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Supplementary appendix

This appendix formed part of the original submission and has been peer reviewed. We post it as supplied by the authors.

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Efficacy and safety of a single dose of casirivimab and imdevimab for the prevention of COVID-19 over an 8-month period: a randomised, double-blind, placebo-controlled trial

SUPPLEMENTARY APPENDIX

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Supplementary Methods

Statistical methods

Sample size calculation

The sample size calculation for this study has been previously described.[1] Briefly, approximately 1248 seronegative participants from 430 households (assuming an average household size of 2.9 participants) would provide greater than 90% power to detect a 50% relative difference in the risk of symptomatic COVID-19 infection (with an assumed 10% attack rate in the placebo group) over the 28-day efficacy assessment period at a two-sided alpha level of 0.05. With a 5% attack rate in the CAS+IMD group (i.e., a 50% relative risk reduction), this between-group difference is equivalent to an odds ratio of 0.47.

Analysis sets

The seronegative modified full analysis set utilised for efficacy analyses included all randomised participants ≥12 years of age who were confirmed by central laboratory testing to be negative for both SARS-CoV-2 by RT-PCR and serology at baseline, excluding participants from the initial descriptive assessment, as previously described.[1] Safety data are reported for all SARS-CoV-2 RT-PCR–negative participants who received study drug, irrespective of serostatus, including those in the initial descriptive assessment, as previously described.[1]

Pharmacokinetic methods

Sample collection and analysis

Blood samples for measurement of casirivimab and imdevimab (CAS+IMD) concentrations in serum were collected and analysed as previously described.[1]

Population pharmacokinetics

Two population pharmacokinetic (PK) models with the same model structure were developed for casirivimab and imdevimab, based on an analysis dataset comprised of 3687 (casirivimab) and 3716 (imdevimab) participants from three Regeneron clinical studies (R10933-10987-COV-2067, NCT04425629; R10933-10987-COV-2069, NCT04452318; R10933-10987-COV-20145, NCT04666441). In brief, the population PK models for casirivimab and imdevimab are both 2-compartment models with linear elimination and first-order absorption following subcutaneous dosing. Stochastic simulations were performed to predict exposure metrics for participants receiving CAS+IMD. One-thousand virtual participants with an approximately equal number of male and females and mean (standard deviation) body weight of 83·6 (21·1) kg were generated by sampling complete covariate vectors for participants in the observed data. Population PK model parameters were fixed to the estimates from the final population PK models with inter-participant variability incorporated via simulated inter-individual random effects. A total of 1000 concentration-time profiles of casirivimab and imdevimab were generated for CAS+IMD dosing regimens (300 mg SC Q3M, 300 mg IV Q3M, 1200 mg SC Q5M, and 1200 mg IV Q5M); concentrations of casirivimab and imdevimab at each simulated timepoint were added to obtain

concentrations of casirivimab and imdevimab combined in serum (population PK manuscript in preparation).

Estimated 50% neutralization titers

The 50% neutralizing titer for CAS+IMD concentration combined in serum was calculated as the ratio of the population PK predicted concentration in serum over 8 monthly intervals to the *in vitro* concentration of CAS+IMD combined required to neutralise the SARS-CoV-2 virus by 50% (IC_{50}; 2·83 ng/mL) for the D614G variant (population PK manuscript in preparation) using an S-protein expressing pseudovirus assay.[2, 3]

