Table 3. Patient Characteristics, Comorbidities, and Hospitalization Outcomes in Monoclonal Antibody Studies for COVID-19

	Clinical Trials			Real-World Cohort Studies		
First Author	Chen[1]	Gottlieb[2]	Weinreich[3]	Kumar[4]	Bariola[5]	Current Study
Study Group	BLAZE-1	BLAZE-1	REGN-COV2	Chicago	Pittsburgh	Detroit
Treatment arm, (n)	BAM, at 3 dose strengths (309)	BAM/E (109)	CAS/IMD, at 2 dose strengths (182)	BAM (218)	BAM (232)	BAM (294)
Comparison arm, (n)	Placebo (143)	Placebo (152)	Placebo (93)	No drug (185)	No Drug (1,160)	BAM/E (349)
Characteristics [a]						
Median Age	45	44	43	66	67	58
Age ≥65 (%)	11	12		54		32
Male (%)	45	48	46	53	47	43
Median BMI	29.4	27.2	30.5	30.5		33
BMI [b] >30 (%)	45	37	45			63
BMI [b] >35 (%)				30		41
BMI [b] >40 (%)	8	6.4			26	22
Black Race (%)	7	4	13	6	5	24
Diabetes (%)				34	33	33
CKD (%)				9	4	10
COPD					26	8
Immunosuppressed				32		21
Moderate Disease (%)	25	18		17		21
Symptom duration, (Median days)	4.0	4.0	3.0	5.0		5.0
Outcomes [a]						
Hospitalization (%)	1.6	0.9	3.0	7.3	6.5	7.5

Abbreviations: BAM, bamlanivimab; BAM/E, bamlanivimab etesevimab combination; CAS/IMD, casirivimab imdevimab combination; BMI, body mass index; COVID-19, coronavirus disease 2019; CKD, chronic kidney disease; COPD, chronic obstructive pulmonary disease.
[a] Characteristics and outcomes provided are for treatment group or combined treatment groups if more than one dose was investigated
[b] Calculated as weight in kilograms divided by height in meters squared
[1] Chen P, Nirula A, Heller B, et al. *N Engl J Med* 2021;384:229-37. DOI: 10.1056/NEJMoa2029849
[2] Gottlieb R, Chen P, Nirula A, et al. *JAMA*. 2021;325(7):632-644. doi:10.1001/jama.2021.0202
[3] Weinreich DM, Sivapalasingam S, Norton T, et al. *N Engl J Med* 2021;384:238-51.
[4] Kumar RN, Wu E, Stosor V, et al. *Clin Infect Dis*. 2021 Apr. doi: 10.1093/cid/ciab305
[5] Bariola JR, McCreary EK, Wadas RJ, et al. *OFID*. 2021 May. doi.org/10.1093/ofid/ofab254

Our patients were older with higher rates of obesity and other comorbidities than those in clinical trials (shown in orange). Compared to other real-world studies (in blue), our cohort of younger, more obese Black patients had similar hospitalization rates of 7.5%.

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501. Implementation and Outcomes of a Program to Coordinate and Administer Monoclonal Antibody Therapy to Long-Term Care Facility Residents with COVID-19

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Session: P-24. COVID-19 Treatment

Background. Long-term care facility (LTCF) residents are at increased risk of severe COVID-19, with CMS data indicating > 20% mortality. BLAZE-1 trial noted lower hospitalization rates in high-risk patients receiving monoclonal antibody (mAb) vs placebo (4.2% vs 14.6%) for mild to moderate infections, making it a treatment option for LTCF residents; however, many LTCF lack staff to prepare and administer mAb therapy. To address this need, Region VII Disaster Health Response Ecosystem (R7DHRE) coordinated via NE Medical Emergency Operations Center (NEMEOC) an ASPR pilot project to facilitate infusion of COVID-19 mAb therapeutics for LTCF residents in the state.

Methods. R7DHRE partnered with Great Plains Health, Nebraska DHHS, Nebraska Antimicrobial Stewardship Assessment and Promotion Program (ASAP) and Infection Control Assessment and Promotion Program (ICAP) to surveil cases in the state, establish distribution/administration pathways, and educate providers on mAb therapeutics. A multi-hub-and-spoke model was created to allow LTCF to work with regional hospitals or pharmacy services to administer drug in their facilities, reducing time to therapy and transmission risk associated with patient transport. A centralized request process was created using a REDCap platform and verification of patient eligibility by ASAP. This request link, informational documents, fact sheets, and custom-built order form templates were hosted on a dedicated ASAP webpage, and details were shared during weekly ICAP LTCF webinars. Outcomes data, including 14- and 28-day COVID-related hospitalizations and mortality, were collected using databases from Nebraska Health Information Initiative and Nebraska DHHS.

