PATHOGENS AND IMMUNITY
In Association with Case Western Reserve University and The Richard J. Fasenmyer Foundation

SUPPLEMENTARY MATERIALS

Corado KC, Chew KW, Giganti MJ, Mu Y, Fletcher CV, Currier JS, Daar ES, Wohl DA, Li JZ, Moser CB, Ritz J, Javan AC, Neytman G, Caskey M, Hughes MD, Smith DM, Eron JJ, ACTIV-2/A5401 Study Team. Safety, Efficacy, and Pharmacokinetics of Combination SARS-CoV-2 Neutralizing Monoclonal Antibodies BMS-986414 (C135-LS) and BMS-986413 (C144-LS) Administered Subcutaneously in Non-Hospitalized Persons with COVID-19 in a Phase 2 Trial. *Pathogens and Immunity*. 2024;9(1):138–155. doi: 10.20411/pai.v9i1.660

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Supplemental Table 1: Definition of Lower Risk of Progression of COVID-19

Lower risk to progression	Not meeting the higher risk to progression definition
Higher risk to progression	Participants are considered at "higher" risk of progression to severe COVID-19 if they have at least one of the following factors: • age 60 years and older and no history of SARS-CoV-2 vaccination • any age with at least one of the following conditions (self-report is acceptable) and no history of SARS-CoV-2 vaccination: 1. current smoker (cigarette smoking within the past 30 days) AND history of at least 100 lifetime cigarettes 2. exogenous or endogenous immunosuppression defined as any of the following: ▪ HIV infection with CD4 count <200 cells/mm3 ▪ receiving corticosteroids equivalent to prednisone ≥20mg daily for at least 14 consecutive days within 30 days prior to study entry ▪ treatment with biologics (e.g., infliximab, abalizumab, ustekinumab, etc.), immunomodulators (e.g., methotrexate, 6MP, azathioprine, etc.), or cancer chemotherapy within 90 days prior to study entry 3. chronic lung disease or asthma requiring daily prescribed therapy 4. obesity (body mass index [BMI] >35; may be based on self-report of height and weight) 5. hypertension, with at least one medication recommended or prescribed 6. cardiovascular disease defined as history of any of the following: myocardial infarction, stroke, transient ischemic attack, heart failure, angina with prescribed nitroglycerin, coronary artery bypass grafts, percutaneous coronary intervention (PCI), carotid endarterectomy, and aortic bypass 7. diabetes mellitus 8. chronic kidney disease requiring hemodialysis or peritoneal dialysis 9. history of cirrhosis 10. active cancer, other than localized skin cancer

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Supplemental Table 2: Analysis of COVID-19 Associated Symptoms Outcomes through Day 28

	BMS mAbs (n=105)	Placebo (n=106)	Analysis Result
Time (days) to sustained symptom improvement for 2 consecutive days[a], median (quartiles)	8 (4, 15)	10 (5, 17)	p=0.19
Enrolled ≤5 days from symptom onset	8 (4, 13)	10 (5, 21)	
Enrolled >5 days from symptom onset	8 (6, 19)	9 (5, 13)	
Time (days) to all targeted symptoms absent for 4 consecutive days[a], median (quartiles)	13 (8, >25)	13 (8, 25)	p=0.69
Time (days) to return to usual pre-COVID-19 health for 2 consecutive days[a], median (quartiles)	12 (6, 25)	16 (8, >27)	p=0.17
Time (days) to return to usual pre-COVID-19 health for 4 consecutive days[a], median (quartiles)	13 (7, >25)	17 (8, >25)	p=0.08
Progression of one or more COVID-19 associated symptoms to a worse status than at day 0[b], n (%)	70 (66.7)	85 (80.2)	RR 0.83 [95%CI: 0.70, 0.98]

BMS mAbs refers to subcutaneously administered BMS-986414 (C135-LS) 200 mg plus BMS-986413 (C144-LS) 200 mg

[a] The time to symptom improvement, time to symptoms absent, and time to return to usual pre-COVID-19 health outcomes were each compared between arms using the Gehan-Wilcoxon test.

[b] The proportion of participants with symptom progression was compared between arms using log-binomial regression and summarized with a risk ratio (RR) and 95% confidence interval (95% CI).

