Safety and Efficacy of a Single Dose of Ad26.COV2.S: ENSEMBLE study results

Janssen Pharmaceutical Companies of Johnson & Johnson

Presenter: Martin F. Ryser, Janssen Pharmaceuticals

janssen
PHARMACEUTICAL COMPANIES OF
Johnson & Johnson

Janssen COVID-19 Vaccine Candidate (Ad26.COV2.S)

ENSEMBLE Phase 3 study enrolled **> 44,000** participants and was conducted in US, Latin America and South Africa **during height of pandemic**

Offers **substantial protection**, especially against severe COVID-19 including hospitalization and death, **irrespective of variant**

Well-tolerated and safe

Single-dose regimen with storage, transportation conditions **compatible within existing distribution channels**

Key Efficacy Findings From Ad26.COV2.S Phase 3, Single-Dose Study Support EUA

85% vaccine efficacy* against severe/critical COVID-19 globally,

- Consistent vaccine efficacy against severe/critical disease across all regions
- Equally high protection in South Africa (n > 6,500) where B.1.351 is highly prevalent (>95%)
- In the trial complete protection against COVID-19 related hospitalizations as of Day 28 and no COVID-19 related deaths in Ad26 group

66% vaccine efficacy* against moderate to severe/critical COVID-19 across all countries

- Protection as of 2 weeks after vaccination

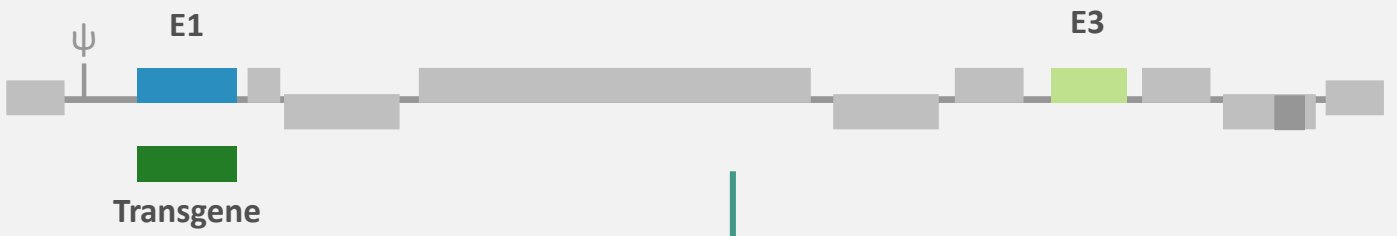
Similar vaccine efficacy demonstrated by age, comorbidities status, sex, race, and ethnicity

* > Day 28

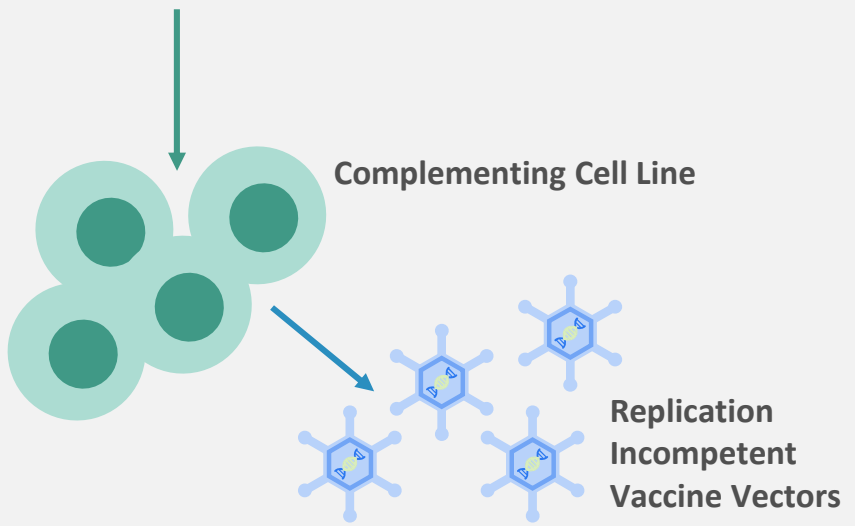
Vaccine Platform and Immunogenicity

Ad26 Vector is Replication Incompetent

Adenovirus genome

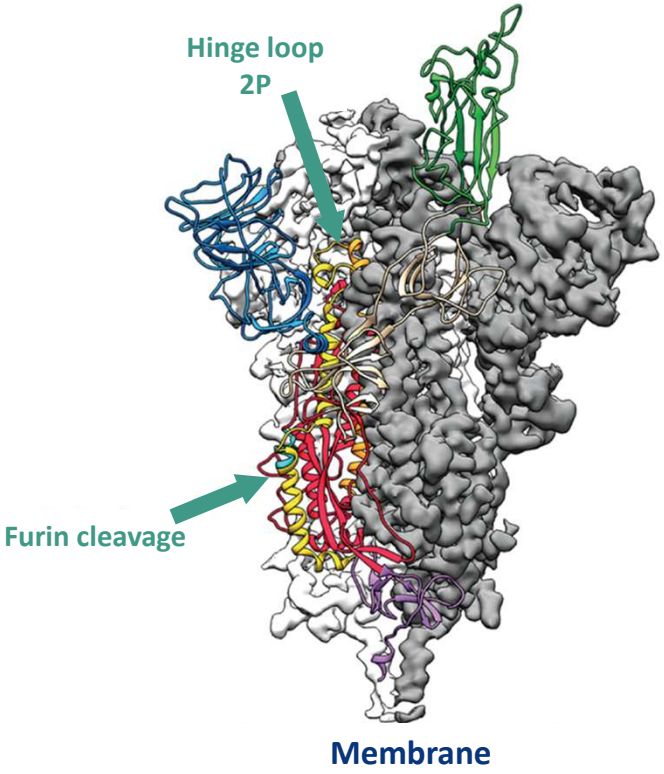


- Janssen Ad26 vector **can not replicate** in the human body
- Cell line grows in medium free of animal components
- Vial of Ad26-based vaccine contains buffer with commonly used ingredients in vaccines
  - No adjuvants, no antibiotics, no preservatives



