Supplemental appendix 2

Supplement to: Safety and immunogenicity of an inactivated virus particle vaccine for SARS-CoV-2, BIV1-CovIran: findings from double-blind, randomised, placebo-controlled, phase I and II clinical trials among healthy adults

Mohraz M, *et al. BMJ Open* 2022; 12:e056872. doi: 10.1136/bmjopen-2021-056872

Table S1. Solicited and unsolicited adverse events among participants aged 18-50 years in Phase I

Adverse events		Solicited AEs						Unsolicited AEs					
		First administration n(%)			Second administration n(%)			First administration n(%)			Second administration n(%)		
		Placebo	3 µg	5 µg	Placebo	3 µg	5 µg	Placebo	3 µg	5 µg	Placebo	3 µg	5 µg
Injection site involvement	Pain in the injection site	2(25.0)	6(25.0)	8(33.3)	4(50.0)	7(30.4)	8(33.3)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(4.2)
	Induration/Swelling in the injection site	0(0.0)	1(4.2)	0(0.0)	0(0.0)	0(0.0)	2(8.3)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
	Erythema/Redness in the injection site	1(12.5)	1(4.2)	0(0.0)	0(0.0)	0(0.0)	2(8.3)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
General reactions	Fatigue	1(12.5)	1(4.2)	0(0.0)	0(0.0)	2(8.7)	5(20.8)	1(12.5)	2(8.3)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
	Myalgia	0(0.0)	6(25.0)	3(12.5)	1(12.5)	5(21.7)	7(29.2)	0(0.0)	3(12.5)	0(0.0)	0(0.0)	3(13)	3(12.5)
	Fever	2(25)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
	Chills	0(0.0)	0(0.0)	2(8.3)	0(0.0)	0(0.0)	2(8.3)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
	Flushing	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(4.3)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(4.3)	0(0.0)
Upper and lower respiratory system disorders	Dyspnea	0(0.0)	1(4.2)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
	Tachypnea	1(12.5)	4(16.7)	0(0.0)	1(12.5)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
	Coughing	0(0.0)	0(0.0)	1(4.2)	1(12.5)	1(4.3)	2(8.3)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
	Sore Throat	1(12.5)	0(0.0)	0(0.0)	1(12.5)	0(0.0)	1(4.2)	0(0.0)	1(4.2)	0(0.0)	1(12.5)	1(4.3)	0(0.0)
	Rhinitis	1(12.5)	0(0.0)	0(0.0)	0(0.0)	1(4.3)	2(8.3)	0(0.0)	0(0.0)	1(4.2)	0(0.0)	1(4.3)	0(0.0)
	Chest pain	1(12.5)	1(4.2)	1(4.2)	0(0.0)	0(0.0)	1(4.2)	0(0.0)	0(0.0)	2(8.3)	0(0.0)	0(0.0)	1(4.2)
Gastrointestinal, stomach and urinary disorders	Nausea/Vomiting	0(0.0)	0(0.0)	2(8.3)	0(0.0)	0(0.0)	1(4.2)	0(0.0)	0(0.0)	0(0.0)	1(12.5)	0(0.0)	1(4.2)
	Abdominal Pain	0(0.0)	1(4.2)	2(8.3)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(4.2)	0(0.0)	0(0.0)	1(4.3)	0(0.0)
	Diarrhea	0(0.0)	0(0.0)	1(4.2)	0(0.0)	2(8.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(4.3)	0(0.0)
	Renal pain	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(4.2)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Skin and subcutaneous tissue disorders	Pruritus	0(0.0)	2(8.3)	2(8.3)	1(12.5)	2(8.7)	1(4.2)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(4.2)
	Erythema	0(0.0)	1(4.2)	0(0.0)	1(12.5)	2(8.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
	Hair loss	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(12.5)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Cardiovascular system disorders	Tachycardia	1(12.5)	1(4.2)	1(4.2)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
	Hypotension (systolic)	0(0.0)	1(4.2)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Nervous system disorders	Headache	3(37.5)	8(33.3)	6(25.0)	2(25.0)	3(13)	7(29.2)	1(12.5)	1(4.2)	0(0.0)	0(0.0)	1(4.3)	2(8.3)
	Dizziness	0(0.0)	2(8.3)	0(0.0)	0(0.0)	2(8.7)	2(8.3)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(4.3)	0(0.0)
	Paresthesia	0(0.0)	1(4.2)	0(0.0)	0(0.0)	0(0.0)	2(8.3)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
	Dysphonia	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(4.2)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Eye involvement	Periorbital Oedema	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(4.2)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
	Abnormal vision	0(0.0)	1(4.2)	0(0.0)	0(0.0)	0(0.0)	1(4.2)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
	Abnormal sensation in eye	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(4.2)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Infections and infestations	Herpes simplex	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(4.3)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)

Table S2. Solicited and unsolicited adverse events among participants aged 51-75 years in Phase I