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Supplemental Table 3: Grade 3 or Higher Treatment-Emergent Adverse Events

Arm	ID	Adverse Event	Grade	Start day	End day	Related to Treatment
BMS mAbs	**1**	Blood creatinine increased	3	20	32	Related
	2	COVID-19 pneumonia	3	2	6	Not Related
	3	COVID-19 pneumonia	3	1	7	Not Related
	4	Suicide attempt	4	14	19	Not Related
	5	COVID-19 pneumonia	3	5	9	Not Related
	6	Lymphocyte count decreased	3	4	46	Not Related
	7	Headache	3	1	3	Not Related
	8	Blood glucose increased	3	14	498	Not Related
Placebo	**9**	Anxiety	3	10	35	Not Related
	10	COVID-19 pneumonia	3	8	13	Not Related
		Hypertransaminasaemia	3	9	44	Not Related
		Lymphopenia	4	3	28	Not Related
	11	Hyperglycaemia	3	3	32	Not Related
	12	COVID-19 pneumonia	3	0	12	Not Related
		Hypoxia	3	2	2	Not Related
	13	Blood bilirubin increased	3	20	503	Not Related
	14	COVID-19 pneumonia	3	3	7	Not Related
	15	COVID-19 pneumonia	3	3	9	Not Related
	16	Adverse drug reaction	4	15	35	Not Related
	17	Hypertension	3	7	252	Not Related
	18	Blood glucose increased	3	14	.	Not Related
	19	Alanine aminotransferase increased	3	14	30	Not Related
		Aspartate aminotransferase increased	3	2	30	Not Related
	20	Blood creatinine increased	4	14	31	Not Related
	21	Heavy menstrual bleeding	3	16	226	Not Related
	22	Anaemia	3	4	.	Not Related

BMS mAbs, subcutaneously administered BMS-986414 (C135-LS) 200 mg plus BMS-986413 (C144-LS) 200 mg. Each numbered ID reflects a unique participant (for several participants more than one grade 3 or higher adverse event was reported).

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Supplemental Table 4: Pharmacokinetic Characteristics by Monoclonal Antibody

Variable	BMS-986414 (C135-LS)	BMS-986413 (C144-LS)
$AUC_{0\text{-}72h}$ (h*µg/mL) Median (quartiles)	n=95 515 (302, 676)	n=95 555 (334, 813)
Concentration Day 1 (µg/mL) Median (quartiles)	n=37 8.5 (5.7, 10.8)	n=37 9.5 (7.7, 13.0)
Concentration Day 3 (µg/mL) Median (quartiles)	n=92 13.3 (9.5, 19.4)	n=92 15.3 (10.2, 23.4)
Cmax (µg/mL) Median (quartiles)	n=98 17.6 (13.8, 22.6)	n=98 16.9 (13.4, 23.6)
Tmax (h) Median (quartiles)	n=98 189 (163, 340)	n=98 162 (93, 169)
$AUC_{0\text{-}\infty}$ (h*µg/mL) Median (quartiles)	n=92 54927 (39067, 67168)	n=93 17445 (13594, 20900)
Half-Life (d) Median (quartiles)	n=92 80.0 (70.4, 89.8)	n=93 25.3 (22.2, 28.9)

Abbreviations: area under the concentration-time curve from time 0 to 72 hours, $AUC_{0\text{-}72h}$; maximum observed concentration, Cmax; time to maximum concentration, Tmax; area under the concentration-time curve from time 0 to infinity, $AUC_{0\text{-}\infty}$ (h*µg/mL); hours, h; days, d

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Supplemental Table 5: Association between log_e-transformed AUC_{0-72h} and Time to Symptom Improvement for 2 Consecutive Days

	BMS mAbs	Hazard Ratio (95% CI)	P-value
Overall (n=95)	BMS-986414	1.46 (0.99, 2.17)	0.057
	BMS-986413	1.18 (0.83, 1.68)	0.36
	BMS-986414+BMS-986413	1.31 (0.89, 1.90)	0.17
≤ 5 days from symptom onset (n=63)	BMS-986414	1.57 (1.01, 2.45)	0.045
	BMS-986413	1.37 (0.92, 2.03)	0.12
	BMS-986414+BMS-986413	1.47 (0.96, 2.25)	0.07
> 5 days from symptom onset (n=32)	BMS-986414	1.22 (0.57, 2.62)	0.60
	BMS-986413	0.81 (0.36, 1.79)	0.60
	BMS-986414+BMS-986413	0.98 (0.44, 2.17)	0.96

