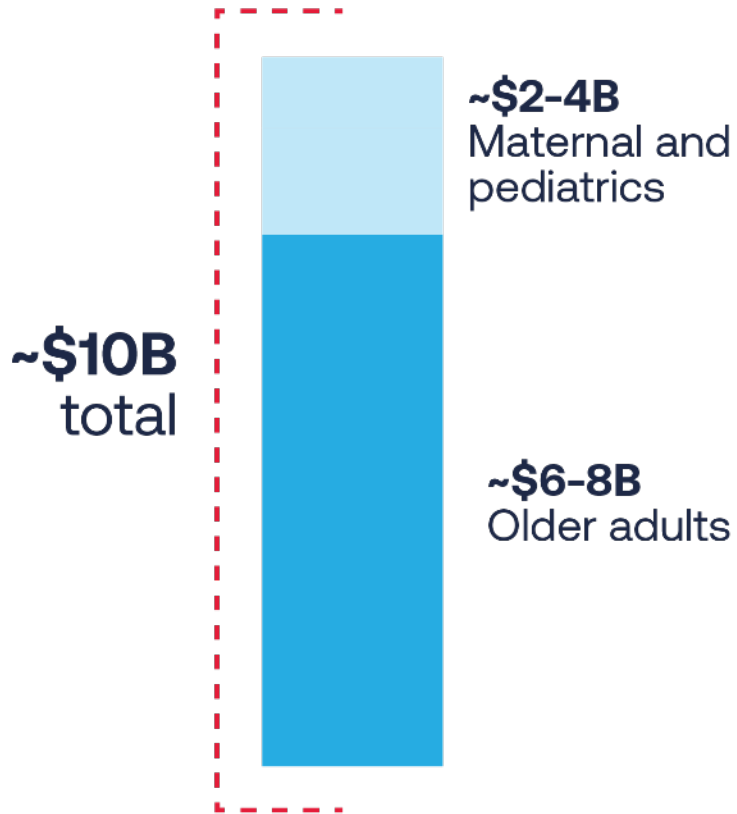
~\$10B

Estimate of peak annual market¹

1. Analyst reports: Leerink investor report: RSV could be next \$10B vaccine market; [FiercePharma](#); GSK and Pfizer earnings reports and internal estimates

Expecting a strong RSV vaccine launch into a large market in 2024

RSV peak global market size^{1,2}



Observed strong consumer awareness and demand in first year of RSV market



~\$2.5B total market sales in 2023³

1. Analyst reports: Leerink investor report: RSV could be next \$10B vaccine market; FiercePharma; GSK and Pfizer earnings reports; and internal estimates

2. FiercePharma

3. GSK and Pfizer earnings reports

Our RSV vaccine has a strong profile

Only mRNA RSV investigational vaccine with positive Phase 3 data

Study demonstrated consistently strong efficacy across vulnerable and older populations¹

83.7% efficacy in overall study population

88.4% efficacy in participants with comorbidities

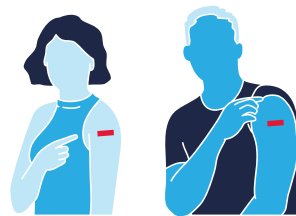
95.4% efficacy in participants aged 70-79 years

¹ Based on pivotal trial primary analysis RSV LRTD with ≥ 2 symptoms: <https://www.nejm.org/doi/pdf/10.1056/NEJMoA2307079>

² As of April 30, 2023

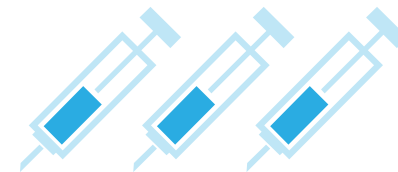
³ www.ncbi.nlm.nih.gov/pmc/articles/PMC7846520/

⁴ www.ncbi.nlm.nih.gov/pmc/articles/PMC7913196/



Well-established safety and tolerability profile for mRNA vaccine technology

- Over 1 billion COVID-19 doses using same mRNA technology
- Most solicited adverse reactions were mild to moderate^{1,2}
- No cases of Guillain-Barre Syndrome (GBS) or Acute disseminated encephalomyelitis (ADEM) have been reported with mRNA-1345 in Phase 3 RSV trial²



Ease of administration

- Single-dose prefilled syringe (PFS)
- HCP customer convenience: only ready-to-use formulation, saving time and reducing administration errors^{3,4}

PFS presentation could relieve some of the burden that falls on pharmacies during the Fall vaccination season

UPI
 CVS, Walgreens pharmacy staff begin 3-day walkout dubbed 'Pharmageddon'

AP
Pharmacist shortages and heavy workloads challenge drugstores heading into their busy season

pharmacy TIMES
 Pharmacists Raise the Alarm About Staffing, Workload

FORTUNE
'These pharmacists always look stressed': Drugstores struggle with thin staffing and recruiting challenges as busiest season begins

Mean observed time for preparation in time & motion study¹

Potential number of doses prepared per hour



PFS

**42.1 seconds (SD: 23.8)
 or
 0.70 minutes**

85 doses/hour

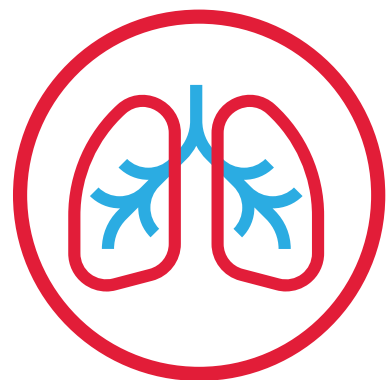


VRR

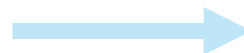
**163.6 seconds (SD: 56.2)
 or
 2.73 minutes**

22 doses/hour

1. Based on Company data, which is on file. Study funded by Moderna. Study results are from a randomized, cross-over time and motion study of prefilled syringe (PFS) vaccine (mRNA-1273) and vaccines requiring reconstitution (VRR). Outcomes include vaccine preparation time; participants were pharmacists, nurses or pharmacy technicians. The results presented on this slide are from predefined interim descriptive analyses at 87.3% of target enrollment (n = 55). The study is ongoing, and the results will be updated. SD = Standard deviation.



