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Latent + other vaccines

Program Pack

Norovirus (mRNA-1403/05)

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 worldwide[1]

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

	United States (per year)[2]	Global (per year)[2,3]
Infections	**~20M** infections	**~685M** infections
Deaths and hospitalizations	**~900** deaths (mostly older adults) **~100K** hospitalizations	**~200K** deaths (~50K among children)
Societal costs	**~$2B** in healthcare costs and lost productivity	**~$60B** in healthcare costs and lost productivity

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

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mRNA-1403/1405 Phase 1 trial design

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

2 x mRNA-1403 Dose Level 1	**2 x mRNA-1405** Dose Level 1
2 x mRNA-1403 Dose Level 2	**2 x mRNA-1405** Dose Level 2
2 x mRNA-1403 Dose Level 3	**2 x mRNA-1405** Dose Level 3
2 x mRNA-1403 Dose Level 4	**2 x mRNA-1405** Dose Level 4
1 x Placebo, 1 x mRNA-1403 Dose Level 4	**1 x Placebo, 1 x mRNA-1405** Dose Level 4

2 x Placebo

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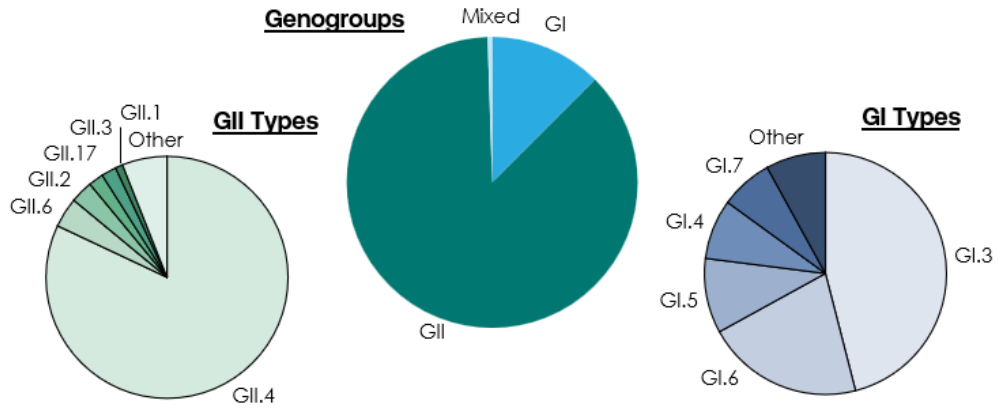
Norovirus vaccine development is challenging due to genotypic diversity and variability over time

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

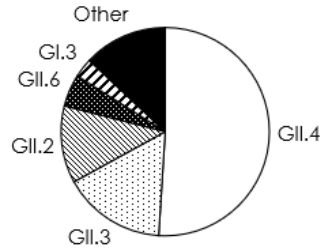
Vaccine development has been challenging to date due to the broad and shifting diversity of genotypes which requires frequent vaccine updates

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
2015-2022



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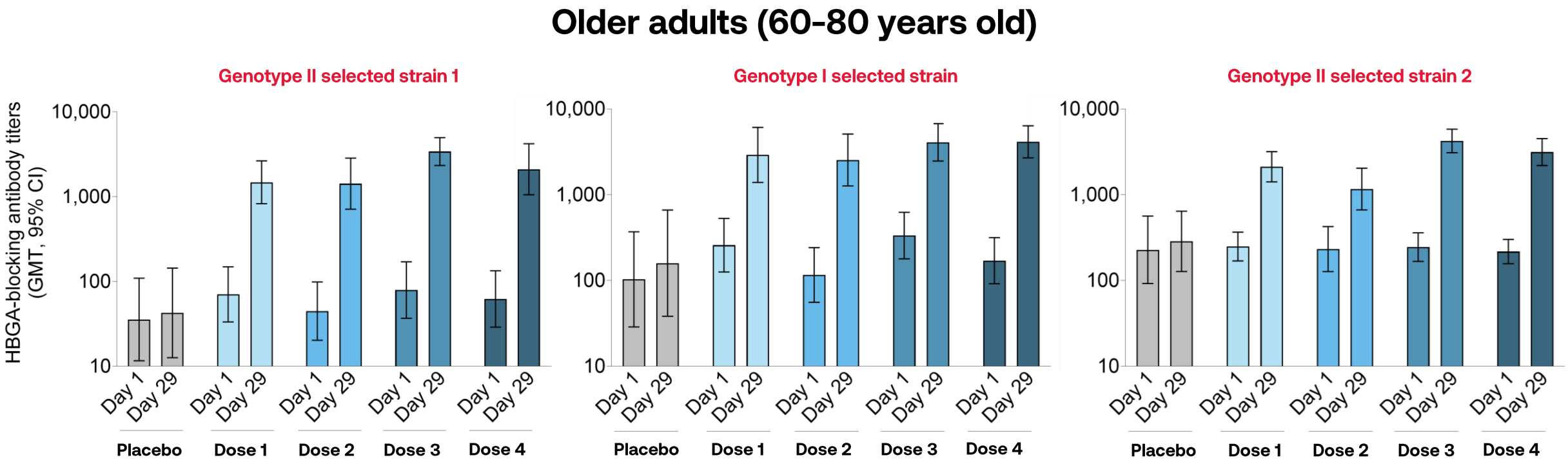
A single dose of mRNA-1403 also elicited robust HBGA-blocking antibody titers against vaccine-matched NoV genogroup I and II genotypes in older adults



