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Supplementary appendix

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Supplementary

Appendix 1

Vaccine composition per dose (0.5 mL):
Component I contains:
Active substance: recombinant adenovirus serotype 26 particles containing the SARS-CoV-2 protein S gene in the amount of $(1.0 \pm 0.5) \times 10^{11}$ particles per dose.
Excipients: Tris (hydroxymethyl) aminomethane, sodium chloride, sucrose, magnesium chloride hexahydrate, ethylenediaminetetraacetic acid (EDTA) disodium salt dihydrate, polysorbate-80, ethanol 95%, and water for injection.
Component II contains:
Active substance: recombinant adenovirus serotype 5 particles containing SARS-CoV-2 protein S gene in the amount of $(1.0 \pm 0.5) \times 10^{11}$ particles per dose.
Excipients: Tris (hydroxymethyl) aminomethane, sodium chloride, sucrose, magnesium chloride hexahydrate, EDTA disodium salt dihydrate, polysorbate-80, ethanol 95%, and water for injection.

Placebo composition per dose (0.5 mL):
Component I contains:
Tris (hydroxymethyl) aminomethane, sodium chloride, sucrose, magnesium chloride hexahydrate, EDTA disodium salt dihydrate, polysorbate-80, ethanol 95%, and water for injection.
Component II contains:
Tris (hydroxymethyl) aminomethane, sodium chloride, sucrose, magnesium chloride hexahydrate, EDTA disodium salt dihydrate, polysorbate-80, ethanol 95%, and water for injection.

Appendix 2

COVID-19 Severity and Symptoms

COVID-19 Severity	**Symptoms**
Mild course	· Body temperature below 38. 5℃, cough, weakness, sore throat; · No symptoms of moderate and severe course
Moderate course	· Fever over 38. 5℃; · Respiratory rate (RR) more than 22/min; · Shortness of breath during physical exertion; · Pneumonia (confirmed by computed tomography [CT] of the lungs); · Oxygen saturation level < 95%; · C-reactive protein (CRP) of blood serum more than 10 mg/l
Severe course	· RR more than 30/min; · Oxygen saturation level ≤ 93%; · Oxygen partial pressure/inspiratory oxygen fraction ≤ 300 mmHg; · Progression of changes in the lungs according to X-ray, CT, ultrasonography (U/S) (increase in the volume of changes in the lungs by more than 50% after 24-48 hours); · Decreased level of consciousness, agitation; · Unstable hemodynamics (systolic blood pressure less than 90 mm Hg or diastolic blood pressure less than 60 mm Hg, diuresis less than 20 mL/hr); · Arterial blood lactate > 2 mmol/l; · More than 2 points on the Sequential Organ Failure Assessment Scale)SOFA) scale
Extremely severe course	· ARF with the need for respiratory support (invasive mechanical ventilation); · Septic shock; · Multiple organ failure; · Changes in the lungs on CT (X-ray) typical of a critical viral lesion (lesion volume is significant or subtotal; 4 CT) or an evidence of ARDS

Appendix 3

Table S1. Seroconversion rate and statistic data (geometric mean and 95% CI of geometric mean) of RBD-specific antibodies at day 42, as measured by ELISA, in participants immunized with vaccine (n=342) or placebo (n=114). Data are divided into groups by age and sex of volunteers, and data are provided for the total data for vaccine and placebo groups.

	Age strata (years)												
	18-30		31-40		41-50		51-60		60+			total	
	Female	Male	Female	Male	Female	Male	Female	Male	Female	Male		Placebo	Vaccine
Number of values	14	14	35	44	45	47	39	45	26	29		114	342
Seroconvertion rate, %	100	100	100	100	97·78	97·87	97·44	97·78	96·15	96·55		14·91	98·25
Geometric mean (95% CI)	18102 (7689-42616)	22067 (11971-40676)	10925 (6807-17532)	10106 (7047-14494)	7940 (4874-12935)	6123 (3658-10250)	8063 (4715-13789)	7129 (4466-11379)	10908 (5462-21785)	8128 (4071-16228)		30·55 (20·18-46·26)	8996 (7610-10635)

Table S2. Seroconversion rate and statistic data (geometric mean and 95% CI of geometric mean) of NtAb at day 42 in participants immunized with vaccine (n=72) or placebo (n=28), as measured by microneutralization assay. Data are divided into groups by age and sex of volunteers, and data are provided for the total data for vaccine and placebo groups.

