AstraZeneca COVID-19 Vaccine (AZD1222)

ACIP COVID-19 Emergency Meeting
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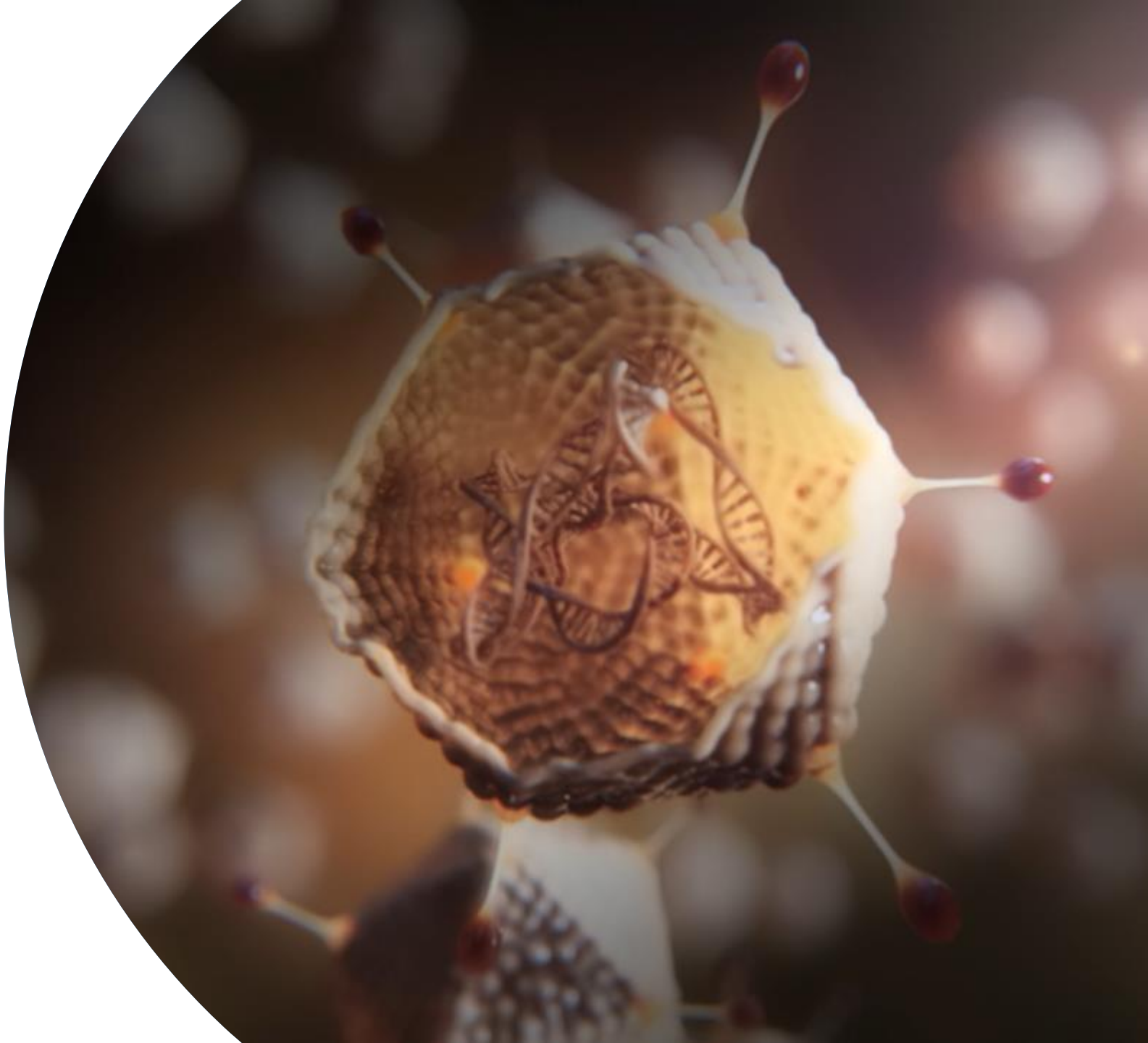

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AGENDA

AZD1222 Adenoviral Platform, Clinical Development Plan & Phase I/II Data

US Phase III Study

Non-IND Phase III Efficacy and Safety Trials (Interim Analysis)

Vaccine Storage & Handling

Summary

Q&A

AZD1222 COVID-19 Vaccine - Executive Summary

Phase III trial in the US is ongoing, enrollment is complete. This trial will be the primary basis for the EUA application with supporting data from the non-IND trials conducted outside the US.

AstraZeneca committed to a partnership with Oxford University to ensure broad and equitable vaccine access globally, not for profit during the pandemic.

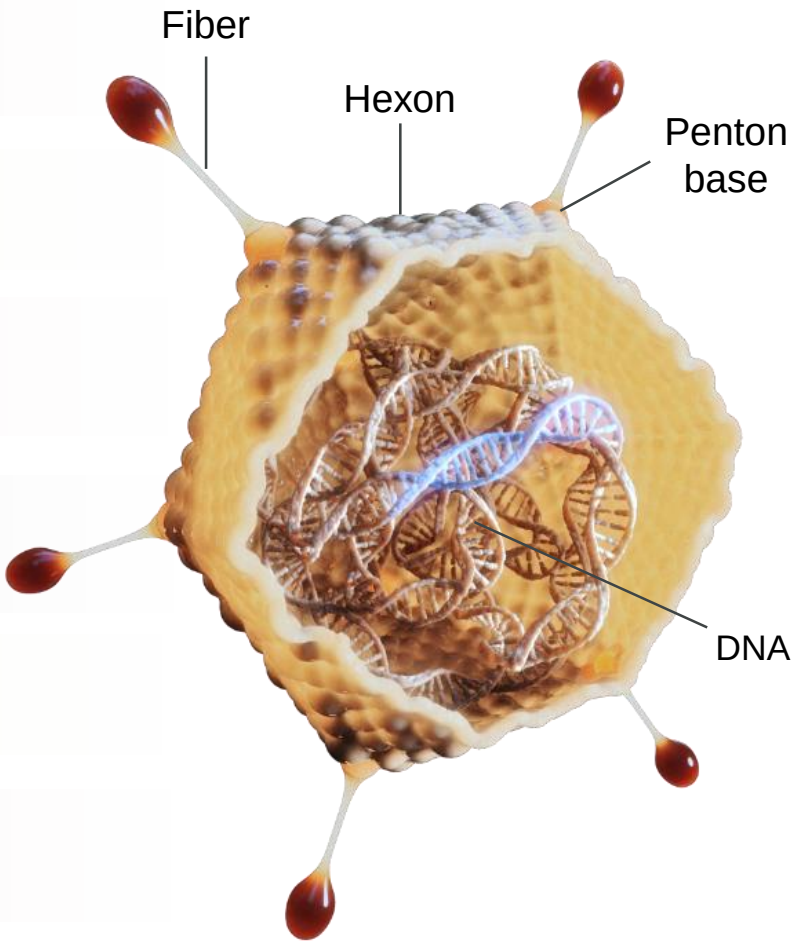
Vaccine immunogenicity, efficacy and safety were demonstrated in four Phase I-III non-IND trials in UK, Brazil & South Africa. Data from these trials supported MHRA (UK) Authorization for Temporary Supply.

