Supplementary material of Kulkarni, et al., "Seropersistence of SII-ChAdOx1 nCoV-19 (COVID-19 vaccine): 6-month follow-up of a randomized, controlled, observer-blind, phase 2/3 immuno-bridging study in Indian adults",

Human Vaccines & Immunotherapeutics, 2024

Additional statistical methods

The immunogenicity population, which consisted of all participants in the immunogenicity/reactogenicity cohort who received at least one dose of study vaccine, provided at least one evaluable post-vaccination serum sample and had baseline data available. This was the primary population for immunogenicity analyses. Safety was analysed in the safety population, which consisted of all participants who received at least one dose of study vaccine and had safety data available.

Demographic baseline characteristics were analysed descriptively by vaccine group. Mean, standard deviation, median, and minimum and maximum values were calculated for quantitative variables, and frequencies and percentages were calculated for categorical variables, including distributions of participants according to gender and age groups.

Supplementary tables

Table S1. Baseline characteristics of the study population

	SII-ChAdOx1 nCoV-19 (*N* = 1,200)	AZD1222 (*N* = 100)	Placebo (*N* = 300)	Total (*N* = 1,600)
Age				
Mean, years (SD)	42.1 (13.24)	46.8 (16.29)	40.2 (13.26)	42.0 (13.52)
Age group, years				
18–59	1,048 (87.3)	74 (74.0)	271 (90.3)	1,393 (87.1)
≥60	152 (12.7)	26 (26.0)	29 (9.7)	207 (12.9)
Sex				
Male	925 (77.1)	80 (80.0)	218 (72.7)	1,223 (76.4)
Female	275 (22.9)	20 (20.0)	82 (27.3)	377 (23.6)
Body mass index				
n	1,200	100	300	1,600
Mean, kg/m^2 (SD)	25.36 (4.154)	25.05 (4.433)	25.29 (4.185)	25.33 (4.176)
Child-bearing potential*				
Yes	147 (53.5)	9 (45.0)	42 (51.2)	198 (52.5)

No	128 (46.5)	11 (55.0)	40 (48.8)	179 (47.5)
SARS-CoV-2 serology results				
Seropositive	26 (2.2)	2 (2.0)	4 (1.3)	32 (2.0)
Seronegative	1,174 (97.8)	98 (98.0)	296 (98.7)	1,568 (98.0)
RT-PCR results				
Negative	1,200 (100)	100 (100)	300 (100)	1,600 (100)
Co-morbidities	284 (23.7)	26 (26.0)	68 (22.7)	378 (23.6)

Data are *n* (%) unless stated otherwise. *Female participants only and percentages are based on the total number of female participants. RT-PCR, reverse transcription polymerase chain reaction; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2; SD, standard deviation.

Table S2. Summary of anti-S and anti-RBD IgG and nAbs in the baseline seronegative population (immunogenicity analysis population)

Timepoint	Statistic	Anti-S		Anti-RBD		nAbs	
		SII-ChAdOx1 nCoV-19 (N = 288)	AZD1222 (N = 96)	SII-ChAdOx1 nCoV-19 (N = 297)	AZD1222 (N = 98)	SII-ChAdOx1 nCoV-19 (N = 288)	AZD1222 (N = 96)
Visit 4 – Day 57 (+14)	n	284	94	284	94	282	94
	GMT	29,192.1	27,573.7	37,253.1	35,423.0	66.1	54.2
	(95% CI)	(25,875.4–32,933.9)	(22,916.6–33,177.2)	(32,757.5–42,365.7)	(29,287.1–42,844.5)	(57.8–75.7)	(43.1–68.2)
	GMFR	354.1	394.7	242.6	249.4	13.3	12.2
	(95% CI)	(293.1–427.8)	(295.6–527.1)	(206.0–285.7)	(191.8–324.3)	(11.5–15.4)	(9.5–15.8)

