

Beste collega's,

Bijgaande afspraak is gemaakt op verzoek van [REDACTED] 5.1.2e

Ik hoop dat u uw agenda kunt vrijmaken voor dit overleg.

Webexgegevens

Vergaderingsnummer (toegangscodes): [REDACTED] (10)(2g)

Wachtwoord voor vergadering: [REDACTED] (10)(2g)

donderdag 26 november 2020

11:30 | (UTC+01:00) Amsterdam, Berlijn, Bern, Rome, Stockholm, Wenen | 30 minuten

Vergadering starten

To: [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]
Cc: [redacted] 5.1.2e [redacted] 5.1.2e @rivm.nl]
From: [redacted] 5.1.2e
Sent: Mon 11/23/2020 8:55:34 AM
Subject: RE: A further update from AstraZeneca on their clinical development
Received: Mon 11/23/2020 8:55:35 AM

Ja, zo las ik het ook

From: [redacted] 5.1.2e <[redacted] 5.1.2e @rivm.nl>
Sent: maandag 23 november 2020 09:49
To: [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>
Cc: [redacted] 5.1.2e <[redacted] 5.1.2e @rivm.nl>
Subject: RE: A further update from AstraZeneca on their clinical development

Interessant. Begrijp ik het goed dat vaccinatieschema dat de beste resultaten geeft, bestaat uit een halve dosis gevolgd door één dosis?
 Dat lijkt me op zich prima doenbaar, maar geeft ook aan hoe goed we voor deze campagne de professionals moeten informeren, per vaccin!

Met vriendelijke groet,

[redacted] 5.1.2e



Rijksinstituut voor Volksgezondheid
 en Milieu
 Ministerie van Volksgezondheid,
 Welzijn en Sport

Dienst Vaccinvoorziening en Preventieprogramma's (RIVM-DVP)

T 030 [redacted] 5.1.2e
 M 06 [redacted] 5.1.2e
 E [redacted] 5.1.2e @rivm.nl

From: [redacted] 5.1.2e <[redacted] 5.1.2e @rivm.nl>
Sent: maandag 23 november 2020 09:43
To: [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>
Cc: [redacted] 5.1.2e <[redacted] 5.1.2e @rivm.nl>
Subject: FW: A further update from AstraZeneca on their clinical development

Dames,
 Ter info,
 Mvrgr

[redacted] 5.1.2e

Van: [redacted] 5.1.2e <[redacted] 5.1.2e @minvws.nl>
Datum: 23 november 2020 om 09:35:37 CET
Aan: [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>
Onderwerp: FW: A further update from AstraZeneca on their clinical development

Ter informatie.