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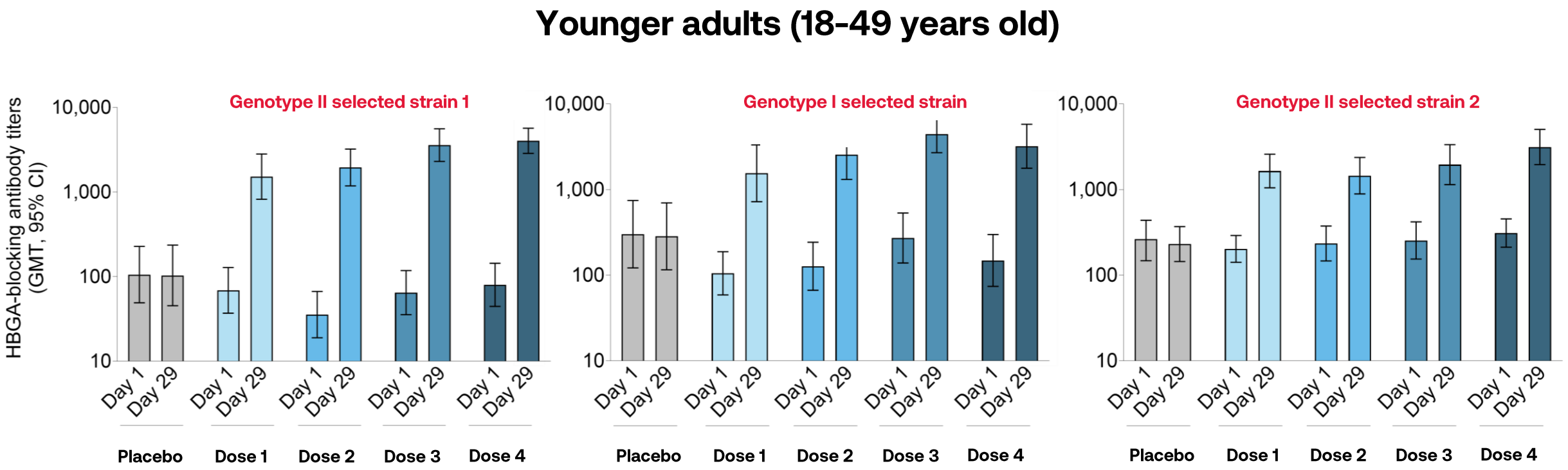

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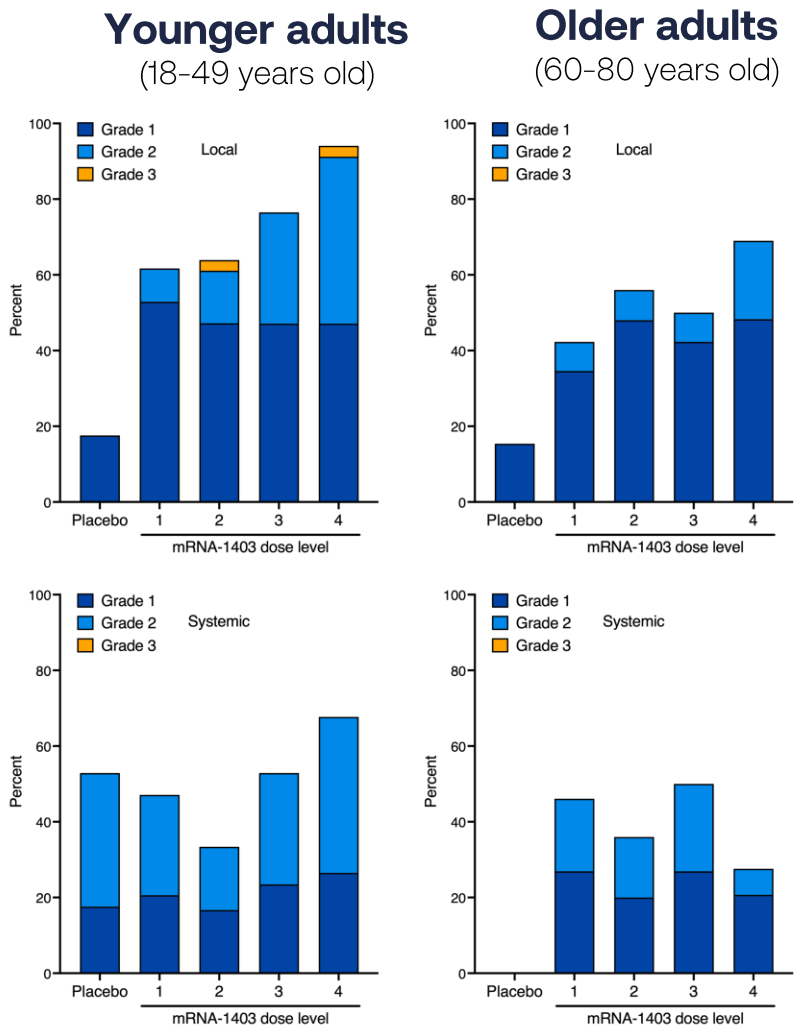
Single dose of mRNA-1403 was well-tolerated across all dose levels evaluated