Adverse events		Solicited AEs				Unsolicited AEs			
		First administration n(%)		Second administration n(%)		First administration n(%)		Second administration n(%)	
		Placebo	5 μg	Placebo	5 μg	Placebo	5 μg	Placebo	5 μg
Injection site involvement	Pain in the injection site	1(12.5)	8(34.8)	2(25)	6(26.1)	0(0.0)	0(0.0)	0(0.0)	1(4.4)
General reactions	Fever	0(0.0)	0(0.0)	0(0.0)	1(4.4)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
	Weakness	0(0.0)	1(4.4)	0(0.0)	3(13.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
	Fatigue	0(0.0)	0(0.0)	0(0.0)	1(4.4)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
	Myalgia	0(0.0)	0(0.0)	1(12.5)	2(8.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
	Flushing	1(12.5)	2(8.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
	Increased sweating	0(0.0)	0(0.0)	0(0.0)	1(4.4)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Upper and lower respiratory system disorders	Rhinitis	0(0.0)	0(0.0)	0(0.0)	1(4.4)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
	Coughing	0(0.0)	0(0.0)	0(0.0)	5(21.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
	Sore Throat	0(0.0)	1(4.4)	0(0.0)	1(4.4)	0(0.0)	0(0.0)	0(0.0)	1(4.4)
	Tachypnea	0(0.0)	0(0.0)	0(0.0)	3(13.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Gastrointestinal, stomach and urinary disorders	Diarrhea	0(0.0)	2(8.7)	0(0.0)	1(4.4)	0(0.0)	0(0.0)	0(0.0)	2(8.7)
	Nausea	0(0.0)	1(4.4)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
	Abdominal Pain	0(0.0)	0(0.0)	0(0.0)	1(4.4)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
	Constipation	0(0.0)	1(4.4)	1(12.5)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Cardiovascular system disorders	Tachycardia	0(0.0)	1(4.4)	0(0.0)	1(4.4)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
	Bradycardia	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(4.4)	0(0.0)	0(0.0)
	Hypertension (Systolic)	0(0.0)	0(0.0)	0(0.0)	1(4.4)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Nervous system disorders	Vertigo	0(0.0)	1(4.4)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
	Headache	1(12.5)	2(8.7)	1(12.5)	3(13.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)

Table S3. Laboratory assessment of the participants aged 18-50 years in Phase I

Test (Unit)	Day	3µg group			5µg group			Placebo group		
		Mean	Range of values	Abnormal values	Mean	Range of values	Abnormal values	Mean	Range of values	Abnormal values
Hematocrit (g/dL)	0	43.7	35.3-51.6	0	43.4	39.9-53.1	0	44.3	42.2-49.4	0
	7	43.4	34.1-50.4	0	43.0	40.4-52.2	0	43.0	42.1-49.5	0
	14	43.1	34.1-50.3	0	43.0	40.5-51.5	0	44.6	39.8-86.0	1
	21	43.3	35.0-49.8	0	42.4	40.0-51.4	0	44.4	39.8-46.8	0
	28	43.1	34.9-50.6	0	43.1	39.4-50.3	0	43.9	40.7-46.6	0
Hemoglobin (g/dL)	0	16.2	11.6-17.4	1	16.0	12.7-17.7	0	14.2	13.3-16.1	0
	7	16.3	11.1-16.9	2	15.9	13.2-16.9	0	13.7	13.3-16.5	0
	14	16.1	11.2-16.9	1	16.0	13.1-17.4	0	14.3	13.1-41.2	1
	21	15.9	11.4-16.9	1	15.8	12.9-16.8	0	14.0	12.9-16.0	0
	28	15.8	11.3-16.9	1	15.8	12.8-16.8	0	13.4	13.0-15.9	0
White Blood Cells (/µliter)	0	6791.7	3660.0-10030.0	2	6400.8	4280.0-9120.0	0	7062.9	3810.0-7450.0	1
	7	6750.8	4000.0-9070.0	0	6746.3	4590.0-9210.0	0	7357.1	3810.0-8800.0	1
	14	6971.7	3200.0-9930.0	1	6995.7	4970.0-9970.0	0	6966.3	5380.0-9080.0	0
	21	7017.4	3880.0-10630.0	1	6771.3	4940.0-9170.0	0	6557.5	5380.0-7750.0	0
	28	6918.2	3560.0-8760.0	2	6397.9	4290.0-9290.0	0	7141.4	3880.0-9270.0	1
Neutrophils (%)	0	58.8	42.9-74.5	0	55.9	41.0-69.7	0	53.0	46.6-60.7	0
	7	57.1	44.0-69.0	0	55.9	40.0-70.1	0	54.5	37.9-60.4	0
	14	55.9	44.6-68.1	0	54.8	41.8-67.0	0	50.1	41.1-62.5	0
	21	58.0	40.0-70.6	0	55.1	44.1-68.7	0	51.3	33.6-66.5	0
	28	58.2	41.0-73.0	0	57.9	37.9-72.0	0	49.0	40.7-61.4	0
Lymphocytes (%)	0	32.5	19.6-38.8	0	33.7	17.3-51.0	0	39.0	30.3-44.0	0
	7	32.7	25.1-46.1	0	34.6	21.8-51.0	0	36.7	30.1-51.7	0
	14	34.1	22.1-43.2	0	36.5	26.7-54.6	0	40.5	29.4-47.6	0
	21	32.2	21.4-49.0	0	33.7	26.0-43.1	0	39.6	25.9-55.4	0
	28	32.4	19.5-50.0	0	32.0	21.9-39.8	0	40.9	29.6-49.2	0
Monocytes (%)	0	6.2	3.5-7.6	0	7.1	4-12.4	0	6.0	4.0-7.6	0
	7	6.9	4.0-8.9	0	5.8	0.2-9.2	0	6.0	4.2-7.5	0
	14	6.7	2.0-9.4	0	6.5	3.0-8.4	0	6.4	5.5-7.0	0
	21	6.5	2.0-9.2	0	7.1	5.0-8.4	0	6.5	5.0-7.3	0
	28	6.0	0.4-8.7	0	6.5	3.0-7.9	0	7.2	5.0-9.8	0
Eosinophils (%)	0	2.4	0.2-5.4	0	2.5	0.4-8.9	0	2.1	0.8-3.5	0
	7	3.1	0.1-10.4	0	3.2	0.7-16.9	0	2.4	1.1-4.2	0
	14	3.2	0.5-10.6	0	3.4	1.0-9.2	0	2.8	1.1-4.7	0
	21	3.7	0.5-6.3	0	3.9	1.0-20.3	0	2.4	1.3-3.5	0
	28	3.3	0.3-15.0	0	3.9	0.7-5.7	0	2.7	1.2-4.3	0
Basophils (%)	0	0.2	0.1-0.5	0	0.3	0.1-1.0	0	0.1	0.1-0.3	0
	7	0.3	0.1-0.6	0	0.4	0.1-2.0	0	0.2	0.1-0.4	0
	14	0.2	0.1-0.3	0	0.2	0.1-0.3	0	0.2	0.1-0.4	0
	21	0.3	0.1-0.5	0	0.2	0.1-0.5	0	0.2	0.1-0.3	0
	28	1.6	0.1-2.0	0	0.4	0.1-3.0	0	0.3	0.1-0.3	·
Platelet count (/µliter)	0	273838.7	162000.0-406000.0	0	258291.7	193000.0-353000.0	0	273500.0	227000.0-353000.0	0
	7	293000.0	176000.0-374000.0	0	268250.0	185000.0-371000.0	0	268125.0	227000.0-351000.0	0
	14	295087.0	178000.0-422000.0	0	273090.9	187000.0-434000.0	0	283750.0	240000.0-348000.0	0
	21	292583.3	182000.0-405000.0	0	277666.7	180000.0-382000.0	0	288125.0	219000.0-338000.0	0
	28	281739.1	160000.0-398000.0	0	263916.7	178000.0-359000.0	0	270500.0	235000.0-290000.0	·
SGOT (U/µliter)	0	20.5	10.0-45.0	1	21.0	14.0-30.0	0	18.9	14.0-23.0	0