Groet,
 [redacted] 5.1.2e

From: EC VACCINES <5.1.2e @ec.europa.eu>
 Sent: Wednesday, November 18, 2020 3:45 PM
 To: 5.1.2e @sozialministerium.at; 5.1.2e @gesundheitsministerium.gv.at;
 5.1.2e @gesundheitsministerium.gv.at; 5.1.2e @bmg.gv.at; 5.1.2e @fagg-afmps.be; 5.1.2e @fagg-afmps.be; 5.1.2e @bda.bg; 5.1.2e @moh.gov.cy;
 5.1.2e @papd.mof.gov.cy; 5.1.2e @phs.moh.gov.cy; 5.1.2e @unob.cz;
 5.1.2e @mzcr.cz; 5.1.2e @mzcr.cz; 5.1.2e @mzcr.cz; 5.1.2e @bmg.bund.de;
 5.1.2e @bmg.bund.de; 5.1.2e @bmg.bund.de; 5.1.2e @dkma.dk; 5.1.2e @sm.ee; 5.1.2e @moh.gov.gr; 5.1.2e @kontozamanis.gr; 5.1.2e @aemps.es;
 5.1.2e @aemps.es; 5.1.2e @formin.fi; 5.1.2e @stm.fi; 5.1.2e @igf.finances.gouv.fr; 5.1.2e @miz.hr; 5.1.2e @hzjz.hr;
 5.1.2e @emmi.gov.hu; 5.1.2e @emmi.gov.hu; 5.1.2e @hse.ie; 5.1.2e @health.gov.ie;
 5.1.2e @hse.ie; 5.1.2e @health.gov.ie; 5.1.2e @health.gov.ie; 5.1.2e @sanita.it; 5.1.2e @vykt.lt; 5.1.2e @ms.etat.lu; 5.1.2e @ms.etat.lu;
 5.1.2e @vmnvd.gov.lv; 5.1.2e @gov.mt; 5.1.2e @minvws.nl; 5.1.2e @urpl.gov.pl;
 5.1.2e @pzh.gov.pl; 5.1.2e @urpl.gov.pl; 5.1.2e @infarmed.pt; 5.1.2e @ms.ro; 5.1.2e @ms.ro;
 5.1.2e @ms.ro; 5.1.2e @gov.se; 5.1.2e @gov.si; 5.1.2e @gov.si;
 5.1.2e @health.gov.sk; 5.1.2e @zva.gov.lv; 5.1.2e @minvws.nl;
 5.1.2e @minbuza.nl; 5.1.2e @gmail.com
 Cc: 5.1.2e (SANTE) <5.1.2e @ec.europa.eu>; 5.1.2e (SANTE) <5.1.2e @ec.europa.eu>;
 5.1.2e (SG-RECOVER) <5.1.2e @ec.europa.eu>; 5.1.2e (SG)
 <5.1.2e @ec.europa.eu>; 5.1.2e (SANTE) <5.1.2e @ec.europa.eu>; 5.1.2e
 5.1.2e (SJ) <5.1.2e @ec.europa.eu>; 5.1.2e (SJ) <5.1.2e @ec.europa.eu>;
 5.1.2e (SJ) <5.1.2e @ec.europa.eu>; 5.1.2e (SANTE)
 <5.1.2e @ec.europa.eu>; 5.1.2e (SANTE) <5.1.2e @ec.europa.eu>; 5.1.2e
 (SANTE) <5.1.2e @ec.europa.eu>; 5.1.2e (SANTE) <5.1.2e @ec.europa.eu>; 5.1.2e
 5.1.2e (SANTE) <5.1.2e @ec.europa.eu>; 5.1.2e (SANTE) <5.1.2e @ec.europa.eu>;
 5.1.2e @ec.europa.eu; 5.1.2e (SANTE) <5.1.2e @ec.europa.eu>; 5.1.2e
 5.1.2e (SANTE) <5.1.2e @ec.europa.eu>; EC VACCINES <5.1.2e @ec.europa.eu>

Subject: Update from Janssen Pharmaceutica NV on their clinical development

Dear Members of the Steering Board,

Please find below a short update provided by Janssen Pharmaceutica NV (Johnson & Johnson):

We are pleased to inform you that we have [initiated](#) our second Phase 3 global study of Janssen's COVID-19 vaccine candidate. The ENSEMBLE 2 study is a complementary trial to the ongoing ENSEMBLE study, which is currently recruiting up to 60,000 people in Latin America, the United States and South Africa. ENSEMBLE 2 will look to enrol up to 30,000 participants worldwide, with trial sites in Belgium, France, Germany, and Spain, among others. In order to evaluate the efficacy of Janssen's COVID-19 vaccine candidate, clinical trial sites in countries and areas with high incidence of COVID-19 and the ability to achieve a rapid initiation were selected, and we are grateful for the support of your EU member states in this important effort.

The ENSEMBLE and ENSEMBLE 2 trials will run in parallel, with ENSEMBLE evaluating a single-dose regimen and ENSEMBLE 2 evaluating a two-dose regimen. While a potentially safe and effective single-dose preventive COVID-19 vaccine would have significant benefits, particularly in a pandemic setting, Janssen's COVID-19 vaccine program has been designed to be extremely thorough and driven by science. As such, we are investigating multiple doses and dosing regimens to evaluate their long-term efficacy.

The Phase 3 ENSEMBLE and ENSEMBLE 2 trials follow [positive interim results](#) from the Company's ongoing Phase 1/2a clinical study, which is studying the safety profile and immunogenicity of both a single-dose and two-dose vaccination in Belgium and the United States. The interim analysis showed that a single dose of the COVID-19 vaccine candidate induced a robust immune response and was generally well-tolerated.

We trust this helps.

With kind regards,
The EC Vaccines Team