Vaccine is supplied in 5 ml preservative free, non-latex multidose vials to be stored at 2-8°C for at least 6 months.

AZD1222 Adenoviral Platform Clinical Development Plan & Phase I/II Data

AZD1222: The Technology

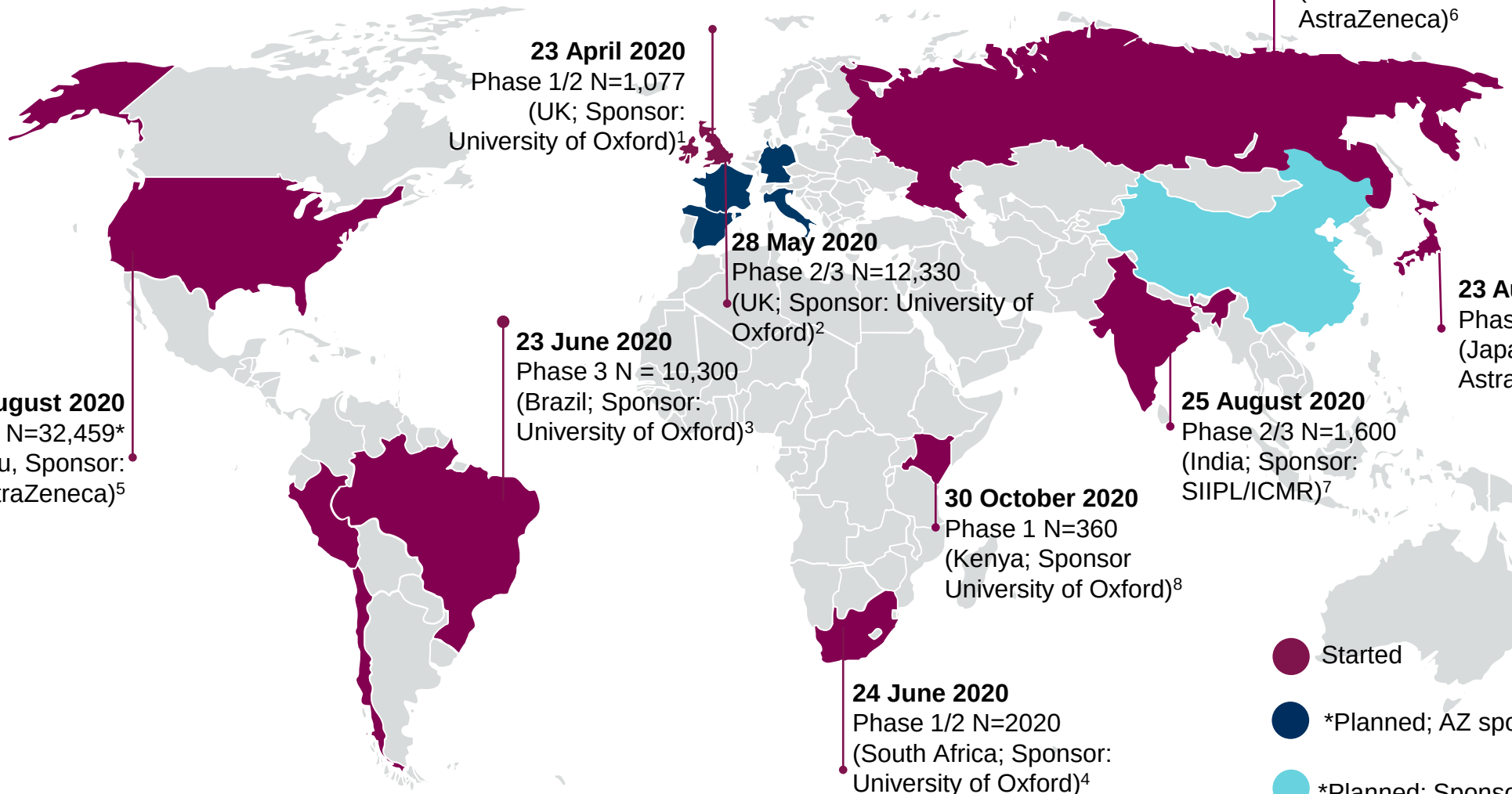
- Non-replicating chimp adenovirus-vectored vaccine expressing nCoV-19 spike[1]
- Non-replicating due to E1 (and E3) gene deletion[2]
- Chimp adenovirus avoids issues with pre-existing immunity to human adenoviruses[2]
- Vaccine antigen encoded in the viral genome – not a structural part of the virion[3]
- Induces strong B- and T-cell responses after a single vaccination[1]
- Prior to April 2020, 12 Phase I studies, 330 subjects vaccinated
- Dose is 5 x 10^{10} viral particles (vp) as an IM injection, 0.5 ml[1]



DNA = deoxyribonucleic acid; IM = intramuscular.