Results. Through this program, 513 doses were administered to LTCF residents. Average time from symptom onset to infusion was 2.6 days. COVID- related hospitalization and mortality rates were lower than previously reported for LTCF residents (Table 1).

Table 1. Debographics and Outcomes of mAb Infusions

	mAb Therapy (n=513)
Demographics	
Age, years, mean (median)	81.8 (84)
Male, n (%)	179 (34.9)
Process Measures	
Average time from symptom onset to infusion, days	2.6
Average time from positive test to infusion, days	2.6
Outcome Measures	
Hospitalizations†, all-cause, n (%)	
14-day	26 (5)
28-day	34 (6.6)
Hospitalizations†, COVID-related, n (%)	
14-day	17 (3.3)
28-day	22 (4.3)
Mortality, n (%)	
14-day	15 (2.9)
28-day	24 (4.7)
Adverse reactions reported, n (%)	4 (0.8)

† Hospitalizations include inpatient admissions and ED visits

Conclusion. By utilizing existing relationships with LTCFs in the region, we established a program to promptly distribute, prepare, and administer monoclonal antibody therapy to LTCF residents in need, preventing COVID-related hospitalizations and deaths.

Disclosures. **James Lawler, MD, MPH, FIDSA**, **Kinsa Health** (Advisor or Review Panel member)**Takeda Pharmaceuticals** (Advisor or Review Panel member) **M. Salman Ashraf, MBBS**, **Merck & Co. Inc** (Grant/Research Support, I have recieved grant funding for an investigator initiated research project from Merck & Con. Inc. However, I do not see any direct conflict of interest related to the submitted abstract)

502. Early COVID-19 Treatment with SARS-CoV-2 Neutralizing Antibody Sotrovimab

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Session: P-24. COVID-19 Treatment

Background. COVID-19 disproportionately results in hospitalization and death in older patients and those with underlying comorbidities. Sotrovimab is a pan-sarbecovirus monoclonal antibody that binds a highly conserved epitope of the SARS-CoV-2 receptor binding domain and has an Fc modification that increases half-life. Sotrovimab retains activity against UK, S. Africa, Brazil, India, New York and California variants in vitro.

Objectives. To evaluate the efficacy and safety of treatment with sotrovimab in high-risk, non-hospitalized patients with mild/moderate COVID-19, as part of the COMET-ICE clinical trial.

Methods. Multicenter, double-blind, phase 3 trial in non-hospitalized patients with symptomatic COVID-19 and ≥1 risk factor for disease progression were randomized 1:1 to an IV infusion of sotrovimab 500 mg or placebo. The primary efficacy endpoint was the proportion of patients with COVID-19 progression, defined as hospitalization > 24 hours or death, due to any cause, ≤29 days of randomization.

Results. The study met the pre-defined primary efficacy endpoint in a preplanned interim analysis: the risk of COVID-19 progression was significantly reduced by 85%

(97.24% CI, 44% to 96%; P = 0.002) in 583 patients. In the final intention-to-treat analysis (N = 1057), the adjusted relative risk reduction was 79% (95% CI, 50% to 91%; p< 0.001) through Day 29 in recipients of sotrovimab (n=528) vs. placebo (n=529). Treatment with sotrovimab (ITT) resulted in a numerical reduction in the need for ER visits for illness management, hospitalization for acute illness management (any duration) or death (any cause) compared to placebo. No participants on sotrovimab required ICU admission, compared to 9 participants on placebo, of whom 4 participants required mechanical ventilation. No participants who received sotrovimab died, compared to 4 participants on placebo. The incidence of adverse events was similar between treatment arms and SAEs were numerically more common in the placebo arm.

Conclusion. Treatment with sotrovimab 500 mg IV resulted in a clinically and statistically significant reduction in progression of COVID-19 to hospitalization or death in patients with mild/moderate disease and was well-tolerated.

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503. In vitro Evaluation of Sitagliptin-HIV-1 Trans-activator Transcription Peptide Nano-formula for Antiviral Activity Against SARS-CoV-2: Drug Repurposing Approach

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Session: P-24. COVID-19 Treatment

Background. The outbreak of COVID-19 pandemic in China regarded as a major health/economic hazard. The importance of coming up with mechanisms for preventing or treating COVID-19 has been felt across the world. This work aimed at examining the efficiency of Sitagliptin (SIT) and human immunodeficiency virus type 1 (HIV-1) trans-activator transcription peptide (TAT) against SARS-CoV-2.

