To: 5.1.2e 5.1.2e 5.1.2e [5.1.2e @rivm.nl]; 5.1.2e 5.1.2e 5.1.2e [5.1.2e @rivm.nl]; 5.1.2e 5.1.2e [5.1.2e @rivm.nl]
Cc: 5.1.2e 5.1.2e 5.1.2e [5.1.2e @rivm.nl]
From: 5.1.2e 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: 5.1.2e 5.1.2e 5.1.2e < 5.1.2e @rivm.nl>
Sent: maandag 23 november 2020 09:49
To: 5.1.2e 5.1.2e < 5.1.2e @rivm.nl>; 5.1.2e 5.1.2e 5.1.2e < 5.1.2e @rivm.nl>; 5.1.2e 5.1.2e < 5.1.2e @rivm.nl>
Cc: 5.1.2e 5.1.2e 5.1.2e < 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,
5.1.2e 5.1.2e 5.1.2e

.....

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

Dienst Vaccinvoorziening en Preventieprogramma's (RIVM-DVP)

.....

T 030 5.1.2e
M 06 5.1.2e
E 5.1.2e @rivm.nl

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

Dames,
Ter info,
Mvrgr
5.1.2e

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

Ter informatie.

Groet,
5.1.2e

975238

Verzonden met BlackBerry Work
(www.blackberry.com)