1. Folegatti PM, et al. *Lancet* 2020;396:467–478; 2. Dicks MDJ, et al. *PLoS One* 2012;7:e40385; 3. Guo J, et al. *Hum Vaccin Immunother* 2018;14:1679–1685.

AZD1222 Clinical Development Plan



02 September 2020
Phase 3 N=100
(Russian Federation; Sponsor: AstraZeneca)[6]

23 April 2020
Phase 1/2 N=1,077
(UK; Sponsor: University of Oxford)[1]

28 May 2020
Phase 2/3 N=12,330
(UK; Sponsor: University of Oxford)[2]

23 August 2020
Phase 1/2 N=256
(Japan; Sponsor: AstraZeneca)[7]

28 August 2020
Phase 3 N=32,459*
(USA, Chile, Peru, Sponsor: AstraZeneca)[5]

23 June 2020
Phase 3 N = 10,300
(Brazil; Sponsor: University of Oxford)[3]

25 August 2020
Phase 2/3 N=1,600
(India; Sponsor: SIIPL/ICMR)[7]

30 October 2020
Phase 1 N=360
(Kenya; Sponsor University of Oxford)[8]

24 June 2020
Phase 1/2 N=2020
(South Africa; Sponsor: University of Oxford)[4]

Started

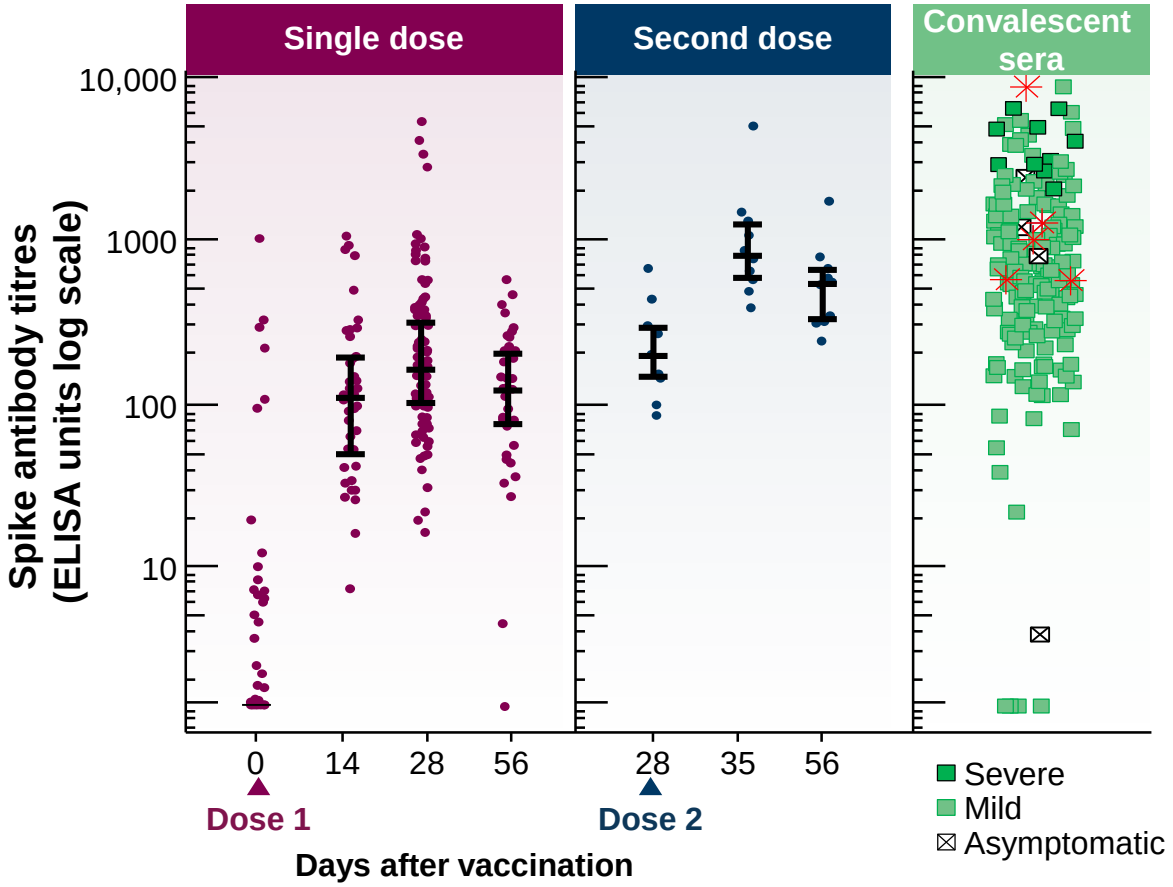
*Planned; AZ sponsored Phase 3 trial

*Planned; Sponsored by BioKangtai