BMS mAbs, subcutaneously administered BMS-986414 (C135-LS) 200 mg plus BMS-986413 (C144-LS) 200 mg; AUC_{0-72h}: area under the concentration-time curve from time 0 to 72 hours; CI, confidence interval

Hazard ratios estimate the relative hazard of symptom improvement for 2 consecutive days corresponding to a 1 log_e h*µg/mL increase in AUC_{0-72h}. Hazard ratio estimates and corresponding 95% CIs were obtained from Cox proportional hazards regression models with an event outcome of time to 2 consecutive days with all targeted symptoms improved from day 0 status. A two-sided p-value from a Wald test is also reported.

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Supplemental Table 6: Association between log_e-transformed Concentration at Day 3 and Difference in Nasopharyngeal Swab SARS-CoV-2 RNA from Day 0 to Day 3

	BMS mAbs	Estimated incremental change (95% CI) in log_{10} SARS-CoV-2 RNA levels per 1 log_e µg/mL increase in Day 3 concentration	P-value
Overall (n=56)	BMS-986414	-0.91 (-1.71, -0.12)	0.024
	BMS-986413	-0.54 (-1.30, 0.23)	0.17
	BMS-986414+BMS-986413	-0.73 (-1.53, 0.07)	0.07
≤ 5 days from symptom onset (n=33)	BMS-986414	-0.79 (-1.82, 0.25)	0.14
	BMS-986413	-0.32 (-1.38, 0.75)	0.56
	BMS-986414+BMS-986413	-0.56 (-1.63, 0.52)	0.31
> 5 days from symptom onset (n=23)	BMS-986414	-1.08 (-2.40, 0.25)	0.11
	BMS-986413	-0.73 (-1.85, 0.39)	0.20
	BMS-986414+BMS-986413	-0.90 (-2.14, 0.33)	0.15

BMS mAbs, subcutaneously administered BMS-986414 (C135-LS) 200 mg plus BMS-986413 (C144-LS) 200 mg; CI, confidence interval; NP, Nasopharyngeal; LLOQ, lower limit of quantification of assay Analyses restricted to participants with day 0 NP SARS-CoV-2 RNA levels ≥ LLOQ. Estimates and corresponding 95% CIs were obtained from interval censored parametric regression models with a normal distribution and adjusted for day 0 NP SARS-CoV-2 RNA levels. A two-sided p-value from a Wald test is also reported.

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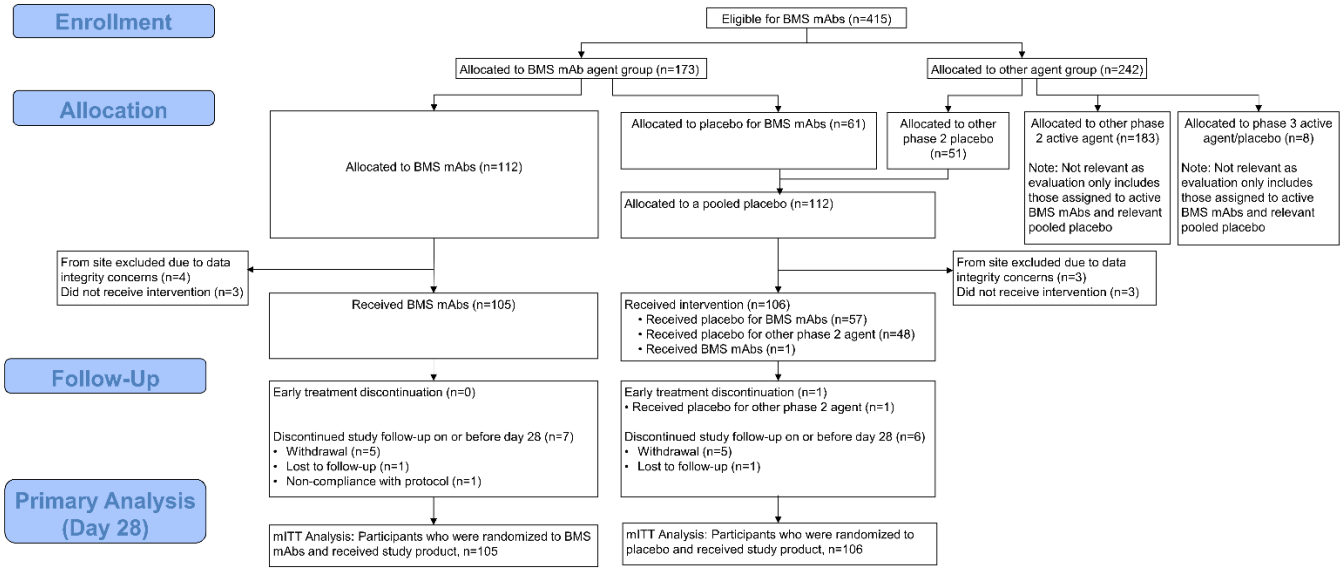
Supplemental Figure 1: Consort Diagram