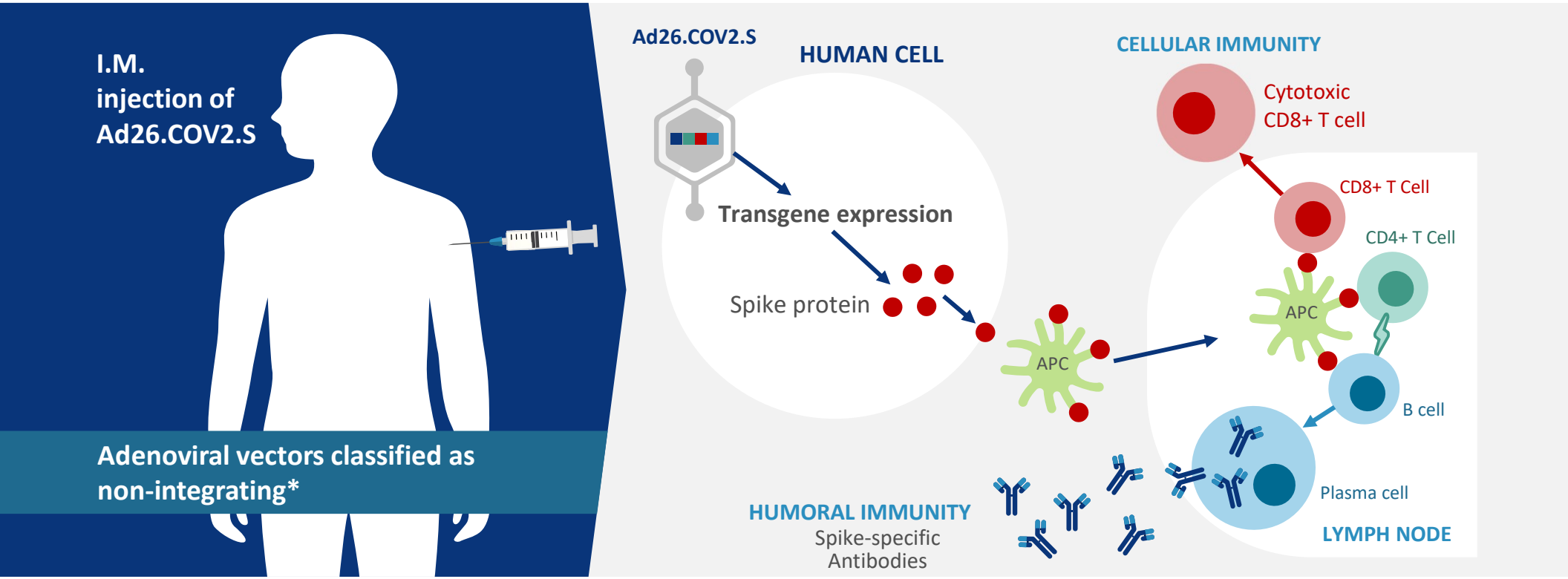
Targeted Immune Response Against SARS-CoV-2 Spike (S)

- Evaluated multiple transgenes encoding different S designs to select vaccine candidate with optimal:
    - Stabilization, expression, immunogenicity, nonclinical efficacy, manufacturability
- Selected S protein in Ad26.COV2.S contains two proline mutations and a knocked out furin cleavage site for optimal stability in prefusion confirmation[2]



1. Bos R, Schuitemaker H et al. *NPJ Vaccines*. 2020 Sep 28;5:91. ,Wrapp et al. *Science*. 2020;367(6483):1260-1263,

Ad26.COV2.S is Replication Incompetent and Expresses SARS-CoV-2 Spike Protein, Eliciting Multiple Immune Responses



*FDA Guidance, 2020

Phase 1/2a (COV1001): First in Human Study

Focus: 2 groups of healthy adults 18 to 55 yrs and ≥ 65 yrs

janssen
PHARMACEUTICAL COMPANIES OF
Johnson & Johnson

COV1001 Evaluated 2 Dose Levels: $5x10^{10}$ vp and $1x10^{11}$ vp in Healthy Adults 18 to 55 yrs and ≥ 65 yrs

Administered in 1-dose or 2-dose regimen

Intramuscular injection

Interim analysis conducted at Day 29

28 days following 1st dose

Evaluated safety and immunogenicity

Summary of Phase 1/2 Immunogenicity Data Following Single Dose of Ad26.COV2.S

Neutralizing antibody titers elicited in ~**96% of adults, independent of age and dose level**

- Titers detected as early as 14 days post vaccination
- Increased in following week and maintained thereafter up to 87 days

Strong CD8+ and Th1 dominated CD4+ T cell responses

- **Minimizes risk for vaccine associated enhanced disease (VAED)**

Both doses had favorable safety profile

- **Lower dose more favorable reactogenicity profile**

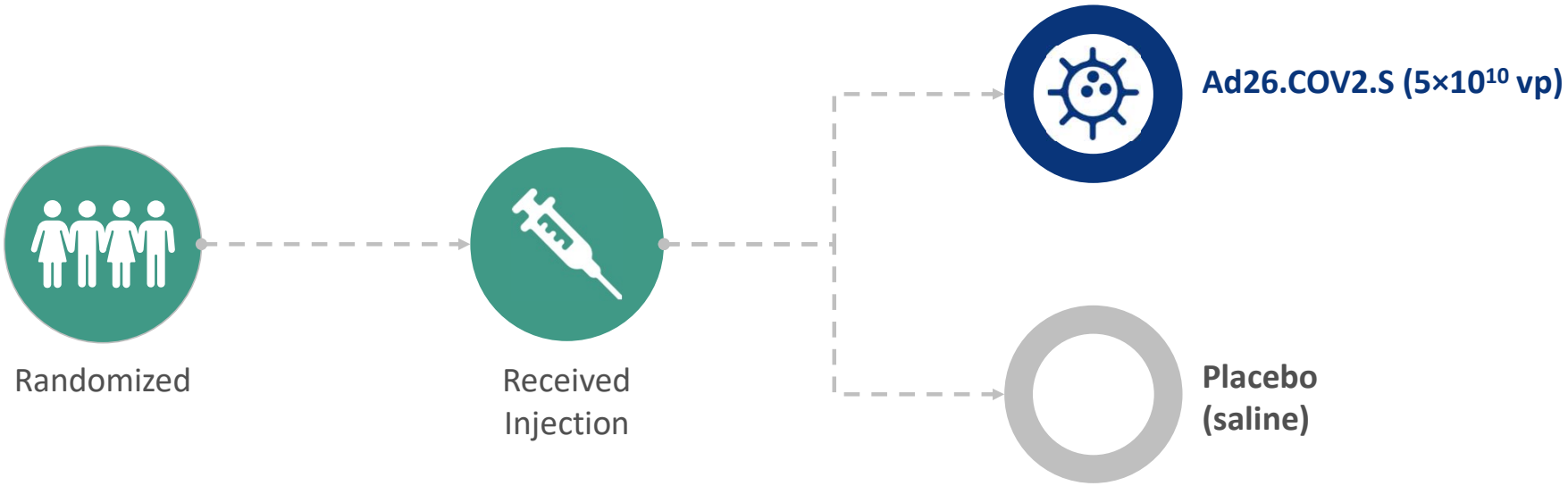
Ad26.COV2.S $5x10^{10}$ vp dose selected for COV3001