	7	20.5	15.0-57.0	3	21.3	14.0-47.0	1	20.0	14.0-30.0	0
	14	19.9	12.0-30.0	0	20.0	13.0-38.0	1	19.5	12.0-25.0	0
	21	20.6	12.0-32.0	0	21.4	12.0-47.0	1	18.1	13.0-26.0	0
	28	NE*	NE	NE	NE	NE	NE	NE	NE	-
	0	18.7	7.0-77.0	3	20.3	4.0-47.0	2	18.0	12.0-31.0	0
	7	20.4	7.7-68.0	3	24.5	7.0-62.0	2	16.6	11.0-42.0	1
SGPT (U/µliter)	14	20.8	9.0-49.0	2	21.5	7.0-55.0	4	20.3	11.0-27.0	0
	21	18.8	7.0-55.0	1	20.4	5.0-42.0	3	17.1	10.0-30.0	0
	28	NE	NE	NE	NE	NE	NE	NE	NE	-
	0	178.0	106.0-374.0	1	185.0	125.0-310.0	1	179.4	93.0-327.0	1
	7	189.5	118.0-288.0	0	188.7	120.0-402.0	1	161.3	64.0-337.0	1
Alkaline phosphatase (U/µliter)	14	176.7	109.0-326.0	1	171.2	33.0-270.0	0	181.9	118.0-277.0	0
	21	194.3	114.0-302.0	0	176.6	118.0-311.0	0	164.1	103.0-238.0	0
	28	NE	NE	NE	NE	NE	NE	NE	NE	-
	0	0.6	0.1-1.5	0	0..58	0.1-1.3	0	0.5	0.19-0.8	0
	7	0.6	0.2-1.4	0	0.6	0.2-1.4	0	0.5	0.3-0.7	0
Bilirubin (mg/dL)	14	0.6	0.2-1.3	0	0.7	0.1-1.4	0	0.5	0.2-1.4	0
	21	0.6	0.3-1.4	0	0.6	0.2-14	0	0.6	0.3-1.0	0
	28	NE	NE	NE	NE	NE	NE	NE	NE	NE
	0	24.1	15.0-34.0	0	25.4	11.0-35.0	0	23.1	19.0-27.0	0
	7	25.8	19.0-33.0	0	29.5	19.0-44.0	0	26.6	21.0-37.0	0
Urea (mg/dL)	14	24.1	11.0-33.0	0	27.0	16.0-48.0	0	23.5	14.0-30.0	0
	21	24.1	13.0-31.0	0	24.5	13.0-31.0	0	22.6	14.0-32.0	0
	28	24.1	15.0-30.0	0	23.4	11.0-35.0	0	23.1	19.0-27.0	·
	0	0.9	0.8-1.25	0	1.0	0.8-1.2	0	1.0	0.86-1.1	0
	7	0.9	0.8-1.2	0	0.9	0.7-1.2	0	1.0	0.8-1.05	0
Creatinine (mg/dl)	14	1.0	0.8-1.2	0	1.0	0.7-1.2	0	0.9	0.8-1.4	0
	21	0.9	0.8-1.2	0	1.0	0.8-1.2	0	1.0	0.8-1.1	0
	28	NE	NE	NE	NE	NE	NE	NE	NE	NE
	0	140.0	137.0-144.0	0	140.3	137.0-144.0	0	139.0	137.0-141.0	0
	7	139.5	136.0-142.0	0	139.3	136.0-144.0	0	139.5	138.0-141.0	0
Sodium (mmol/L)	14	139.7	137.0-143.0	0	140.0	137.0-142.0	0	140.4	138.0-142.0	0
	21	140.3	138.0-143.0	0	140.0	138.0-145.0	0	139.8	138.0-143.0	0
	28	NE	NE	NE	NE	NE	NE	NE	NE	NE
	0	3.9	3.5-4.3	0	4.1	3.7-4.4	0	4.1	3.7-4.6	0
	7	4.1	3.8-4.6	0	4.1	3.6-4.5	0	4.0	3.6-4.1	0
Potassium (mmol/L)	14	4.0	3.5-4.5	0	4.1	3.7-4.9	0	4.1	3.8-4.3	0
	21	4.1	3.5-4.9	0	4.1	3.7-4.6	0	4.0	3.6-4.4	0
	28	NE	NE	NE	NE	NE	NE	NE	NE	NE

