



200 Tech Square • Cambridge, MA 02139  
 phone 617 (10)(2e) • fax 617 (10)(2e)

*Hooggachte heer De Jonge,*

Ik schrijf u naar aanleiding van enkele cruciale mijlpalen die Moderna recentelijk heeft weten te bereiken, in ons streven om ervoor te zorgen dat landen over de hele wereld, waaronder Nederland, toegang kunnen krijgen tot ons Covid-19 kandidaat-vaccin, mRNA-1273, zodra deze voor gebruik wordt goedgekeurd.

We hebben onlangs drie belangrijke mijlpalen bereikt. Ten eerste hebben we vergevorderde verkennende gesprekken met de Europese Commissie afgerond over het leveren van tot 160 miljoen doses mRNA-1273 vaccins aan de Europese lidstaten. Dit getuigt van een groeiend vertrouwen in mRNA-1273 en het potentieel ervan om de bevolking tegen de gevolgen van COVID-19 te beschermen. De positieve afronding van de verkennende gesprekken is bedoeld om ervoor te zorgen dat de lidstaten in heel Europa, inclusief Nederland, vroegtijdig toegang kunnen krijgen tot veilige en effectieve COVID-19-vaccins.

Ten tweede hebben we tussentijdse gegevens aangekondigd over de veiligheid en immunogeniciteit van ons mRNA-vaccin tegen SARS-CoV-2 bij volwassenen tussen de 56-70 jaar en volwassenen ouder dan 71 jaar, die we graag met u willen delen (zie bijlage). We weten dat 7 miljoen mensen in Nederland 50 jaar of ouder zijn, wat betekent dat deze gegevens voor u zeer relevant moeten zijn. We zijn geïnteresseerd om dit nader met u te bespreken aangezien u een portefeuille van kandidaat-vaccins voor Nederlanders in overweging neemt.

Ten derde hebben we, om te zorgen voor een sterke bevoorrading van Europa en daarbuiten, speciale productiemiddelen in Europa beschikbaar gesteld. Wereldwijd verwachten we vanaf 2021 ongeveer 500 miljoen doses van ons vaccin per jaar te kunnen leveren en mogelijk tot 1 miljard doses per jaar. In Europa werken we samen met Europese strategische productiepartners zoals (10)(2a) voor de verwerking en productie. Dit is een gerichte toeleveringsketen om Europese landen en andere regio's in de wereld van ons vaccin te voorzien.

In het kader van deze drie hierboven uiteengezette mijlpalen willen we u graag onze beschikbaarheid aanbieden om u te ontmoeten op een moment dat het u uitkomt. We richten ons ook tot de heer (10)(2e)

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We waarderen de mogelijkheid om met u en uw team een open dialoog te voeren, en eventueel met andere nationale deskundigen die u van belang acht, met het doel om inzichten te delen in de rol die ons kandidaat-vaccin kan spelen bij het genereren van tal van oplossingen.



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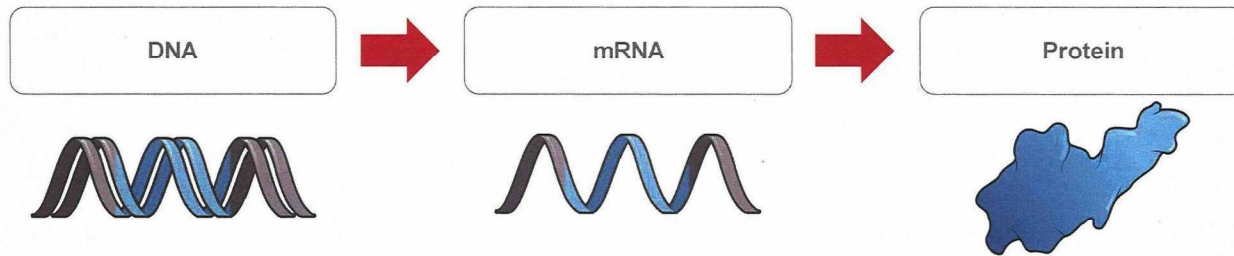
We kijken uit naar uw reactie en de mogelijkheid om met u te bespreken hoe we kunnen bijdragen aan het beëindigen van de Covid-19 pandemie in Nederland.