- **Data from interim analysis on mRNA-1403 candidate through completion of Day 29 visits**
- **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



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Norovirus mRNA-1403 Phase 1 Safety

No safety concerns were identified through data cut-off

There were no deaths or AEs leading to study withdrawal through data cut-off

Within 28 days after any injection, there were no SAEs, AESIs, deaths, or AEs leading to study withdrawal reported

None of the SAEs and AESIs reported through data cut-off were assessed as related to study injection

No clinically meaningful or dose-dependent trends in unsolicited AEs were evident among participants who received mRNA-1403 vs. placebo

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mRNA-1403 Phase 3 study design

Phase 3 was designed to test the efficacy, safety and immunogenicity of a trivalent norovirus vaccine

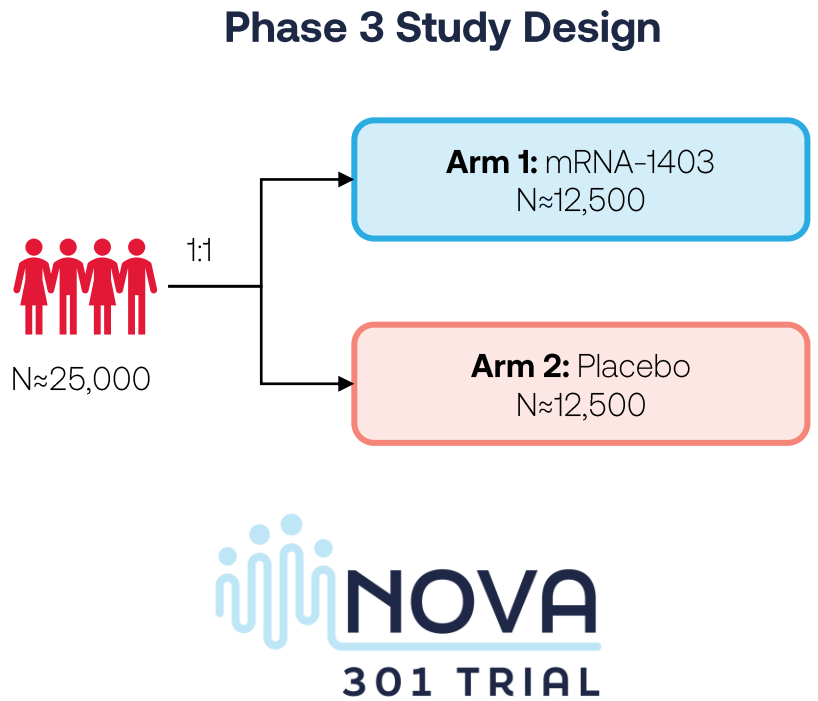
Design
Randomized, observer-blind, placebo-controlled study

Number of participants
~25,000 adults ≥ 18 years old (~20,000 ≥ 60 yo; ~5000 ≥ 18 and ≤59 yo)

Vaccination schedule
Single dose of mRNA-1403 or Placebo

Site location
Northern Hemisphere (United States, Canada, UK, Japan)

Southern Hemisphere and Equatorial Region (Australia, Panama)



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Norovirus summary

Immunogenicity

- Robust 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

Latest updates

- 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

- Phase 3 readout

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Medical and scientific presentations

ECSMID 2025 (Noro incidence)

https://s29.q4cdn.com/435878511/files/doc_presentations/2025/Apr/14/Norovirus-poster-Med-Attend-Norovirus.pdf

IDWeek 2024 (Phase 1/2 interim results)

https://s29.q4cdn.com/435878511/files/doc_presentations/2024/Oct/19/NoroPh12-IDweek24-Oct15.pdf

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Forward-looking statements

This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including regarding: the ability of Moderna's vaccine candidates to address challenges associated with norovirus genotypic diversity and variability; expected market opportunity; and development candidate activities. In some cases, forward-looking statements can be identified by terminology such as “may,” “should,” “expects,” “intends,” “plans,” “aims,” “anticipates,” “believes,” “estimates,” “predicts,” “potential,” “continue,” or the negative of these terms or other comparable terminology, although not all forward -looking statements contain these words. The forward-looking statements in this 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 those described in Moderna’s most recent Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (SEC) and in subsequent filings made by Moderna with SEC, which are available on the SEC's website at www.sec.gov. Except as required by law, Moderna disclaims any intention or responsibility for updating or revising any forward-looking statements in this presentation in the event of new information, future developments or otherwise. These forward-looking statements are based on Moderna’s current expectations and speak only as of the date referenced on the first page.

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