Supplementary Results

RT-PCR–confirmed SARS-CoV-2 infections regardless of serostatus

Symptomatic SARS-CoV-2 infection

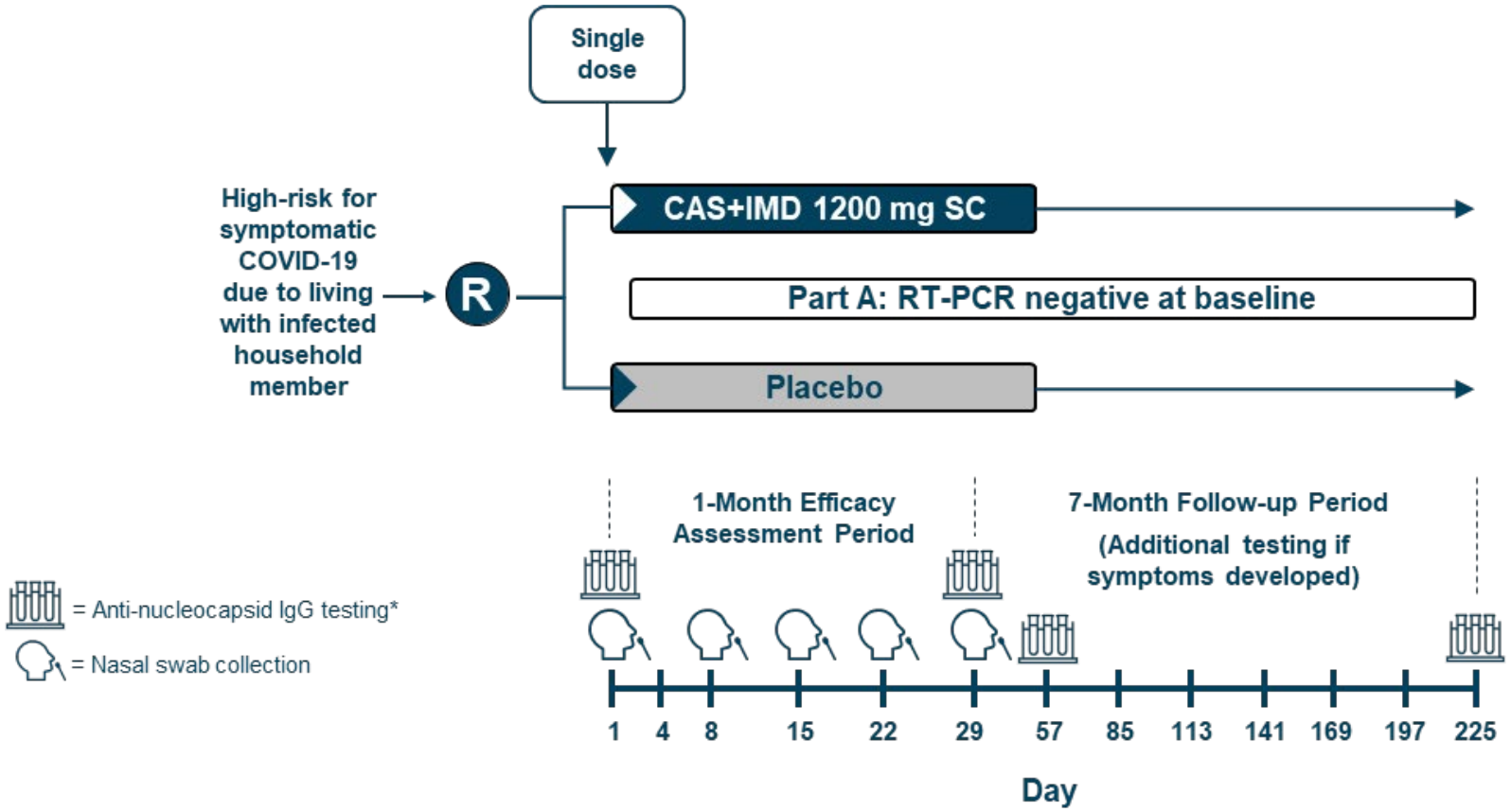
In an analysis that included all SARS-CoV-2 RT-PCR–negative participants at baseline regardless of baseline serostatus, there was a 79·7% risk reduction in symptomatic RT-PCR–confirmed SARS-COV-2 infections with CAS+IMD versus placebo during the entire 8-month study (25/1174 [2·1%] and 120/1143 [10·5%], respectively; adjusted odds ratio (95% confidence interval [CI]), 0·19 (0.12–0.29); nominal p<0·0001).

Any SARS-CoV-2 infection (symptomatic or asymptomatic)

In an analysis that included all SARS-CoV-2 RT-PCR–negative participants at baseline regardless of serostatus, there was a 64·4% risk reduction in any RT-PCR–confirmed SARS-COV-2 infections (symptomatic or asymptomatic) with CAS+IMD versus placebo during the entire 8-month study (72/1174 [6·1%] and 197/1143 [17·2%], respectively; adjusted odds ratio (95% CI), 0·31 (0.24–0.42); nominal p<0·0001).

