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Pictured: A representation of a coronavirus

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This presentation contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding, among other things: future operating and financial performance, product development, market position and business strategy. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Johnson & Johnson. Risks and uncertainties include, but are not limited to: risks related to the impact of the COVID-19 global pandemic, such as the scope and duration of the outbreak, government actions and restrictive measures implemented in response, material delays and cancellations of medical procedures, supply chain disruptions and other impacts to our business, or on our ability to execute business continuity plans, as a result of the COVID-19 pandemic; economic factors, such as interest rate and currency exchange rate fluctuations; competition, including technological advances, new products and patents attained by competitors; challenges inherent in new product research and development, including uncertainty of clinical success and obtaining regulatory approvals; uncertainty of commercial success for new and existing products; challenges to patents; the impact of patent expirations; the ability of the company to successfully execute strategic plans; the impact of business combinations and divestitures; manufacturing difficulties or delays, internally or within the supply chain; product efficacy or safety concerns resulting in product recalls or regulatory action; significant adverse litigation or government action, including related to product liability claims; changes to applicable laws and regulations, including tax laws and global health care reforms; trends toward health care cost containment; changes in behavior and spending patterns of purchasers of health care products and services; financial instability of international economies and legal systems and sovereign risk; increased scrutiny of the health care industry by government agencies. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 29, 2019, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," in the company's most recently filed Quarterly Report on Form 10-Q and the company's subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at <a href="https://www.jnj.com">www.jnj.com</a> or on request from Johnson & Johnson. Any forward-looking statement made in this presentation speaks only as of the date of this presentation. Johnson & Johnson does not undertake to update any forward-looking statement as a result of new information or future events or developments.

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A reconciliation of these non-GAAP financial measures to the most directly comparable GAAP financial measures can be found in the accompanying financial schedules of the earnings release and the Investor Relations section of the Company's website at www.investor.jnj.com.



# Proprietary AdVac® Technology Platform is the Foundation of the Janssen Investigational COVID-19 Vaccine



- Replication incompetent human adenovirus 26 (Ad26) vector expressing target antigen
- Induction of humoral and cellular immune responses
  - Humoral: Antibody responses against structural proteins with neutralizing activity and/or other unique functionalities
  - Cellular: CD4-T cell responses with a Th1 signature and CD8 T-cell responses
- No sign of vaccine associated enhanced respiratory disease in preclinical models after breakthrough infection<sup>1</sup>
- Extensive clinical experience with Janssen Ad26-based vaccines (>110,000 participants vaccinated) show these to have a
  favorable safety & tolerability profile in the populations studied to date<sup>1</sup>
- On 1 July 2020, Johnson & Johnson received approval from the European Medicines Agency for Janssen's Ad26 based Preventive Ebola Vaccine<sup>2</sup>

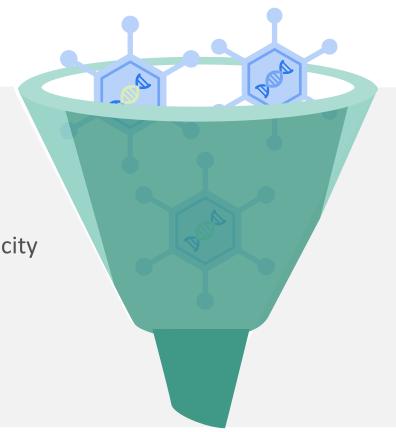


#### Several Janssen COVID-19 Vaccine Candidates Were Evaluated

**Antigens** 

SARS-CoV-2 Spike protein (S)

Multiple constructs designed for optimal stabilization, expression and antigenicity



Vaccine candidates

#### **Selection criteria**

Theoretical considerations

Stabilization

Signal peptide

Expression of antigen

Manufacturability of vaccine

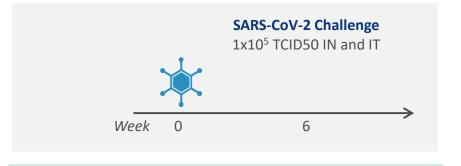
Immunogenicity in preclinical/animal models