*Not evaluated

Table S4. Laboratory assessment of the participants aged 51-75 years in Phase I

Test (Unit)	Day	5µg group			Placebo group		
		Mean	Range of values	Abnormal values	Mean	Range of values	Abnormal values
Hematocrit (g/dL)	0	43.9	33.0-50.3	0	46.0	43.1-54.6	0
	7	42.5	39.5-50.7	0	45.6	42.1-50.4	0
	14	43.5	35.6-50.6	0	42.5	42.0-50.1	0
	21	43.0	37.2-48.9	0	44.8	41.1-50.2	0
	28	43.1	32.8-50.2	0	44.2	41.1-50.3	0
Hemoglobin (g/dL)	0	13.0	14.1-18.0	0	15.0	14.1-18.0	0
	7	14.0	11.1-17.4	2	15.1	13.8-16.8	0
	14	15.0	11.0-17.1	1	14.0	13.8-16.5	0
	21	14.0	10.1-16.6	1	14.0	13.6-16.6	0
	28	14.0	10.2-16.8	1	14.0	13.6-16.5	0
White Blood Cells (/µliter)	0	6159.6	4300.0-9130.0	0	6692.9	3940.0-9360.0	0
	7	6110.0	4350.0-9050.0	0	6577.5	5090.0-9030.0	0
	14	6212.4	4010.0-9930.0	0	6204.3	3630.0-7640.0	0
	21	6235.0	5080.0-8210.0	0	6290.0	3490.0-7990.0	1
	28	6470.0	3860.0-9430.0	0	6621.7	3980.0-8870.0	0
Neutrophils (%)	0	56.7	41.6-66.3	0	56.8	37.9-66.8	0
	7	53.9	40.1-65.5	0	61.4	40.9-76.0	0
	14	59.4	46.4-73.0	0	50.0	37.0-74.3	0
	21	58.6	41.2-63.0	0	52.7	38.5-70.7	0
	28	56.5	45.8-65.0	0	49.8	38.0-66.0	0
Lymphocytes (%)	0	34.3	25.0-48.0	0	34.4	22.0-56.0	0
	7	37.0	26.0-45.0	0	32.1	19.0-48.0	0
	14	34.8	22.0-44.0	0	35.1	28.0-55.0	0
	21	34.3	6.0-46.0	0	35.9	23.0-52.0	0
	28	35.0	17.0-41.0	0	40.0	26.0-56.0	0
Monocytes (%)	0	6.3	4.0-9.5	0	5.3	3.0-9.4	0
	7	6.1	3.0-9.0	0	6.3	3.9-7.7	0
	14	6.0	3.0-11.0	0	5.8	2.7-9.0	0
	21	6.2	4.0-8.7	0	6.0	3.7-9.9	0
	28	5.2	2.0-8.8	0	5.6	4.0-8.0	0
Eosinophils (%)	0	3.8	0.8-9.0	0	3.2	0.8-8.0	0
	7	3.1	0.9-12.0	0	6.0	2.7-10.0	0
	14	2.8	0.7-10.0	0	4.7	0.7-5.2	0
	21	4.1	1.0-15.0	0	4.3	0.9-5.4	0
	28	3.5	1.0-14.0	0	4.0	1.0-7.0	0
Basophils (%)	0	1.0	0.4-2.3	0	1.0	0.6-1.0	0
	7	2.0	0.2-1.4	0	0.7	0.6-0.9	0
	14	1.0	0.6-1.5	·	0.9	0.6-1.6	0
	21	1.0	0.5-1.2	0	0.7	0.3-1.1	0
	28	1.0	0.3-1.3	0	0.7	0.6-0.7	0
Platelet count (/µliter)	0	265045.5	204000.0-425000.0	0	264125.0	205000.0-318000.0	0
	7	277434.8	195000.0-381000.0	0	267857.1	58000.0-323000.0	1
	14	275428.6	153000.0-384000.0	0	273571.4	60000.0-322000.0	1
	21	279190.5	226000.0-386000.0	0	270500.0	21000.0-312000.0	0