Hoogachtend,

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**mRNA-1273 Vaccine Against COVID-19**  
**Phase 1 Interim Analysis of Older Adult Cohorts (ages 56-70 and 71+)**  
August 26, 2020

## Forward-looking statements and Disclaimer

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This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended including, but not limited to, statements concerning the potential for mRNA-1273 to generate neutralizing antibodies in older adults, the potential for adverse side effects from mRNA-1273, the scaling of manufacturing for mRNA-1273, tolerability, stability and shelf-life of mRNA-1273 under different conditions and temperatures, and the ability to supply doses under certain timeframes. In some cases, forward-looking statements can be identified by terminology such as "will," "may," "should," "expects," "intends," "plans," "aims," "anticipates," "believes," "estimates," "predicts," "potential," "continue," or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. The forward-looking statements in this 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: the ability to manufacture and deliver doses at the scale required by agreements with customers; preclinical and clinical development is lengthy and uncertain, especially for a new class of medicines such as mRNA, and therefore our preclinical programs or development candidates may be delayed, terminated, or may never advance to or in the clinic; no commercial product using mRNA technology has been approved, and may never be approved; mRNA drug development has substantial clinical development and regulatory risks due to the novel and unprecedented nature of this new class of medicines; despite having ongoing interactions with the U.S. Food and Drug Administration (FDA) or other regulatory agencies, the FDA or such other regulatory agencies may not agree with the Company's regulatory approval strategies, components of our filings, such as clinical trial designs, conduct and methodologies, or the sufficiency of data submitted; the fact that the rapid response technology in use by Moderna is still being developed and implemented; the fact that the safety and efficacy of mRNA-1273 has not yet been established; potential adverse impacts due to the global COVID-19 pandemic such as delays in clinical trials, preclinical work, overall operations, regulatory review, manufacturing and supply chain interruptions, adverse effects on healthcare systems and disruption of the global economy; and those risks and uncertainties described under the heading "Risk Factors" in Moderna's most recent Quarterly Report on Form 10-Q 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](http://www.sec.gov). Except as required by law, Moderna disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this presentation in the event of new information, future developments or otherwise. These forward-looking statements are based on Moderna's current expectations and speak only as of the date hereof.

## Phase 1 study of mRNA-1273 vaccine against COVID-19

### *Presentation of older adult cohorts*

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- Presentation at Advisory Committee on Immunization Practices (ACIP) meeting
- At the 100 µg dose, mRNA-1273 was generally safe and well-tolerated in all age cohorts
- At the 100 µg dose, mRNA-1273 induced consistently high levels of neutralizing antibody titers in all participants in the 56-70 (n=10) and 71+ age cohorts (n=10); titers were 2-3 fold above those seen in convalescent sera
- mRNA-1273 elicited Th1-biased CD4 T cell responses in the 56-70 and 71+ age cohorts
- Neutralizing antibody titers and T cell responses in the 56-70 and 71+ age cohorts were consistent with those reported in younger adults

# Phase 1 trial overview

## Led by the National Institutes of Health (NIH)

**Key objective:**

- To assess the safety, reactogenicity and immunogenicity of mRNA-1273

**Study design:**

- Phase 1, open-label dose ranging clinical trial in healthy adults
- Subjects received an intramuscular (IM) injection (0.5 milliliter [mL]) of mRNA-1273 on Days 1 and 29 in the deltoid muscle and will be followed through 12 months post second vaccination (Day 394)

**Primary endpoint:**

- Safety and reactogenicity of a 2-dose vaccination schedule of mRNA-1273, given 28 days apart

**Secondary endpoint:**

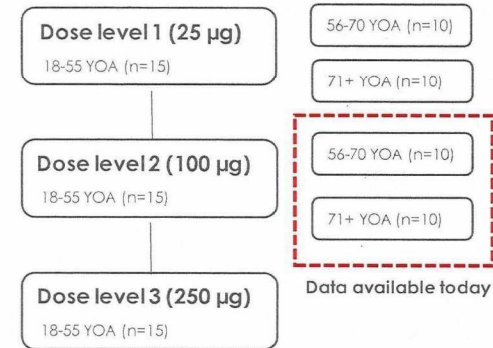
- Evaluate the immunogenicity to the SARS-CoV-2 S protein following a 2-dose vaccination schedule of mRNA-1273 at Day 57

**Trial progress/details:**

- Original 3 dose cohorts 25 µg, 100 µg and 250 µg (18-55 years old) Day 57 data published in *The New England Journal of Medicine*<sup>1</sup>
- Interim analysis of the 100 µg dose for the 56-70 and 71+ age cohorts available today
- 50 µg dose across three age cohorts (18-55, 56-70 and 71+) are fully enrolled