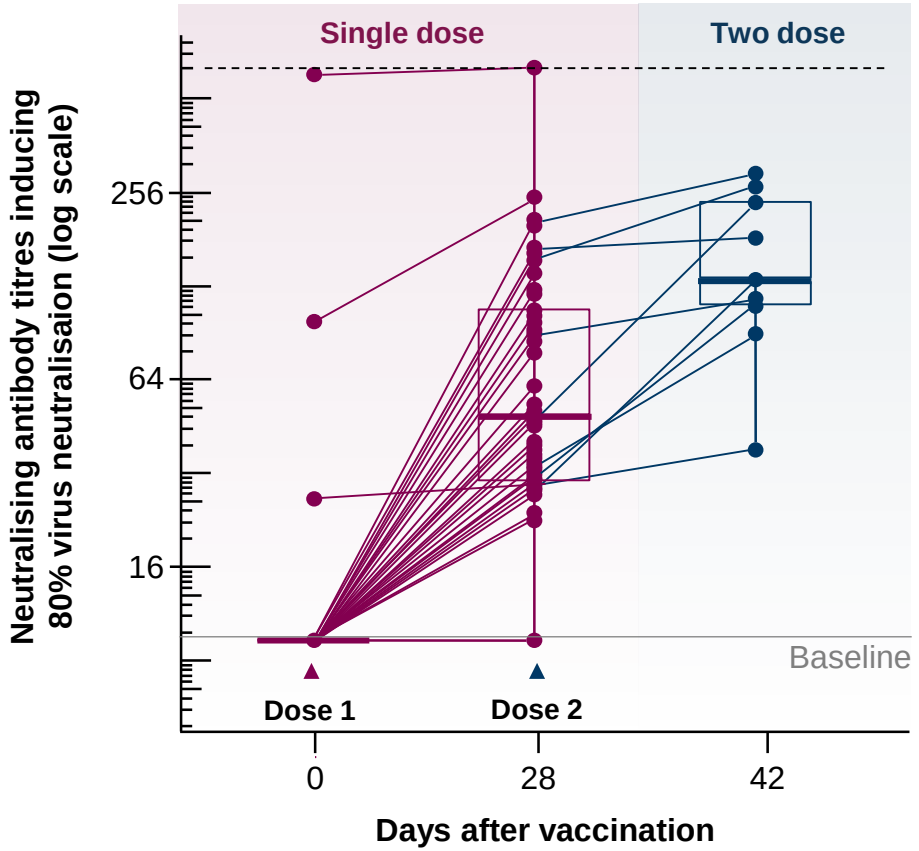
1. Study NCT04324606. ClinicalTrials.gov website; 2. Study NCT04400838. ClinicalTrials.gov website; 3. Study NCT04536051. ClinicalTrials.gov website 4. Study NCT04444674. ClinicalTrials.gov website, 5. Study NCT04516746. ClinicalTrials.gov website; 6. Study NCT04540393 ClinicalTrials.gov website; 7. AstraZeneca. Data on File; 8. University of Oxford press release. (Accessed 05 November 2020).*Participants enrolled by January 15, 2021.

AZD1222 Induced Robust Antibody Responses At Levels In A Similar Range To Those Seen In Convalescent COVID-19 Patients In Phase I/II Study COV001

SARS-CoV-2 spike antibodies peaked one month after injection and were elevated after two doses in a similar range to convalescent sera

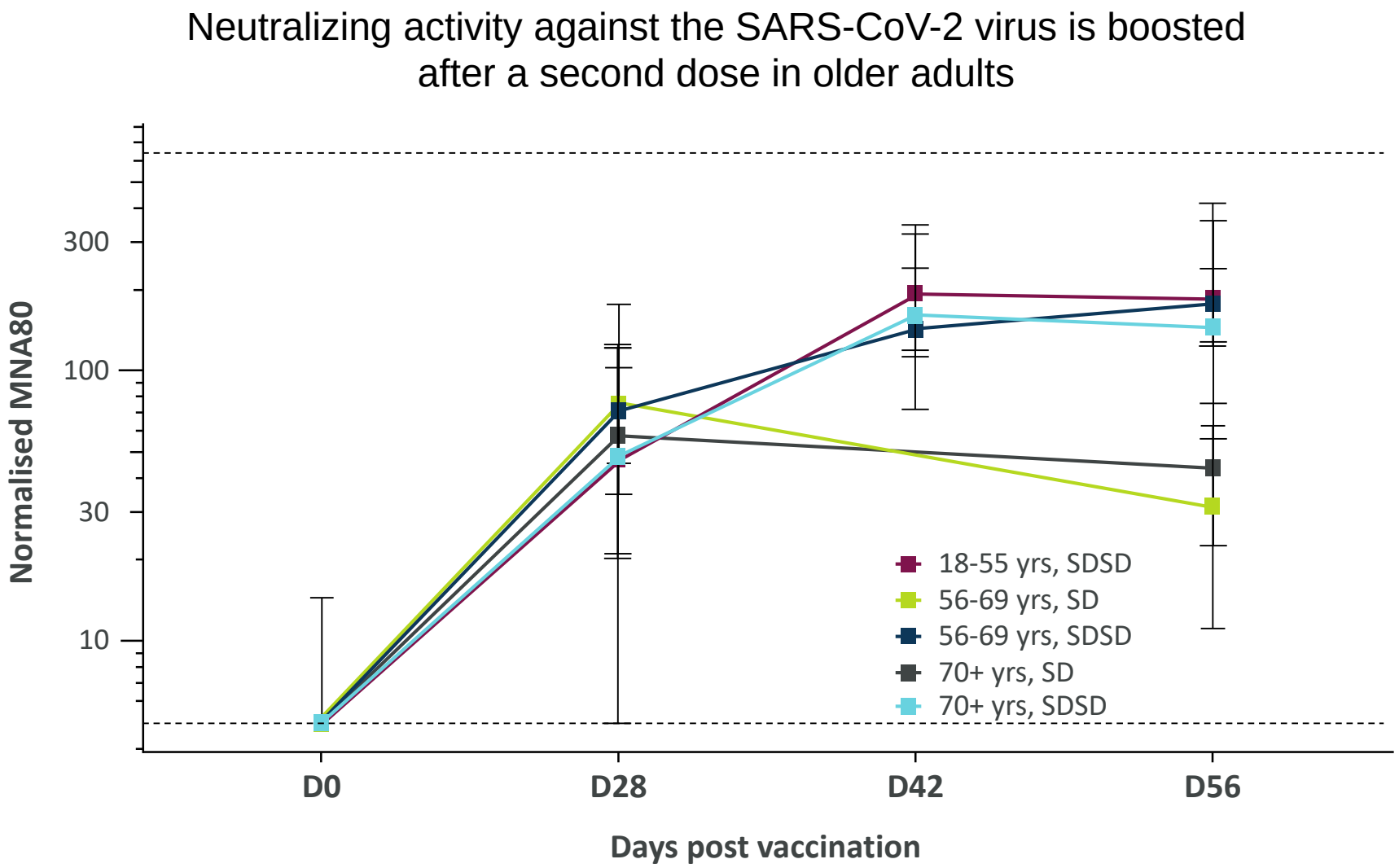


Neutralizing activity against SARS-CoV-2 in 91% vaccines after a single dose and 100% after two doses in micro-neutralisation assay (IC80)



Folegatti P et al. *The Lancet*. 2020.