Flu
vaccines



~\$7B

2024 market estimate¹

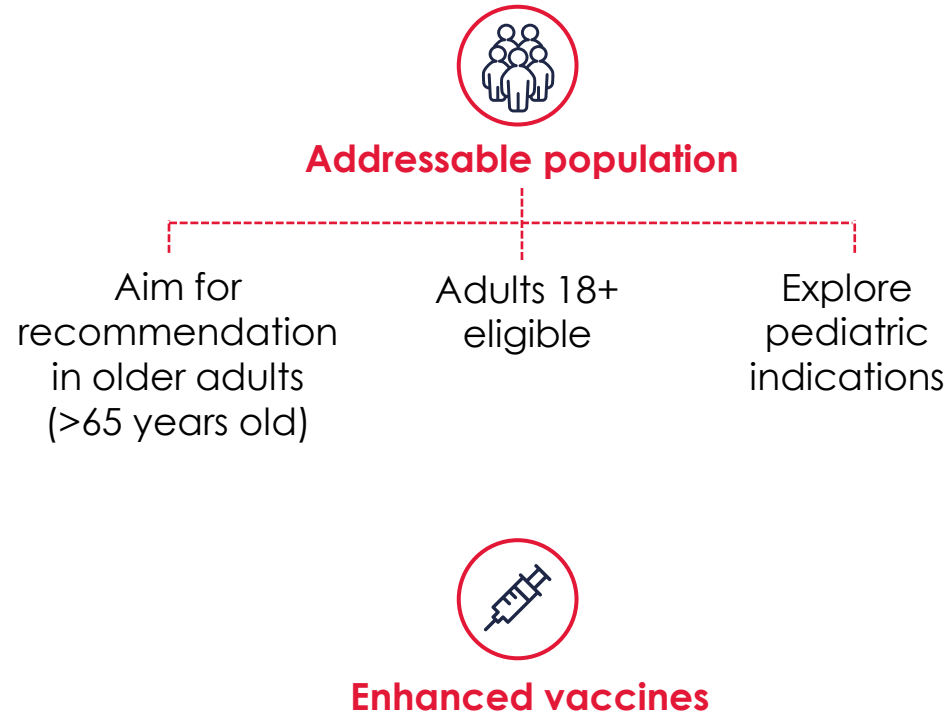
1. EvaluatePharma. Influenza vaccine

Flu: opportunity to expand the market with next-generation premium vaccines

Current influenza market ~\$7 billion

Market expected to grow with rise in more effective vaccines

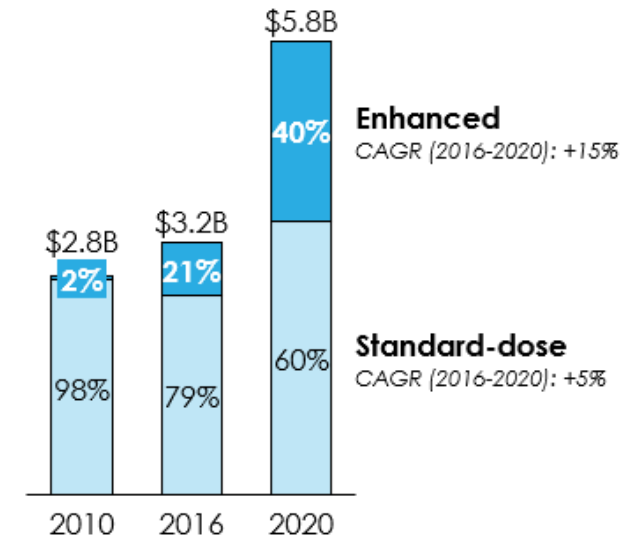
Market dynamics



Premium vaccines with improved vaccine efficacy get a higher price (>\$50/dose) and are growing at a faster rate²

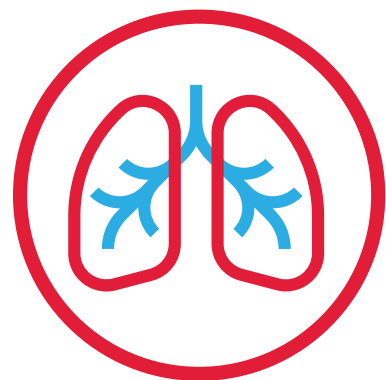
Reported Global Influenza Vaccine Sales³

USD, billions

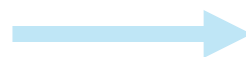


Source: EvaluatePharma, IQVIA MIDAS, Sanofi Vaccine Day (2021); High-dose products include Fluzone HD, Flublok, Fluad, total sales estimated

1. EvaluatePharma. Influenza vaccine : Worldwide | Overview
 2. <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/VaccinesPricing>
 3. EvaluatePharma, IQVIA MIDAS, Sanofi Vaccine Day (2021); High-dose products include Fluzone HD, Flublok, Fluad, total sales estimated