Selection of lead vaccine candidate for first-in-human study:

Ad26.COV2.S (encodes a full length membrane-bound Sprotein with stabilizing mutations)



# A Single Dose of Ad26.COV2.S Protects the Lower and Upper Respiratory Tract of SARS-CoV-2 Challenged Non-Human Primates

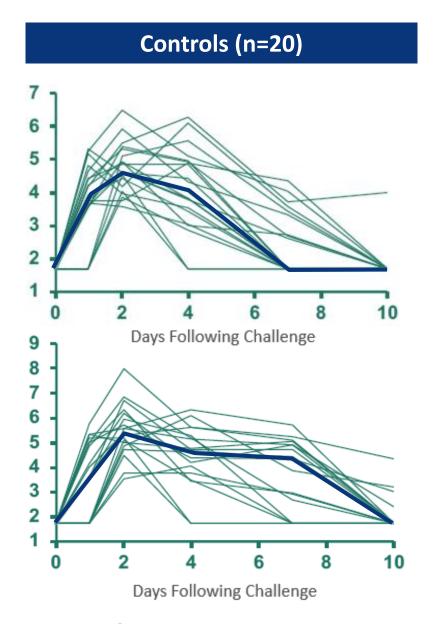


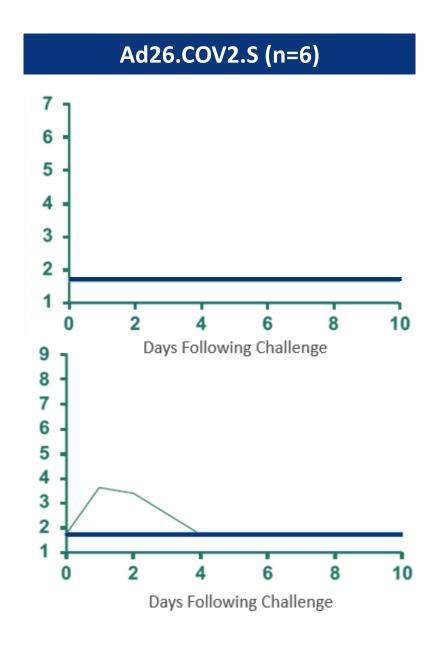
BAL

Log sgmRNA Copies / ml

Log sgmRNA Copies / Swab

**Nasal Swab** 





Rhesus macaques were challenged by the intranasal (IN) and intratracheal (IT) routes with 1x10<sup>5</sup> TCID SARS-CoV-2



## Janssen Investigational COVID-19 Vaccine Phase 1/2a Study: COV1001\* – First in Human

**Objective:** Phase 1/2a trial is evaluating the safety, reactogenicity and immunogenicity of the investigational SARS-CoV-2 vaccine, Ad26.COV2.S in:

- healthy adults aged 18 to 55 years, as well as adults aged 65 years and older
- at 2 dose levels  $(5x10^{10} \text{ vp and } 1x10^{11} \text{ vp})$
- administered in 1 dose and 2 dose regimens, as an intramuscular injection

Additional objectives to assess duration of immune response and boostability

Study Design: Randomized placebo-controlled Phase 1/2a study taking place in the U.S. and Belgium (NCT04436276)

**Enrollment target:** 1045 participants

**Cohort 1** 

18-55 years

N: 400

Safety and immunogenicity in younger adults (ongoing)

Cohort 2



18-55 years

N: 270

Duration of immune response and boosting

**Cohort 3** 



N: 375

Safety and immunogenicity in older adults (ongoing)

\*NLM Identifier: NCT04436276



# Janssen Investigational COVID-19 Vaccine Phase 1/2a Study: COV1001<sup>1,2</sup> Randomization Based on Dose Level and Dosing Regimen in Cohorts 1 and 3