	28	280476.2	183000.0-378000.0	0	277428.6	203000.0-323000.0	0
	0	23.3	16.0-36.0	0	24.8	18.0-35.0	0
	7	23.4	16.0-36.0	0	27.8	21.0-35.0	0
SGOT (U/µliter)	14	21.7	16.0-32.0	0	23.3	19.0-33.0	0
	21	21.8	16.0-43.0	0	20.0	17.0-24.0	0
	28	NE*	NE	NE	NE	NE	NE
	0	19.0	8.0-40.0	0	22.1	13.0-39.0	0
	7	19.0	8.0-47.0	1	21.3	11.0-50.0	2
SGPT (U/µliter)	14	18.6	7.0-30.0	0	22.6	13.0-37.0	0
	21	18.4	10.0-42.0	0	17.8	10.0-31.0	0
	28	NE	NE	NE	NE	NE	NE
	0	165.3	73.0-383.0	1	163.1	101.0-359.0	1
	7	174.7	73.0-366.0	2	197.6	136.0-295.0	0
Alkaline phosphatase (U/µliter)	14	178.5	72.0-316.0	1	171.7	126.0-307.0	1
	21	183.2	88.0-392.0	1	167.4	133.0-320.0	1
	28	NE	NE	NE	NE	NE	NE
	0	0.6	0.4-1.4	1	0.5	0.3-0.7	0
	7	0.6	0.4-1.3	1	0.7	0.5-0.9	0
Bilirubin (mg/dL)	14	0.5	0.1-1.1	0	0.6	0.1-0.9	0
	21	1.0	0.1-1.0	0	0.5	0.2-1.1	0
	28	NE	NE	NE	NE	NE	NE
	0	32.0	22.0-52.0	0	29.5	20.0-49.0	0
	7	29.5	22.0-44.0	0	30.1	22.0-42.0	0
Urea (mg/dL)	14	28.2	17.0-43.0	0	27.9	18.0-47.0	0
	21	32.2	21.0-46.0	0	31.6	24.0-49.0	0
	28	NE	NE	NE	NE	NE	NE
	0	1.0	0.7-1.1	0	1.0	0.7-1.1	0
	7	1.0	0.7-1.2	0	1.0	0.7-1.0	0
Creatinine (mg/dl)	14	1.0	0.7-1.2	0	1.0	0.7-1.0	0
	21	1.0	0.7-1.2	0	0.9	0.7-1.2	0
	28	NE	NE	NE	NE	NE	NE
	0	140.6	138.0-143.0	0	140.3	139.0-141.0	0
	7	140.5	137.0-143.0	0	140.6	138.0-143.0	0
Sodium (mmol/L)	14	141.4	139.0-142.0	0	141.3	138.0-143.0	0
	21	140.6	137.0-143.0	0	140.9	139.0-143.0	0
	28	NE	NE	NE	NE	NE	NE
	0	4.2	3.7-4.6	0	4.0	3.7-4.6	0
	7	4.0	3.5-4.8	0	4.0	3.5-4.2	0
Potassium (mmol/L)	14	4.0	3.9-4.5	0	4.0	3.8-4.6	0
	21	4.0	3.8-4.6	0	4.0	4.0-4.4	0
	28	NE	NE	NE	NE	NE	NE

*Not evaluated

Note: The following laboratory parameters were assessed during the study among all 88 participants of both stages in Phase I at days 0, 7, 14, 21 and 28 after vaccination. As many as 44 participants had abnormal laboratory values; however, none of them were clinically significant. On day 7 after the first injection, a 56-year-old man in the placebo group was presented with thrombocytopenia, which was not severe according to the guidelines of Food and Drug Administration (Guidance for Industry, Toxicity Grading Scale for Healthy Adult and Adolescent Volunteers Enrolled in Preventive Vaccine Clinical Trials). He didn't have any clinical signs or symptoms and his platelets returned to normal levels without any actions in the next timepoint.

Table S5. Geometric mean titres, geometric mean ratios, and seroconversion rates of anti-spike IgG (EuroImmun) at different time points in Phase I and Phase II

Antibody	Geometric mean titer (95% CI)			Geometric mean ratio (95% CI)		Seroconversion rate* (95% CI)		
	3µg	5µg	Placebo	3µg	5µg	3µg	5µg	Placebo
Phase I: Stage I								
Day 0	0.32 (0.20-0.51)	0.19 (0.13-0.27)	0.12 (0.09-0.18)	2.57 (1.12-5.9)	1.51 (0.79-2.88)	N/A**	N/A	N/A
Day 14	0.69 (0.35-1.36)	0.40 (0.24-0.65)	0.12 (0.09-0.18)	5.49 (1.67-18.1)	3.19 (1.34-7.61)	29.17 (12.62-51.09)	33.33 (15.63-55.32)	0 (0-0)
Day 21	1.30 (0.67-2.50)	4.44 (3.10-6.36)	0.20 (0.15-0.27)	6.39 (2.04-19.98)	21.89 (11.58-41.36)	41.67 (22.11-63.36)	91.67 (73.00-98.97)	0 (0-0)
Day 28	1.26 (0.65-2.41)	4.37 (3.43-5.57)	0.13 (0.10-0.17)	9.68 (3.11-30.09)	33.68 (21.62-52.47)	41.67 (22.11-63.36)	91.67 (73.00-98.97)	0 (0-0)
Phase I: Stage II								
Day 0	N/A	0.20 (0.12-0.32)	0.13 (0.07-0.21)	N/A	1.56 (0.67-3.63)	N/A	N/A	N/A
Day 14	N/A	0.33 (0.18-0.63)	0.12 (0.08-0.20)	N/A	2.73 (0.93-8.02)	N/A	9.09 (1.12-29.16)	0 (0-0)
Day 21	N/A	1.89 (1.11-3.22)	0.12 (0.08-0.20)	N/A	15.42 (6.18-38.49)	N/A	63.64 (40.66-82.80)	0 (0-0)
Day 28	N/A	3.07 (1.82-5.18)	0.14 (0.08-0.26)	N/A	21.40 (8.59-53.32)	N/A	77.27 (54.63-92.18)	12.5 (0.32-52.65)
Phase II								
Day 0	N/A	0.25 (0.21-0.29)	0.25 (0.18-0.36)	N/A	0.99 (0.69-1.43)	N/A	N/A	N/A
Day 28	N/A	1.42 (1.17-1.73)	0.36 (0.25-0.53)	N/A	3.91 (2.56-5.95)	N/A	63.64 (56.72-70.16)	16.36 (7.77-28.80)
Day 42	N/A	4.52 (3.95-5.17)	0.61 (0.38-0.96)	N/A	7.48 (5.26-10.62)	N/A	83.25 (77.49-88.05)	25.45 (14.67-39.00)

**Not applicable

Note: Anti-spike IgG (EuroImmun antibody) was reported for both Phases. For Phase I, findings were reported at baseline (day 0), two weeks after the first vaccination (day 14), and two weeks after the second vaccination (day 28) for 3 µg, 5 µg and placebo groups. For Phase II, findings were reported at baseline (day 0), four weeks after the first vaccination (day 28), and two weeks after the second vaccination (day 42) for 5µg and placebo groups. In stage I, one participant in the 3 µg group became PCR positive for COVID-19 on day 7th after the first dose and was thus excluded from the study. In stage II, one participant in the 5 µg group was excluded from the study and did not receive any doses due to white coat syndrome. Another participant in the 5 µg group of Stage II became PCR positive for COVID-19 within a day after second injection and thus was excluded from data analysis. In Phase II, 11 participants in the 5µg group were excluded from the study due to positive RT-PCR for COVID-19 after first injection (N=9), death due to suicide via cyanide toxicity (N=1) and co-administration of another COVID-19 vaccine platform without prior notice (N=1).

