



Janssen COVID-19 vaccine Ad26.COV2.S

WHO consultation on COVID-19 vaccines research

13 August 2021

Frank Struyf, Clinical Franchise Leader COVID-19 vaccine program

Pictured: a representation of a coronavirus

v2.0

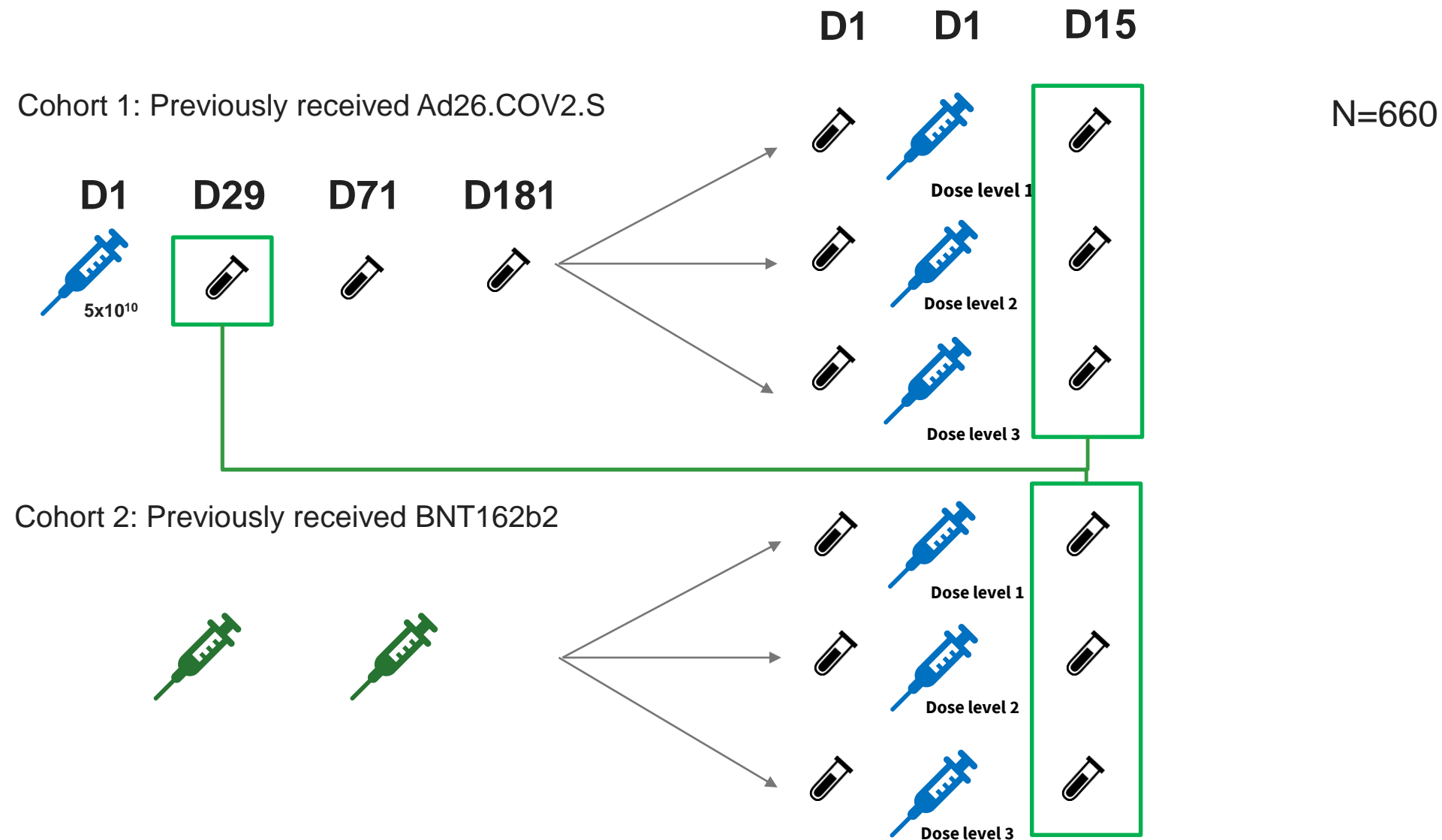
Request from WHO

Vaccine developers update about their current progress and plans to generate evidence to inform discussions on the need and pertinence of booster vaccines

Janssen/J&J position on the need and pertinence of booster vaccines for Ad26.COV2.S

- Today Janssen does not have a final position on the need for a booster dose. The outcome of ongoing studies will help to define our recommendation.
- Ongoing studies are addressing:
 - Efficacy after the authorized one-dose schedule, and additional studies using a two-dose primary schedule
 - Duration of protection
 - Persistence of immune responses over time, including anamnestic response and booster response, to the original strain and variants of concern
 - Detailed analysis of immune correlates of protection
- Analyses at the end of the double-blind phase of our ENSEMBLE1 study (COV3001) of a one dose regimen are ongoing. The study is being conducted in 3 continents/8 countries and includes monitoring how efficacy and immune responses evolve when new variants emerge/become dominant.
- ENSEMBLE2 (COV3009), for which results should become available later this year, will inform if and how a second dose further improves the vaccine efficacy, especially regarding symptomatic (not severe) infection.
- Immunogenicity results after two doses of vaccine, given with intervals of 2 and 3 months, are available. These show robust increase in binding and neutralizing titers after a second vaccine dose, with higher antibody levels if the second dose is administered after a 3-month interval.
- Preliminary data are available on a booster dose being given 6 months after a first dose. Antibody titers 7 days after the second dose increase approximately 9-fold compared to the titers 29 days post dose 1. Similar levels of antibody are achieved in 18-55 and above 65 years of age. These data also show good persistence of antibody levels up to at least 6 months after the first dose.
- Janssen is involved in studies sponsored by UK government and NIH that assess heterologous prime-boost schedules. Data are expected to become available in the September/October timeframe.
- Janssen has started a more extensive study (COV2008) evaluating booster responses in individuals who received either a single shot of Ad26.COV2.S or 2 doses of mRNA vaccine as primary regimen.

COV2008: Janssen-sponsored Booster study



Primary objective: Compare immunogenicity after booster to immunogenicity after primary regimen

<https://clinicaltrials.gov/ct2/show/NCT04999111> accessed 13 August 2021

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