Combination respiratory vaccines



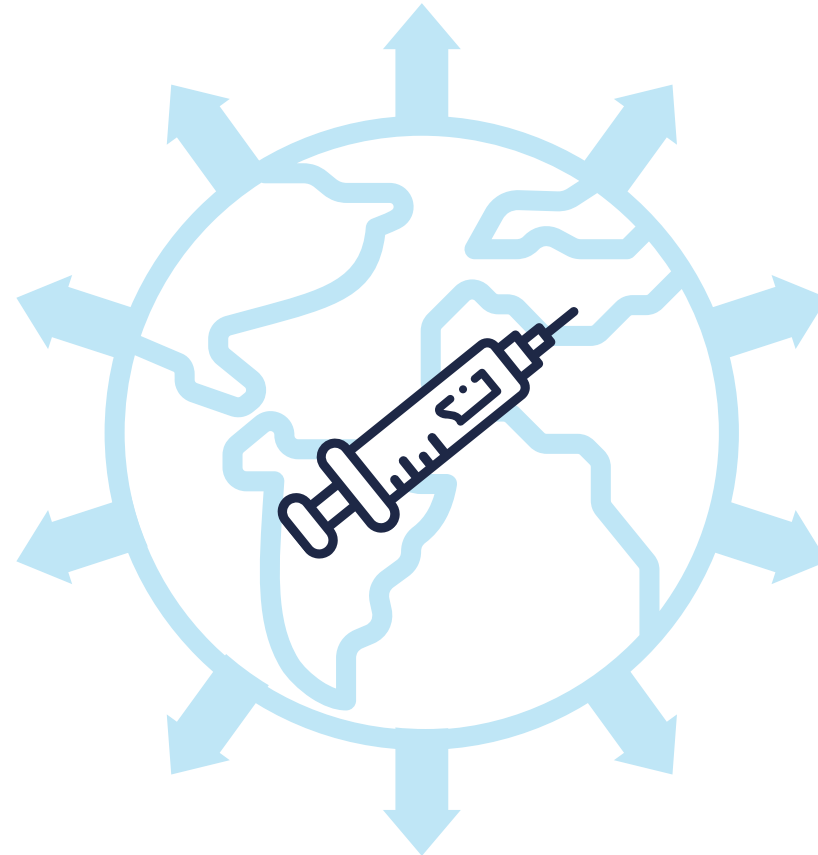
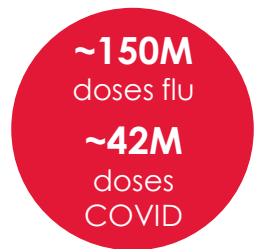
Potential to expand
respiratory market

We believe combination vaccines will expand the current seasonal respiratory vaccine market

Current annual global flu market



U.S. flu and COVID-19 market

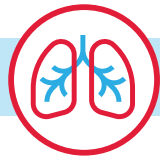


Increased vaccine value to health ecosystem

Improve COVID-19 vaccination rates & compliance

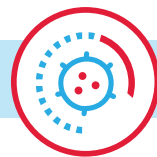
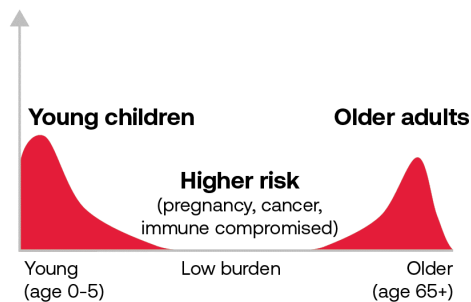
Market shift towards more effective vaccines

Respiratory and latent + other viruses represent large unmet or underserved medical needs



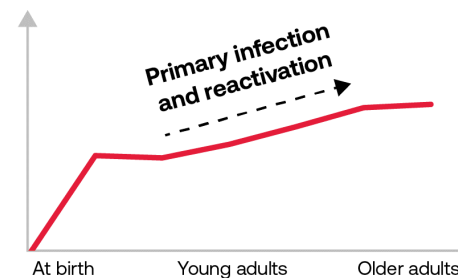
Respiratory viruses

- Highest burden in the young, old and immunocompromised
- Respiratory infections are a top cause of death globally



Latent viruses

- Immediate impact of infection (e.g., birth defects, mono)
- Long-term sequelae from latent infections (cancer, autoimmune)



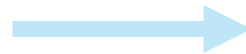
Human and economic costs from infectious diseases highlight the need for effective vaccines

Moderna's Latent + Other vaccine pipeline is targeting large addressable markets



**Latent +
Other**

CMV, VZV, EBV,
Norovirus



\$25B+

Estimate of peak annual
market¹

1. Evaluate Pharma and internal estimates

CMV: opportunity to be first CMV vaccine in multi-billion dollar latent vaccine market



Build and expand the CMV market

- Women of child-bearing age (~4 million births a year in the U.S.)¹
- Adolescents / primary prevention