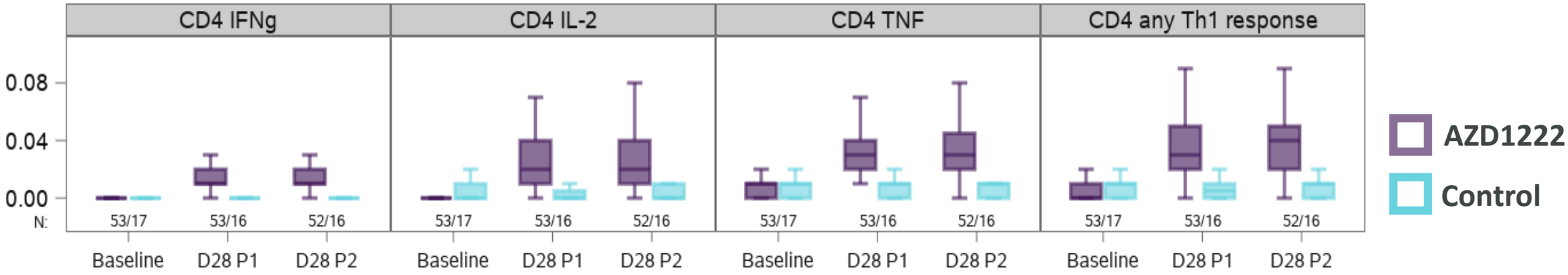
Robust Humoral Response In Older Adults Receiving AZD1222 In COV002



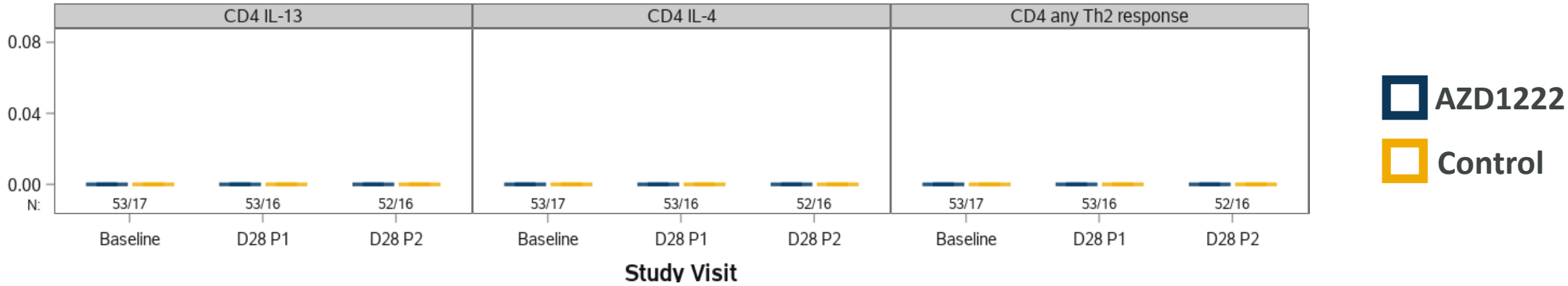
Ramasamy M et al. *Lancet*. 2020

AZD1222 Induced A Robust Th1 Biased T-Cell Response In COV001 And COV002 Participants

Th1 cytokines were induced following stimulation with overlapping SARS-CoV-2 peptides



Limited Th2 cytokines were induced following stimulation with overlapping SARS-CoV-2 peptides



D28 P1 = Day 28 post 1st Dose, D28 P2 = Day 28 post 2nd Dose. Boxplots display the median and 1st and 3rd quartiles. Th1 data result indicates percentage of CD69+ cells expressing IFNγ, IL-2, TNFα (or any Th1 cytokine) after stimulation with SARS-CoV-2 S1 peptide pool (similar results were seen with S2 peptide pool). Th2 data result indicates percentage of CD69+ cells expressing IL-4, IL-13 (or either Th2 cytokine). Background percentage was subtracted from the stimulated percentage prior to analysis. Stimulated percentages less than the background percentage were set to 0%.

Exploratory analysis, Unpublished results

AZD1222 Was Well Tolerated In Phase I/II Studies

Most AEs were mild to moderate in severity and majority resolved within 1 to 7 days

- Local and systemic reactions ~20% less frequent after the 2nd dose

AEs were similar in nature to those previously reported

- Injection site pain, feeling feverish, muscle ache and headache

Local and systemic reactions were more common in participants given AZD1222 than MenACWY

Less reactogenicity (local and systemic) in older adults

- >70 years about 30% fewer mild/moderate local reactions than <55 years
- >70 years about 20% fewer systemic reactions than <55 years

Ramasamy MN et al. *Lancet*. 2020. https://doi.org/10.1016/S0140-6736(20)32466-1. Accessed January 21, 2021.

US Phase III Trial
D8110C00001
Design, Objectives, Diversity

Phase III Study D8110C00001 To Evaluate Safety And Efficacy Of AZD1222 In Over 30,000 Volunteers

Start: 28 August 2020

Randomized (2:1)

N >30,000

AZD1222
$5x10^{10}$ viral particles
2 IM doses
N=20,000

Saline Placebo
2 IM doses
N=10,000

- Given by intra-muscular injection, 0.5 ml
- Study ongoing in the US, Chile and Peru (NCT04516746. ClinicalTrials.gov website)
- Subjects 18+ yo
- 25% subjects 65+ yo

- Study enrollment diversity targets were selected in agreement with US Government/OWS recommendations.

IM = intramuscular; yo = years old.

1. Study NCT04516746. ClinicalTrials.gov website; 2. AstraZeneca Pharmaceuticals LP. Clinical Study Protocol (D8110C00001).

