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First-in-Human Study to Evaluate Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of a Rapidly Developed SARS-COV-2 Therapeutic Antibody, AOD01, in Healthy Adults

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Supplementary Table S1: Subject disposition (All randomised)

	AOD01					Placebo (N=8)	All (N=24)
	1 Dose Cohorts				2 Dose Cohort		
	2 mg/kg (N=3)	5 mg/kg (N=4)	10 mg/kg (N=3)	20 mg/kg (N=3)	20 mg/kg (N=3)		
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Subjects not treated	0	1 (25.0)	0	0	0	0	1 (4.2)
Subjects treated	3 (100.0)	3 (75.0)	3 (100.0)	3 (100.0)	3 (100.0)	8 (100.0)	23 (95.8)
Subjects who completed study treatment	3 (100.0)	3 (75.0)	3 (100.0)	3 (100.0)	3 (100.0)	8 (100.0)	23 (95.8)
Subjects who discontinued study treatment	0	0	0	0	0	0	0
Subjects who completed study	3 (100.0)	3 (75.0)	3 (100.0)	3 (100.0)	3 (100.0)	8 (100.0)	23 (95.8)
Subjects who discontinued study	0	1 (25.0)	0	0	0	0	1 (4.2)
Primary Reason for Study Discontinuation	-	-	-	-	-	-	-
Other	0	1 (25.0)	0	0	0	0	1 (4.2)

N sample size for the group, *n* number of subjects

Supplementary Table S2: COVID-19 signs and symptoms (Safety set)

COVID-19 Signs and Symptoms	AOD01					Placebo (N=8)	All (N=23)
	1 Dose Cohorts				2 Dose Cohort		
	2 mg/kg (N=3)	5 mg/kg (N=3)	10 mg/kg (N=3)	20 mg/kg (N=3)	20 mg/kg (N=3)		
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Day 7	0	0	0	0	NA	1 (12.5)	1 (4.3)
Headache	0	0	0	0	-	1 (12.5)	1 (4.3)
Day 8	0	0	1 (33.3)	0	0	0	1 (4.3)
Runny nose	0	0	1 (33.3)	0	0	0	1 (4.3)
Day 9	NA	NA	NA	NA	1 (33.3)	0	1 (4.3)
Diarrhoea	-	-	-	-	1 (33.3)	0	1 (4.3)
Day 15	0	0	0	1 (33.3)	0	0	1 (4.3)
Diarrhoea	0	0	0	1 (33.3)	0	0	1 (4.3)
Day 22	0	0	0	0	0	1 (12.5)	1 (4.3)
Headache	0	0	0	0	0	1 (12.5)	1 (4.3)
Day 29	0	0	0	0	0	1 (12.5)	1 (4.3)
Headache	0	0	0	0	0	1 (12.5)	1 (4.3)
Day 43	0	0	0	1 (33.3)	0	1 (12.5)	2 (8.7)
Cough	0	0	0	1 (33.3)	0	0	1 (4.3)
Runny nose	0	0	0	1 (33.3)	0	0	1 (4.3)
Headache	0	0	0	0	0	1 (12.5)	1 (4.3)
Day 57	0	0	0	0	1 (33.3)	2 (25.0)	3 (13.0)
Runny nose	0	0	0	0	1 (33.3)	0	1 (4.3)
Diarrhoea	0	0	0	0	0	1 (12.5)	1 (4.3)
Headache	0	0	0	0	0	1 (12.5)	1 (4.3)
Day 71	0	0	0	0	0	0	0
Day 92	0	1 (33.3)	0	1 (33.3)	0	1 (12.5)	3 (13.0)
Runny nose	0	0	0	1 (33.3)	0	0	1 (4.3)
Diarrhoea	0	1 (33.3)	0	0	0	0	1 (4.3)
Headache	0	0	0	0	0	1 (12.5)	1 (4.3)

COVID-19 coronavirus disease 2019, *N* sample size for the group, *n* number of subjects

Supplementary Table S3: Statistical assessment of dose proportionality for AOD01 in healthy volunteers (Pharmacokinetic analysis set)

Dose Range	Parameter (units)	Intercept	Estimated Slope	Standard Error of the Slope	90% CI of the Slope	Dose Proportionality Criteria
2 mg/kg - 20 mg/kg	C_{max} (µg/mL)	5.12	1.05	0.0757	(0.911, 1.19)	(0.903, 1.10)
	$AUC_{0\text{-tlast}}$ (h*µg/mL)	9.98	1.09	0.0469	(1.00, 1.17)	(0.903, 1.10)
	$AUC_{0\text{-inf}}$ (h*µg/mL)	10.1	1.05	0.0459	(0.971, 1.14)	(0.903, 1.10)
5 mg/kg - 20 mg/kg	C_{max} (µg/mL)	5.49	0.898	0.139	(0.635, 1.16)	(0.839, 1.16)
	$AUC_{0\text{-tlast}}$ (h*µg/mL)	9.93	1.11	0.0898	(0.941, 1.28)	(0.839, 1.16)
	$AUC_{0\text{-inf}}$ (h*µg/mL)	9.99	1.10	0.0901	(0.926, 1.27)	(0.839, 1.16)
2 mg/kg - 10 mg/kg	C_{max} (µg/mL)	5.11	1.05	0.119	(0.825, 1.28)	(0.861, 1.14)
	$AUC_{0\text{-tlast}}$ (h*µg/mL)	10.0	1.07	0.0577	(0.957, 1.18)	(0.861, 1.14)
	$AUC_{0\text{-inf}}$ (h*µg/mL)	10.1	1.02	0.0533	(0.914, 1.12)	(0.861, 1.14)

$AUC_{0\text{-}inf}$ area under the concentration-time curve from time 0 to infinity, $AUC_{0\text{-}tlast}$ area under the concentration-time curve from time 0 to the time of the last measurable concentration, C_{max} maximum observed plasma concentration