Timepoint	Statistic	Anti-S		Anti-RBD		nAbs	
		SII-ChAdOx1 nCoV-19 (*N* = 288)	AZD1222 (*N* = 96)	SII-ChAdOx1 nCoV-19 (*N* = 297)	AZD1222 (*N* = 98)	SII-ChAdOx1 nCoV-19 (*N* = 288)	AZD1222 (*N* = 96)
Visit 6 –	*n*	249	86	249	86	80	29
Day 180	GMT	9,769.8	14,942.8	11,234.9	18,472.2	25.2	27.4
(+28)	(95% CI)	(8,177.3–11,672.4)	(9,869.9–22,623.1)	(9,234.1–13,669.2)	(12,102.8–28,193.6)	(17.6–36.0)	(12.4–60.3)
	GMFR	117.9	197.8	72.4	126.1	5.0	6.4
	(95% CI)	(92.7–150.0)	(120.7–323.9)	(57.8–90.6)	(78.6–202.2)	(3.4–7.3)	(2.8–14.9)

Anti-RBD, anti-receptor binding domain; anti-S, anti-spike; CI, confidence interval; GMFR, geometric mean fold rise; GMT, geometric mean titer; IgG, immunoglobulin; nAb, neutralizing antibody.

Table S3. Proportion of participants with seroconversion for anti-S and anti-RBD IgG and nAbs in the baseline seronegative population (immunogenicity analysis population)

Timepoint	Statistic	Anti-S		Anti-RBD		nAbs	
		SII-ChAdOx1 nCoV-19 (N = 288)	AZD1222 (N = 96)	SII-ChAdOx1 nCoV-19 (N = 288)	AZD1222 (N = 96)	SII-ChAdOx1 nCoV-19 (N = 288)	AZD1222 (N = 96)
Visit 4 – Day 57 (+14)	N evaluated	284	94	284	94	282	94
	Seroconversion, n (%)	280 (98.6)	94 (100.0)	277 (97.5)	93 (98.9)	241 (85.5)	79 (84.0)
	95% CI	96.4–99.6	96.2–100.0	95.0–99.0	94.2–100.0	80.8–89.4	75.0–90.8
Visit 6 – Day 180 (+28)	N evaluated	249	86	249	86	80	29
	Seroconversion, n (%)	239 (96.0)	85 (98.8)	232 (93.2)	82 (95.3)	46 (57.5)	15 (51.7)
	95% CI	92.7–98.1	93.7–100.0	89.3–96.0	88.5–98.7	45.9–68.5	32.5–70.6

Anti-RBD, anti-receptor binding domain; anti-S, anti-spike; CI, confidence interval; IgG, immunoglobulin; nAb, neutralizing antibody.

Table S4. Incidence of COVID-19 (symptomatic, asymptomatic, and symptomatic + asymptomatic) after first dose of study vaccine (Day 1) through Day 180

Parameter	ChAdOx1 nCoV-19 (N = 1,200)	Placebo (N = 300)	AZD1222 (N = 100)
Symptomatic COVID-19	43 (3.6)	19 (6.3)	5 (5.0)
	(2.6–4.8)	(3.9–9.7)	(1.6–11.3)
Asymptomatic COVID-19	45 (3.8)	9 (3)	3 (3.0)
	(2.7–5.0)	(1.4–5.6)	(0.6–8.5)
Symptomatic + asymptomatic COVID-19	88 (7.3)	28 (9.3)	8 (8.0)
	(5.9–9.0)	(6.3–13.2)	(3.5–15.2)
Hospitalization for COVID-19	13 (1.1)	3 (1.0)	1 (1.0)
	(0.6–1.8)	(0.2–2.9)	(0–5.4)
Severe COVID-19	0	1 (0.3)	0
		(0–1.8)	
Deaths	0	0	0

Data are *n* (%) and 95% CI. CI, confidence interval; COVID-19, coronavirus disease 2019.