Table S6. Solicited and unsolicited adverse events among participants aged 18-75 years in Phase II

Adverse events		Solicited AEs				Unsolicited AEs			
		First administration n(%)		Second administration n(%)		First administration n(%)		Second administration n(%)	
		Placebo	5 μg	Placebo	5 μg	Placebo	5 μg	Placebo	5 μg
Injection site involvement	Pain at injection site	9(16.1)	45(20.1)	10(17.9)	33(15.5)	0(0.0)	1(0.4)	0(0.0)	11(5.2)
	Redness at injection site	0(0.0)	1(0.4)	0(0.0)	1(0.5)	0(0.0)	0(0.0)	0(0.0)	1(0.5)
General reactions	Myalgia	2(3.6)	14(5.4)	2(3.6)	9(4.2)	0(0.0)	2(0.9)	0(0.0)	3(1.4)
	Weakness	0(0.0)	7(3.1)	0(0.0)	1(0.5)	0(0.0)	3(1.3)	1(1.8)	4(1.9)
	Fever	2(3.6)	7(3.1)	1(1.8)	2(0.9)	0(0.0)	1(0.4)	0(0.0)	2(0.9)
	Chills	0(0.0)	1(0.4)	0(0.0)	1(0.4)	0(0.0)	0(0.0)	1(1.8)	3(1.4)
	Fatigue	0(0.0)	0(0.0)	0(0.0)	6(2.8)	0(0.0)	0(0.0)	0(0.0)	1(0.5)
	Flushing	0(0.0)	4(1.8)	1(1.8)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
	Increased sweating	1(1.8)	2(0.9)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
	Skeletal pain	0(0.0)	0(0.0)	1(1.8)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	2(0.9)
	Sleep disorder	0(0.0)	0(0.0)	0(0.0)	1(0.5)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Upper and lower respiratory system disorders	Sore throat	1(1.8)	3(1.3)	0(0.0)	1(0.5)	0(0.0)	1(0.4)	2(3.6)	5(2.3)
	Coughing	1(1.8)	3(1.3)	0(0.0)	0(0.0)	0(0.0)	2(0.9)	1(1.8)	0(0.0)
	Rhinitis	1(1.8)	2(0.9)	0(0.0)	0(0.0)	0(0.0)	2(0.9)	1(1.8)	0(0.0)
	Dyspnea	0(0.0)	0(0.0)	0(0.0)	1(0.5)	0(0.0)	0(0.0)	0(0.0)	1(0.5)
	Epistaxis	0(0.0)	1(0.4)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
	Tachypnea	0(0.0)	0(0.0)	1(1.8)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
	Chest pain	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.5)
Gastrointestinal, stomach and urinary disorders	Abdominal pain	0(0.0)	1(0.4)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	3(1.4)
	Diarrhea	1(1.8)	2(0.9)	2(3.6)	3(1.4)	0(0.0)	1(0.4)	1(1.8)	2(0.9)
	Nausea	0(0.0)	1(0.4)	0(0.0)	2(0.9)	0(0.0)	0(0.0)	0(0.0)	1(0.5)
	Vomiting	0(0.0)	1(0.4)	0(0.0)	3(1.4)	0(0.0)	0(0.0)	1(1.8)	0(0.0)
Skin and subcutaneous tissue disorders	Pruritus	0(0.0)	0(0.0)	0(0.0)	1(0.5)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
	Skin rashes	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1 (1.8)	0(0.0)
	Acne	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1 (1.8)	0(0.0)
Cardiovascular system disorders	Hypotension (systolic)	0(0.0)	1(0.4)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
	Hypertension (systolic)	0(0.0)	0(0.0)	0(0.0)	1(0.5)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
	Tachycardia	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1 (0.4)	0(0.0)	0(0.0)
Nervous system disorders	Dizziness	0(0.0)	1(0.4)	0(0.0)	1(0.5)	0(0.0)	1(0.4)	1(1.8)	1(0.5)
	Headache	1(1.8)	12(5.4)	7(3.3)	7(3.3)	1(1.8)	2(0.9)	2(3.6)	7(3.3)
	Dysphonia	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.4)	0(0.0)	0(0.0)
Infections and infestations	Fungal dermatitis	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.5)
	Dental Abscess	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1 (0.4)	0(0.0)	0(0.0)

Table S7. Geometric mean titres, geometric mean ratios, and seroconversion rates of neutralising antibody at different time points in Phase I and Phase II after sensitivity analysis

