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Covid-19: Sanofi and GSK to seek regulatory authorisation for protein based vaccine

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Sanofi and GlaxoSmithKline's covid-19 vaccine has 57.9% (95% confidence interval 26.5% to 76.7%) efficacy against any symptomatic disease, the companies have reported.

In a phase 3 trial in which more than 10 000 adults were randomised to receive two doses of the vaccine or placebo, 21 days apart, researchers found it to have 100% efficacy against severe disease and hospital admission (0 v 10 cases in placebo group after one dose, 0 v 4 cases after two doses) and 75% efficacy against moderate or severe disease (3 v 11 cases).

Early data has also indicated 77% efficacy against any symptomatic disease associated with the delta variant, French drug company Sanofi has said. So far, details of the trial have been released only through press release, although the companies said full study results will be published later this year.

Thomas Triomphe, executive vice president of Sanofi vaccines, said, "No other global phase 3 efficacy study has been undertaken during this period with so many variants of concern, including omicron, and these efficacy data are similar to the recent clinical data from authorised vaccines."

The protein based vaccine can be kept at refrigerator temperatures, making it easier to store and transport than some of the other vaccines, such as the mRNA vaccines (Pfizer-BioNTech and Moderna), which require shipping and long term storage at -20°C or lower.

Melanie Saville, executive director of vaccine research and development at the Coalition for Epidemic Preparedness Innovations (CEPI), told *The BMJ*, "Protein based vaccines like GSK-Sanofi's updated candidate offer a new era in the global covid-19 vaccination effort ... Protein based candidates may generate different immunological profiles from other covid-19 vaccine approaches, which may have a favourable profile in certain demographics, like the elderly or young populations. These vaccines are generally well tolerated."

She added that as the vaccine is stable at refrigerator temperatures, "it doesn't require the complex cold chains that have limited the use of other covid-19 vaccines in remote or low resource settings" and should reduce vaccine waste globally.

In a separate trial, the vaccine was tested as a booster dose for people who had previously had two doses of an mRNA or adenovirus vaccine (such as Oxford-AstraZeneca). The booster dose was found to increase neutralising antibodies 18-fold to 30-fold across different vaccine platforms and age groups.

Across both studies, the vaccine was well tolerated in younger and older adults with no safety concerns, the press release said.

The companies are now in discussions with regulatory authorities, including the US Food and Drug Administration and European Medicines Agency, and plan to submit for regulatory authorisation shortly.

GSK vaccines president, Roger Connor, said, "The evolving epidemiology of covid-19 demonstrates the need for a variety of vaccines. Our adjuvanted protein based vaccine candidate uses a well established approach that has been applied widely to prevent infection with other viruses, including pandemic flu. We are confident that this vaccine can have an important role as we continue to address this pandemic and prepare for the post-pandemic period."