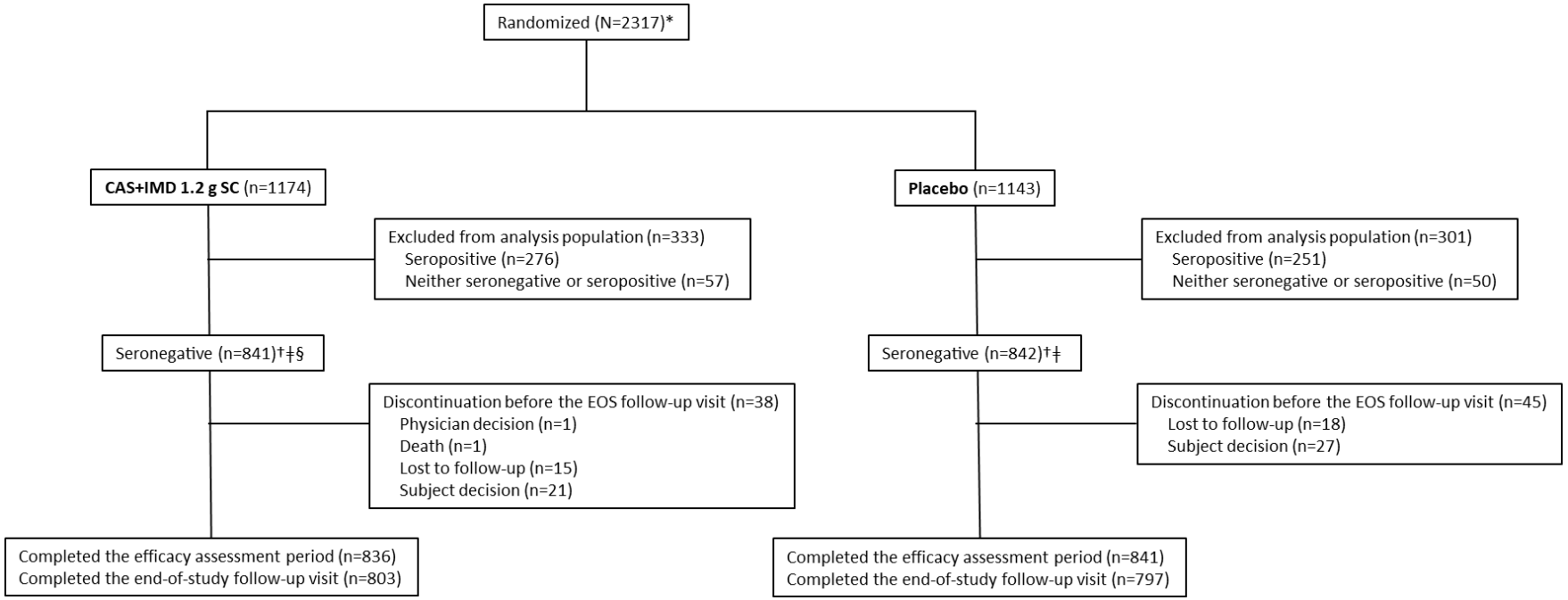
Supplementary Figures

Figure S1: Schematic overview of the study design



*Baseline serologic testing also included anti-spike [S1] IgA and anti-spike [S1] IgG, in addition to anti-nucleocapsid IgG.
CAS+IMD=casirivimab and imdevimab. RT-PCR=reverse transcription polymerase chain reaction. SC=subcutaneous.

Figure S2: Flow diagram for the SARS-CoV-2 RT-PCR–negative population



*Excludes the 554 participants from the initial descriptive assessment for efficacy analyses; these participants were included in the safety analysis population (N=2867).
†A participant was categorised at baseline as seronegative if all available serologic tests (anti-spike [S1] IgA, anti-spike [S1] IgG, and anti-nucleocapsid IgG) were negative and as seropositive if any serologic test was positive.
‡This is the primary efficacy analysis population (seronegative mFAS-A).
§One participant was randomised but did not receive CAS+IMD; this participant was included in the primary efficacy analysis population (seronegative mFAS-A).
CAS+IMD=casirivimab and imdevimab. EOS=end of study. RT-PCR=reverse transcription polymerase chain reaction. SARS-CoV-2=severe acute respiratory syndrome coronavirus 2. SC=subcutaneous.