**mRNA-1273-P101 Study Design**  
YOA = years of age



Slide 4

1. Jackson L, Anderson EJ, Roupheael NG, et al. An mRNA vaccine against SARS-CoV-2-preliminary report. N Engl J Med. 14 Jul 2020; DOI: 10.1056/NEJMoa2022483 Interim Immunogenicity Report



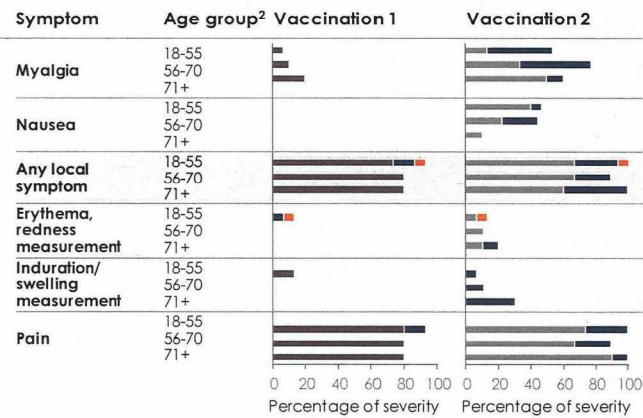
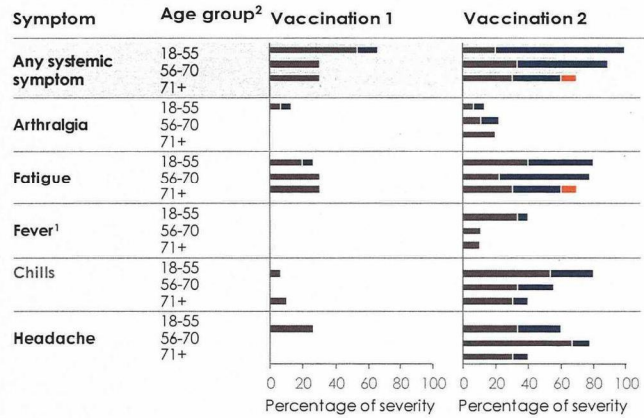
# 100 µg mRNA-1273 well-tolerated across age groups

## Phase 1: No Vaccine-Related SAEs Have Been Reported

Solicited Local and Systemic Symptoms Followed for 7 Days Post-vaccination

Majority of symptoms resolved within 2 days, some persisted as long as 5 days

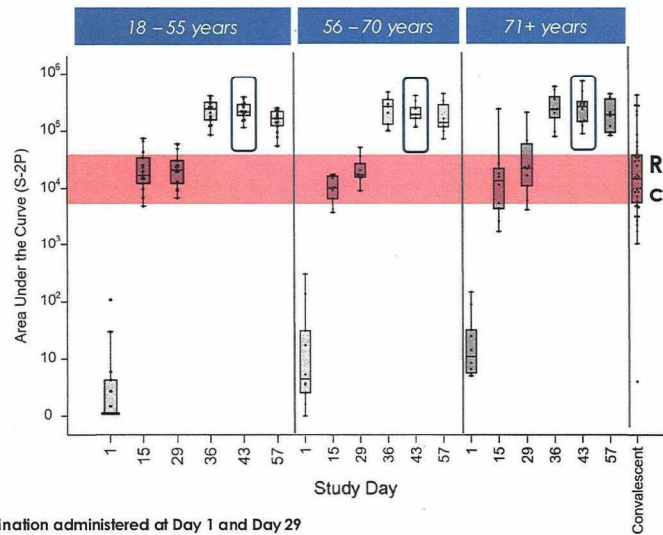
■ Grade 1 (mild) ■ Grade 2 (moderate) ■ Grade 3 (severe)



1. Fever percentages reflect the number of subjects with at least one measurement available in the data system as the denominator. This denominator may differ from other systemic symptoms, which are solicited in-clinic at the post-dose assessment  
 2. 18-55: N=15; 56-70: N=10; 71+: N=10; N = All subjects receiving Dose 1 with any solicited event data recorded in the database