	Age strata (years)						Total			Sex	
	18-30	31-40	41-50	51-60	60+		Placebo	Vaccine		Female	Male
Number of values	7	15	22	21	7		28	72		26	46
Seroconvertion rate, %	85·71	100·00	90·91	100·00	100·00		7·14	95·83		96·15	95·65
Geometric mean	53·84	72·94	48·32	28·75	36·23		1·562	44·47		48·21	42·49
Lower 95% CI of geo. mean	8·198	44·25	22·21	16·71	13·21		1·117	31·79		25·51	28·42
Upper 95% CI of geo. mean	353·5	120·2	105·1	49·49	99·35		2·185	62·2		91·08	63·51

Table S3. Statistic data (median, 25% and 75% percentile, 95%CI, Mean) of antigen-specific PBMC cell IFNɣ production at day of vaccination and day 28, as measured by ELISA, in participants injected with Gam-COVID-Vac or placebo.

	Vaccine					Placebo			
	Before vaccination		28 day			Before vaccination		28 day	
	unstimulated	antigen stimulated	unstimulated	antigen stimulated		unstimulated	antigen stimulated	unstimulated	antigen stimulated
Number of values	44	44	44	44		14	14	14	14
25% Percentile	0·229	0·251	0·129	13·940		0·169	0·192	0·099	0··116
Median	0·498	0·439	0·432	32·770		0·408	0·547	0·475	0·410
75% Percentile	0·697	0·650	0·875	50·760		0·621	0·674	0·804	0·856
95% CI of median									
Actual confidence level	95·12%	95·12%	95·12%	95·12%		98·71%	98·71%	98·71%	98·71%
Lower confidence limit	0·300	0·336	0·220	21·640		0·130	0·170	0·099	0·096
Upper confidence limit	0·639	0·538	0·634	40·940		0·708	0·708	0·847	0·952
Mean	0·483	0·473	1·072	46·360		0·432	0·482	0·454	0·476

Table S4. Serious adverse events by MedDRA system organ class and preferred term at any time during the study, in randomised participants who received at least one dose of vaccine

SAE list	Vaccine Gam-COVID-Vac N=16427			Placebo N=5435		
System and organ class and preferred term (MedDRA 23.1)	**Number of subjects**	**Number of cases**	**% of all subjects**	**Number of subjects**	**Number of cases**	**% of all subjects**
Subjects with any serious adverse event	45	47	0·274	23	23	0·423
Vascular Disorders	10	10	0·061	3	3	0·055
Deep Vein Thrombosis	1	1	0·006	0	0	0·000
Disorder of regulation of the autonomic nervous system	1	1	0·006	0	0	0·000
Hemorrhagic stroke	0	0	0·000	1	1	0·018
Hypertension	1	1	0·006	0	0	0·000
Transient ischemic attack	1	1	0·006	0	0	0·000
Hypertensive crisis	2	2	0·012	0	0	0·000
Cerebral circulation failure	1	1	0·006	0	0	0·000
Vascular encephalopathy	1	1	0·006	0	0	0·000
Vertebrobasilar insufficiency	0	0	0·000	1	1	0·018
Acute myocardial infarction	2	2	0·012	1	1	0·018
Infections and invasions	8	8	0·049	14	14	0·258
COVID-19	2	2	0·012	11	11	0·202
Appendicitis	1	1	0·006	0	0	0·000
Acute sinusitis	1	1	0·006	0	0	0·000
Upper Respiratory Tract Infection	1	1	0·006	0	0	0·000
Extremity abscess	1	1	0·006	0	0	0·000
Bacterial pneumonia	0	0	0·000	1	1	0·018
Viral bronchitis	1	1	0·006	0	0	0·000
Complicated appendicitis	0	0	0·000	2	2	0·037
Jaw abscess	1	1	0·006	0	0	0·000
Reproductive system and breast disorders	3	3	0·018	2	2	0·037

