

Supplementary Appendix

Supplementary to: Tang J, Zhu C, Xu Q, et al. Immunogenicity of Tetravalent Protein Vaccine, SCTV01E-2 against SARS-CoV-2 EG.5 Subvariant: a Phase 2 Trial.

This appendix has been provided by the authors to give readers additional information about the work.

Supplementary Appendix	1
Table S1. Demographic Characteristics of Participants in the Immunogenicity Per-Protocol Set ...	3
Figure S1. Subgroup Analysis of GMT and LS GMR of Live Virus nAb against Omicron EG.5 ...	5
Figure S2. Subgroup Analysis of SRR of Live Virus nAb against Omicron EG.5	6
Figure S3. Subgroup Analysis of GMT and LS GMR of Live Virus nAb against Omicron XBB.1	7
Figure S4. Subgroup Analysis of SRR of Live Virus nAb against Omicron XBB.1	8

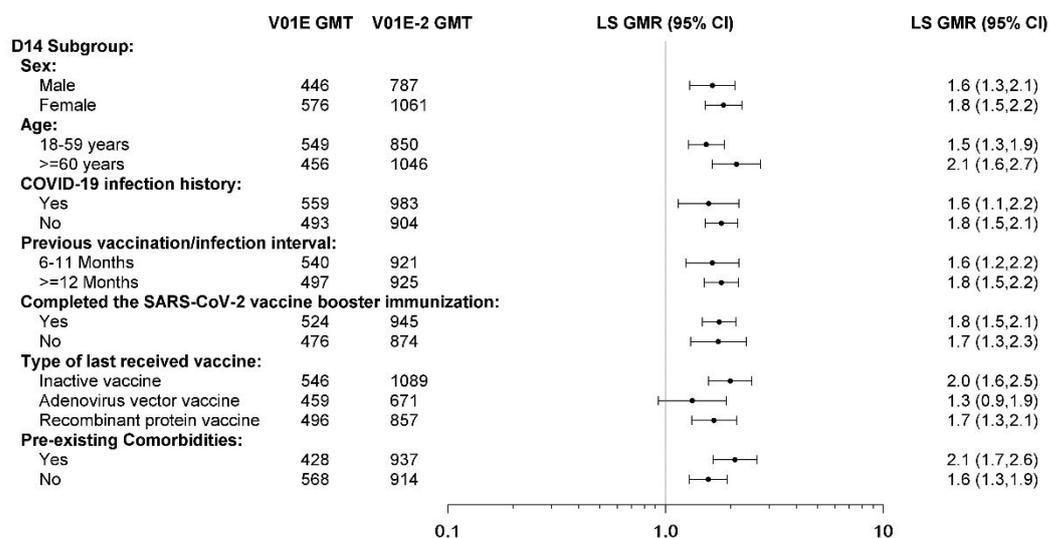
Table S1. Demographic Characteristics of Participants in the Immunogenicity Per-Protocol Set

	SCTV01E (N = 196) n (%)	SCTV01E-2 (N = 203) n (%)	Total (N = 399) n (%)
Age (Year)			
N	196	203	399
Mean (SD)	55.9 (12.5)	55.0 (11.7)	55.4 (12.1)
Median (Min, Max)	57.5 (20, 81)	58.0 (19, 83)	58.0 (19, 83)
Age subgroups-randomization, n (%)			
18-59 years	120 (61.2)	121 (59.6)	241 (60.4)
≥60 years	76 (38.8)	82 (40.4)	158 (39.6)
Sex, n (%)			
Male	91 (46.4)	93 (45.8)	184 (46.1)
Female	105 (53.6)	110 (54.2)	215 (53.9)
Nation, n (%)			
Han	195 (99.5)	203 (100.0)	398 (99.7)
Others	1 (0.5)	0	1 (0.3)
BMI (kg/m²) ‡			
N	196	203	399
Mean (SD)	26.0 (3.5)	26.5 (3.5)	26.3 (3.5)
Median (Min, Max)	25.8 (18.9, 38.6)	26.6 (16.4, 39.8)	26.1 (16.4, 39.8)
History of SARS-CoV-2 infection, n (%)			
Yes	53 (27.0)	52 (25.6)	105 (26.3)
No	143 (73.0)	151 (74.4)	294 (73.7)
Previous vaccination/infection interval, n (%)			
6-11 months	62 (31.6)	63 (31.0)	125 (31.3)
≥12 months	134 (68.4)	140 (69.0)	274 (68.7)
IgM at baseline			
Positive	0	0	0
Negative	196 (100.0)	203 (100.0)	399 (100.0)

	SCTV01E (N = 196) n (%)	SCTV01E-2 (N = 203) n (%)	Total (N = 399) n (%)
Booster dose of COVID-19 vaccine, n (%)			
Yes	143 (73.0)	145 (71.4)	288 (72.2)
No	53 (27.0)	58 (28.6)	111 (27.8)
Type of last received COVID-19 vaccine-randomization, n (%)			
Inactive vaccine	91 (46.4)	97 (47.8)	188 (47.1)
Adenovirus vector vaccine	38 (19.4)	33 (16.3)	71 (17.8)
Recombinant protein vaccine	67 (34.2)	73 (36.0)	140 (35.1)
Other vaccines	0	0	0
Pre-existing comorbidities, n (%)			
Yes	74 (37.8)	90 (44.3)	164 (41.1)
No	122 (62.2)	113 (55.7)	235 (58.9)

‡ BMI, the body mass index. The body-mass index is the weight in kilograms divided by the square of the height in meters.