## Binding antibodies comparable across age groups

S-2P binding antibodies (ELISA)- 100 µg at Day 1 and Day 29

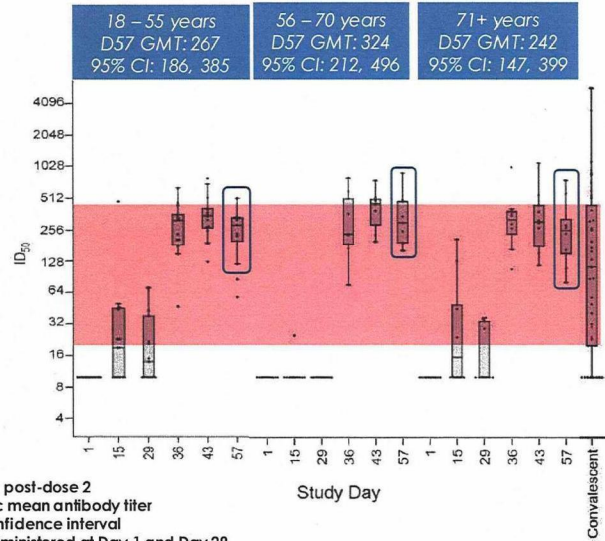


- 100 µg two-dose series seroconverted all participants after the first vaccination
- After the first vaccination, AUC for all age groups exceeded the median of convalescent sera
- After two vaccinations, all age groups are equivalent to high-titer convalescent sera (i.e., upper quartile)



## Distribution of antibody titers in pseudovirus neutralization assay comparable across age groups

Pseudovirus neutralization assay titers (ID<sub>50</sub>)- 100 µg at Day 1 and Day 29



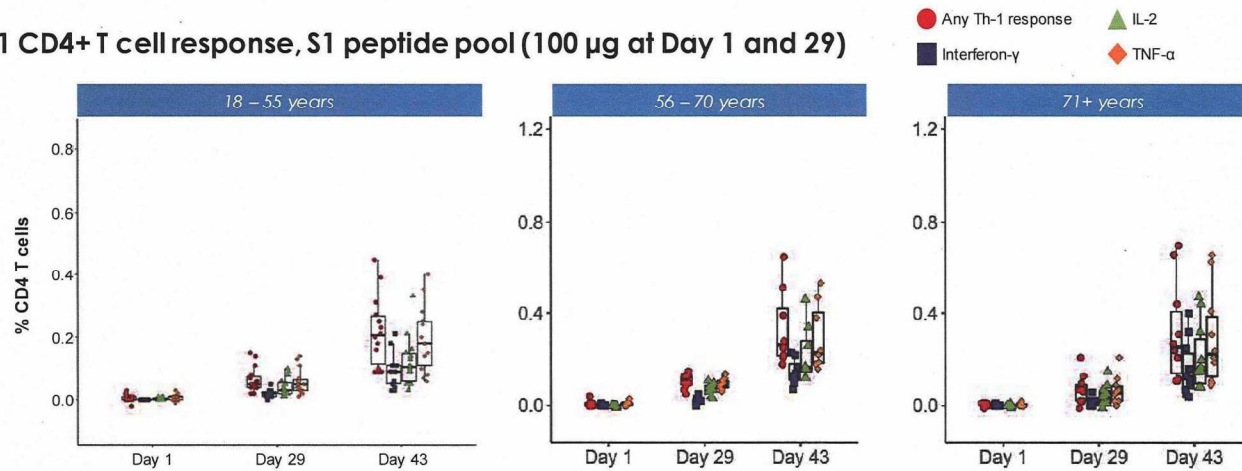
D57: one month post-dose 2  
 GMT: geometric mean antibody titer  
 95% CI: 95% confidence interval  
 Vaccination administered at Day 1 and Day 29

Range of convalescent sera

- After second vaccination, pseudovirus neutralization responses were detected in all participants
- Pseudovirus neutralization titers were comparable across age groups
- Pseudovirus neutralization titer for 56-70 and 71+ YOA above convalescent sera median titer at Day 57

## mRNA-1273 elicited Th1-biased CD4 T cell responses in all participants

### Th1 CD4+ T cell response, S1 peptide pool (100 µg at Day 1 and 29)



- Vaccination with 100 µg mRNA-1273 led a Th1-biased CD4+ T-cell response across all age groups
- Th2 phenotype was rare (data not shown)