Prostatitis	2	2	0·012	1	1	0·018
Dysfunctional Uterine Bleeding	0	0	0·000	1	1	0·018
Pain in the epididymis	1	1	0·006	0	0	0·000
Heart Disorders	4	6	0·024	1	1	0·018
Atrial fibrillation	3	5	0·018	1	1	0·018
Chest pain	1	1	0·006	0	0	0·000
Injury, intoxication and complications of procedures	6	6	0·037	0	0	0·000
Bacterial food poisoning	1	1	0·006	0	0	0·000
Ankle fracture	1	1	0·006	0	0	0·000
Brain concussion	1	1	0·006	0	0	0·000
Humerus fracture	1	1	0·006	0	0	0·000
Fracture of the thoracic vertebra	1	1	0·006	0	0	0·000
Alcohol poisoning	1	1	0·006	0	0	0·000
Gastrointestinal disorders	4	4	0·024	0	0	0·000
Diverticulum perforation	1	1	0·006	0	0	0·000
Pancreatitis	1	1	0·006	0	0	0·000
Abdominal pain	2	2	0·012	0	0	0·000
Kidney and urinary tract disorders	2	2	0·012	0	0	0·000
Renal colic	1	1	0·006	0	0	0·000
Renal abscess	1	1	0·006	0	0	0·000
Liver and biliary tract disorders	3	3	0·018	0	0	0·000
Acute cholecystitis	1	1	0·006	0	0	0·000
Sphincter of Oddi dysfunction	1	1	0·006	0	0	0·000
Biliary colic	1	1	0·006	0	0	0·000
Immune System Disorders	1	1	0·006	0	0	0·000
Hypersensitivity	1	1	0·006	0	0	0·000
Muscle, skeletal and connective tissue disorders	1	1	0·006	0	0	0·000
Back pathology	1	1	0·006	0	0	0·000

General disorders and reactions at the injection site	1	1	0·006	0	0	0·000
Medical Device Infection	1	1	0·006	0	0	0·000
Pregnancy, the puerperium and perinatal conditions	0	0	0·000	1	1	0·018
Spontaneous abortion	0	0	0·000	1	1	0·018
Respiratory, Chest and Mediastinal Disorders	0	0	0·000	1	1	0·018
Interstitial lung disease	0	0	0·000	1	1	0·018
Nervous System Disorders	2	2	0·012	1	1	0·018
Recurrence of multiple sclerosis	0	0	0·000	1	1	0·018
Vestibular Ataxia	1	1	0·006	0	0	0·000
Syncope	1	1	0·006	0	0	0·000

Table S5. Rare adverse events by MedDRA system organ class and preferred term in randomised participants who received two doses. AEs registered in <0.1% of volunteers