Group	Dose 1 (Day 1)	Dose 2 (Day 57)	4
1	5×10 <sup>10</sup> vp	5×10 <sup>10</sup> vp	
2	5×10 <sup>10</sup> vp	Placebo	4
3	1×10 <sup>11</sup> vp	1×10 <sup>11</sup> vp	
4	1×10 <sup>11</sup> vp	Placebo	
5	Placebo	Placebo	
Day 29		29 Day	8



Interim analysis Day 29, (28 days post Dose 1)<sup>3</sup> Safety and immunogenicity (ELISA, VNA, CD4 Th1/Th2, CD8)



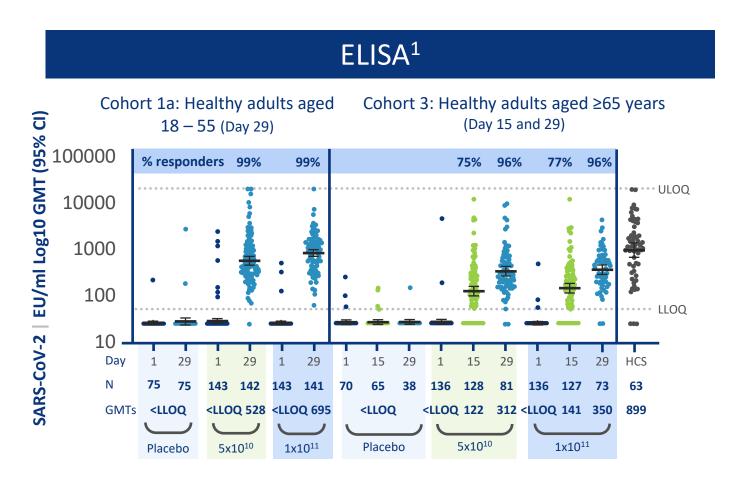
Primary analysis Day 85, (28 days post Dose 2) Safety and immunogenicity (ELISA, VNA, CD4 Th1/Th2, CD8) Study is ongoing as of Sept 2020)

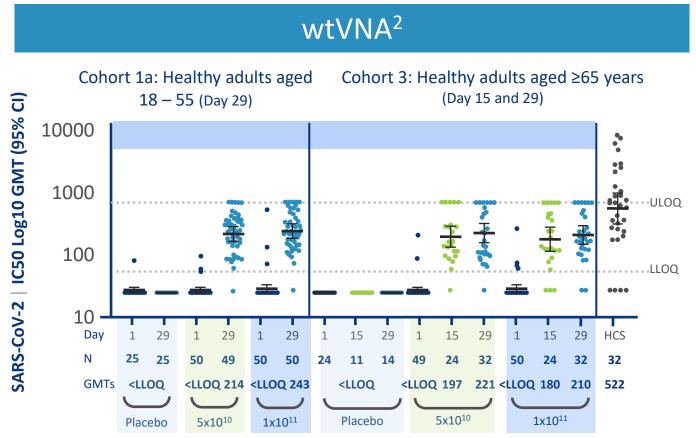
<sup>1</sup>NLM Identifier: NCT04436276

Vp: Viral particle ELISA, enzyme-linked immunosorbent assay; VNA, virus-neutralizing antibody; CD4, a glycoprotein; CD8, a glycoprotein; Th1, T helper Type 1 cell; Th2, T helper Type 2 cell



Humoral Immunity after Vaccination with Placebo or Ad26.COV2.S (5x10<sup>10</sup> vp or 1x10<sup>11</sup> vp)