Methods. SIT-TAT nano-conjugates were prepared according to a full three-factor bi-level (2^3) factorial design. SIT concentration (mM, X1), TAT concentration (mM, X2), and pH (X3) were selected as the factors. Particle size (nm, Y1) and zeta potential (mV, Y2) were assessed as responses. Characterization of the optimized formula for Fourier-transformed infrared (FTIR) and Transmission electron microscope was carried out. In addition, IC50 in Vero E6 cells, In vitro 3CL-protease inhibition and docking tests were investigated.

Results. The prepared complex's formula was as follows 1: 1 SIT: TAT molar ratio, whereas zeta potential and particle size values were at 34.17 mV and 97.19 nm, respectively. This combination did exhibit its antiviral potentiality against SARS-CoV-2 via IC50 values of 9.083 5.415, and 16.14 μM for TAT, SIT-TAT, and SIT, respectively. In addition, the complex SIT-TAT showed a significant (P < 0.001) viral-3CL-protease inhibitory effect (IC50 = 3.959 μM ± 0.011) in comparison to isolated components (IC50 = 10.93 μM ± 0.25) and TAT (IC50 = 8.128 μM ± 0.42). This was further confirmed via in silico study. Molecular docking investigation has shown promising binding affinity of the formula components towards SARS-CoV-2 main protease (3-CL).

Conclusion. While offering significant binding interactions with protein's key pocket residues, an optimized formulation of SIT-TAT could guarantee both the enhanced delivery to the target cells and the improved cellular uptake. The presented findings would guarantee further investigations regarding formula optimization against SARS-CoV-2.

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504. Case SEries: Nasal Antimicrobial Photodisinfection (APDT) as Treatment Protocol for Asymptomatic and Early Stage COVID-19 Patients

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Session: P-24. COVID-19 Treatment

Background. Targeted reduction of SARS-CoV-2 viral load in the nose may mitigate the severity of lower tract respiratory disease as well as reduce hospitalization and mortality rates. Nasal Photodisinfection has been deployed for 10 years in Canadian hospitals reducing post-surgical infections. The objective of thiswork was to demonstrate effectiveness of APDT in early stage COVID-19 and asymptomatic carriers.

Methods. A cohort of 40 COVID-19 positive patients were treated with nasal photodisinfection (Steriwave) at a private clinic. All patients were previously identified by PCR as SARS-CoV-2 positive and admitted into the treatment cohort. BD rapid antigen nares testing was used before and after Photodisinfection treatment. Of the 40 patients, 13 were female and 27 were male. Age range was 9- 56 years of age. Treatment involved 3-4 applications of photosensitizer and 16-24 minutes per patient of treatment time. Patients were followed up within 24 hours, 48 hours as well as day 5 and 6 and day 10/11. Patients filled out a COVID-19 score card.

Results. Results demonstrated APDT was capable of significant and rapid viral load reduction in COVID-19 carriers. 100% of patients were converted from positive rapid antigen test to negative. 60% of patients reported fever resolution within 24 hours. Fever resolution occurred in 100% of patients within 48hours. Moreover, results demonstrated accelerated resolution of COVID-19 symptoms and significantly improved mental health benefits from reduction of COVID-19 related stress and anxiety. None of the patients experienced severe symptoms and no patients were hospitalized. Safety outcomes demonstrated no patient safety issues with only minor transient side effects (rhinorrhea, sneezing) observed. Moreover, the treatment procedure was pain-free and well tolerated by all patients.

Conclusion. Photodisinfection-based nasal decolonization anti-viral efficacy was demonstrated with improved outcomes for all patients treated in this case series. Significant rapid viral load reduction was confirmed by rapid antigen tests in all patients. More clinical studies are warranted in support of Photodisinfection based therapy for upper respiratory infections such as COVID-19.

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505. Impact of Remdesivir on SARS-CoV-2 Clearance in a Real-Life Setting: A Matched-Cohort Study

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COVID-BioB Study Group

Session: P-24. COVID-19 Treatment

Background. Evidence regarding the impact of remdesivir (RDV) on SARS-CoV-2 viral clearance (VC) is scarce. Aim of this study was to compare VC timing in COVID-19 patients who received RDV with those who did not.

Methods. Matched-cohort study conducted (25 February 2020-15 April 2021) at the IRCSS San Raffaele, Milan, Italy. The study enrolled hospitalized patients with pneumonia and a SARS-CoV-2 positive nasopharyngeal swab (NPS) at admission and at least one NPS during follow-up. Follow-up started at hospital admission and ended at the date of the first negative NPS (within 30 days after discharge). Patients who received RDV (cases) and patients who did not (controls) were matched based on age (±5 years), sex and PaO_2/FiO_2 (P/F; ±10 mmHg) values at admission. NPS were analyzed with RT-PCR. Results described as median (IQR) or frequency (%). Time to VC was estimated with Kaplan-Meier curve and compared with log-rank test.