		Vaccine N = 9258*		Placebo N = 3038*	
		N cases	% cases	N cases	% cases
Skin and subcutaneous tissue disorders [10040785]	Acneform dermatitis [10012432]	1	0·011	0	0·000
	Allergic skin reaction [10001729]	1	0·011	0	0·000
	Allergic rash [10001717]	5	0·054	1	0·033
	Alopecia [10001760]	2	0·022	0	0·000
	Itching [10037087], Itching of the upper limbs [10079579]	4	0·043	5	0·165
	Skin rash [10040913]	9	0·097	5	0·165
	Petechial rash [10034756]	1	0·011	0	0·000
	Rash [10037844]	3	0·032	0	0·000
	Eczema [10014200]	1	0·011	0	0·000
Disorder of the organ of vision [10015919]	Eyeball pain [10015906]	1	0·011	0	0·000
	Dry eye [10015921]	0	0·000	2	0·066
	Macular and posterior pole degeneration [10025405]	1	0·011	0	0·000
	Cataract [10007739]	0	0·000	1	0·033
	Keratoconjunctivitis [10023348]	1	0·011	0	0·000
	Blurred field of vision [10005886]	1	0·011	0	0·000
	Tearing [10043171]	1	0·011	1	0·033
	Disorder of vision [10047516]	1	0·011	0	0·000
	Chalazion [10020377]	1	0·011	0	0·000
Reproductive system and breast disorders [10038604]	Vaginitis [10046950]	1	0·011	0	0·000
	Prolonged erection [10068039]	1	0·011	0	0·000
	Corpus luteum cyst [10011116]	1	0·011	0	0·000
	Disorder of the menstrual cycle [10013236]	1	0·011	0	0·000
Kidney and urinary tract disorders [10038359]	Pain in the kidney area [10056691]	1	0·011	0	0·000
	Colic, renal [10009885]	1	0·011	1	0·033
	Nocturia [10029446]	1	0·011	0	0·000
	Exacerbation of cystitis [10011785]	1	0·011	0	0·000
	Frequent urination [10027562]	2	0·022	2	0·066
Mental disorders [10037175]	Lack of concentration [10027348]	1	0·011	0	0·000
	Decreased libido [10024419]	1	0·011	0	0·000
	Drowsiness [10041014]	1	0·011	0	0·000
Vascular disorders [10047065]	Left-sided deep vein thrombosis [10024105]	1	0·011	0	0·000
	Superficial thrombophlebitis of the leg [10042557]	0	0·000	1	0·033
Nervous	Metallic taste [10043135]	3	0·032	0	0·000

system disorders [10029205]	Paresthesia [10033775]	1	0·011	1	0·033
Immune system disorders [10021428]	Allergic reaction [10001718]	14	0·151	3	0·099
	Local allergic reaction to adhesives [10076376]	4	0·043	1	0·033
Infections and invasions [10021881]	Gastroenteritis [10017888]	0	0·000	1	0·033
	Herpes [10019944], Herpes virus infection [10019971], Labial herpes [10019942]	8	0·086	4	0·132
	Otitis [10033071]	2	0·022	0	0·000
	Pyelonephritis [10037596]	1	0·011	0	0·000
Metabolic and nutritional disorders [10027433]	Dyslipidemia [10058108]	1	0·011	0	0·000
	Decreased appetite [10003020]	1	0·011	0	0·000
Benign, malignant and unspecified neoplasms (incl.cysts and polyps) [10029104]	Benign neoplasm of the eyelid [10063707]	1	0·011	0	0·000
Hearing and labyrinth disorders [10013993]	Noise in ears [10014018]	1	0·011	1	0·033
Blood and lymphatic system disorders [10005329]	Axillary lymphadenitis [10050824], Axillary lymph node enlargement [10003875]	6	0·065	1	0·033

*Data obtained from volunteers who received both doses of vaccine based on analysis performed at database lock on 11/18/2020. The total number of volunteers at the time of database lock is 12296, including 9258 in vaccine group and 3038 in placebo group.

During the analysis of rare adverse events in the vaccine group, 91 AEs were identified, of which 82 grade 1 (90,1%), 9 grade 2 (9,9%); in the placebo group, 31 AEs were identified, of which 29 were grade 1 (93,5%), 2 grade 2 (6,5%).

Grades were determined according to next documents:

- Guidance for Industry. Toxicity Grading Scale for Healthy Adult and Adolescent Volunteers Enrolled in Preventive Vaccine Clinical Trials. U.S. Department of Health and Human Services, September 2007.
- Common Terminology Criteria for Adverse Events (CTCAE) Version 5.0, U.S. Department of Health and Human Services, November 2017.

