Durability of Antibody Responses Elicited by a Single Dose of Ad26.COV2.S and Substantial Increase Following Late Boosting¹


Interim Immunogenicity: Janssen COVID-19 Vaccine Phase 1/2a (COV1001) & Phase 2 (COV2001)³

**Phase 1/2a COV1001¹**
Safety, Reactogenicity, & Immunogenicity in a Homologous Boosting Regimen
Randomized, double-blind, placebo-controlled study in healthy adults

**Phase 2a COV2001²**
Safety and Immunogenicity in a Low-Dose Homologous Boosting Regimen
Randomized, double-blind, placebo-controlled study in healthy adults

<table>
<thead>
<tr>
<th>Study</th>
<th>Cohort/Group</th>
<th>Data Available per Age Group</th>
<th>Day 1 Primary Vaccination</th>
<th>6 Months after Vaccination³</th>
</tr>
</thead>
<tbody>
<tr>
<td>COV1001</td>
<td>Cohort 1a</td>
<td>18-55 years (n=25)</td>
<td>5x10¹⁰ vp</td>
<td>NA</td>
</tr>
<tr>
<td></td>
<td>Cohort 2aᵇ</td>
<td>18-55 years (n=17)</td>
<td>5x10¹⁰ vp</td>
<td>5x10¹⁰ vp</td>
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<tr>
<td></td>
<td>Cohort 3</td>
<td>≥65 years (n=22)</td>
<td>5x10¹⁰ vp</td>
<td>NA</td>
</tr>
<tr>
<td>COV2001</td>
<td>Group 5ᶜ</td>
<td>18-55 years (n=44ᵈ)</td>
<td>5x10¹⁰ vp</td>
<td>1.25x10¹⁰ vpᵉ</td>
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<tr>
<td></td>
<td></td>
<td>≥65 years (n=29ᵈ)</td>
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</tbody>
</table>

¹Participants received a homologous booster dose of Ad26.COV2.S. ²Data is only being reported for 1 of 5 groups. ³Data is only being reported for 1 of 10 dosing groups. ⁴Participants who received the boost, ⁵Antigen presentation dose

NA, not applicable; vp, viral particles.

After a single $5 \times 10^{10}$ vp dose of Ad26.COV2.S:

**For cohort 1a: 18–55-year-old: 8-month follow-up**
- NAb detectable in 21/22 (95%) participants up to at least D239 with NAb levels similar to those D29 post primary vaccination (GMT 226 versus 224)

**For cohort 3: ≥65-year-old: 9-month follow-up**
- NAb detectable in 13/19 (68%) participants at D268 with NAb levels representing a 2.3-fold reduction versus D29 post primary vaccination (GMT 114 versus 258)

Cl, confidence interval; GMT, geometric mean titers; LLOQ, lower limit of quantification; NAb, neutralizing antibodies; vp, viral particles.

Durability of Spike Binding Ab Response up to 6 months post Single Ad26.COV2.S Dose (5x10^{10} vp) & Booster Dose Impact, in 18–55-year-old Participants from a Phase 1/2a Trial (COV1001)

In Cohort 2a: 18–55-year-old (N=17)

After a single 5x10^{10} vp dose of Ad26.COV2.S:

- **PRE-Boost**: BAB detectable in all participants (100%) at D29 & further increased to GMC 900 at 6 months with 100% of participants still having detectable Abs

After 5x10^{10} vp booster dose at 6 months

- At 7d and 28 post-boost (D190 & D211): BAB rise observed in all participants (GMC 3779 and 5108)
  - 4.7 and 5.7-fold higher BAB levels at day 7 and day 29 post boost versus immediate PRE-boost levels (GMC 900)
  - 9- and 12-fold higher BAB levels at day 7 and day 29 post boost versus D29 post dose 1 (GMC 418)


Ab, antibody; BAB, Spike binding antibodies; CI, confidence interval; ELISA, enzyme-linked immunosorbent assay; GMC, geometric mean concentrations; LLOQ, lower limit of quantification; ULOQ, upper limit of quantification; PD1, post-dose 1, vp, viral particles.
Durability of Spike Binding Ab Responses 6 months post Single Ad26.COV2.S Dose (1.25x10^{10} vp) & Impact of Low-Dose Boost in 18–55 and ≥65-year-old Participants
Phase 2 Trial (COV2001)

For 18-55 and ≥65-year-old: 6-month follow-up
A single 5x10^{10} vp dose of Ad26.COV2.S elicited detectable BAbs at D15, increased to D29 & remained stable through D85 for both age groups.

At 6 months post primary vaccination:
- BAbs undetectable in 2/44 (5%) 18–55 year-old and 4/29 (14%) participants ≥65 years old.
- BAbs levels slightly lower at all timepoints in participants ≥65 years old compared to those 18-55.

After 1.25x10^{10} vp homologous booster dose at 6 months in 18–55 year-old (N=44) and ≥65-year-old (N=29):
- At 7d post-boost (D176): 3.6-fold higher versus immediate PRE-boost levels.
- At 28d post-boost (D197): BAbs levels further increased:
  - 6.9-fold higher versus immediate PRE-boost levels.
  - 6.4-fold higher BAbs levels v D29 post dose 1.
- Of note: while post low-dose booster kinetics were slower in ≥65-year-old adults, the magnitude of response by D28 post-boost was similar in both age groups.
- Most participants with no detectable titers pre boost responded to a booster dose, indicative of anamnestic response and high quality of the immune memory elicited by single dose regimen.


Ab, antibody; BAbs, Spike binding antibodies; CI, confidence interval; GMC, geometric mean concentrations, LLOQ, lower limit of quantification; PD1, post-dose 1; vp, viral particles.
Durability of Antibody Responses Elicited by a Single Dose of Ad26.COV2.S and Substantial Increase of Antibody Responses Following Late Boosting

Interim Immunogenicity: Janssen COVID-19 Vaccine Phase 1/2a (COV1001) & Phase 2 (COV2001)¹

These data demonstrate that a single dose of Ad26.COV2.S elicits durable protective immunity for at least 8 months irrespective of age

- Consistent with previously published data from cohort 1b of the Phase 1/2a study demonstrating stable humoral immune responses for 8 months after primary vaccination, including against Beta and Delta variants of concern²

A homologous booster with Ad26.COV2.S at 6 months after primary vaccination leads to a rapid increase in humoral immune responses to 9 times the levels achieved on day 29 following the primary vaccination, in both 18–55-year-old adults as well as older adults above 65 years of age