Supplementary Tables

Table S1: Summary of COVID-19 vaccination in SARS-CoV-2 RT-PCR–negative and seronegative participants*

	CAS+IMD 1200 mg SC (n=841)	Placebo (n=842)	Total (n=1683)
Time to first COVID-19 vaccination			
n (%)	290 (34·5)	296 (35·2)	586 (34·8)
Mean days (SD)	112·1 (44·71)	112·7 (45·02)	112·4 (44·83)
Median days (Q1:Q3)	108·5 (81·0:143·0)	109·0 (85·0:145·0)	109·0 (82·0:145·0)
During the efficacy assessment period (≤29 days since administration), n (%)	9 (1·1)	7 (0·8)	16 (1·0)
During follow-up (>29 days since administration), n (%)	281 (33·4)	289 (34·3)	570 (33·9)

*Population includes participants who were SARS-CoV-2 RT-PCR–negative and seronegative at baseline, excluding participants from the initial descriptive assessment.
CAS+IMD=casirivimab and imdevimab. RT=reverse transcription polymerase chain reaction. SARS-CoV-2=severe acute respiratory syndrome coronavirus 2. SC=subcutaneous. SD=standard deviation.

Table S2: Demographics and baseline characteristics in SARS-CoV-2 RT-PCR–negative participants regardless of serostatus*

	CAS+IMD 1200 mg SC (n=1174)	Placebo (n=1143)	Total (n=2317)
Age, years			
Mean (SD)	41·9 (15·88)	42·1 (15·57)	42·0 (15·73)
≥50, n (%)	411 (35·0)	404 (35·3)	815 (35·2)
Sex, n (%)			
Male	539 (45·9)	555 (48·6)	1094 (47·2)
Female	635 (54·1)	588 (51·4)	1223 (52·8)
Race, n (%)			
White	990 (84·3)	962 (84·2)	1952 (84·2)
Black or African American	128 (10·9)	123 (10·8)	251 (10·8)
Asian	33 (2·8)	29 (2·5)	62 (2·7)
American Indian or Alaska Native	3 (0·3)	5 (0·4)	8 (0·3)
Native Hawaiian or Pacific Islander	2 (0·2)	2 (0·2)	4 (0·2)
Other	18 (1·5)	22 (1·9)	40 (1·7)
Ethnicity, n (%)			
Hispanic or Latino	558 (47·5)	566 (49·5)	1124 (48·5)
Not Hispanic or Latino	612 (52·1)	570 (49·9)	1182 (51·0)
Other	4 (0·3)	7 (0·6)	11 (0·5)
Mean weight, kg (SD)	81·2 (19·22)	81·8 (19·83)	81·5 (19·52)
Body-mass index, kg/m^2			
Mean (SD)	28·5 (6·06)	28·8 (6·32)	28·6 (6·19)
≥30, n (%)	416 (35·4)	400 (35·0)	816 (35·2)

*Population includes participants who were SARS-CoV-2 RT-PCR–negative regardless of serostatus, excluding participants from the initial descriptive assessment.

CAS+IMD=casirivimab and imdevimab. RT-PCR=reverse transcription polymerase chain reaction. SARS-CoV-2=severe acute respiratory syndrome coronavirus 2. SC=subcutaneous. SD=standard deviation.

Table S3: Proportion of participants who had a SARS-CoV-2–related medically attended visit during the 8-month study*

	CAS+IMD 1200 mg SC (n=841)	Placebo (n=842)	Total (n=1683)
Participants with ≥1 medically attended visit, n (%)	1 (0·1)	16 (1·9)	17 (1·0)
Hospitalization	0 (0)	6 (37·5)	6 (35·3)
Emergency room†	0 (0)	4 (25·0)	4 (23·5)
Urgent care†	1 (100)	7 (43·8)	8 (47·1)

*Population includes participants who were SARS-CoV-2 RT-PCR–negative and seronegative at baseline, excluding participants from the initial descriptive assessment.

†One participant in the placebo group had an emergency room visit and an urgent care visit.