Table S6. Demographic and anthropometric characteristics of volunteers 60+ years (Number of volunteers (%) or Mean±SD)

Index	Group	
	Vaccine	Placebo
Total number	1611 (100·0%)	533 (100·0%)
Age		
60-69	1318 (81·8%)	456 (85·6%)
70-79	265 (16·4%)	71 (13·3%)
80+	28 (1·8%)	6 (1·1%)
Sex		
Female	704 (43·7%)	221 (41·5%)
Male	907 (56·3%)	312 (58·5%)
Ethnicity		
White	1601 (99·4%)	531 (99·6%)
Asian	9 (0·6%)	2 (0·4%)
Other	1 (0·1%)	0 (0·0%)
Age· years	65·7±4·5	65·3±4·2
Body weight· kg	81·6±15·6	82·1±15·7
Height· cm	169·9±8·9	170·8±9·2
BMI· kg / m2	27·94±4·17	27·98±4·25
The presence of concomitant diseases (Diabetes mellitus, hypertension, ischemic heart disease, obesity and others)*		
No	857/1611 (53·2%)	287/533 (53·8%)
Yes	754/1611 (46·8%)	246/533 (46·2%)
Risk of infection in volunteers*		
High**	1/1582 (0·1%)	3/526 (0·6%)
Medium **	370/1582 (23·4%)	119/526 (22·6%)
General**	1211/1582 (76·5%)	404/526 (76·8%)

* The data on the number of volunteers from the total number in the group for which there is a description of this parameter are presented

** High risk - work involves interaction with patients with a confirmed diagnosis of COVID-19
Medium risk - professional contact with a large number of people (general practitioners· social workers· shop assistants, etc.)
General risk - no additional risks associated with professional activities

Table S7. Adverse events registered during the analyzed period and noted in 0·3% or more subjects over 60 years old in the Vaccine/Placebo group, by classes of organ systems, preferred terms and groups

	Vaccine N = 1029		Placebo N = 340	
	Number of subjects	% of all subjects	Number of subjects	% of all subjects
Flu-like illness	156	15·2	30	8·8
Local reaction	56	5·4	4	1·2
Asthenia	26	2·5	9	2·6
Injection site reaction	5	0·5	1	0·3
Malaise	5	0·5	2	0·6
Pyrexia	5	0·5	1	0·3
Fever sensation	4	0·4	1	0·3
Hypertension	40	3·9	10	2·9
Headache	30	2·9	9	2·6
Tonsillitis	8	0·8	0	0·0
Cough	10	1·0	1	0·3
Rhinorrhea	7	0·7	4	1·2
Nasal congestion	5	0·5	2	0·6
Contact dermatitis	39	3·8	3	0·9
Diarrhea	8	0·8	1	0·3
Nausea	7	0·7	3	0·9
Dyspepsia	5	0·5	0	0·0
Abdominal discomfort	3	0·3	1	0·3
Elevated body temperature	23	2·2	3	0·9
Myalgia	9	0·9	3	0·9
Arthralgia	4	0·4	1	0·3

Table S8. Efficacy against moderate/severe COVID-19 cases at different time points after dose 1

Efficacy Against moderate/severe COVID-19 First moderate/severe COVID-19 Occurrence					
Timeframe	Total number of cases	Vaccine N cases (N volunteers)	Placebo N cases (N volunteers)	Vaccine efficacy (95% CI) 100x(1-OR)	P value
From 1 to 7 days after dose 1	10	7 (16427)	3 (5435)	22,8 (0·0-78·6)	0,7174
From 8 to 14 days after dose 1	7	4 (15269)	3 (5091)	55,5 (0·0-88·1)	0,3771
From 15 to 21 days after dose 1	9	4 (14999)	5 (4950)	73,6 (13·1-91·9)	0,0476
After 21 days after dose 1	20	0 (14964)	20 (4902)	100 (94·4-100·0)	<0·0001