Phase III Study D8110C00001 Case Definition Of Symptomatic COVID-19 Disease

Primary efficacy endpoint: *Symptomatic illness*

- First case of SARS-CoV-2 RT-PCR-positive symptomatic illness occurring > 14 days post administration of study intervention. Participants included if they meet following criteria at any point from Day 1 (initial visit) through Day 14

Subjects will be counted as a case if they have: 1) One or more category A findings OR 2) Two or more category B symptoms

Specificity (Pathogen Confirmation)	Category A: Lower respiratory tract involvement (one or more)	Category B: Systemic/ other symptoms (two or more)
SARS-CoV-2 confirmed • Positive RT-PCR	• Pneumonia diagnosed by chest x-ray, or CT scan • O_2 sat of ≤ 94% on room air or 2 percentage point drop from baseline • New or worsening dyspnea/ shortness of breath	• Fever > 37.8˚ C (100˚ F) or feverishness • New or worsening cough • Myalgia/ muscle pain • Fatigue that interferes with activities of daily living • Vomiting or diarrhea • Anosmia or ageusia

Safety endpoint:

- Occurrence of adverse events :
  1) Incidence of AEs for 28 days post each dose
  2) Incidence of AEs, MAAEs, and AESIs from Day 1 post treatment throughout study

AE = adverse event; AESI = adverse event of special interest; MAAE = medically attended adverse events.
AstraZeneca Pharmaceuticals LP. Clinical Study Protocol (D8110C00001).

Phase III Study D8110C00001 Diversity And Enrollment

Race	Enrolled[a]
Hispanic/Latin	11.2%
Black or African American	9.8%
Asian	5.3%
American Indian	1.8%
Hawaiian or Pacific Islander	0.4%
White	71.5%

[a]US enrollment only

Age groups and comorbidities[b]	Enrolled
65+ years old	23.6%
<65 years old	76.4%
Has comorbidity	57.8%
No comorbidity	42.2%

[b]Comorbidities include: Chronic Kidney Disease, COPD, Heart Failure, Coronary Artery Disease, Diabetes, Asthma, High Blood Pressure, Liver Disease, BMI 30+.

32,459 participants enrolled; 26,327 received second dose by Jan 21, 2021

Phase III Study D8110C00001 Clinical Hold Summary

- Study was initiated on 28 Aug and paused by AstraZeneca on 6 Sep. Clinical hold was issued on 9 Sep and lifted on 23 Oct; study restarted on 28 Oct
- The study was paused due to an event of transverse myelitis reported in the Phase II/III study conducted by the University of Oxford in the UK
- **Information provided to FDA:**
  - Additional details on neurological events in studies sponsored by AstraZeneca and University of Oxford
  - Analyses of available clinical safety data from AZD1222 and ChAdOx-1 viral vector platform studies
- **Changes in study conduct implemented**
  - Updated risk language in Informed Consent Form (ICF) and Investigator Brochure (IB)
  - Protocol changes
  - Establishment of independent expert neurology panel
  - Accelerated/increased safety reporting

Non-IND Phase II/III Program Interim Results (Data Cut: November 4th)

Interim Analysis Provided For Regulatory Approval:
23,745 Participants Across Four Studies

UK COV001 (N=1,077)[1]	UK COV002 (N=12,390)[1]	Brazil COV003(N=10,300)[1]	S. Africa COV005 (N=2,070)[1]
Phase I/II single-blinded, adults aged 18–55 yrs	**Phase II/III** single-blinded, ≥18 years (including elderly)	**Phase III** single-blinded, ≥18 years (including elderly)	**Phase I/II** double-blinded, adults aged 18–65 yrs

Primary endpoint: Efficacy (number of virologically confirmed symptomatic cases of COVID-19 [NAAT positive])[1]

- **Global statistical analysis plan for pooling data** developed
- Prespecified analyses that would contribute to assessment of efficacy

11,636[2]

In UK/Brazil Phase 3 studies met inclusion criteria for the primary efficacy analysis

The median follow-up post-dose 1 and dose 2 was 132 and 63 days, respectively

23,745[2]

In all 4 studies met inclusion criteria for the safety analysis

The median follow-up (AZD1222 group) post-dose 1 and dose 2 was 105 and 62 days, respectively

The cutoff date for inclusion in the analysis was November 4, 2020, and the data lock date was November 21, 2020
NAAT = nucleic acid amplification test.

1. Voysey M, et al. Article and supplementary appendix. *Lancet*. 2020. http://dx.doi.org/10.1016/S0140-6736(20)32661-1. Accessed January 21, 2021; 2. COVID-19 Vaccine AstraZeneca, solution for injection in multidose container COVID-19 Vaccine (ChAdOx1-S [recombinant]). https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/949772/UKPAR_COVID_19_Vaccine_AstraZeneca_05.01.2021.pdf. Accessed January 8, 2021.

Summary of Phase III Interim Pooled Efficacy Analyses For AZD1222

In a diverse cohort (geographically and ethnically) pooled analysis demonstrated 70.4% (95.8% CI: 54.8% to 80.6%) efficacy at preventing symptomatic COVID-19

- **Subgroup analysis with SD/SD demonstrated efficacy at preventing symptomatic COVID-19 of 62.1% (41.0% to 75.7%)**

There were no hospitalizations or severe COVID-19 in vaccinated participants from 21 days after first dose

MenACWY = meningococcal group A, C, W, and Y conjugate vaccine; SAE = severe adverse event.

Voysey M, et al. *Lancet*. 2020. http://dx.doi.org/10.1016/S0140-6736(20)32661-1. Accessed January 21, 2021.

Across Four Studies, AZD1222 Exhibited A Favorable Safety Profile

Across all four studies, SAEs occurred in 168 participants (<1%)
79 of whom received AZD1222 (0.7%) and 89 of whom received MenACWY or saline control (0.8%)

There were 175 SAEs, of which 4 were considered possibly related to intervention (either the experimental vaccine or the control)

AZD1222 group

- **Pyrexia:** 2 days after dose 1; treated with paracetamol and resolved the same day
- **Transverse myelitis:** 14 days after dose 2

Control group

- **Autoimmune hemolytic anemia:** 10 days after MenACWY
- **Transverse myelitis**: 2 months after first control dose

Solicited Adverse Events, the majority usually resolved within a few days of vaccination.