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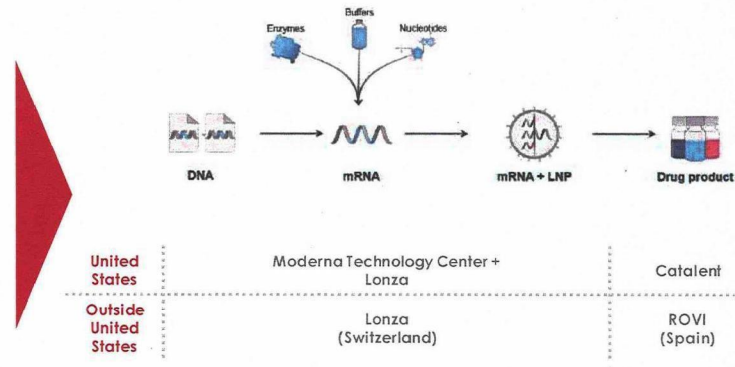
Jackson L, Anderson EJ, Roupheal NG, et al. An mRNA vaccine against SARS-CoV-2- preliminary report. N Engl J Med. 14 Jul 2020; DOI: 10.1056/NEJMoa2022483  
Interim Immunogenicity Report

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## Manufacturing and distribution update

### Key takeaways

- Collaboration with partners Lonza, Catalent and ROVI
- On track to supply 500 million to 1 billion doses per year at the Phase 3 selected dose of 100 µg
- Current storage and distribution conditions at -20° Celsius/-4° Fahrenheit with point of care temperature at normal refrigerated conditions (2-8° Celsius/36-46° Fahrenheit)<sup>1</sup>
- No onsite dilution or special handling needed



## mRNA-1273 vaccine against COVID-19

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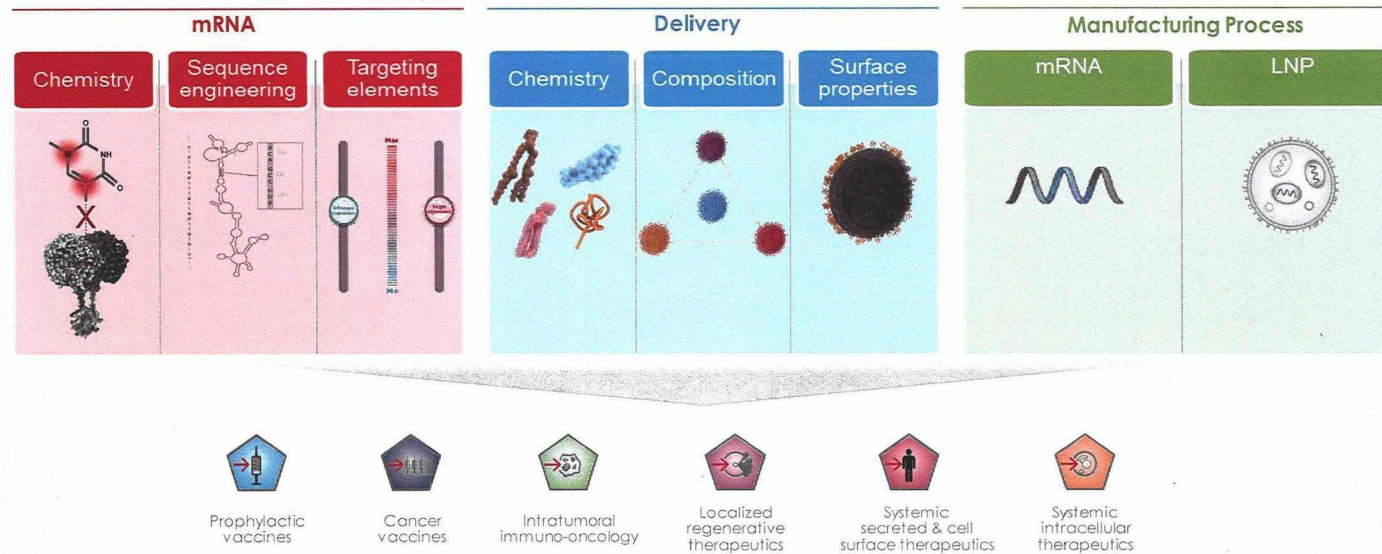
- **Phase 1 clinical data**
  - Neutralizing antibody titers were observed in 100% of evaluated participants across all age groups
  - In the pseudovirus (ID<sub>50</sub>) neutralization assay, at the 100 µg dose, mRNA-1273 induced consistently high levels of neutralizing antibody titers in all participants in the young adult and older adult cohorts
  - In the live SARS-CoV-2 (PRNT<sub>80</sub>) neutralization assay in the younger adult cohort, the Day 43 geometric mean titer levels at the Phase 3 selected dose of 100 µg were above those seen in reference convalescent sera<sup>1</sup>
- **Nonhuman primate data publication<sup>2</sup>**
  - Two-dose vaccination schedule of mRNA-1273 led to rapid protection against SARS-CoV-2 infection in both the lungs and nose of non-human primates
- **COVE Phase 3 study of mRNA-1273<sup>3</sup>**
  - As of Tuesday, August 25<sup>th</sup>, 15,239 participants have been enrolled