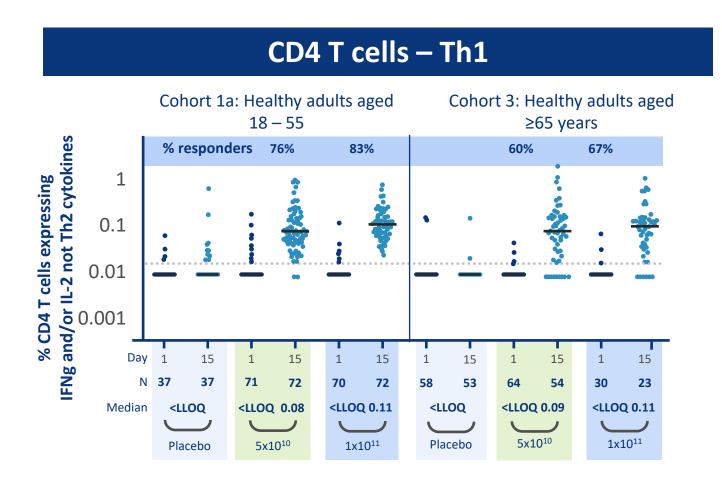


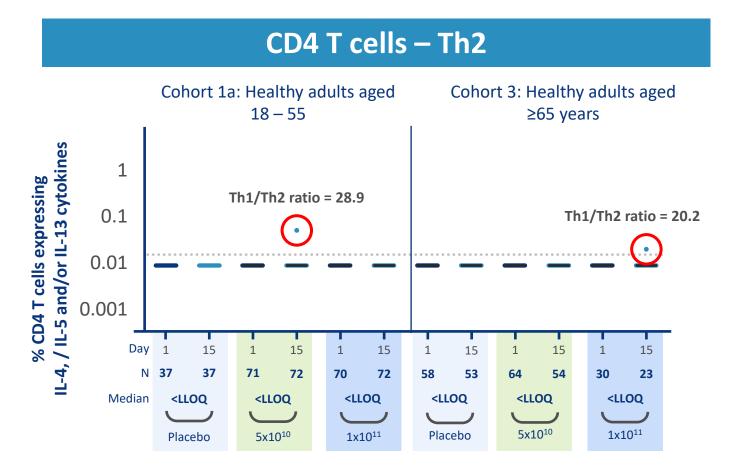
vp: viral particles; ELISA: Enzyme-linked Immunosorbent Assay; wtVNA: wild type viral neutralizing assay; GMT: geometric mean tier HCS: human convalescent sera Data on file Janssen Vaccines & Prevention B.V.



<sup>\*</sup>NLM Identifier: NCT04436276

CD4 Responses 14 days after Vaccination with Placebo or Ad26.COV2.S (5x10<sup>10</sup> vp or 1x10<sup>11</sup> vp)





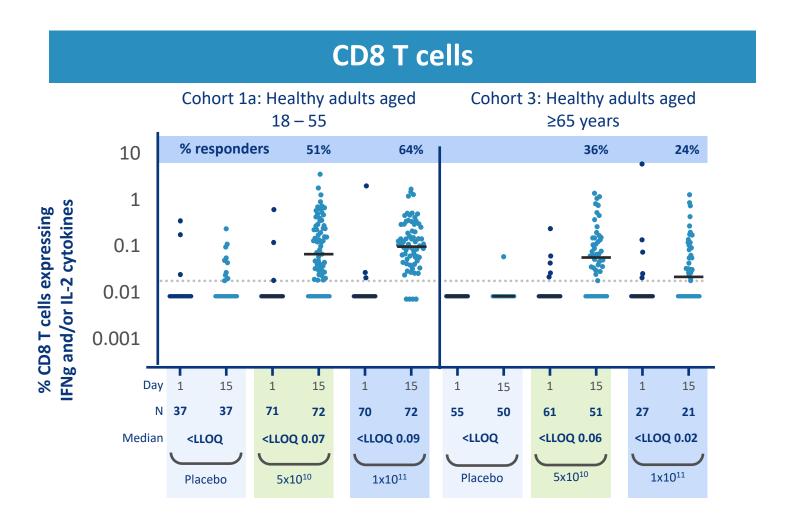
\*NLM Identifier: NCT04436276

vp: viral particles; IFNg: interferon gamma; IL: Interleukin

Data on file Janssen Vaccines & Prevention B.V.