New indications

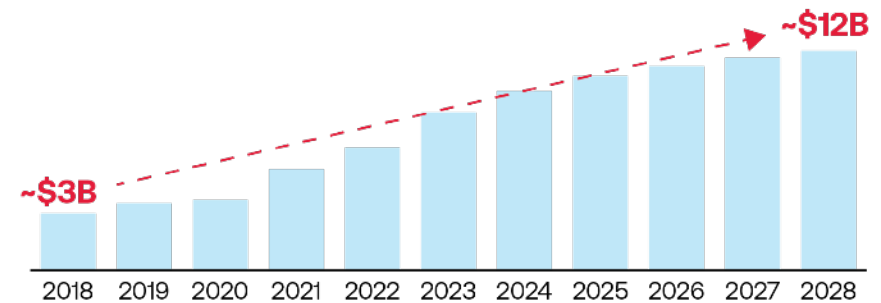
- CMV transplant population



No vaccine currently on market; potential launch in 2026

Worldwide Gardasil (HPV) Sales²

\$540-\$810 per course



Demand is more constant over time, and market increases by expanding eligible populations (i.e., age de-escalation)

CMV expected to be a \$2-5 billion annual market³

1. CDC: <https://www.cdc.gov/nchs/fastats/births.htm>
 2. Gardasil is a registered trademark of Merck Sharpe & Dohme Corp.; Price: Annual report; Revenue: Evaluate Pharma estimates
 3. Internal estimates

EBV: potential to address and reduce the burden and cost of EBV infection in multiple populations



Infectious mononucleosis (IM) population

- 10 year olds
- Catch-up for 11-25 year olds



Multiple sclerosis (MS) population

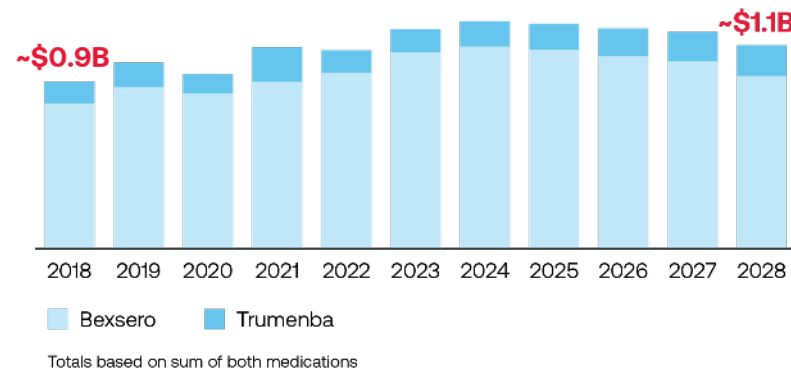
- Prevention
- Treatment



No vaccine currently on market

Meningococcal B vaccine sales¹

Historic and forecast



Total annual MS economic burden²

\$85B

- ~\$42B pharma
- ~\$21B other direct medical
- ~\$22B direct

IM is \$1.0 - 1.5B opportunity; MS prevention/treatment is \$10B opportunity

1. Evaluate Pharma; 2. Zimmermann. CNS Drugs. 2018. 32(12):1145, Bebo. Neurology. 2022; 98:e1810

VZV: opportunity to enter a large and growing market

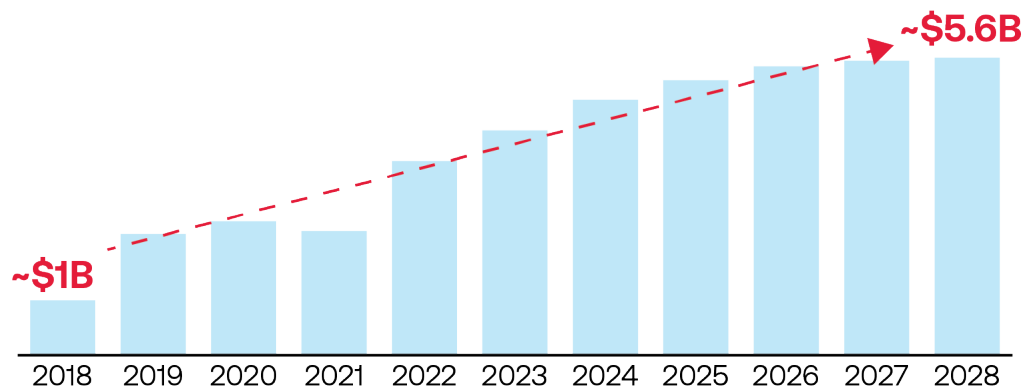


Eligible 50+ population
35% penetrated in U.S.



Potential to enter a growing and underserved market

Worldwide Shingrix sales¹
Historic and forecast



Large prevalent population not yet fully penetrated

VZV could be a \$5-6 billion annual market¹

1. Shingrix is a registered trademark of GlaxoSmithKline Biologicals, S.A. Revenue: Evaluate Pharma estimates; Price. Annual report

Norovirus: market for norovirus vaccine similar to rotavirus vaccine market in pediatrics with opportunity to expand into adult market



Adult/Older adults

Older adults and immunocompromised are at most risk



Burden is expected to rise with societal aging



Pediatric

Highest incidence of norovirus is in children

\$1.6B

Infant market for rotovirus¹

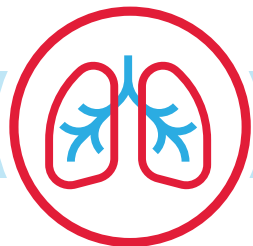


No vaccine currently on market

Norovirus could be \$3-6B market²

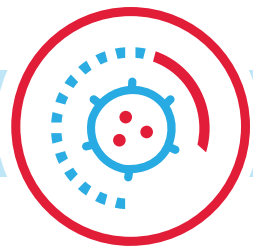
1. Evaluate Pharma; 2. Internal estimate