1. Jackson L, Anderson EJ, Roupael NG, et al. An mRNA vaccine against SARS-CoV-2- preliminary report. N Engl J Med. 14 Jul 2020; DOI: 10.1056/NEJMoa2022483 Interim Immunogenicity Report
2. Corbett K, Flynn B, Foulds L, et al. Evaluation of the mRNA-1273 vaccine against SARS-CoV-2 in nonhuman primates. N Engl J. Med. 28 Jul 2020; DOI: 10.1056/NEJMoa2024671
3. Moderna COVE study: <https://www.modernatx.com/cove-study>

Slide 10

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# Moderna's mRNA platform



Slide 11

Moderna Annual Science Day Presentation, 02 Jun 2020  
<https://investors.modernatx.com/static-files/5c1ed4992-c730-4841-b756-d653c9ab9a9b>

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**Our mission**

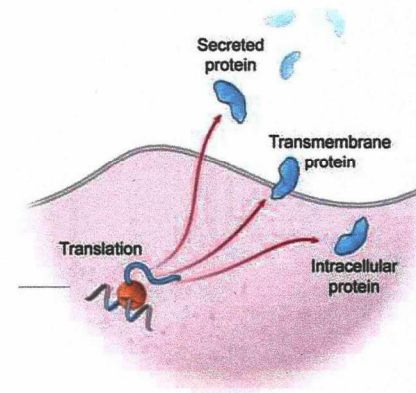
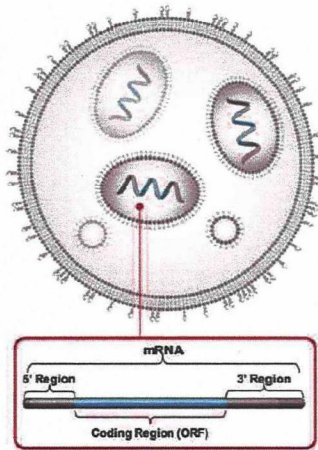
*To deliver on the promise of mRNA science to create a new generation of transformative medicines for patients.*

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Please join us virtually for  
**R&D Day**

Thursday, Sept. 17<sup>th</sup>, 2020  
8:00 AM – 12:30 PM ET

*Webcast link will be available on  
our website*



**Palijsma, M.N.W.**

**Van:** (10)(2e)  
**Verzonden:** donderdag 10 september 2020 13:44  
**Aan:** \_Dienstpostbus Digitale Balie  
**CC:** (10)(2e); (10)(2e); (10)(2e); (10)(2e); (10)(2e); (10)(2e);  
 \_Dienstpostbus Directiesecretariaat DMO; \_Dienstpostbus Secretariaat PG  
**Onderwerp:** FW: Invitation to scientific meeting with Moderna  
**Bijlagen:** Elderly Ph 1 Data - Final (08.26.20).pdf; Minister De Jonge - Invitation to scientific meeting with Moderna.pdf

Beste collega Digitale Balie,

Graag bijgaande vmbrief in behandeling nemen en uitzetten op PG.

Dank en groet,

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Verzonden met BlackBerry Work(www.blackberry.com)

**Van:** Office of the CEO <(10)(2e)@modernatx.com>  
**Verzonden:** 9 sep. 2020 17:53  
**Naar:** Minister van VWS <(10)(2e)@minvws.nl>  
**Cc:** (10)(2e)@minvws.nl  
**Onderwerp:** Invitation to scientific meeting with Moderna

Dear Minister de Jonge,

I hope this finds you well.

I am pleased to extend the attached invitation to you for a meeting at your convenience as we reach a number of crucial milestones in the development of our vaccine candidate mRNA-1273 furthering our goal of bringing mRNA technology to the benefit of European and global citizens in the fight against COVID-19.

I would like to offer our availability to meet with you and your team, to share insights into the science and data behind mRNA-1273, hear your views and answer any questions you may have regarding the role our vaccine candidate could play in a portfolio of solutions to address the current crisis.

The Moderna team and I very much look forward to the opportunity to bring our mRNA technology to Europe.

Thank you in advance for your time and consideration.

Kind Regards,

(10)(2e)

[modernatx.com](mailto:(10)(2e)@modernatx.com)





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