Van: [redacted]@ec.europa.eu <[redacted]@ec.europa.eu>
Datum: maandag 23 nov. 2020 9:26 AM
Aan: [redacted]@sozialministerium.at <[redacted]@sozialministerium.at>, [redacted]@gesundheitsministerium.gv.at <[redacted]@gesundheitsministerium.gv.at>, [redacted]@gesundheitsministerium.gv.at <[redacted]@gesundheitsministerium.gv.at>, [redacted]@bmg.gv.at <[redacted]@bmg.gv.at>, [redacted]@fagg-afmps.be <[redacted]@fagg-afmps.be>, [redacted]@fagg-afmps.be <[redacted]@fagg-afmps.be>, [redacted]@bda.bg <[redacted]@bda.bg>, [redacted]@moh.gov.cy <[redacted]@moh.gov.cy>, [redacted]@papd.mof.gov.cy <[redacted]@papd.mof.gov.cy>, [redacted]@phs.moh.gov.cy <[redacted]@phs.moh.gov.cy>, [redacted]@unob.cz <[redacted]@unob.cz>, [redacted]@mzcr.cz <[redacted]@mzcr.cz>, [redacted]@mzcr.cz <[redacted]@mzcr.cz>, [redacted]@mzcr.cz <[redacted]@mzcr.cz>, [redacted]@bmg.bund.de <[redacted]@bmg.bund.de>, [redacted]@bmg.bund.de <[redacted]@bmg.bund.de>, [redacted]@bmg.bund.de <[redacted]@bmg.bund.de>, [redacted]@dkma.dk <[redacted]@dkma.dk>, [redacted]@sm.ee <[redacted]@sm.ee>, [redacted]@moh.gov.gr <[redacted]@moh.gov.gr>, [redacted]@kontozamanis.gr' <[redacted]@kontozamanis.gr'>, [redacted]@aemps.es <[redacted]@aemps.es>, [redacted]@aemps.es <[redacted]@aemps.es>, [redacted]@formin.fi <[redacted]@formin.fi>, [redacted]@stm.fi <[redacted]@stm.fi>, [redacted]@igf.finances.gouv.fr <[redacted]@igf.finances.gouv.fr>, [redacted]@miz.hr <[redacted]@miz.hr>, [redacted]@hzjz.hr <[redacted]@hzjz.hr>, [redacted]@emmi.gov.hu <[redacted]@emmi.gov.hu>, [redacted]@emmi.gov.hu <[redacted]@emmi.gov.hu>, [redacted]@hse.ie <[redacted]@hse.ie>, [redacted]@health.gov.ie <[redacted]@health.gov.ie>, [redacted]@hse.ie <[redacted]@hse.ie>, [redacted]@health.gov.ie <[redacted]@health.gov.ie>, [redacted]@health.gov.ie <[redacted]@health.gov.ie>, [redacted]@sanita.it <[redacted]@sanita.it>, [redacted]@vvkt.lt <[redacted]@vvkt.lt>, [redacted]@ms.etat.lu <[redacted]@ms.etat.lu>, [redacted]@ms.etat.lu <[redacted]@ms.etat.lu>, [redacted]@vmnvd.gov.lv <[redacted]@vmnvd.gov.lv>, [redacted]@gov.mt <[redacted]@gov.mt>, [redacted], [redacted]. [redacted] ([redacted]) <[redacted]@minvws.nl>, [redacted]@urpl.gov.pl <[redacted]@urpl.gov.pl>, [redacted]@pzh.gov.pl <[redacted]@pzh.gov.pl>, [redacted]@urpl.gov.pl <[redacted]@urpl.gov.pl>, [redacted]@infarmed.pt <[redacted]@infarmed.pt>, [redacted]@ms.ro <[redacted]@ms.ro>, [redacted]@ms.ro <[redacted]@ms.ro>, [redacted]@gov.se <[redacted]@gov.se>, [redacted]@gov.si <[redacted]@gov.si>, [redacted]@gov.si <[redacted]@gov.si>, [redacted]@health.gov.sk <[redacted]@health.gov.sk>, [redacted]@zva.gov.lv <[redacted]@zva.gov.lv>, [redacted], [redacted]. <[redacted]@minvws.nl>, [redacted]@minbuza.nl <[redacted]@minbuza.nl>, [redacted]@gmail.com <[redacted]@gmail.com>
Kopie: [redacted]@ec.europa.eu <[redacted]@ec.europa.eu>, [redacted]@ec.europa.eu <[redacted]@ec.europa.eu>, [redacted]@ec.europa.eu <[redacted]@ec.europa.eu>, [redacted]@ec.europa.eu <[redacted]@ec.europa.eu>, [redacted]@ec.europa.eu <[redacted]@ec.europa.eu>, [redacted]@ec.europa.eu <[redacted]@ec.europa.eu>, [redacted]@ec.europa.eu <[redacted]@ec.europa.eu>, [redacted]@ec.europa.eu <[redacted]@ec.europa.eu>, [redacted]@ec.europa.eu <[redacted]@ec.europa.eu>, [redacted]@ec.europa.eu <[redacted]@ec.europa.eu>, [redacted]@ec.europa.eu <[redacted]@ec.europa.eu>, [redacted]@ec.europa.eu <[redacted]@ec.europa.eu>, [redacted]@ec.europa.eu <[redacted]@ec.europa.eu>, [redacted]@ec.europa.eu <[redacted]@ec.europa.eu>, [redacted]@ec.europa.eu <[redacted]@ec.europa.eu>, [redacted]@ec.europa.eu <[redacted]@ec.europa.eu>
Onderwerp: A further update from AstraZeneca on their clinical development

Dear Members of the Steering Board,

Please find below a further update from AstraZeneca, along with the company's press release published today:

> I am pleased to inform you that AstraZeneca has just announced positive high-level results from an interim analysis of AZD1222 trials in the UK and Brazil. The data show that the vaccine was highly effective in preventing COVID-19 infection, the primary endpoint, and no hospitalisations or severe cases of the disease were reported in participants receiving the vaccine.
> Two different dosing regimens demonstrated efficacy with one showing a better profile. One dosing regimen showed vaccine efficacy of 90% when AZD1222 was given as a half dose, followed by a full dose at least one month apart, and another dosing regimen showed 62% efficacy when given as two full doses at least one month apart.
> No serious safety events have been confirmed related to the vaccine and AZD1222 was well tolerated across both dosing regimens, with even fewer adverse reactions seen in the regimen showing 90% efficacy. The full analysis of the interim results is being submitted for publication in a peer-reviewed journal. AstraZeneca will now immediately prepare regulatory submission of the data to authorities around the world including the European Medicines Agency (EMA).