Sadoff, Le Gars, NEJM, 2021

Phase 3 Study COV3001 (ENSEMBLE) Efficacy and Safety

COV3001: Randomized, Double-Blind, Phase 3 Trial

Evaluating efficacy, safety, immunogenicity of single dose of Ad26.COV2.S



Randomization stratified by site, age group, and absence / presence of comorbidities

COV3001: Co-Primary Endpoints

Vaccine efficacy to prevent moderate to severe/critical COVID-19

- at least 14 days after vaccination
- at least 28 days after vaccination

Primary Hypothesis:

- Lower limit of 95% confidence interval >30%

Per Protocol Population

COV3001: Case Definition for Moderate COVID-19

RT-PCR or molecular test confirmation of SARS-CoV-2 infection

AND

At any time during observation period:

≥ 1 new or worsening sign or symptoms		≥ 2 new or worsening sign or symptoms	
• Respiratory rate ≥ 20 bpm • Abnormal oxygen saturation (> 93% on room air) • Evidence of pneumonia • Deep Vein Thrombosis (DVT) • Shortness of breath	**OR**	• Fever • Heart rate ≥ 90 bpm • Shaking chills • Muscle pain • Changes to olfaction or taste • Gastrointestinal symptoms • Red or bruised looking feet or toes	• Malaise • Headache • Cough • Sore throat

bpm, beats per minute; RT-PCR, real-time polymerase chain reaction.

COV3001: Case Definition for Severe / Critical COVID-19

RT-PCR or molecular test confirmation of SARS-CoV-2 infection

AND

At any time during observation period:

≥ 1 of these signs or symptoms

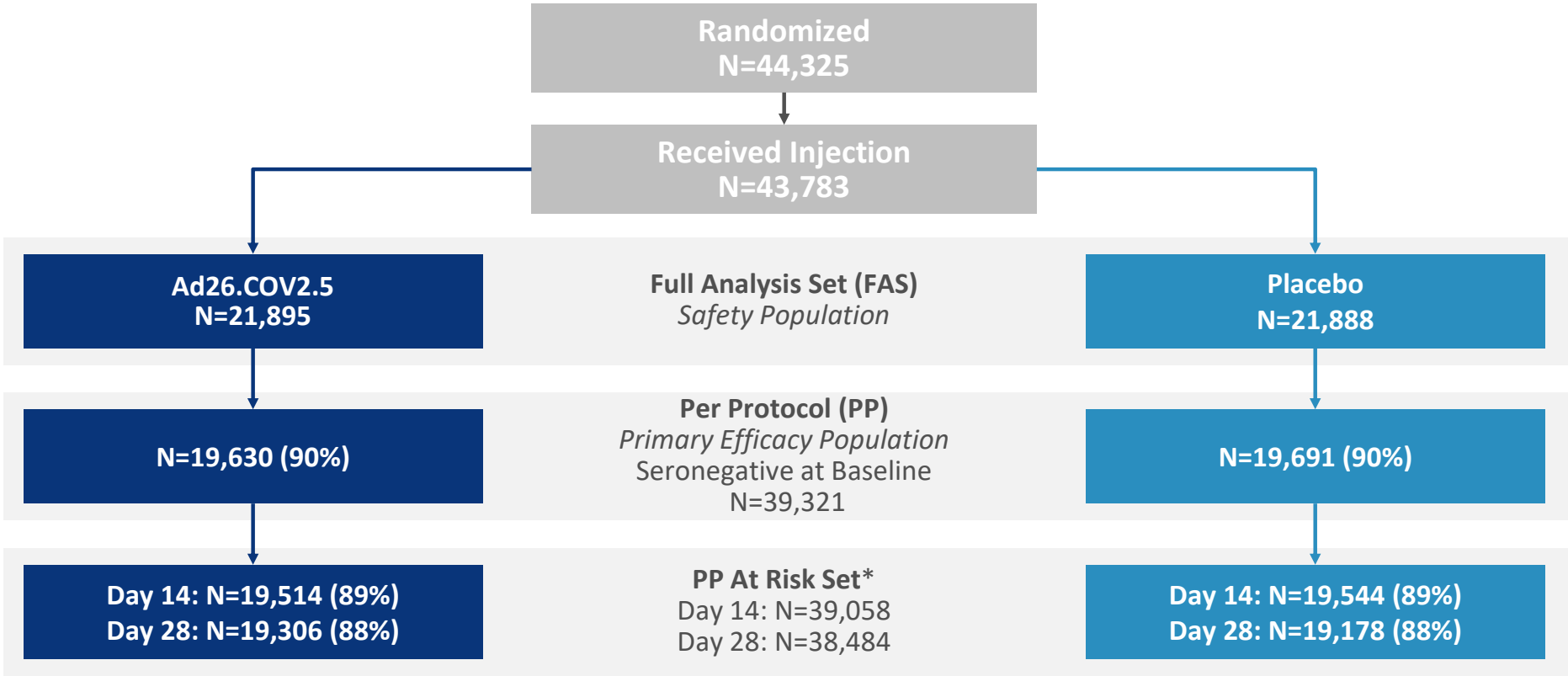
- **Clinical signs indicative of severe systemic illness:** Respiratory rate ≥30 bmp, heart rate ≥125 bpm, SpO_2≤ 93% on room air at sea level or PaO_2/FiO_2 <300 mmHg
- **Respiratory failure:** Needing high-flow oxygen, non-invasive ventilation, mechanical ventilation, or extracorporeal membrane oxygenation [ECMO]
- **Evidence of shock:** Systolic blood pressure <90 mmHg, diastolic blood pressure <60 mmHg, or requiring vasopressors
- **Significant acute renal, hepatic, or neurologic dysfunction**
- **Admission to ICU**
- **Death**

bpm, beats per minute; FiO_2, fraction of inspired oxygen; ICU, intensive care unit; PaO_2, oxygen partial pressure; RT-PCR, real-time polymerase chain reaction; SpO_2, oxygen saturation.