Antibody	Geometric mean titer (95% CI)			Geometric mean ratio (95% CI)		Seroconversion rate* (95% CI)		
	3µg	5µg	Placebo	3µg	5µg	3µg	5µg	Placebo
Phase I: Stage I								
Day 0	1.43 (1.22-1.68)	1.19 (0.74-1.92)	1.55 (1.20-2.01)	0.92 (0.69-1.23)	0.76 (0.35-1.67)	N/A**	N/A	N/A
Day 14	1.51 (0.93-2.45)	2.09 (1.26-3.48)	2.36 (0.70-8.00)	0.64 (0.23-1.73)	0.89 (0.31-2.49)	0 (0-0)	19.05 (5.45-41.91)	12.5 (0.32-52.65)
Day 21	4.80 (2.46-9.34)	6.32 (2.79-14.29)	1.31 (1.08-1.60)	3.66 (1.28-10.48)	4.82 (1.29-18.03)	25.00 (8.66-49.10)	57.14 (34.02-78.18)	0. (0-0)
Day 28	4.97 (2.26-10.89)	14.75 (7.43-29.26)	2.76 (0.63-12.11)	1.80 (0.42-7.79)	5.35 (1.39-20.54)	35.00 (15.39-59.22)	71.43 (47.82-88.72)	37.5 (8.52-75.51)
Phase I: Stage II								
Day 0	N/A	0.37 (0.28-0.48)	0.56 (0.41-0.76)	N/A	0.65 (0.41-1.04)	N/A	N/A	N/A
Day 14	N/A	0.92 (0.42-2.02)	0.31 (0.20-0.49)	N/A	2.93 (0.78-10.97)	N/A	22.73 (7.82-45.37)	0 (0-0)
Day 21	N/A	5.39 (2.69-10.83)	0.80 (0.46-1.40)	N/A	6.70 (2.05-21.94)	N/A	77.27 (54.63-92.18)	12.5 (0.32-52.65)
Day 28	N/A	12.52 (7.29-21.51)	0.85 (0.27-2.66)	N/A	14.81 (5.11-42.93)	N/A	100 (84.56-100)	12.5 (0.32-52.65)
Phase II								
Day 0	N/A	0.23 (0.20-0.26)	0.28 (0.21-0.38)	N/A	0.80 (0.60-1.08)	N/A	N/A	N/A
Day 28	N/A	1.16 (0.85-1.57)	0.30 (0.19-0.47)	N/A	3.92 (2.03-7.54)	N/A	51.24 (44.11-58.34)	14.00 (5.82-26.74)
Day 42	N/A	10.98 (8.32-14.47)	0.62 (0.32-1.18)	N/A	17.76 (9.36-33.71)	N/A	85.07 (79.38-89.70)	28.00 (16.23-42.49)

**Not applicable

Geometric mean titres for neutralising antibody is reported in µg/ml.

Note: For Phase I, findings were reported at baseline (day 0), two weeks after the first vaccination (day 14), and two weeks after the second vaccination (day 28) for 3 µg, 5 µg and placebo groups. For Phase II, findings were reported at baseline (day 0), four weeks after the first vaccination (day 28), and two weeks after the second vaccination (day 42) for 5µg and placebo groups. In stage I, one participant in the 3 µg group became PCR positive for COVID-19 on day 7th after the first dose and was thus excluded from the study. In stage II, one participant in the 5 µg group was excluded from the study and did not receive any doses due to white coat syndrome. Another participant in the 5 µg group of Stage II became PCR positive for COVID-19 within a day after second injection and thus was excluded from data analysis. In Phase II, 11 participants in the 5µg group were excluded from the study due to positive RT-PCR for COVID-19 after first injection (N=9), death due to suicide via cyanide toxicity (N=1) and co-administration of another COVID-19 vaccine platform without prior notice (N=1).

Table S8. Geometric mean titres, geometric mean ratios, and seroconversion rates of anti-receptor binding IgG at different time points in Phase I and Phase II after sensitivity analysis

Antibody	Geometric mean titer (95% CI)			Geometric mean ratio (95% CI)		Seroconversion rate* (95% CI)		
	3µg	5µg	Placebo	3µg	5µg	3µg	5µg	Placebo
Phase I: Stage I								
Day 0	0.10 (0.10-0.10)	0.14 (0.08-0.23)	0.10 (0.10-0.10)	1.00 (1.00, 1.00)	1.38 (0.60, 3.13)	N/A**	N/A	N/A
Day 14	0.21 (0.10-0.44)	2.24 (1.18-4.29)	0.10 (0.10-0.10)	2.11 (0.67, 6.64)	22.44 (7.90, 63.73)	20.00 (5.73, 43.66)	80.95 (58.09, 94.55)	0 (0, 0)
Day 21	0.58 (0.24-1.39)	8.38 (5.65-12.43)	0.14 (0.08-0.28)	4.04 (0.98, 16.58)	58.39 (28.42, 119.98)	20.00 (5.73, 43.66)	95.24 (76.18, 99.88)	12.5 (0.32, 52.65)
Day 28	0.86 (0.37-2.01)	8.12 (6.05-10.89)	0.12 (0.09-0.16)	7.25 (1.9, 27.67)	68.27 (41.67, 111.87)	65.00 (40.78, 84.61)	95.24 (76.18, 99.88)	0 (0, 0)
Phase I: Stage II								
Day 0	N/A	0.14 (0.10-0.21)	0.10 (0.10-0.10)	N/A	1.40 (0.74, 2.65)	N/A	N/A	N/A
Day 14	N/A	0.30 (0.14-0.66)	0.10 (0.10-0.10)	N/A	3.03 (0.84, 10.86)	N/A	22.73 (7.82, 45.37)	0 (0, 0)
Day 21	N/A	4.00 (1.84-8.71)	0.10 (0.10-0.10)	N/A	39.98 (11.05, 144.58)	N/A	77.27 (54.63, 92.18)	0 (0, 0)
Day 28	N/A	6.02 (3.26-11.13)	0.10 (0.10-0.10)	N/A	60.23 (21.83, 166.16)	N/A	86.36 (65.09, 97.09)	0 (0, 0)
Phase II								
Day 0	N/A	0.21 (0.18-0.25)	0.19 (0.14-0.25)	N/A	1.15 (0.82, 1.61)	N/A	N/A	N/A
Day 28	N/A	0.98 (0.76-1.27)	0.26 (0.17-0.42)	N/A	3.74 (2.14, 6.54)	N/A	51.24 (44.11, 58.34)	20.00 (10.03, 33.72)
Day 42	N/A	2.86 (2.37-3.44)	0.38 (0.23-0.64)	N/A	7.44 (4.75, 11.65)	N/A	77.61 (71.21, 83.18)	30.00 (17.86, 44.61)

*,**Not applicable

Geometric mean titres for anti-receptor binding domain IgG is reported in RU/ml.