Our vaccine portfolio targets large addressable markets



Respiratory vaccines TAM

\$27B+

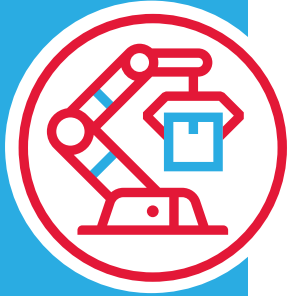


Latent + Other vaccines TAM

\$25B+

Total Moderna infectious disease vaccine TAM

\$52B+


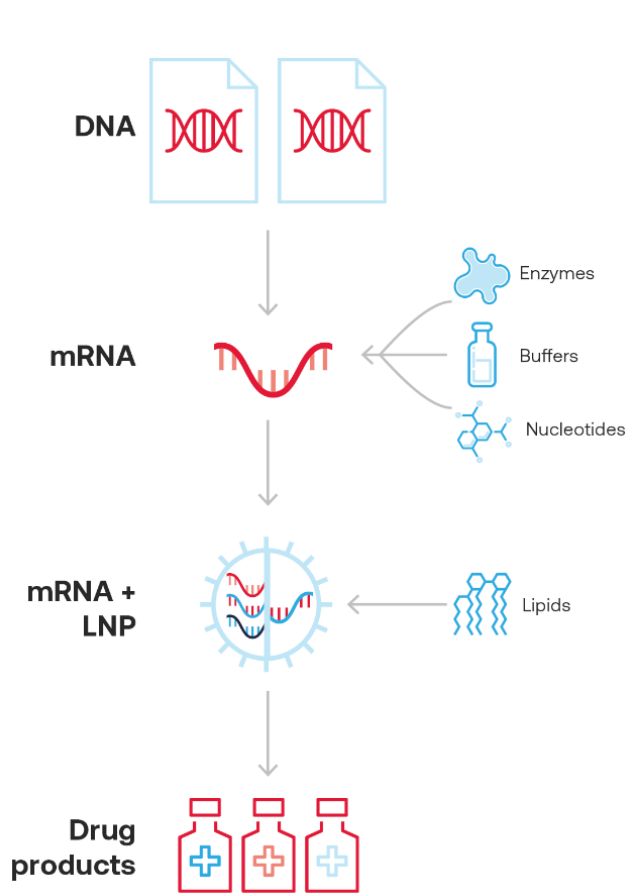


Manufacturing

Jerh Collins

Chief Technical Operations and Quality Officer

mRNA manufacturing is a platform



Similar processes



Fast process improvements



Chemistry



Lower capital investment



Quality



Speed



Scale



Cost efficiency

Moderna Technology Center at Norwood is a fully integrated manufacturing facility



Plasmid



mRNA



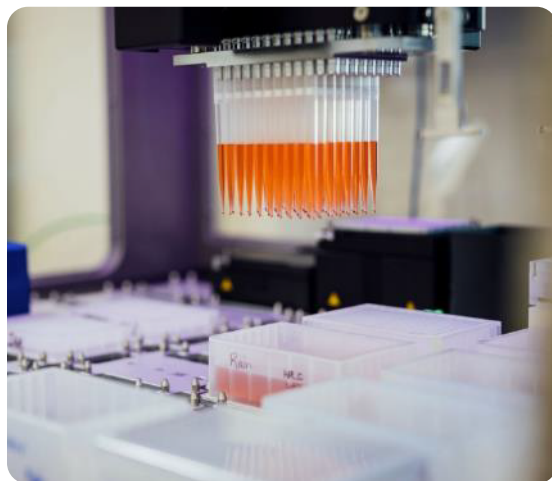
LNP



Fill/Finish



QC



Footprint tomorrow: We are building an agile global manufacturing network to meet commercial demand and support our growing pipeline



Norwood, MA, USA

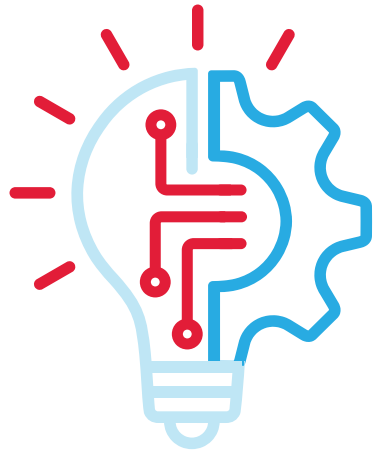
Footprint tomorrow: We are building an agile global manufacturing network to meet commercial demand and support our growing pipeline



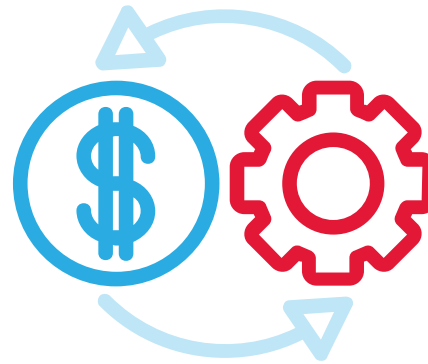
Footprint tomorrow: We are building an agile global manufacturing network to meet commercial demand and support our growing pipeline



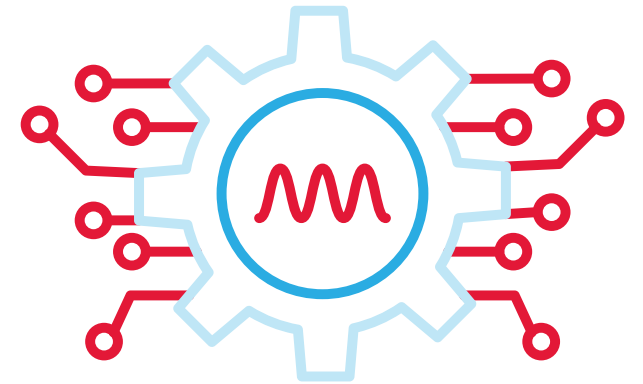
Manufacturing innovation supports expanding commercialization of diverse pipeline through efficiency and productivity gains