Study COV3001

Disposition and Efficacy Results

COV3001 Disposition of Participants



*PP At Risk set: Excluded participants with positive polymerase chain reaction (PCR) test for SARS-CoV-2 between vaccination and day of efficacy assessment

COV3001: No Relevant Differences at Baseline Between Vaccine and Placebo Groups Globally

Full Analysis Set	Ad26.COV2.S N = 21,895		Placebo N = 21,888	
	n	%	n	%
Sex, female	9,820	45%	9,902	45%
Mean Age (SD), years	50.7 (15.1)		50.7 (15.0)	
Age group				
18-59	14,564	67%	14,547	66%
≥ 60	7,331	33%	7,341	34%
≥ 65	4,259	19%	4,302	20%
≥ 75	809	4%	732	3%
Race				
American Indian* or Alaska Native	2,083	10%	2,060	9%
Asian	743	3%	687	3%
Black or African American	4,251	19%	4,264	20%
Native Hawaiian or other Pacific Islander	58	0.3%	48	0.2%
White	12,858	59%	12,838	59%
Multiple, unknown, not reported	1,901	9%	1,989	9%
Ethnicity				
Hispanic or Latino	9,874	45%	9,963	46%

*Includes American Indians from North and South Americas

COV3001: Global Participants with Comorbidities Similar Between Vaccine and Placebo Groups

Full Analysis Set **Baseline Comorbidity* Category, ≥ 2%**	**Ad26.COV2.S** N = **21,895**		**Placebo** N = **21,888**	
	n	**%**	**n**	**%**
≥ 1 risk factor	8,936	40.8%	8,922	40.8%
Obesity ≥ 30 kg/m^2	6,277	28.7%	6,215	28.4%
Hypertension	2,225	10.2%	2,296	10.5%
Type 2 Diabetes Mellitus	1,600	7.3%	1,549	7.3%
Serious heart conditions	497	2.3%	511	2.3%

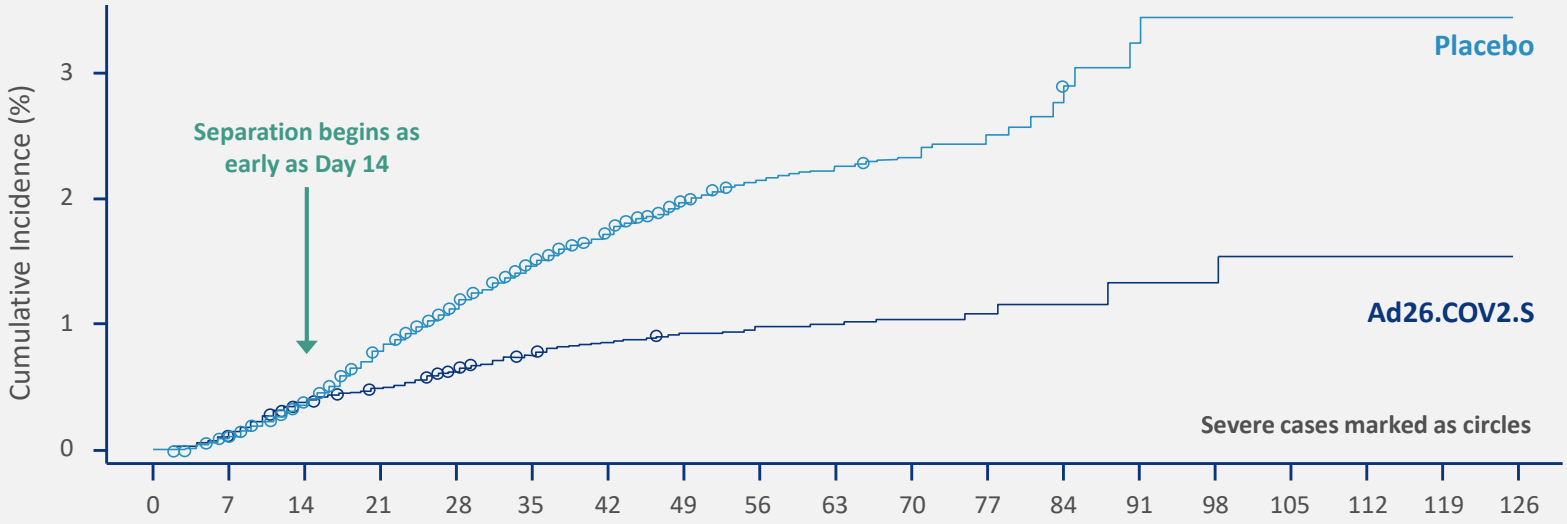
*Pre-existing medical risk factor for developing severe COVID-19

COV3001 Met Co-Primary Endpoints: Ad26.COV2.S Protects Against Moderate to Severe/Critical COVID-19 Globally

PP At Risk Set	**> Day 14**		**> Day 28**	
	Ad26.COV2.S N = 19,514	**Placebo** N = 19,544	**Ad26.COV2.S** N = 19,306	**Placebo** N = 19,178
Number of confirmed cases, n	116	348	66	193
Person-years	3,117	3,096	3,102	3,071
Vaccine efficacy (adjusted 95% CI)	66.9% (59.0, 73.4)		66.1% (55.0, 74.8)	

COV3001, Participants seronegative at baseline, confirmed: positive PCR centrally confirmed COVID-19 cases, global data.

Kaplan Meier Shows Early Onset of Protection Against Moderate to Severe/Critical COVID-19



Participants at Risk																			
Ad26.COV2.S	19744	19725	19669	19642	19612	19578	18541	14909	10930	7831	3998	1468	713	484	483	482	142	31	0
Placebo	19822	19804	19745	19652	19579	19488	18411	14814	10823	7740	3876	1439	708	485	482	480	133	27	0
Cumulative number of cases																			
Ad26.COV2.S	0	27	76	96	126	151	168	178	184	188	189	191	191	192	193	193	193	193	193
Placebo	0	22	81	168	237	299	351	387	407	416	423	425	430	432	432	432	432	432	432

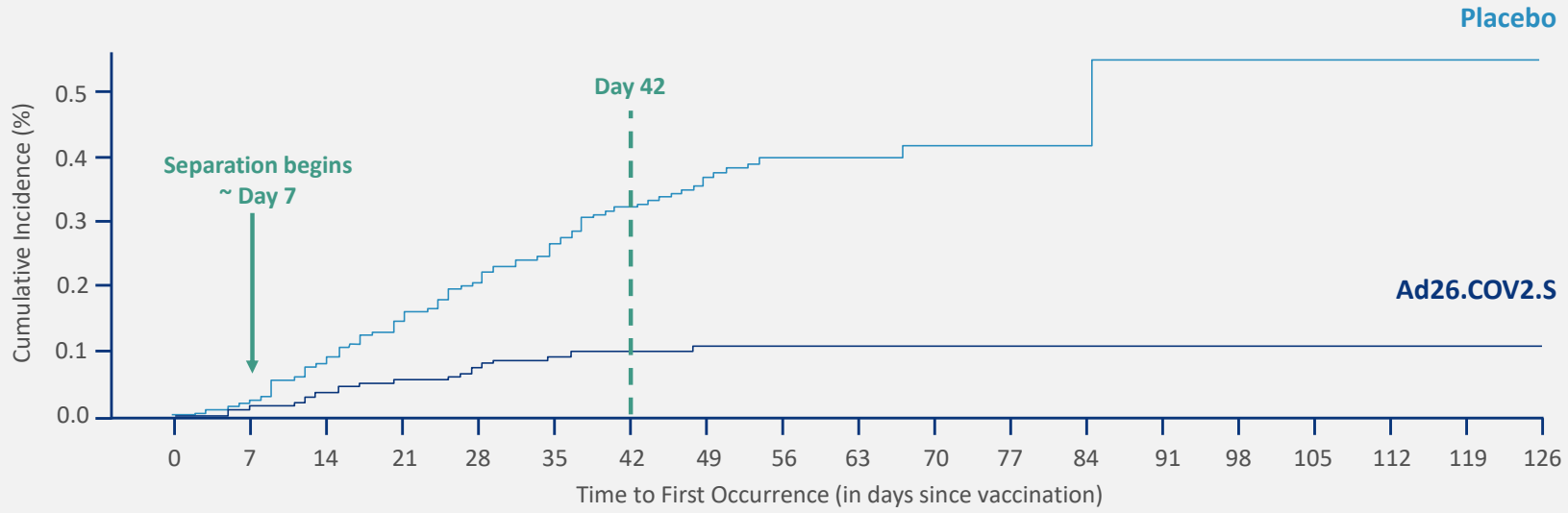
COV3001; Full Analysis Set; baseline seronegative; confirmed: positive PCR centrally confirmed COVID-19 cases

