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Van: 5.1.2e)
Verzonden: maandag 23 november 2020 11:41
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Onderwerp: FW: AstraZeneca/Oxford AZD1222 vaccine met primary efficacy endpoint in preventing COVID-19
Bijlagen: AZD1222 HLR RNS_FINAL.pdf

Beste collega's digitale balie,

Graag bijgaande mail innemen in Marjolein en doorzetten ter behandeling naar de PD Covid19.

Alvast dank hiervoor.

Groet,

5.1.2e

Met vriendelijke groet,

5.1.2e
5.1.2e

Ministerie van Volksgezondheid, Welzijn en Sport | Directie Bestuurlijk en Politieke Zaken |
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☎ +3170 5.1.2e +316 5.1.2e | A 5.1.2e 5.1.2e @minvws.nl | www.rijksoverheid.nl |
Bij VWS geldt een legitimatieplicht voor de toegang tot het ministerie. Dit betekent dat bij uw bezoek aan VWS om geldige legitimatie wordt gevraagd voor u het pand verder kunt betreden. Graag vraag ik uw aandacht hiervoor. Alvast bedankt voor de medewerking

Van: 5.1.2e 5.1.2e @astrazeneca.com>
Verzonden: maandag 23 november 2020 08:19
Aan: Minister van VWS < 5.1.2e minvws.nl>
CC: 5.1.2e < 5.1.2e @astrazeneca.com>
Onderwerp: AstraZeneca/Oxford AZD1222 vaccine met primary efficacy endpoint in preventing COVID-19

Dear Minister De Jonge, Minister Van Ark,

We are 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, with no hospitalisations or severe cases of the disease 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 related to the vaccine have been confirmed and AZD1222 was well tolerated across both dosing regimens. 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.

Today marks an important milestone in our fight against the pandemic. This vaccine's efficacy and safety confirm that it will have an immediate impact on this public health emergency, reducing hospitalisations and saving lives. 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. Meanwhile, the promise of the low dose regimen means that through our existing agreement with the European Commission to provide up to 5.1.1c doses of AZD1222 vaccine across the EU, our dose capacity could potentially go further, and more people could be vaccinated quickly in Europe and around the world.

Please find attached the official company announcement with further information.

We would like to thank you for your continued partnership and would welcome the opportunity to speak with you to discuss today's announcement in greater detail.

Best regards,

5.1.2e

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News Release

Regulatory News Service

This announcement contains inside information

23 November 2020 07:00 GMT

AZD1222 vaccine met primary efficacy endpoint in preventing COVID-19

Two different dosing regimens demonstrated efficacy with one showing a better profile

No hospitalisations or severe cases of COVID-19 in participants treated with AZD1222

Positive high-level results from an interim analysis of clinical trials of AZD1222 in the UK and Brazil showed the vaccine was highly effective in preventing COVID-19, the primary endpoint, and no hospitalisations or severe cases of the disease were reported in participants receiving the vaccine. There were a total of 131 COVID-19 cases in the interim analysis.

One dosing regimen (n=2,741) 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 (n=8,895) showed 62% efficacy when given as two full doses at least one month apart. The combined analysis from both dosing regimens (n=11,636) resulted in an average efficacy of 70%. All results were statistically significant (p<=0.0001). More data will continue to accumulate and additional analysis will be conducted, refining the efficacy reading and establishing the duration of protection.

An independent Data Safety Monitoring Board determined that the analysis met its primary endpoint showing protection from COVID-19 occurring 14 days or more after receiving two doses of the vaccine. No serious safety events related to the vaccine have been confirmed. AZD1222 was well tolerated across both dosing regimens.

AstraZeneca will now immediately prepare regulatory submission of the data to authorities around the world that have a framework in place for conditional or early approval. The Company will seek an Emergency Use Listing from the World Health Organization for an accelerated pathway to vaccine availability in low-income countries. In parallel, the full analysis of the interim results is being submitted for publication in a peer-reviewed journal.

Professor [redacted] 5.1.2e, Chief Investigator of the Oxford Vaccine Trial at Oxford, said: "These findings show that we have an effective vaccine that will save many lives. Excitingly, we've found that one of our dosing regimens may be around 90% effective and if this dosing regime is used, more people could be vaccinated with planned vaccine supply. Today's announcement is only possible thanks to the many volunteers in our trial, and the hard working and talented team of researchers based around the world."