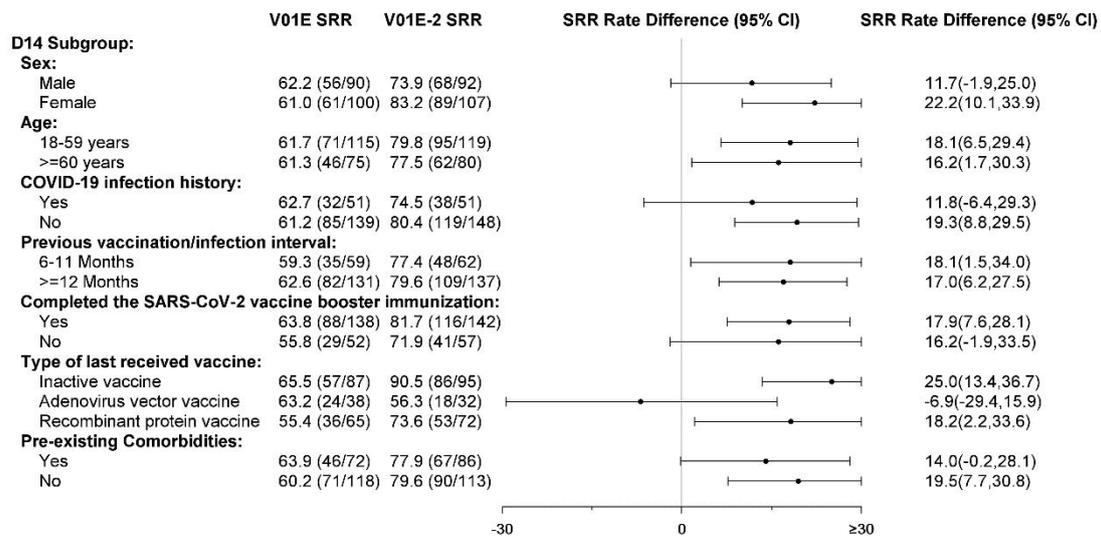
Figure S1. Subgroup Analysis of GMT and LS GMR of Live Virus nAb against Omicron EG.5



The subgroup analysis was conducted among the population in the immunogenicity per-protocol set, who had a valid immunogenicity test result prior to the administration of study vaccines and after the administration of study vaccines and had a negative result of anti-spike receptor binding domain (RBD) IgM test at baseline but without major protocol deviations.

Abbreviations: GMT, geometric mean titer; LS GMR, least square geometric mean ratio.

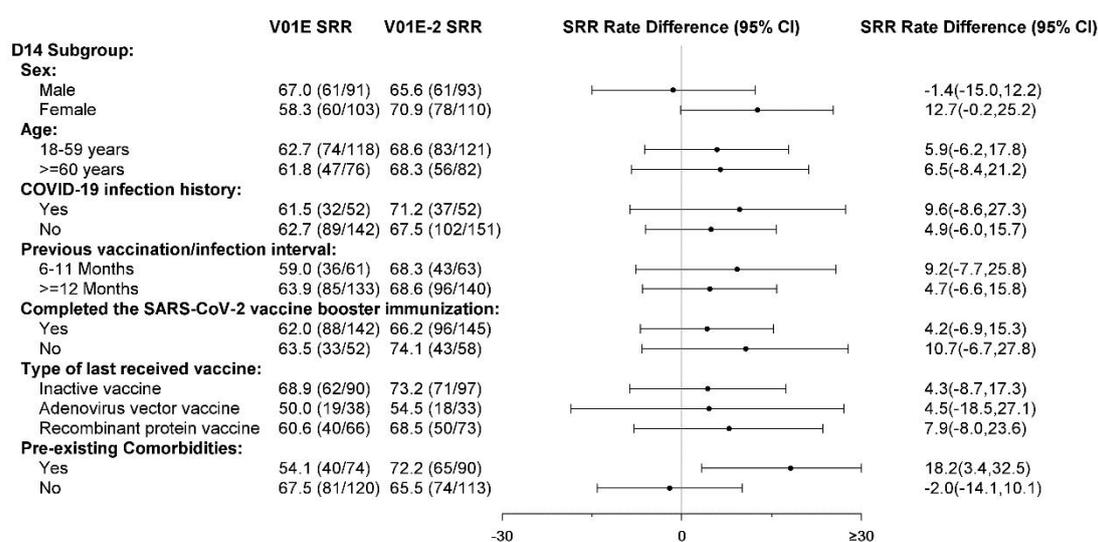
Figure S2. Subgroup Analysis of SRR of Live Virus nAb against Omicron EG.5



The subgroup analysis was conducted among the population in the immunogenicity per-protocol set, who had a valid immunogenicity test result prior to the administration of study vaccines and after the administration of study vaccines and had a negative result of anti-spike receptor binding domain (RBD) IgM test at baseline but without major protocol deviations. Seroresponse was defined as a change from below the low limit of quantitation (LLOQ) to equal to or above LLOQ, or more than a 4-fold rise if the baseline is equal to or above LLOQ in nAb from baseline.

Abbreviations: SRR, seroresponse rate.

Figure S4. Subgroup Analysis of SRR of Live Virus nAb against Omicron XBB.1.



The subgroup analysis was conducted among the population in the immunogenicity per-protocol set, who had a valid immunogenicity test result prior to the administration of study vaccines and after the administration of study vaccines and had a negative result of anti-spike receptor binding domain (RBD) IgM test at baseline but without major protocol deviations. Seroreponse was defined as a change from below the low limit of quantitation (LLOQ) to equal to or above LLOQ, or more than a 4-fold rise if the baseline is equal to or above LLOQ in nAb from baseline.

Abbreviations: SRR, seroreponse rate.