CD8 Responses 14 days after Vaccination with Placebo or Ad26.COV2.S (5x10<sup>10</sup> vp or 1x10<sup>11</sup> vp)



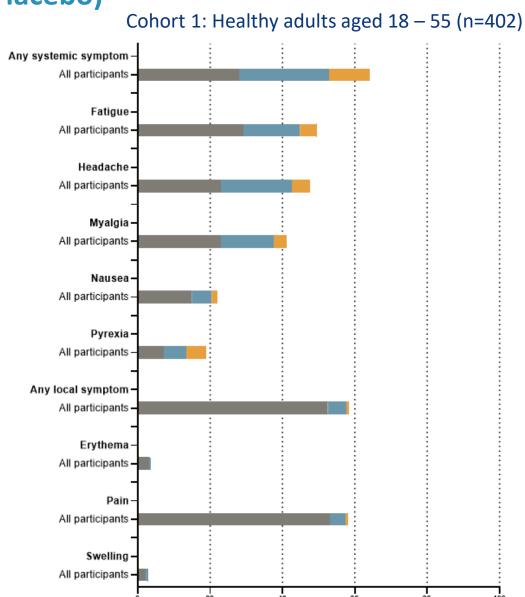
\*NLM Identifier: NCT04436276

vp: viral particles; IFNg: interferon gamma; IL: Interleukin

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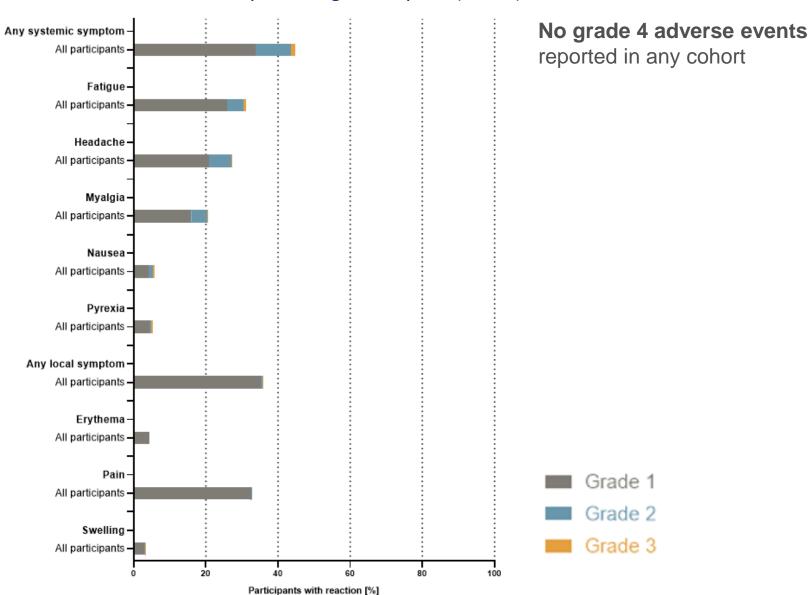


Safety & Reactogenicity Assessment Post-Dose 1 (Blinded – Pooled Groups of 5x10<sup>10</sup> vp or 1x10<sup>11</sup> vp, Placebo)



Participants with reaction [%]

Cohort 3: Healthy adults aged ≥65 years (n=403)



## Janssen Investigational COVID-19 Vaccine Phase 3 Study: COV3001\*

### A Study of Ad26.COV2.S for the Prevention of SARS-CoV-2-Mediated COVID-19 in Adults (ENSEMBLE)

- A multicenter, randomized, double-blind, placebo-controlled, phase 3 study evaluating the efficacy and safety of Ad26.COV2.S for the prevention of SARS-CoV-2-mediated COVID-19
- Locations: Argentina, Brazil, Chile, Colombia, Mexico, Peru, South Africa, and United States
- Continuous, sequential monitoring for safety and efficacy
- Full protocol openly accessible at <a href="https://www.jnj.com/coronavirus/covid-19-phase-3-study-clinical-protocol">https://www.jnj.com/coronavirus/covid-19-phase-3-study-clinical-protocol</a>