- Reactogenicity; the most frequently reported AEs were mild to moderate in severity including injection site tenderness (>60%); injection site pain, headache, fatigue (>50%); myalgia, malaise (>40%); pyrexia, chills (>30%); and arthralgia, nausea (>20%).
- Generally milder and reported less frequently after second dose and in older adults (≥65 years old)

MenACWY = meningococcal group A, C, W, and Y conjugate vaccine; SAE = severe adverse event.

Voysey M, et al. *Lancet*. 2020. http://dx.doi.org/10.1016/S0140-6736(20)32661-1. Accessed January 21, 2021.

Vaccine Storage And Handling

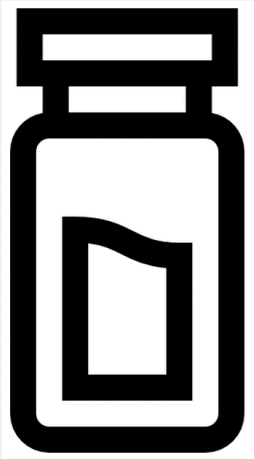
AZD1222 Storage And Administration

Storage

Refrigerator

- Store in refrigerator (2 to 8°C)
- Shelf life = 6 months
- Do not freeze
- Keep vials in outer carton to protect from light

Administration



Multi-dose Vial

- After first puncture cumulatively store up to 6 hours at room temperature or up to 48 hours at 2-8°C with total storage time not to exceed 48 hours.
- No dilution or reconstitution

Summary

Summary: AZD1222 offers a potential to address the Global COVID-19 Crisis

- **AZD1222 induces robust immune responses against the SARS-CoV-2 S protein:**
  - Spike Antibodies increased after a second dose with GMTs comparable to convalescent sera
  - Neutralizing Antibodies titers observed in all participants following 2nd dose
  - Strong Th-1 biased CD4+ T Cell response observed
- **US Phase III study ongoing with 32,459 participants enrolled with co-morbidities, older adults and diverse backgrounds**
  - 26,327 received second dose by Jan 21, 2021
- **Efficacy and safety were demonstrated in four Phase I-III studies in UK, Brazil and South Africa**
- **AZD1222 has the potential to address the SARS-CoV-2 pandemic and has been authorized in 18 countries (under emergency use or full approval as of January 25, 2021)**

GMT = geometric mean titer.

Thank You

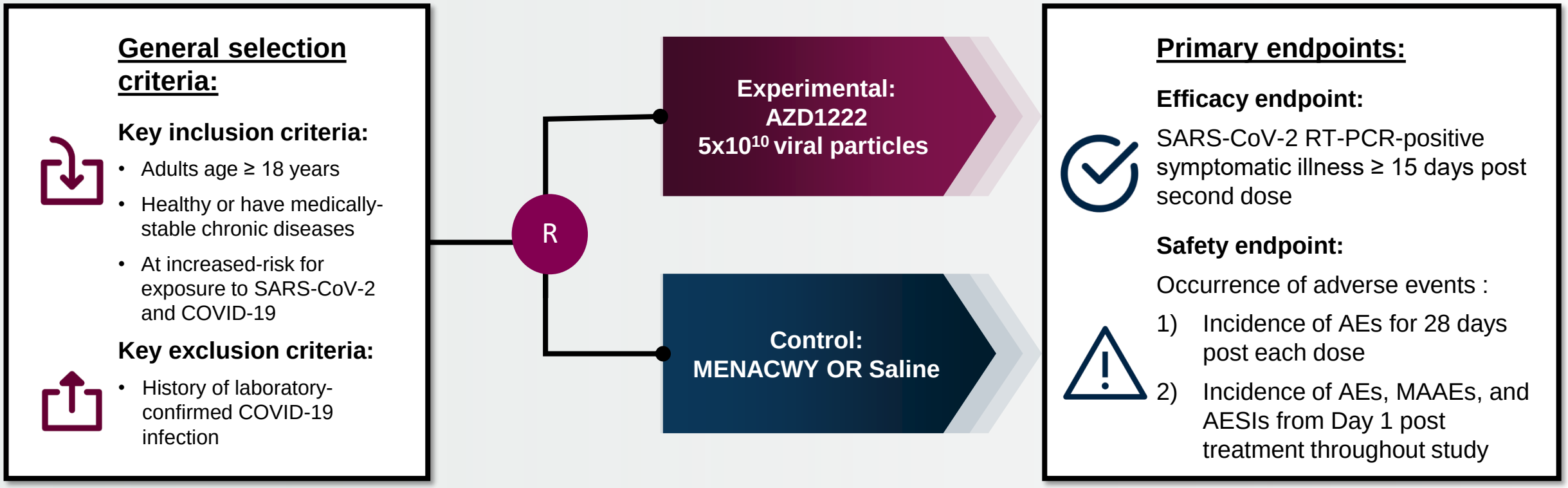
to our collaborators, investigators and subjects:

- University of Oxford
- BARDA
- NIAID
- DoD
- The AstraZeneca Team
- Clinical trial sites personnel and investigators
- **All our trial participants**

Q&A

Back-Up

Phase II/III Program to evaluate safety and efficacy of AZD1222 in over 20,000 volunteers



AE = adverse event; AESI = adverse event of special interest.

Voysey M, et al. Article and supplementary appendix. *Lancet*. 2020. http://dx.doi.org/10.1016/S0140-6736(20)32661-1. Accessed January 21, 2021.