Continuing to pioneer new technologies, including advanced robotics

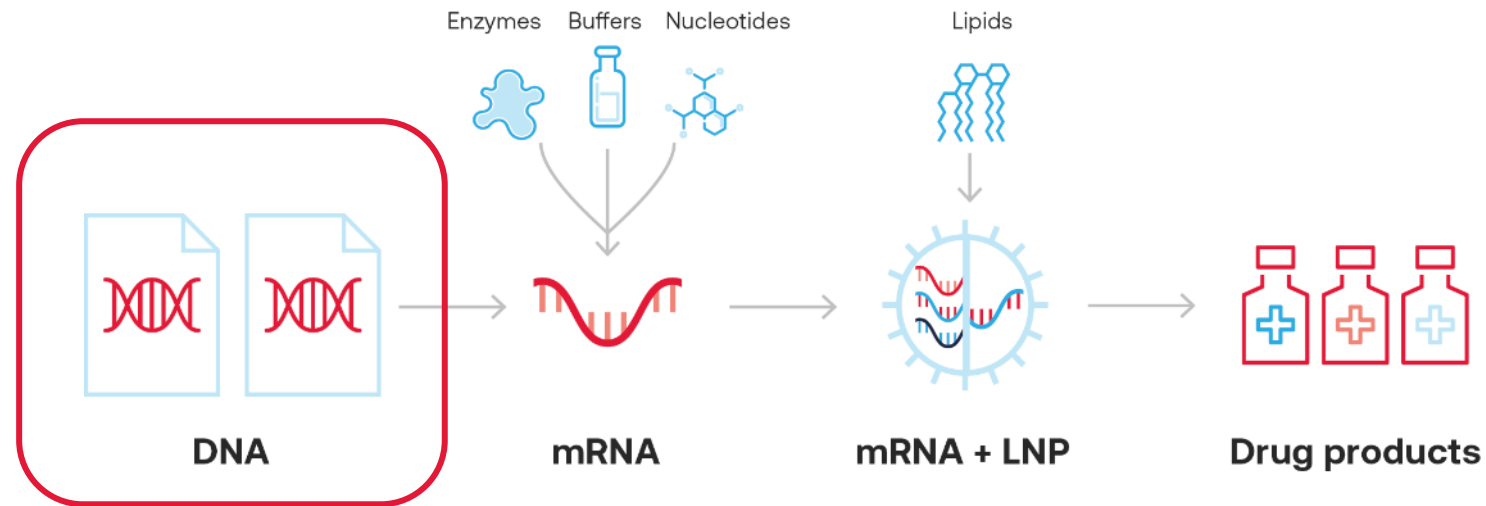


Driving network and capital efficiency



Applying AI and other advanced digital solutions

Moderna technology is reshaping how we manufacture DNA, increasing efficiency and further reducing speed to market



What is the technology?

A precise enzyme mixture that allows chemical synthesis for, **rapid amplification of plasmid DNA**

What does it mean for us?

Reduced time from sequence identification to mRNA synthesis, **increasing overall speed**

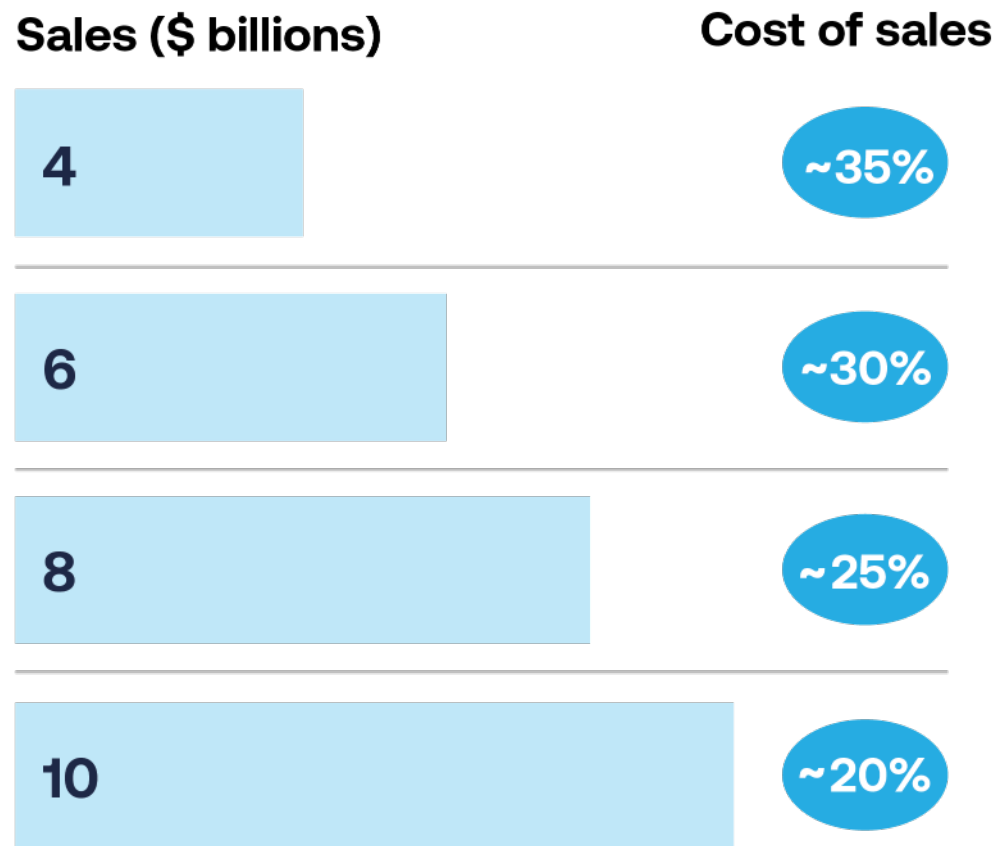
How will we use it?