Appendix 4

A detailed description of the condition of volunteers with fatal COVID-19

The first COVID-19 fatal subject has developed symptoms 4 days after receiving the first dose of vaccine. After 3 days of self home treatment using antipyretic (NSAIDs) drugs without informing clinicians, subject was hospitalized with viral pneumonia verified by CT and COVID-19 test. During hospitalization, in addition to hypertension with a predominant heart lesion without heart failure, diagnosed at the outpatient screening stage, the subject after a comprehensive instrumental examination revealed advanced chronic concomitant diseases not identified at the screening stage and that were unawareable for patient, such ashepatomegaly and fatty hepatosis (by CT and ultrasound scans). Echocardiography revealed left ventricular hypertrophy with dilatation of the left atrium and thickening of the ascending aorta and of the aortic and mitral valves. During 10 days of hospitalization the condition remained stably severe, with the progression of viral lung lesions on CT, the development of acute respiratory distress syndrome and multiple organ failure. On the day 16 the development of hypercoagulable syndrome with occlusion of the left popliteal artery and left leg arteries, myocardial ischemia in the posterior wall of the left ventricle and an episode of ventricular tachycardia, stopped by electro-pulse therapy, led to a subsequent sudden and progressive deterioration of the condition without effect from cardiopulmonary resuscitation.

The second subject, also fatal from COVID-19, became ill (self-diagnosed) on the 5th day after receiving the first dose of the vaccine. After 7 days of self home treatment using antipyretic (NSAIDs) drugs without informing clinicians, subject was hospitalized with viral pneumonia verified by CT and COVID-19 test. Comprehensive additional examination diagnosed a severe comorbid background not identified at medical examination and that were unawareable for patient (in addition to non-insulin dependent diabetes mellitus type II,hypertension with predominantly heart disease without heart failure, obesity alimentary-constitutional genesis of I degree): coronary heart disease, postinfarction cardiosclerosis after a previous myocardial infarction, diabetic angiopathy of the lower limbs, cholelithiasis, chronic calculous cholecystitis were revealed. In the hospital, decompensation of diabetes mellitus was diagnosed on the background of severe viral pneumonia and therapy with systemic glucocorticosteroids, as well as a worsening of the course of arterial hypertension and the appearance of signs of heart failure, which could have a negative effect on the course of the disease as a whole and on its outcome. Moreover, signs of acute respiratory distress syndrome were growing, multiple organ failure progressed, laboratory and instrumental data did not exclude the development of repeated myocardial infarction, the development of thromboembolic syndrome against the background of hypercoagulable syndrome, the development of pulmonary and cerebral edema, which led to death.

Appendix 5

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Appendix 6

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10. Limited Liability Company NEARMEDIC PLUS, 125252, Moscow

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19. Limited Liability Company "Clinic of New Medical Technologies ARCHIMED V" (LLC "Clinic ARCHIMED V"), 119261, Moscow

20. State budgetary institution of health care of the city of Moscow "City polyclinic № 109 of the Department of health of the city of Moscow", 109548, Moscow

21. State Budgetary Institution of Health of the City of Moscow "City Polyclinic No. 219 of the Department of Healthcare of the City of Moscow", 123480, Moscow

22. State budgetary institution of health care of the city of Moscow "City polyclinic No. 115 of the Department of health care of the city of Moscow", 123308, Moscow

23. State Budgetary Institution of Healthcare of the City of Moscow "City Polyclinic No. 210 of the Department of Healthcare of the City of Moscow", 115211, Moscow

24. State budgetary institution of health care of the city of Moscow "City polyclinic № 175 of the Department of health of the city of Moscow", 105568, Moscow

25. State budgetary institution of health care of the city of Moscow "City polyclinic № 64 of the Department of health of the city of Moscow", 107023, Moscow