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Covid-19: Pfizer and BioNTech submit vaccine for US authorisation

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Pfizer and BioNTech have submitted their covid-19 vaccine candidate to the US Food and Drug Administration (FDA) for emergency use authorisation, after concluding a phase III trial.

The mRNA vaccine candidate, BNT162b2, was found to be 95% effective 28 days after the first dose. The phase III trial evaluated 170 confirmed cases of covid-19, 162 of which were observed in the placebo group. There were 10 severe cases, nine of which were in the placebo group.

In its announcement, Pfizer said the vaccine could be available to high risk populations in the US by the end of December 2020. Globally, it plans to produce 50m doses in 2020 and up to 1.3bn doses by the end of 2021. The companies have started submission processes in Europe, as well as Australia, Canada, and Japan.

The phase III trial began on 27 July and enrolled 43 661 participants. Around 42% of global participants and 30% of US participants had "racially and ethnically diverse backgrounds," while 41% of global and 45% of US participants were aged 56 to 85 years. Pfizer has said efficacy was consistent across age, sex, race, and ethnicity demographics, with 94% efficacy in adults aged over 65 years. No results from the trial have yet been published.

The FDA submission includes solicited safety data from a randomised subset of around 8000 participants aged 18 or over and unsolicited safety data from around 38 000 trial participants who were followed for a median of two months after the second vaccine dose. The trial's data monitoring committee has not reported any serious safety concerns related to the vaccine.

Oxford publishes phase II results

Meanwhile, the University of Oxford covid-19 vaccine team have reported their phase II trial results in the *Lancet*, concluding that the vaccine candidate (ChAdOx1 nCoV-19) produced a similar immune response in old and young adults.[1]

The study found that 14 days after the second dose, 208 (>99%) of 209 boosted participants had neutralising antibody responses. T cell responses peaked at day 14 after a single standard dose of the vaccine candidate (18-55 years: median 1187 spot forming cells (SFCs) per million peripheral blood mononuclear cells; 56-69 years: 797 SFCs; and ≥70 years: 977 SFCs).

The trial, carried out between May 30 and August 8, involved 560 healthy adults (95% identified as white), including 240 people aged over 70. Participants received either one or two doses of the vaccine.

While the team may be a few weeks behind other vaccine candidates[2 3] in terms of releasing phase III data, the team are optimistic that their vaccine will be accessible. Speaking at the Science Media Centre, professor of vaccinology Sarah Gilbert, who is leading the Oxford trial, said, "The university wanted a partner that would enable us to get this vaccine out across the whole world, not just in high income countries.

"The manufacturing technology that is used is one that can be rolled out more inexpensively than some of the other technologies that are in development now. We are pleased to see that AstraZeneca manufacturing plans encompass manufacturing with many different partners in different parts of the world and at a large scale. They are looking to produce this for a low price per dose."

Looking at safety, the paper said local and systemic reactions were more common in participants given the covid-19 vaccine candidate compared with the control vaccine, and the reactions reported were similar to those previously known, such as injection site pain, feeling feverish, muscle ache, headache. These reactions were less common in older adults (aged ≥56 years) than younger adults. As of 26 October 2020, 13 serious adverse events had been reported during the study period, none of which were considered to be related to either study vaccine.

The trial was funded by various research bodies, as well as AstraZeneca.

1 Ramasamy MN, Minassian AM, Ewer KJ, et al. Safety and immunogenicity of ChAdOx1 nCoV-19 vaccine administered in a prime-boost regimen in young and old adults (COV002): a single-blind, randomised, controlled, phase 2/3 trial. *Lancet* 2020. www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)32466-1/fulltextdoi: 10.1016/S0140-6736(20)32466-1.

2 Mahase E. Covid-19: Vaccine candidate may be more than 90% effective, interim results indicate. *BMJ* 2020;371:m4347. doi: 10.1136/bmj.m4347 pmid: 33168562

3 Mahase E. Covid-19: Moderna vaccine is nearly 95% effective, trial involving high risk and elderly people shows. *BMJ* 2020;371:m4471doi: 10.1136/bmj.m4471.