- Currently in use in development
- Adopting in our INT program in 2025
- Portfolio planning is underway

Our network and capital efficiency will drive more predictable cost of sales

Capacity better-positioned to scale with volume

Respiratory cost of sales % at different sales levels





R&D Investment Strategy

Jamey Mock

Chief Financial Officer

The platform is working



Respiratory vaccine pipeline

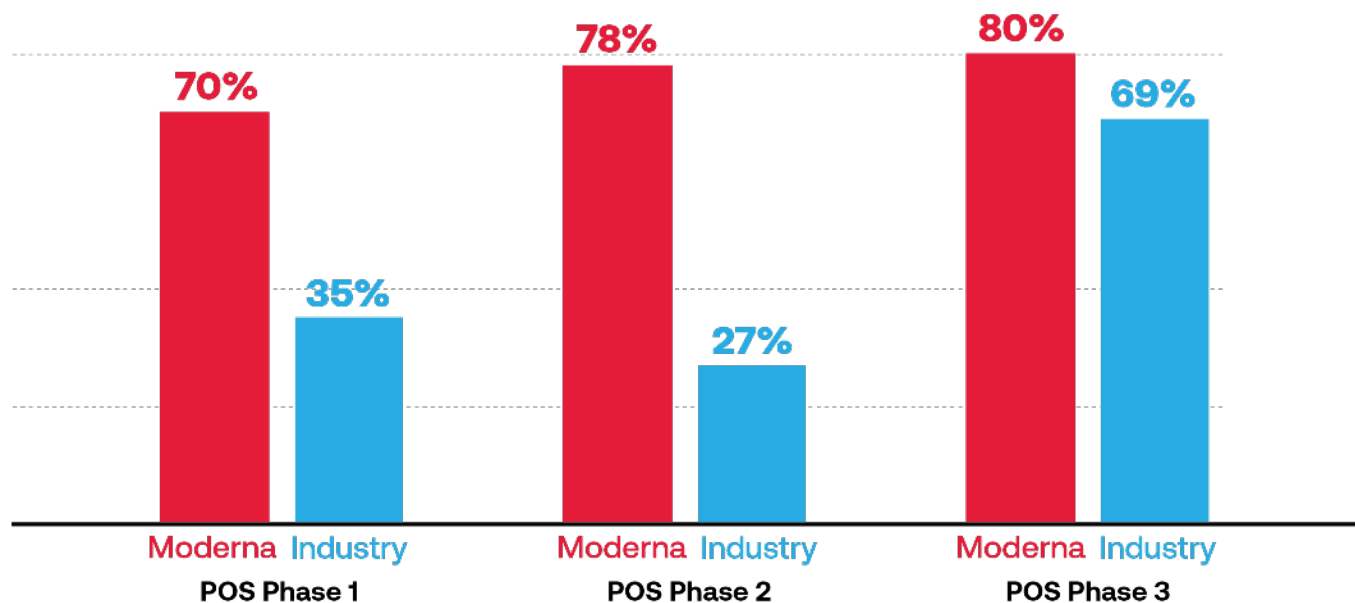
- COVID-19 mRNA-1283



Latent + Other vaccine pipeline

- Norovirus positive Phase 1 data
- EBV positive Phase 1 data
- VZV positive Phase 2 data

Moderna's rate of success with our platform technology has been higher than industry standard¹



1. Statistics for Moderna based upon internal data and are based upon: 20 Phase 1 trials, 9 Phase 2 trials, and 5 Phase 3 trials. Only concluded trials for unique molecular entities are included in data; strain updates for a program are not counted separately. Early trials establishing platform technology not intended for commercialization are excluded from Phase 1 trial counts. Industry statistics derived from Wong et al., *Biostatistics* (2019) 20, 2, pp 273-286.

R&D will continue to be our top capital allocation priority over the next 3 years