CAS+IMD=casirivimab and imdevimab. RT-PCR=reverse transcription polymerase chain reaction. SARS-CoV-2=severe acute respiratory syndrome coronavirus 2. SC=subcutaneous.

Table S4: Treatment-emergent adverse events ≥2% in any study group during the 8-month study by baseline serology status*†

Participants, n (%)	Combined serostatus		Seronegative		Seropositive		Other	
Primary system organ class Preferred term	**CAS+IMD 1200 mg SC (n=1439)**	**Placebo (n=1428)**	**CAS+IMD 1200 mg SC (n=1028)**	**Placebo (n=1067)**	**CAS+IMD 1200 mg SC (n=337)**	**Placebo (n=296)**	**CAS+IMD 1200 mg SC (n=74)**	**Placebo (n=65)**
Infections and infestations	193 (13·4)	322 (22·5)	142 (13·8)	270 (25·3)	40 (11·9)	42 (14·2)	11 (14·9)	10 (15·4)
Asymptomatic COVID-19	71 (4·9)	119 (8·3)	51 (5·0)	94 (8·8)	17 (5·0)	22 (7·4)	3 (4·1)	3 (4·6)
COVID-19	29 (2·0)	149 (10·4)	22 (2·1)	138 (12·9)	6 (1·8)	9 (3·0)	1 (1·4)	2 (3·1)
General disorders and administration site conditions	104 (7·2)	84 (5·9)	77 (7·5)	65 (6·1)	17 (5·0)	13 (4·4)	10 (13·5)	6 (9·2)
Injection site rection	60 (4·2)	26 (1·8)	46 (4·5)	21 (2·0)	10 (3·0)	3 (1·0)	4 (5·4)	2 (3·1)
Respiratory, thoracic, and mediastinal disorders	89 (6·2)	68 (4·8)	65 (6·3)	54 (5·1)	18 (5·3)	6 (2·0)	6 (8·1)	8 (12·3)
Cough	40 (2·8)	21 (1·5)	25 (2·4)	16 (1·5)	12 (3·6)	2 (0·7)	3 (4·1)	3 (4·6)
Oropharyngeal pain	29 (2·0)	26 (1·8)	19 (1·8)	19 (1·8)	7 (2·1)	5 (1·7)	3 (4·1)	2 (3·1)
Nervous system disorders	53 (3·7)	78 (5·5)	35 (3·4)	61 (5·7)	14 (4·2)	10 (3·4)	4 (5·4)	7 (10·8)
Headache	39 (2·7)	62 (4·3)	25 (2·4)	47 (4·4)	11 (3·3)	10 (3·4)	3 (4·1)	5 (7·7)

*Population includes participants who were SARS-CoV-2 RT-PCR–negative at baseline, including participants from the initial descriptive assessment.
†Serologic testing included anti-spike [S1] IgA, anti-spike [S1] IgG, and anti-nucleocapsid IgG. A participant was categorised at baseline as seronegative if all available serologic tests were negative and as seropositive if any serologic test was positive. Participants that had only borderline serology test results or no data were categorised as "other".
CAS+IMD=casirivimab and imdevimab. RT-PCR=reverse transcription polymerase chain reaction. SARS-CoV-2=severe acute respiratory syndrome coronavirus 2. SC=subcutaneous.