High Vaccine Efficacy Against Severe/Critical COVID-19

PP At Risk Set	> Day 14		> Day 28	
	Ad26.COV2.S N = 19,514	**Placebo** N = 19,544	**Ad26.COV2.S** N = 19,306	**Placebo** N = 19,178
Number of confirmed cases, n	14	60	5	34
Vaccine efficacy (adjusted 95% CI)	76.7% (54.6, 89.1)		85.4% (54.2, 96.9)	

COV3001; Confirmed: positive PCR centrally confirmed COVID-19 cases. CI, confidence interval; PP, per protocol

Time to First Occurrence of Severe/Critical COVID-19 Demonstrates Early Onset of Protection



Participants at risk																			
Ad26.COV2.S	19744	19741	19734	19725	19718	19705	18685	15043	11046	7919	4039	1481	720	490	490	489	146	31	0
Placebo	19822	19817	19799	19779	19760	19725	18682	15088	11069	7939	3995	1485	732	500	497	495	137	29	0
Number of cases																			
Ad26.COV2.S	0	3	7	11	16	18	20	21	21	21	21	21	21	21	21	21	21	21	21
Placebo	0	5	18	32	44	55	65	73	76	76	77	77	78	78	78	78	78	78	78

COV3001; Full analysis set. Baseline seronegative. Confirmed: positive PCR centrally confirmed COVID-19 cases

Data Support Substantial Effect on Prevention of COVID-19 Related Hospitalizations

PP At Risk Set (MRU, SAE and MA-COV information)	**Ad26.COV2.S** Cases, n	**Placebo** Cases, n	**VE** (95% CI)
> Day 14			
PCR+ cases from any source, regardless of central confirmation	2	29	93.1% (72.7, 99.2)
> Day 28			
PCR+ cases from any source, regardless of central confirmation	0	16	100.0% (74.3, 100.0)

COV3001; Sources: MRU (Medical Resource Utilization), SAE, and MA-COV (medical attendance-COV). CI, confidence interval; PP, per protocol; VE, Vaccine efficacy
Onset is earliest of either AE linked to COVID-19 or onset of COVID-19 episode following SAP algorithm.

Ad26.COV2.S Data Support Protection Against COVID-19-Related Deaths

Full Analysis Set (cutoff of Jan 22, 2021)	**Ad26.COV2.S** N = 21,895	**Placebo** N = 21,888
All cause mortality	3	16
COVID-19-related death > Day 1	0	5*

***One PCR+ participant at baseline, not included**

Full Analysis Set From January 22, 2021 to February 5, 2021	**Ad26.COV2.S** N = 21,895	**Placebo** N = 21,888
All cause mortality	2	4
COVID-19-related death > Day 1	0	1

- All COVID-19 associated deaths occurred in South Africa

COV3001; non-confirmed: all COVID-19 cases with a positive PCR from any source, regardless of central confirmation;

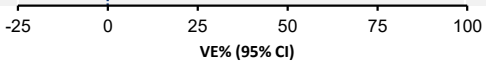
Subset of Data Show Effect Against Asymptomatic/Undetected COVID-19

Per Protocol	>Day 29		VE (95%CI)
	Ad26.COV2.S N = 19,630	Placebo N = 19,691	
Serology Risk Set (Day 71 Serology Results)	N = 1,346	N = 1,304	
Seroconverted SARS-CoV-2 (Day > 29)[a]	18	50	65.5% (39.9, 81.1)
Seroconverted SARS-CoV-2 without previous symptoms (Day > 29)[a,b]	10	37	74.2% (47.1, 88.6)

[a] Serologically converted: positive serology (Non-S protein) test without SARS-CoV-2 positive RT-PCR before positive serology test irrespective of previous symptoms.
[b] Without previous symptoms: no COVID-19 symptoms occurred before positive serology test at any point during study. CI, confidence interval; VE, vaccine efficacy

Overall VE Against Moderate to Severe/Critical COVID-19 Consistent Across Prespecified Subgroups

Per Protocol	# Events / N		>Day 28	
	Ad26.COV2.S N = 19,630	Placebo N = 19,691	Moderate to Severe/Critical COVID-19	Vaccine Efficacy (95% CI)
PP Risk Set	113 / 19,306	324 / 19,178		65.5% (57.2, 72.4)
Age				
18 – 59 years	87 / 12,617	259 / 12,527		66.8% (57.5, 74.3)
≥ 60 years	26 / 6,689	65 / 6,651		60.4% (36.8, 75.9)
Participants with comorbidities (all ages)				
Yes	44 / 7,684	105 / 7,626		58.6% (40.6, 71.6)
No	69 / 11,622	219 / 11,552		68.8% (59.0, 76.6)
Sex				
Male	54 / 10,764	176 / 10,649		69.8% (58.9, 78.2)
Female	59 / 8,538	148 / 8,525		60.3% (46.0, 71.2)
Race and ethnicity				
Non-Hispanic / Latino	52 / 10,131	163 / 9,957		68.8% (57.2, 77.6)
Hispanic / Latino	59 / 8,688	153 / 8,741		61.3% (47.4, 71.8)
White	64 / 11,994	187 / 11,912		66.2% (54.8, 74.9)
Black	21 / 3,330	66 / 3,300		68.6% (48.0, 81.8)



COV3001; global; non-confirmed: all COVID-19 cases with a positive PCR from any source, regardless of central confirmation