Pascal Soriot, Chief Executive Officer, said: "Today marks an important milestone in our fight against the pandemic. This vaccine's efficacy and safety confirm that it will be highly effective against COVID-19 and will have an immediate impact on this public health emergency. Furthermore, the vaccine's simple supply chain and our no-profit pledge and commitment to

broad, equitable and timely access means it will be affordable and globally available, supplying hundreds of millions of doses on approval."

The pooled analysis included data from the COV002 Phase II/III trial in the UK and COV003 Phase III trial in Brazil. Over 23,000 participants are being assessed following two doses of either a half-dose/full-dose regimen or a regimen of two full doses of AZD1222 or a comparator, meningococcal conjugate vaccine called MenACWY or saline. The global trials are evaluating participants aged 18 years or over from diverse racial and geographic groups who are healthy or have stable underlying medical conditions.

Clinical trials are also being conducted in the US, Japan, Russia, South Africa, Kenya and Latin America with planned trials in other European and Asian countries. In total, the Company expects to enrol up to 60,000 participants globally.

The Company is making rapid progress in manufacturing with a capacity of up to 3 billion doses of the vaccine in 2021 on a rolling basis, pending regulatory approval. The vaccine can be stored, transported and handled at normal refrigerated conditions (2-8 degrees Celsius/ 36-46 degrees Fahrenheit) for at least six months and administered within existing healthcare settings.

AstraZeneca continues to engage with governments, multilateral organisations and collaborators around the world to ensure broad and equitable access to the vaccine at no profit for the duration of the pandemic.

COV002

COV002 is a single-blinded, multi-centre, randomised, controlled Phase II/III trial assessing the safety, efficacy and immunogenicity of AZD1222 in 12,390 participants in the UK. Trial participants to date are aged 18 years or over, who are healthy or have medically stable chronic diseases and are at increased risk for being exposed to the SARS-CoV-2 virus. Participants receive one or two intramuscular doses of a half dose (~2.5 $x10^{10}$ viral particles) or full dose (~$5x10^{10}$ viral particles) of AZD1222 or comparator, meningococcal vaccine MenACWY. Participants have blood samples drawn and clinical assessments for safety as well as immunogenicity at multiple timepoints up to one year post-vaccination. Suspected cases presenting with compatible symptoms were tested for virological confirmation by COVID-19 PCR. In addition, weekly swabbing are done for detection of infection and assessment of vaccine efficacy against infection.

COV003

COV003 is a single-blinded, multi-centre, randomised, controlled Phase III trial assessing the safety, efficacy, and immunogenicity of AZD1222 in 10,300 participants in Brazil. Trial participants to date are aged 18 years or over, who are healthy or have medically stable chronic diseases and are at increased risk for being exposed to the SARS-CoV-2 virus. Participants are randomised to receive two intramuscular doses of a full dose (~$5x10^{10}$ viral particles) of AZD1222 or comparator, meningococcal vaccine MenACWY as first dose and a saline placebo as second dose. Participants have blood samples drawn and clinical assessments for safety as well as immunogenicity at multiple timepoints up to one year post-vaccination. Suspected cases presenting with compatible symptoms were tested for virological confirmation by COVID-19 PCR.

AZD1222

AZD1222 was co-invented by the University of Oxford and its spin-out company, Vaccitech. It uses a replication-deficient chimpanzee viral vector based on a weakened version of a common cold virus (adenovirus) that causes infections in chimpanzees and contains the genetic material of the SARS-CoV-2 virus spike protein. After vaccination, the surface spike protein is produced, priming the immune system to attack the SARS-CoV-2 virus if it later infects the body.

AstraZeneca

AstraZeneca (LSE/STO/Nasdaq: AZN) is a global, science-led biopharmaceutical company that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of diseases in three therapy areas - Oncology, Cardiovascular, Renal & Metabolism, and Respiratory & Immunology. Based in Cambridge, UK, AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. Please visit astrazeneca.com and follow the Company on Twitter @AstraZeneca.

Contacts

For details on how to contact the Investor Relations Team, please click here. For Media contacts, click here.

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Company Secretary
AstraZeneca PLC