Table S5: Serious treatment-emergent adverse events during the 8-month study*†

System organ class Preferred term –participants, n (%)	CAS+IMD 1200 mg SC (n=1439)	Placebo (n=1428)
Participants with at least one serious TEAE	24 (1·7)	23 (1·6)
Infections and infestations	7 (0·5)	12 (0·8)
Pneumonia	2 (0·1)	1 (<0·1)
Abscess limb	1 (<0·1)	0
Appendicitis	1 (<0·1)	2 (0·1)
Gangrene	1 (<0·1)	0
Gastroenteritis	1 (<0·1)	0
Osteomyelitis	1 (<0·1)	0
Sepsis	1 (<0·1)	1 (<0·1)
Soft tissue infection	1 (<0·1)	0
COVID-19	0	5 (0·4)
COVID-19 pneumonia	0	3 (0·2)
Pyelonephritis	0	1 (<0·1)
Scrotal abscess	0	1 (<0·1)
Injury, poisoning, and procedural complications	7 (0·5)	3 (0·2)
Road traffic accident	2 (0·1)	0
Ankle fracture	1 (<0·1)	0
Burns second degree	1 (<0·1)	0
Foot fracture	1 (<0·1)	0
Post procedural complication	1 (<0·1)	0
Post procedural haemorrhage	1 (<0·1)	0
Post procedural inflammation	1 (<0·1)	0
Tibia fracture	1 (<0·1)	0
Traumatic lung injury	1 (<0·1)	0
Gunshot wound	0	1 (<0·1)
Humerus fracture	0	1 (<0·1)
Soft tissue injury	0	1 (<0·1)
Cardiac disorders	3 (0·2)	1 (<0·1)
Acute myocardial infarction	2 (0·1)	0
Cardiac failure congestive	1 (<0·1)	0
Cardio-respiratory arrest	1 (<0·1)	0
Cardiac arrest	0	1 (<0·1)
Nervous system disorders	2 (0·1)	1 (<0·1)
Syncope	1 (<0·1)	0

Transient ischaemic attack	1 (<0·1)	0
Cerebral infarction	0	1 (<0·1)
Pregnancy, puerperium, and perinatal conditions	2 (0·1)	2 (0·1)
Abortion spontaneous	1 (<0·1)	2 (0·1)
Pre-eclampsia	1 (<0·1)	0
Gastrointestinal disorders	1 (<0·1)	0
Abdominal pain upper	1 (<0·1)	0
Hepatobiliary disorders	1 (<0·1)	1 (<0·1)
Cholecystitis acute	1 (<0·1)	0
Cholelithiasis	0	1 (<0·1)
Neoplasms benign, malignant, and unspecified (incl. cysts and polyps)	1 (<0·1)	1 (<0·1)
Cervix carcinoma recurrent	1 (<0·1)	0
Invasive ductal breast carcinoma	0	1 (<0·1)
Psychiatric disorders	1 (<0·1)	3 (0·2)
Schizophrenia	1 (<0·1)	0
Mania	0	1 (<0·1)
Suicidal ideation	0	2 (0·1)
Renal and urinary disorders	1 (<0·1)	0
Acute kidney injury	1 (<0·1)	0
Skin and subcutaneous tissue disorders	1 (<0·1)	0
Diabetic foot	1 (<0·1)	0
Reproductive system and breast disorders	0	1 (<0·1)
Breast haematoma	0	1 (<0·1)
Vascular disorders	0	2 (0·1)
Essential hypertension	0	1 (<0·1)
Hypertensive urgency	0	1 (<0·1)

*Population includes participants who were SARS-CoV-2 RT-PCR–negative at baseline regardless of serostatus, including participants from the initial descriptive assessment.
CAS+IMD=casirivimab and imdevimab. COVID-19=coronavirus disease 19. SC=subcutaneous.

Table S6: Population PK predicted concentration of casirivimab and imdevimab combined in serum and estimated 50% neutralizing titer (NT_{50}) over time following a single 1200-mg SC dose of CAS+IMD

Time		CAS+IMD Concentration (mg/L)*	Estimated NT_{50}*†
Day	Month		
30	1	52·2 (33·7, 77·7)	1:18,418 (1:11890, 1:27415)
60	2	25·0 (10·6, 46·0)	1:8,821 (1:3740, 1:16230)
90	3	12·0 (3·32, 28·1)	1:4,234 (1:1171, 1:9914)
120	4	5·77 (1·01, 17·5)	1:2,036 (1:356, 1:6174)
150	5	2·73 (0·32, 11·1)	1:963 (1:113, 1:3916)
180	6	1·29 (0·096, 7·02)	1:455 (1:33·9, 1:2478)
210	7	0·62 (0·029, 4·45)	1:219 (1:10·2, 1:1570)
240	8	0·30 (0·009, 2·93)	1:106 (1:3·03, 1:1034)

*Median (5^{th}, 95^{th} percentile). †Estimated as concentration of CAS+IMD combined in serum/IC_{50} against D614G variant (2·83 ng/mL). See supplemental methods section "estimated 50% neutralization titers" for additional information.
CAS+IMD=casirivimab and imdevimab. IC_{50}=half-maximal inhibitory concentration. SC= subcutaneous.

References

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