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Sanofi, GSK to seek regulatory authorisation for COVID-19 vaccine

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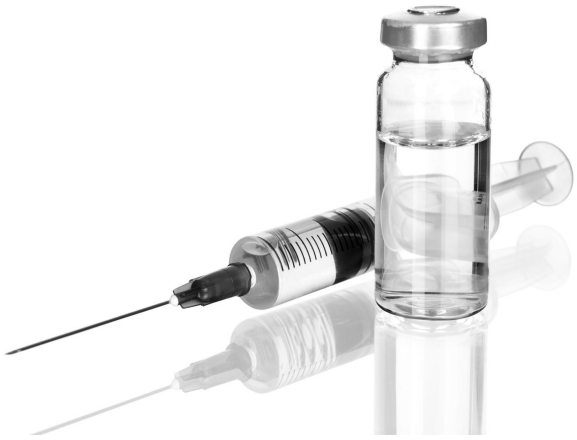

Sanofi and GSK intend to submit data from both their booster and Phase 3 efficacy trials as the basis for regulatory applications for a COVID-19 vaccine. The public health relevance of the refrigerator temperature-stable adjuvanted protein-based Sanofi-GSK vaccine is strongly supported by the induction of robust immune responses and a favourable safety profile in multiple settings.

In participants who had received a primary series of an already authorised mRNA or adenovirus vaccine, the Sanofi-GSK booster vaccine induced a significant increase in neutralising antibodies of 18- to 30-fold across vaccine platforms and age groups. When the Sanofi-GSK vaccine was used as a two-dose primary series followed by a booster dose, neutralising antibodies increased 84- to 153-fold compared to pre-boost levels.

When used as a two-dose primary series, the Sanofi-GSK vaccine delivered robust levels of neutralising antibodies, with GMTs reaching 3711 units. For comparison, a panel of sera from volunteers in the same age range who received two doses of an already approved and highly effective mRNA vaccine displayed a GMT of 1653 units, measured simultaneously in the same laboratory.

Across both studies, the Sanofi-GSK vaccine was well-tolerated in younger and older adults with no safety concerns.

The companies are in discussions with regulatory authorities, including the US FDA and European Medicines Agency (EMA), and plan to submit the totality of the data generated with this vaccine candidate to support regulatory authorisations.