Vaccine Efficacy Across Age Groups With/Without Co-morbidities

		Day >14		Day >28	
		Point estimate	95% CI	Point estimate	95% CI
18-59 without co-morbidities	**Moderate/severe**	66%	(56.1; 73.3)	68%	(56.8; 76.6)
18-59 with co-morbidities	**Moderate/severe**	64%	(49.4; 74.6)	64%	(44.3; 77.3)
≥60 without co-morbidities	**Moderate/severe**	76%	(56.3; 87.6)	72%	(45.0; 87.3)
≥60 with co-morbidities	**Moderate/severe**	65%	(42.2; 79.4)	42%	(-13.1; 71.6)

- In primary analysis vaccine efficacy is slightly lower in participants with co-morbidities from Day >28
  - **Limitations:** difference in follow-up period between subgroups and limited case numbers
- Day >14 analysis consistent with other subgroups

*All subgroup analysis are based on any positive PCR (regardless of central confirmation); CI, Confidence interval

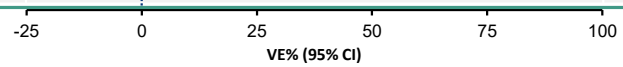
Ad26.COV2.S Protects Against COVID-19-Related Hospitalizations in Participants ≥ 60 years with Comorbidities

Per Protocol Set	Ad26.COV2.S	Placebo	VE (95% CI)
COVID-19-related Hospitalizations ≥ 60 years with Comorbidities *(Per Protocol Set)*			
> Day 14	2	11	82% (16, 98)
> Day 28	0	5	-
COVID-19 Related Deaths ≥ 60 years with Comorbidities *(Full Analysis Set)*			
> Day 1	0	2	-

Non-confirmed: all COVID-19 cases with a positive PCR from any source, regardless of central confirmation.
Onset based on earliest AE and/or COVID-19 episode. Derived based on PCR test with symptoms; CI, Confidence interval; VE, Vaccine efficacy

Vaccine Efficacy Consistently High Across Key Countries > Days 28

Country *% Variant*	Severity	# Events / N		> Day 28
		Ad26.COV2.S N = 19,306	Placebo N = 19,178	Vaccine Efficacy (95%CI)
United States 96% D614G 3% CAL.20C	Moderate-Severe/Critical	32 / 8,958	112 / 8,835	72.0% (58.2, 81.7)
	Severe/Critical	1 / 8,958	7 / 8,835	85.9% (-9.4, 99.7)
Brazil 69% P.2 lineage 31% D614G	Moderate-Severe/Critical	24 / 3,354	74 / 3,312	68.1% (48.8, 80.7)
	Severe/Critical	1 / 3,354	8 / 3,312	87.6% (7.8, 99.7)
South Africa 95% B.1.351 3% D614G	Moderate-Severe/Critical	23 / 2,449	64 / 2,463	64.0% (41.2, 78.7)
	Severe/Critical	4 / 2,449	22 / 2,463	81.7% (46.2, 95.4)



South Africa	*PP At Risk Set (N=4,912)*	**Hospitalizations >Day 28*:**	0 vs 6 (Ad26.COV2.S vs placebo)
	Full Analysis Set (N=6,576)	**COVID-related deaths:**	0 vs 5** (Ad26.COV2.S vs placebo)

COV3001; Non-confirmed: all COVID-19 cases with a positive PCR from any source, regardless of central confirmation.
*Sources: MRU (Medical Resource Utilization), SAE, and MA-COV (medical attendance-COV); **6th case excluded due to positive PCR test at baseline

Single Dose of Ad26.COV2.S Offers Substantial Protection Against COVID-19, Irrespective of Variant

85% VE* against severe disease
- Onset of protection as early as 7 days after vaccination
- In the trial complete protection against COVID-19 related hospitalizations as of Day 28. No COVID-19 related deaths in Ad26 group

66% VE* against moderate to severe disease across all countries
- Onset evident as early as Day 14, and increased through Day 56

Protection against all symptomatic disease consistent with primary endpoint

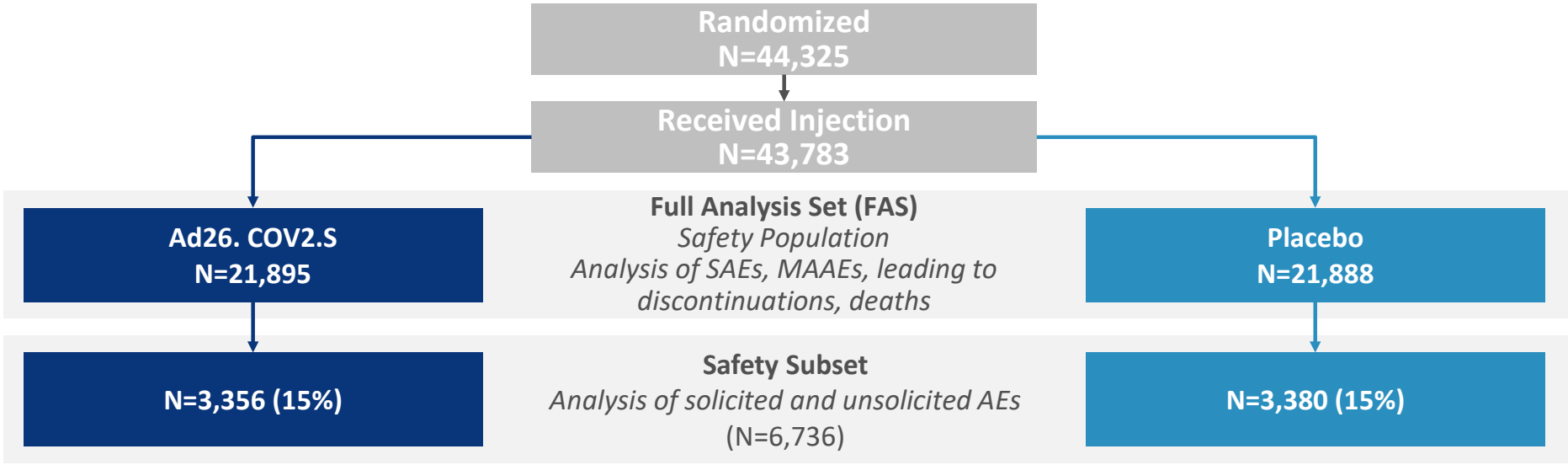
High-quality, robust data at a time when the incidence of SARS-CoV-2 was increasing, and new, highly transmissible variants were emerging