Efficacy Based On Symptomatic, Virologically-Confirmed COVID-19 Cases > 14 Days Post 2nd Dose

	Total number of cases	AZD1222 n/N (%)	Control n/N (%)	VE (95% CI) unless indicated
All LD/SD and SD/SD recipients	131	30/5807 (0.5%)	101/5829 (1.7%)	70.4% (54.8%, 80.6%)[a]
COV002 (UK)	86	18/3744 (0.5%)	68/3804 (1.8%)	73.5% (55.5%, 84.2%)
LD/SD recipients	33	3/1367 (0.2%)	30/1374 (2.2%)	90.0% (67.4%, 97.0%)[b,c]
SD/SD recipients	53	15/2377 (0.6%)	38/2430 (1.6%)	60.3% (28.0%, 78.2%)
COV003 (Brazil) SD/SD	45	12/2063 (0.6%)	33/2025 (1.6%)	64.2% (30.7%, 81.5%)[b]
All SD/SD recipients	98	27/4440 (0.6%)	71/4455 (1.6%)	62.1% (41.0%, 75.7%)

[a]95.8% CI used for primary analysis. [b]Vaccine efficacy calculated from a reduced robust Poisson model that was not adjusted for age. All other models included an adjustment for age. [c]P value for interaction term comparing LD/SD with SD/SD is P=0.010.
CI = confidence interval; LD = low dose (2.2×10^{10} vp); SD = standard dose (5×10^{10} vp); vp = virus particles.
Voysey M, et al. *Lancet*. 2020. http://dx.doi.org/10.1016/S0140-6736(20)32661-1. Accessed January 21, 2021.

Longer Dose Interval Was Associated With Increased Spike-Binding Antibody Responses in Participants Seronegative At Baseline

SD/SD

Subgroup	Baseline GMT (95% CI)	28 days after dose 1 GMT (95% CI)	28 days after dose 2 GMT (95% CI)
Dose interval			
<6 weeks	(N=481) **60.51** (54.1, 67.7)	(N=479) **8734.08** (7883.1, 9676.9)	(N=443) **22222.73** (20360.5, 24255.3)
6–8 weeks	(N=137) **58.02** (46.3, 72.6)	(N=99) **7295.54** (5857.4, 9086.7)	(N=116) **24363.10** (20088.5, 29547.3)
9–11 weeks	(N=110) **48.79** (39.6, 60.1)	(N=87) **7492.98** (5885.1, 9540.2)	(N=106) **34754.10** (30287.2, 39879.8)
≥12 weeks	(N=154) **52.98** (44.4, 63.2)	(N=152) **8618.17** (7195.4, 10322.3)	(N=154) **63181.59** (55180.1, 72343.4)

LD/SD

Subgroup	Baseline GMT (95% CI)	28 days after dose 1 GMT (95% CI)	28 days after dose 2 GMT (95% CI)
Dose interval			
<6 weeks	(N=3) **50.92** (3.9, 669.2)	(N=3) **7496.44** (1461.4, 38454.7)	(N=3) **22121.36** (8547.7, 57250.2)
6–8 weeks	-	-	-
9–11 weeks	(N=30) **64.09** (40.4, 101.6)	(N=30) **4803.21** (3255.7, 7086.4)	(N=29) **36928.89** (24509.6, 55641.2)
≥12 weeks	(N=35) **52.42** (37.7, 72.9)	(N=35) **6750.27** (4184.6, 10889.0)	(N=35) **66274.91** (49546.6, 88651.1)

Similar results were seen with the nAb responses by pseudoneutralisation assay

nAb = neutralizing antibody.

COVID-19 Vaccine AstraZeneca, solution for injection in multidose container COVID-19 Vaccine (ChAdOx1-S [recombinant]).
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/949772/UKPAR_COVID_19_Vaccine_AstraZeneca_05.01.2021.pdf. Accessed January 8, 2021.

Vaccine Efficacy Is Higher With a Longer Interval Between Doses

Subgroup analyses of vaccine efficacy as a function of dose interval showed a trend for increasing vaccine efficacy associated with longer dose interval

Vaccine efficacy by dose interval at interim analysis: COVID-19 cases: ≥15 days post second dose

Case definition: Primary – any COVID-19	Participants with events, n (%)		Vaccine efficacy (%)	95% CI (%)	P-value
	AZD1222 n / N (%)	Control n / N (%)			
Dose interval					
8–11 weeks	9 / 1444 (0.62)	34 / 1488 (2.28)	72.85	(43.45, 86.97)	<0.001
> 11 weeks	7 / 2093 (0.33)	39 / 2116 (1.84)	81.90	(59.53, 91.90)	<0.001

CI – confidence interval.

COVID-19 Vaccine AstraZeneca, solution for injection in multidose container COVID-19 Vaccine (ChAdOx1-S [recombinant]). https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/949772/UKPAR_COVID_19_Vaccine_AstraZeneca_05.01.2021.pdf. Accessed January 8, 2021.

Vaccine Efficacy: Single Dose And In Subjects With Co-Morbidities

Single Dose: Participants were censored from the analysis at the earliest time point of when they received a second dose or at 12 weeks post dose 1

	Total Events	AZD1222 n (%) N=7998	Control n (%) N=7982	Vaccine efficacy (%) (95% CI)	p-value
Occurring 22 days after 1st dose through 2nd dose up until 12 weeks	56	12 (0.15)	44 (0.55)	73.00 (48.79, 85.76)	<0.001

Co-morbidities

	Vaccine efficacy (%)	95% CI
Comorbid population[a]	73.4	48.5, 86.3

[a]Comorbidity was defined as BMI ≥30 kg/m2, cardiovascular disorder, respiratory disease or diabetes. The proportion of subjects with comorbidities at baseline was substantial (36%): Obesity (20%); Cardiovascular disease (11%) - Mainly hypertension (5%); Respiratory disease (12%) - Mainly asthma (8%); Diabetes (2%).

COVID-19 Vaccine AstraZeneca, solution for injection in multidose container COVID-19 Vaccine (ChAdOx1-S [recombinant]). https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/949772/UKPAR_COVID_19_Vaccine_AstraZeneca_05.01.2021.pdf. Accessed 8 Jan 2021.

Phase III Study D8110C00001 Inclusion/Exclusion Criteria

Key inclusion criteria:

- Adults age ≥ 18 years
- Healthy or have medically-stable chronic diseases
- At increased-risk for exposure to SARS-CoV-2 and COVID-19
- Able to understand and comply with study requirements/procedures

Key exclusion criteria:

- History of laboratory-confirmed COVID-19 infection

AstraZeneca Pharmaceuticals LP. Clinical Study Protocol (D8110C00001).