This vaccine's efficacy and safety confirm that it will have an immediate impact on this public health emergency, reducing hospitalisations and saving lives. Meanwhile, the promise of the 90% efficacy of the low dose regimen means that more people can potentially be vaccinated more quickly with existing dose capacity in Europe and around the world. The vaccine can be stored, transported and handled at 2-8 °C (about 34-42 °F) for at least six months, enabling easy use within existing healthcare settings.
Please see here the official company announcement with further information.

We wish a very good start of the week!

With best regards,

The EC Vaccines Team

From: EC VACCINES <5.1.2e@ec.europa.eu>
Sent: Thursday, November 19, 2020 1:52 PM
To: 5.1.2e@sozialministerium.at; 5.1.2e@gesundheitsministerium.gv.at; 5.1.2e@gesundheitsministerium.gv.at; 5.1.2e <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 5.1.2e@bmg.bund.de; 5.1.2e 5.1.2e <5.1.2e@bmg.bund.de>; 5.1.2e@dkma.dk; 5.1.2e 5.1.2e <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 5.1.2e <5.1.2e@igf.finances.gouv.fr>; 5.1.2e 5.1.2e <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 5.1.2e <5.1.2e@health.gov.ie>; 5.1.2e@sanita.it; 5.1.2e@vvkt.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@gov.se; 5.1.2e@gov.si; 5.1.2e@gov.si; 5.1.2e@health.gov.sk; 5.1.2e@zva.gov.lv; R.A. <5.1.2e@minvws.nl>; 5.1.2e@minbuza.nl; 5.1.2e@gmail.com
Cc: 5.1.2e 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 5.1.2e (SG-RECOVER) <5.1.2e@ec.europa.eu>; 5.1.2e 5.1.2e (SG) <5.1.2e@ec.europa.eu>; 5.1.2e 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 5.1.2e (SJ) <5.1.2e@ec.europa.eu>; 5.1.2e 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 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 5.1.2e 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 5.1.2e (SANTE) <5.1.2e@ec.europa.eu>; EC VACCINES <5.1.2e 5.1.2e@ec.europa.eu>
Subject: FW: Update from AstraZeneca on their clinical development

Dear Members of the Steering Board,

Please find below an update from AstraZeneca on their clinical development:

> I would like to share with you the interim results published today in The Lancet from the ongoing COV002 Phase II/III trial of AZD1222 in the UK, led by the University of Oxford. The data showed that AZD1222 demonstrated lower local and systemic reactions in older adults (≥56-69 years and ≥70 years) than younger adults (≥18-55 years) and generated similar robust immune responses against the SARS-CoV-2 virus across all adult age groups, which was boosted after a second dose.

We trust this helps.

With best regards,
The EC Vaccines Team

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 < 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 5.1.2e < 5.1.2e @bmg.bund.de>; 5.1.2e @dkma.dk; 5.1.2e 5.1.2e < 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 5.1.2e < 5.1.2e @igf.finances.gouv.fr>; 5.1.2e 5.1.2e < 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 5.1.2e < 5.1.2e @health.gov.ie>; 5.1.2e @sanita.it; 5.1.2e @vvkt.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 @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 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 5.1.2e (SG-RECOVER) < 5.1.2e @ec.europa.eu>; 5.1.2e 5.1.2e (SG) < 5.1.2e @ec.europa.eu>; 5.1.2e 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 5.1.2e (SJ) < 5.1.2e @ec.europa.eu>; 5.1.2e 5.1.2e (SJ) < 5.1.2e @ec.europa.eu>; 5.1.2e 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 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 5.1.2e 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 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