High levels of protection consistent across subgroups, countries and regions*

*> Day 28, VE, Vaccine efficacy

Study COV3001: Safety Results

COV3001 Safety Subset Includes Data on Solicited and Unsolicited Adverse Events



Safety analysis cut off date: January 22, 2021

Safety Data Met FDA Guidelines for Median Follow-Up of At Least 8 weeks

Median follow up after vaccination was 58 days

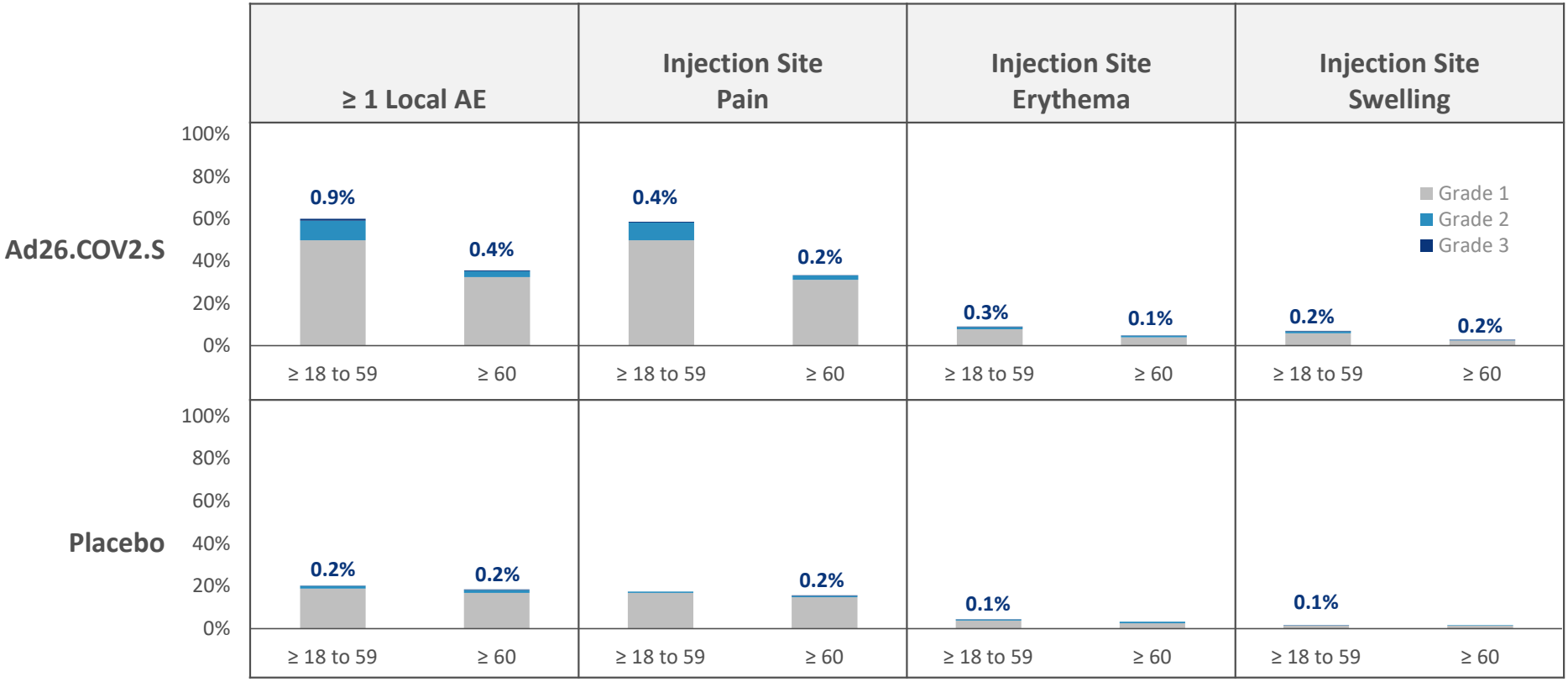
Full Analysis Set: 55% had ≥ 8 weeks of follow-up

Safety Subset: nearly all (99.9%) completed post-vaccination period of Day 1-29

COV3001; safety analysis cut off date: January 22, 2021

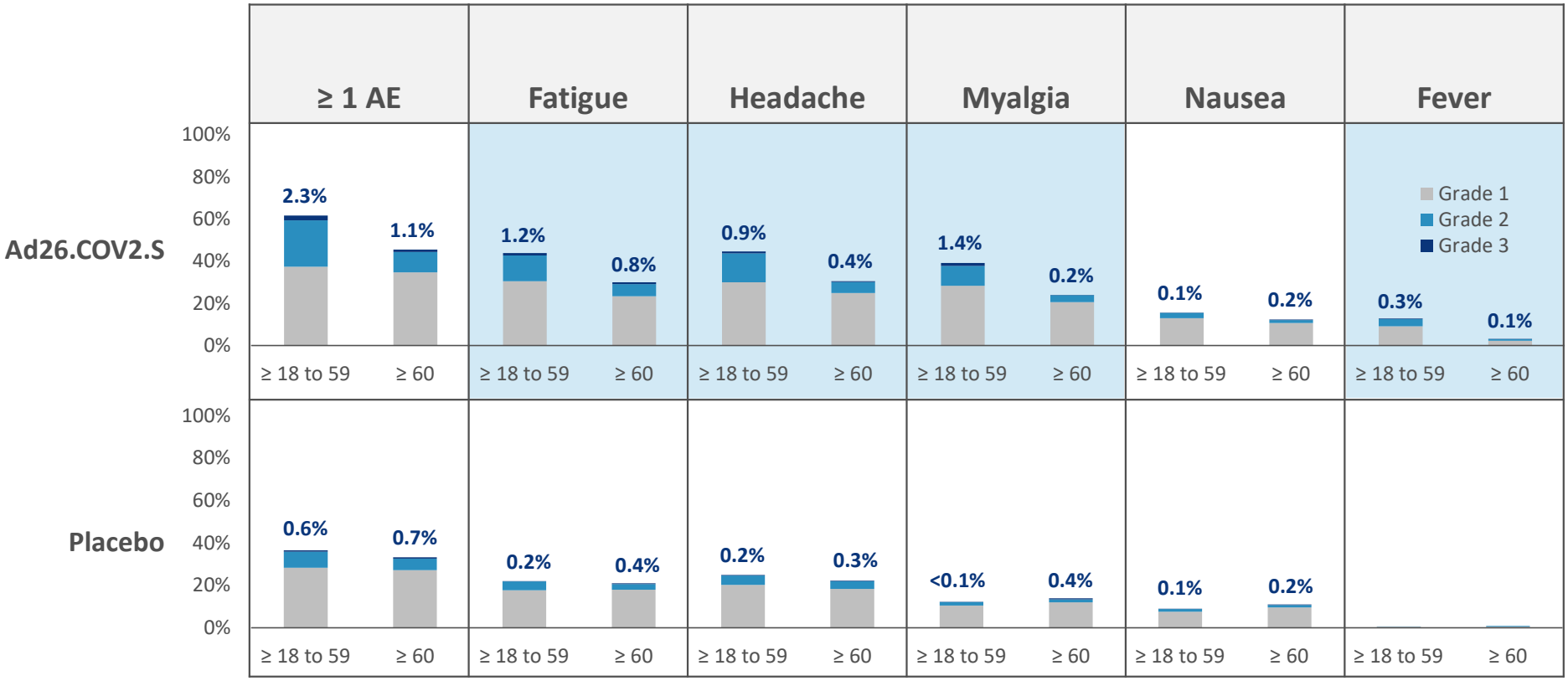
Study COV3001: Solicited Adverse Events

Local Adverse Events, Nearly All Grade 1 and 2 in Severity, All Events Resolved 2-3 Days After Injection