Spend Drivers

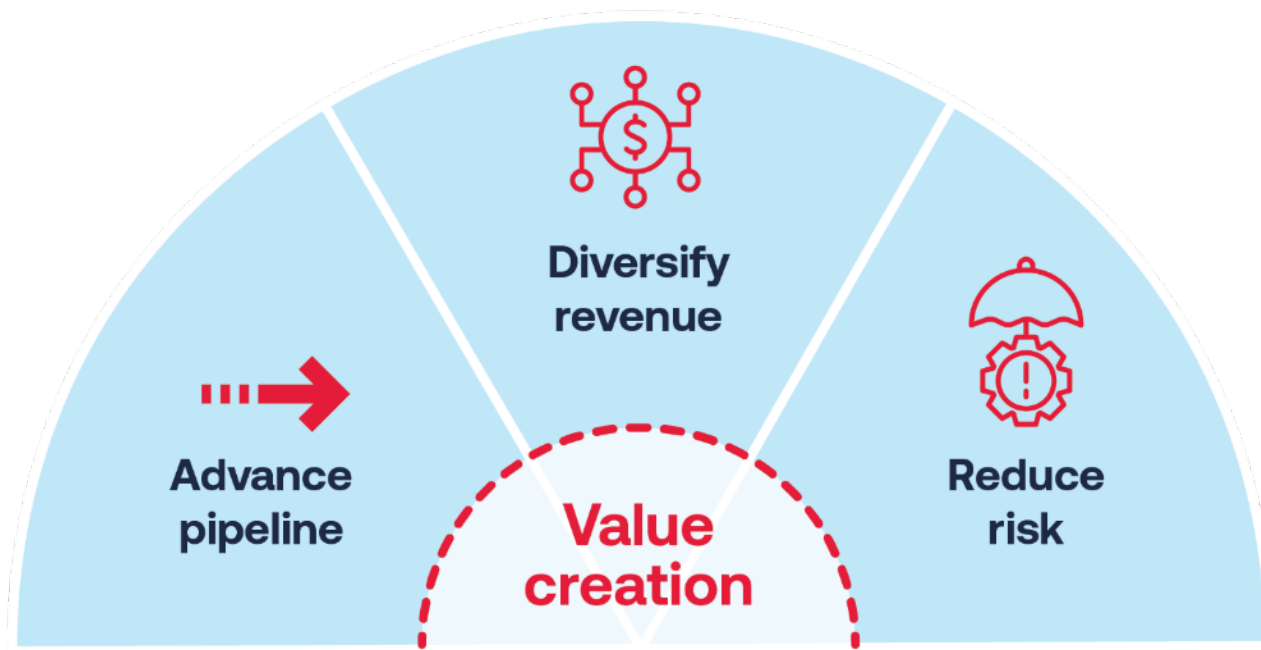
	2024	2025	2026
#1	Respiratory	Respiratory	Latent + Other ID
#2	Latent + Other ID	Latent + Other ID	Respiratory
#3	Oncology	Oncology	Oncology
#4	Rare Disease	Rare Disease	Rare Disease
#5	Platform investments		

Continued near term investments in Respiratory portfolio to support next wave of respiratory launches, combinations, and life cycle management

Latent + other showing positive early clinical data
 Potential progression into late-stage development across a breadth of programs: EBV, VZV, Norovirus, and continuation of CMV

R&D investment strategy

Prioritization parameters

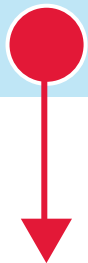


Deliver the greatest possible impact to people through mRNA medicines.

Funding options

- Self-fund
- Project financing
- Partnerships

Moderna and Blackstone Life Sciences announce development and commercialization funding agreement



Funding for flu program

- Strengthen label of product
- Support regulatory obligations



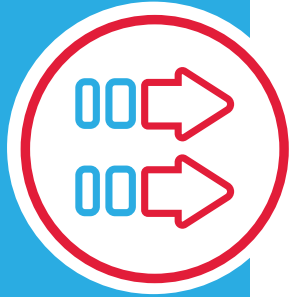
Key terms

- Up to \$750M
- Return based on cumulative commercial milestones and royalties (low single digits)



R&D framework

- Expect funding to offset R&D expense
- No change to 2024 R&D framework of ~\$4.5B
- Enables pipeline acceleration

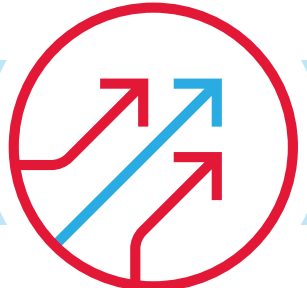


Looking Ahead

Stéphane Bancel

Chief Executive Officer

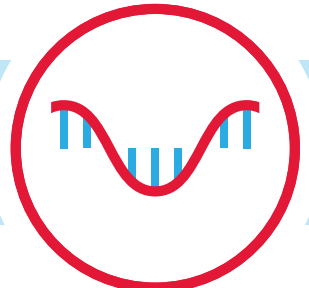
The opportunity ahead in infectious disease vaccines



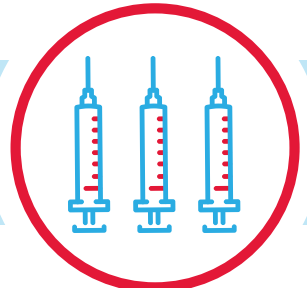
Multiple potential vaccine product launches in the next 3+ years



Total addressable market (TAM) for our infectious disease portfolio is \$52B+



Our lead in mRNA technology enables innovative products such as Norovirus, EBV and VZV



Financial characteristics of our vaccine franchise are attractive, based on a leverageable platform

Moderna is positioned to be a leading provider of vaccines in multiple indications

Beyond vaccines: advances in therapeutics pipeline



Progress in multiple Individualized Neoantigen Therapy (INT) studies with partner Merck

- **Adjuvant melanoma:** potential for accelerated approval
- **Phase 3 studies enrolling:** adjuvant melanoma; adjuvant non-small cell lung cancer
- **Phase 2, 2/3 studies starting:** cutaneous squamous cell carcinoma; adjuvant bladder; adjuvant renal cell carcinoma



Rare diseases

Propionic Acidemia (PA) and Methylmalonic Acidemia (MMA) moving into registrational studies



Inhaled pulmonary therapeutics

Cystic fibrosis study advancing to multiple ascending dose (partnered with Vertex)

Thank you