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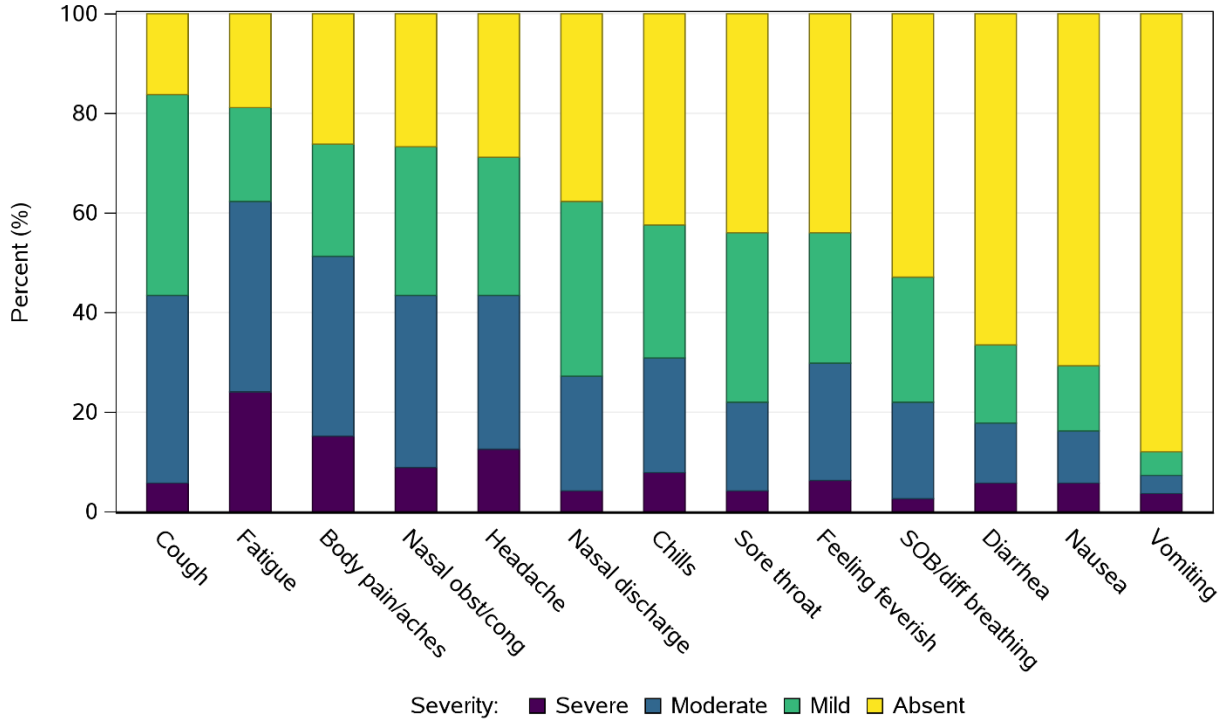
Supplemental Figure 2: Baseline Symptoms by Severity



SOB: Shortness of Breath
Distribution of severity of 13 targeted symptoms on Day 0. Severity scored as severe (purple), moderate (blue), mild (green), or absent (yellow). Targeted symptoms are ordered by prevalence.

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