†Moderate defined as one sign and one symptom from a list of signs, such as heart rate >90 bpm and symptoms such as shortness of breath or cough or 2 symptoms from a list of symptoms or Severe COVID-19 defined in FDA guidance

\*NLM Identifier: NCT04505722



## **Phase 3 ENSEMBLE Clinical Trial Pause Summary**

- Clinical trials to resume recruiting and dosing in the U.S., following an expert and independent investigation of a serious adverse event (SAE) in our Phase 3 ENSEMBLE trial
- No greater priority than the health and safety of the people we serve every day around the world. We are committed to the safety, well-being and privacy of the participants and all those involved in our trials
- We plan to disclose clinical trial data in our COVID-19 trials once those data are presented or published at pre-specified milestones and will proactively disclose regulatory trial holds requested by health authorities

#### OUR COMPANY

Johnson & Johnson Prepares to Resume Phase 3 ENSEMBLE Trial of its Janssen COVID-19 Vaccine Candidate in the U.S.

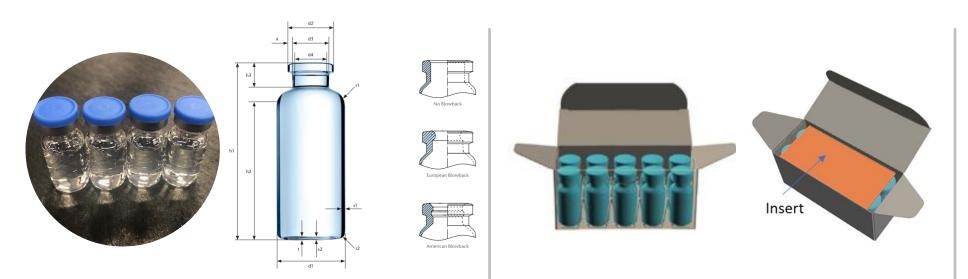
#### Updated Statement October 23, 2020

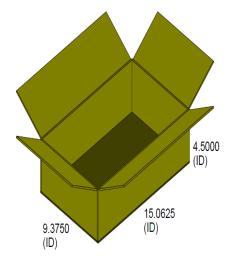
Johnson & Johnson announced today that it is preparing to resume recruitment in the pivotal Phase 3 ENSEMBLE trial of its investigational Janssen COVID-19 vaccine in the United States after a temporary pause.

The independent Data Safety and Monitoring Board (DSMB) overseeing the ENSEMBLE study has recommended resuming trial recruitment. Following consultation with the U.S. Food and Drug Administration (FDA), preparations to resume the trial in the United States, including submissions for approval by the Institutional Review Boards, are now underway. Discussions with other regulators around the world to resume the clinical trial program are progressing.



# Janssen Investigational COVID-19 Vaccine Anticipated Pandemic Supply Configuration & Storage Conditions





#### **Primary packaging**

#### 2R glass vial\*

- No preservative and no reconstitution required
- Blue matte finish (3769) button with silver crimp combination
- High volume 5-dose vial for EUA
- 0.5 ml per dose (5x10<sup>10</sup> vp)

#### Secondary packaging

- 10 vials per carton
- 1 product insert per carton
- Dimensions:
  - L: 93 mm (3.66 inches)
  - W: 38 mm (1.50 inches)
  - D: 54 mm (2.13 inches)

#### **Tertiary packaging**

- 48 cartons per shipper case
- Carton material: solid bleached sulfate (SBS)
- Dimensions:
  - L: 383 mm (15.06 inches)
  - W:238 mm (9.38 inches)
  - D: 114 mm (4.50 inches)



Anticipated storage conditions (under EUA)



Long-term storage<sup>†</sup>:

-20°C

Up to 2 years

End-user storage:

2-8°C

Up to 3 months

After first use:

2-8°C

Up to 6 hours

<sup>\*</sup>Blue 3769 button/ silver crimp combination for high volume 5 dose vial; †Long term storage by manufacturer or distributor ONLY – not to be refrozen by end-user





PHARMACEUTICAL COMPANIES OF Johnson