

To: [redacted] 5.1.2e [redacted] 5.1.2e [redacted] @rivm.nl]; [redacted] 5.1.2e [redacted] 5.1.2e [redacted] @rivm.nl]; [redacted] 5.1.2e
[redacted] 5.1.2e [redacted] 5.1.2e [redacted] @rivm.nl]
From: [redacted] 5.1.2e
Sent: Wed 12/2/2020 7:11:28 AM
Subject: Doorst: Respond to [redacted] 5.1.2e
Received: Wed 12/2/2020 7:11:29 AM

Ter info - dit wisten we inmiddels al.

Mvrgr

[redacted] 5.1.2e

Van: [redacted] 5.1.2e <[redacted] 5.1.2e @modernatx.com>
Datum: 2 december 2020 om 05:37:43 CET
Aan: [redacted] 5.1.2e <[redacted] 5.1.2e @rivm.nl>
Onderwerp: RE: Respond to [redacted] 5.1.2e

Dear [redacted] 5.1.2e

Apologies for the slightly delayed response.

As you may have seen from the EMA Press Release that the target CHMP date to conclude the Assessment for Moderna's Vaccine is January 12th.

The EC's decision will follow within days.

<https://www.ema.europa.eu/en/news/ema-receives-application-conditional-marketing-authorisation-moderna-covid-19-vaccine>

I hope this helps.

Regards,

[redacted] 5.1.2e

From: [redacted] 5.1.2e <[redacted] 5.1.2e @rivm.nl>
Sent: Monday, November 30, 2020 12:26 PM
To: [redacted] 5.1.2e <[redacted] 5.1.2e @modernatx.com>
Cc: [redacted] 5.1.2e <[redacted] 5.1.2e @modernatx.com>; [redacted] 5.1.2e <[redacted] 5.1.2e @rivm.nl>; [redacted] 5.1.2e <[redacted] 5.1.2e @rivm.nl>; [redacted] 5.1.2e <[redacted] 5.1.2e @rivm.nl>; [redacted] 5.1.2e <[redacted] 5.1.2e @rivm.nl>; [redacted] 5.1.2e <[redacted] 5.1.2e @minvws.nl>
Subject: RE: Moderna Milestones: Phase III data interim analysis & shelf-life stability

EXTERNAL

Good afternoon [redacted] 5.1.2e

Many thanks for your timely reply and the info provided!

If you receive the data / time table from EMA could you pls let us know later today – this important info would be VERY much appreciated.

Thanks for your support,

Best regard,

[redacted] 5.1.2e

From: 5.1.2e <5.1.2e@modernatx.com>
Sent: maandag 30 november 2020 18:17
To: 5.1.2e <5.1.2e@rivm.nl>
Cc: 5.1.2e <5.1.2e@modernatx.com>; 5.1.2e <5.1.2e@rivm.nl>; 5.1.2e <5.1.2e@rivm.nl>; 5.1.2e <5.1.2e@rivm.nl>; 5.1.2e <5.1.2e@minvws.nl>
Subject: RE: Moderna Milestones: Phase III data interim analysis & shelf-life stability

Good morning 5.1.2e

Thank you for your email and call this morning.

Please see our comments below regarding your questions.

Please let me know if you have any further questions or need any clarification.

Regards,

5.1.2e

From: 5.1.2e <5.1.2e@rivm.nl>
Sent: Monday, November 30, 2020 7:56 AM
To: 5.1.2e <5.1.2e@modernatx.com>
Cc: 5.1.2e <5.1.2e@modernatx.com>; 5.1.2e <5.1.2e@rivm.nl>; 5.1.2e <5.1.2e@rivm.nl>; 5.1.2e <5.1.2e@rivm.nl>; 5.1.2e <5.1.2e@minvws.nl>
Subject: RE: Moderna Milestones: Phase III data interim analysis & shelf-life stability
Importance: High

EXTERNAL

Good morning 5.1.2e

Hope you are doing well.

We would appreciate to receive additional info on timelines asap and hope you can provide following dates (best case estimates):

- CHMP – positive opinion
- Approval EMA

• In response to these questions, the EMA informed that they will be issuing today a timetable regarding the Opinion and Authorization procedure.

Will make sure to keep you posted.

- OMCL releases (or waiver requested?)

→ Our plan is to have BASG, Austria and AEMPS, Spain supporting the OMCL testing for EU (with ANSM, France as a potential third option).

The Transfer activities are ongoing with Austria exclusively. The readiness of Austrian lab is expected by Mid Dec 15th. In addition, their lead time for testing batches is between 10-14 days. This is why, we have sent a letter to the EDQM requesting a temporary waiver.

- First shipments to national hubs (Netherlands) – what is the chance we will receive market authorized

product in December this year?

- We will be providing delivery allocations based on the EU's allocation direction. Those initial deliveries will be provided to all contracted Member States.
- Any info with respect FMD-barcodes on packaging – Falsified Medicines Directive?
- We do have a 2D DataMatrix on our primary labels and our artwork does have anti-counterfeiting security features that we cannot disclose at this time.

Could we please receive your info (best case scenario) within 3 hours?

Provided info will be treated confidential.

We hope you can help us with this urgent request from our MoH.

Many thanks and best regards,

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Ministry of Health, Welfare and Sport
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<http://www.rivm.nl>

From: 5.1.2e <5.1.2e@modernatx.com>

Sent: maandag 16 november 2020 15:17

To: 5.1.2e <5.1.2e@rivm.nl>; 5.1.2e <5.1.2e@rivm.nl>; 5.1.2e <5.1.2e@rivm.nl>; 5.1.2e <5.1.2e@rivm.nl>; 5.1.2e <5.1.2e@rivm.nl>

Cc: 5.1.2e <5.1.2e@modernatx.com>

Subject: Moderna Milestones: Phase III data interim analysis & shelf-life stability

Dear all,

I hope this finds you well.

On behalf of the whole Moderna team, I wanted to share a quick note to thank you for your time in speaking with us on November 2. We found our discussion interesting and valuable, and wanted to reaffirm that we are available to address any additional questions you may have over the coming weeks and months.

We also wanted to take this opportunity to share two key milestones with you: 1) the first interim analysis of our Phase III study, known as the COVE study, for our COVID-19 vaccine candidate mRNA-1273, and 2) an announcement on longer shelf-life. Both press releases are attached.

Please do not hesitate to reach out should you have any questions.

Best Wishes,

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ModernaTX, Inc.

Mobile: +1 (617) 5.1.2e modernatx.comThe Moderna logo consists of the word "moderna" in a lowercase, sans-serif font. The letters "o", "d", "e", and "a" are red, while "m", "r", "n", and "a" are black. A horizontal dashed line is positioned below the letters "o", "d", and "e".

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