COV3001; Safety Subset

Systemic Adverse Events Transient with Median Duration of 1-2 Days



COV3001; Safety Subset

Study COV3001:
Unsolicited Adverse Events

Similar Rates of Unsolicited AEs Between Groups

	Ad26.COV2.S		Placebo	
Unsolicited Adverse Events	**n**	**%**	**n**	**%**
Safety Subset	**N = 3,356**		**N = 3,380**	
Any Adverse Event (AE)	440	13%	407	12%
Full Analysis Set (FAS)	**N = 21,895**		**N = 21,888**	
Any Medically-Attended Adverse Event (MAAE)	304	1.4%	408	1.9%
Any Serious Adverse Event (SAE)	90	0.4%	137	0.6%
Not COVID-19 Related SAE	83	0.4%	96	0.4%
Any death (reported through January 22, 2021)	3	<0.1%	16	0.1%
COVID-19 related deaths	0	-	5*	-

COV3001;*Excludes PCR+ participants at baselines, cut of as of February 5, 2021;

No Evidence of Vaccine-Associated Enhanced Respiratory Disease (VAERD)

- **Clinical data confirms nonclinical observations that theoretical risk for VAERD is low**
  - Data demonstrated Th1 dominant immune responses
  - Breakthrough infections in Ad26.COV2.S group milder than those in placebo
- **DSMB continuously monitored all cases of COVID-19 for patterns suggestive of VAERD, none found**

COV3001. DSMB, Data Safety Monitoring Board.

Other Adverse Events of Interest

Full Analysis Set	Ad26.COV2.S N = 21,895	Placebo N = 21,888
	n	n
Hypersensitivity*	77	65
Thrombotic and Thromboembolic Events**	14	10
Convulsions	4***	1
Tinnitus	6	0
Peripheral neuropathy	2	2
Guillain-Barre Syndrome	1	1
Bell's Palsy	3	2

COV3001
*No anaphylaxis
**Most had relevant predisposed medical conditions and/or other factors
***Three participants with history of epilepsy, one additional followed transverse sinus thrombosis

Hypersensitivity Events

Full Analysis Set Preferred Term, n	Ad26.COV2.S N = 21,895	Placebo N = 21,888
Hypersensitivity Cases, n (%)	**77 (0.4%)**	**65 (0.3%)**
Rash	35	23
Urticaria	8	5
Hypersensitivity	9*	6
Dermatitis/eczema	10	16
Edema/swelling	7	3
Eye, nose, throat manifestation	10	16
Cardiovascular	0	1

* Includes 1 related SAE of Type IV (delayed) hypersensitivity

- **Non-serious dermatologic conditions** most common hypersensitivity AEs
- Mean time to onset after vaccination: **5.7 days**
- Mean resolution time: **13 days**
- **Majority Grade 1 or 2**

In COV3001 no cases met Brighton Collaboration criteria for anaphylaxis
Similar profile observed with other Ad26 vaccines

Thrombotic and Thromboembolic Events

Full Analysis Set	Ad26.COV2.S N = 21,895	Placebo N = 21,888
	n	n
Total number of participants with any event	14	10
Venous thromboembolic events		
Deep vein thrombosis	6	2
Pulmonary embolism	4	1
Transverse sinus thrombosis	1	0
Thrombosed hemorrhoid	0	1
Total participants with venous events	**11**	**4**
Arterial thromboembolic events		
Cerebrovascular events	3*	3
Cardiovascular events	1	3
Total participants with arterial events	**3**	**6**

COV3001
*2 events occurred in one participant

Benefits of Ad26.COV2.S Outweigh Known and Potential Risks

- Demonstrated **acceptable safety and reactogenicity** profile
- Overall, reactogenicity **mild and transient**
  - Grade 3 reactogenicity rare
- Most AEs **mild or moderate**
  - Generally **resolved 1 to 2 days** post vaccination
- Safety further supported by > 193,000 individuals exposed to Janssen Ad26-based vaccines

Vaccine Safety and Effectiveness Monitoring Post-Authorization

Surveillance of Adverse Events Following Immunizations (AEFIs), prespecified AESIs, known vaccine concerns

Signal detection through Janssen's global safety database and external databases, eg. VAERS in the US

Monitor long-term safety and effectiveness through observational and active surveillance studies

Health insurance claims databases, EHRs in US and Europe

AESI: Adverse Events of Special Interest; VAERS: Vaccine Adverse Event Reporting System; EHR: Electronic Health Record

Next steps

Additional Key Studies

COV3009: two-dose regimen Phase 3 efficacy study

Immunogenicity and safety studies in children, 0 – 17 years
Adolescent study recruitment ongoing

Pregnant women
Planned to begin late March/early April 2021

Immunocompromised individuals
Planned to begin Q3 2021

Post-authorization observational safety and effectiveness studies
Including pregnancy exposure registry

Logistical, Practical Advantages to Help Simplify Distribution and Expand Vaccine Access of Single Dose Ad26.COV2.S

Single, 0.5ml dose

5 doses per vial

No dilution required

Stored for 3 months at normal refrigerator temperatures, 2° to 8° C (36° to 46° F)

2-year shelf life when frozen, -25° to -15° C (-13° to 5° F)

Prepared for large-scale manufacturing

Shipping fits into existing supply chain infrastructure

Summary

Benefits of Ad26.COV2.S Outweigh Known and Potential Risks

Efficacy	• Offers substantial protection, especially against severe COVID-19 including hospitalization and death, irrespective of variant • Similar VE by age, comorbidities status, sex, race, and ethnicity
Safety	• Acceptable safety and reactogenicity profile. • Results consistent with tolerability, safety of other Ad26-based vaccines
Ongoing Monitoring	• Safety and effectiveness monitoring plans • Cross-over plan for participants who received placebo
Traditional Shipping, Storage	• Stored at normal refrigerator temperatures • 2-year shelf life when frozen
1-Dose Vaccine	• Specifically studied as 1-dose regimen • increase vaccination capacity and coverage of population