Note: For Phase I, findings were reported at baseline (day 0), two weeks after the first vaccination (day 14), and two weeks after the second vaccination (day 28) for 3 µg, 5 µg and placebo groups. For Phase II, findings were reported at baseline (day 0), four weeks after the first vaccination (day 28), and two weeks after the second vaccination (day 42) for 5µg and placebo groups. In stage I, one participant in the 3 µg group became PCR positive for COVID-19 on day 7th after the first dose and was thus excluded from the study. In stage II, one participant in the 5 µg group was excluded from the study and did not receive any doses due to white coat syndrome. Another participant in the 5 µg group of Stage II became PCR positive for COVID-19 within a day after second injection and thus was excluded from data analysis. In Phase II, 11 participants in the 5µg group were excluded from the study due to positive RT-PCR for COVID-19 after first injection (N=9), death due to suicide via cyanide toxicity (N=1) and co-administration of another COVID-19 vaccine platform without prior notice (N=1).

Table S9. Geometric mean titres, geometric mean ratios, and seroconversion rates of anti-spike glycoprotein IgG at different time points in Phase I and Phase II after sensitivity analysis

Antibody	Geometric mean titer (95% CI)			Geometric mean ratio (95% CI)		Seroconversion rate* (95% CI)		
	3µg	5µg	Placebo	3µg	5µg	3µg	5µg	Placebo
Phase I: Stage I								
Day 0	0.40 (0.16-0.97)	0.16 (0.10-0.25)	0.11 (0.09-0.13)	3.71 (0.91, 15.04)	1.51 (0.74, 3.08)	N/A**	N/A	N/A
Day 14	1.17 (0.34-4.07)	1.60 (0.62-4.08)	0.19 (0.08-0.46)	6.08 (0.81, 45.45)	8.28 (1.71, 40.17)	30.00 (11.89, 54.28)	71.43 (47.82, 88.72)	12.5 (0.32, 52.65)
Day 21	6.52 (2.75-15.46)	50.89 (31.94-81.08)	0.68 (0.30-1.55	9.55 (2.30, 39.68)	74.53 (31.47, 176.52)	80.00 (56.34, 94.27)	100 (83.89, 100)	75.00 (34.91, 96.81)
Day 28	6.72 (2.50-18.02)	67.26 (50.90-88.89)	0.30 (0.13-0.73)	22.15 (4.38, 111.94)	221.87 (116.74, 421.67)	80.00 (56.34, 94.27)	100 (83.89, 100)	50.00 (15.70, 84.30)
Phase I: Stage II								
Day 0	N/A	0.33 (0.14-0.75)	0.27 (0.11-0.67)	N/A	1.23 (0.29, 5.18)	N/A	N/A	N/A
Day 14	N/A	0.69 (0.24-1.98)	0.19 (0.10-0.34)	N/A	3.69 (0.63, 21.75)	N/A	18.18 (5.19, 40.28)	0 (0, 0)
Day 21	N/A	19.56 (7.63-50.09)	0.17 (0.09-0.31)	N/A	117.17 (24.04, 571.11)	N/A	72.73 (49.78, 89.27)	0 (0, 0)
Day 28	N/A	53.69 (29.09-99.10)	0.18 (0.09-0.40)	N/A	292.79 (98.91, 866.70)	N/A	86.36 (65.09, 97.09)	12.5 (0.32, 52.65)
Phase II								
Day 0	N/A	0.51 (0.38-0.68)	0.33 (0.19-0.55)	N/A	1.55 (0.82, 2.94)	N/A	N/A	N/A
Day 28	N/A	8.19 (5.89-11.39)	0.64 (0.34-1.22)	N/A	12.73 (6.14, 26.42)	N/A	70.15 (63.31, 76.38)	24.00 (13.06, 38.17)
Day 42	N/A	37.12 (28.86-47.76)	2.98 (1.29-6.86)	N/A	12.46 (6.51, 23.82)	N/A	82.09 (76.08, 87.13)	48.00 (33.66, 62.58)

*,**Not applicable

Geometric mean titres for anti-spike glycoprotein IgG RU/ml is reported in RU/ml.

Note: For Phase I, findings were reported at baseline (day 0), two weeks after the first vaccination (day 14), and two weeks after the second vaccination (day 28) for 3 µg, 5 µg and placebo groups. For Phase II, findings were reported at baseline (day 0), four weeks after the first vaccination (day 28), and two weeks after the second vaccination (day 42) for 5µg and placebo groups. In stage I, one participant in the 3 µg group became PCR positive for COVID-19 on day 7th after the first dose and was thus excluded from the study. In stage II, one participant in the 5 µg group was excluded from the study and did not receive any doses due to white coat syndrome. Another participant in the 5 µg group of Stage II became PCR positive for COVID-19 within a day after second injection and thus was excluded from data analysis. In Phase II, 11 participants in the 5µg group were excluded from the study due to positive RT-PCR for COVID-19 after first injection (N=9), death due to suicide via cyanide toxicity (N=1) and co-administration of another COVID-19 vaccine platform without prior notice (N=1).