Methods. We conducted a retrospective matched study of all cancer patients diagnosed with mild to moderate COVID-19 who received bamlanivimab in our acute cancer care center (ACCC) from December 2020 to February 2021. These patients were compared to a control group of cancer patients who presented to our ACCC and were diagnosed with mild to moderate COVID-19 from March to November 2020 before the introduction of bamlanivimab. Control patients were matched by age and underlying malignancy. All patients had a baseline oxygen saturation ≥ 94% and an absolute neutrophil count > 500 mm^3. Demographics, clinical characteristics, and outcome that included COVID-related admissions, oxygen desaturation, ICU admission and 30-day mortality were compared in both groups.

Results. A total of 108 patients were analyzed with 54 patients in each group, of which 59% consisted of hematologic malignancies, and 33% were ≥ 65 years. The presenting symptoms were similar in both groups and mainly consisted of cough, fever, and dyspnea. Patients who received bamlanivimab were less likely to be admitted to the hospital (24% vs. 91%; p< 0.0001), experience oxygen desaturation < 94% during follow-up (11% vs 44%; p=0.0001), require oxygen supplement (7% vs. 44%; p< 0.0001), or be admitted to the ICU (4% vs 15%; p=0.046). No 30-day mortality was observed in the bamlanivimab group with 2 (4%) occurring in the control group. However, the difference was not significant.

Conclusion. Bamlanivimab decreased hospital and ICU admissions in cancer patients. In addition, bamlanivimab reduced oxygen requirement and the risk of hypoxia and progression to severe disease in this patient population.

Disclosures. **Samuel L. Aitken, PharmD, MPH, BCIDP**, Melinta Therapeutoics (Individual(s) Involved: Self): Consultant, Grant/Research Support

543. Molnupiravir Maintains Antiviral Activity Against SARS-CoV-2 Variants In Vitro and in Early Clinical Studies

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Session: P-24. COVID-19 Treatment

Background. Molnupiravir (MOV, MK-4482, EIDD-2801) is an orally administered prodrug of N-hydroxycytidine (NHC, EIDD-1931), a nucleoside with broad antiviral activity against a range of RNA viruses. MOV acts by driving viral error catastrophe following its incorporation by the viral RdRp into the viral genome. Given its mechanism of action, MOV activity should not be affected by substitutions in the spike protein present in SARS-CoV-2 variants of concern which impact efficacy of therapeutic neutralizing antibodies and vaccine induced immunity. We characterized MOV activity against variants by assessing antiviral activity in vitro and virologic response from the Phase 2/3 clinical trials (MOVe-In, MOVe-Out) for treatment of COVID-19.

Methods. MOV activity against several SARS-CoV-2 variants, was evaluated in an in vitro infection assay. Antiviral potency of NHC (IC50) was determined in Vero E6 cells infected with virus at MOI ~0.1 by monitoring CPE. Longitudinal SARS-CoV-2 RNA viral load measures in participants enrolled in MOVe-In and MOVe-Out were analyzed based on SARS-CoV-2 genotype. Sequences of SARS-CoV-2 from study participants were amplified from nasal swabs by PCR and NGS was performed on samples with viral genome RNA of >22,000 copies/ml amplified by primers covering full length genome with Ion Torrent sequencing to identify clades represented in trial participants. SARS-CoV-2 clades were assigned using clade.nextstrain.org.

Results. In vitro, NHC was equally effective against SARS-CoV-2 variants B.1.1.7 (20I), B.1351 (20H), and P1 (20J), compared with the original WA1 (19B) isolate. In clinical trials, no discernable difference was observed in magnitude of viral response measured by change from baseline in RNA titer over time across all clades represented including 20A through 20E and 20G to 20I. No participants at the time of the study presented with 20F, 20J, or 21A.

Conclusion. Distribution of clades in participants in MOVe-In and MOVe-Out was representative of those circulating globally at the time of collection (Oct 2020 – Jan 2021). Both in vitro and clinical data suggest that spike protein substitutions do not impact antiviral activity of MOV and suggest its potential use for the treatment of SARS-CoV-2 variants.

Disclosures. **Jay Grobler, PhD**, **Merck & Co., Inc.** (Employee, Shareholder) **Julie Strizki, PhD**, **Merck & Co., Inc.** (Employee, Shareholder) **Nicholas Murgolo, PhD**, **Merck & Co., Inc.** (Employee, Shareholder) **Wei Gao, PhD**, **Merck & Co., Inc.** (Employee, Shareholder) **Youfang Cao, PhD**, **Merck & Co.** (Employee) **Ying Zhang, PhD**, **Merck & Co., Inc.** (Employee, Shareholder) **Jiejun Du, PhD**, **Merck & Co., Inc.** (Employee, Shareholder) **Manoj Nair, PhD**, **Merck & Co., Inc.** (Grant/Research Support, Scientific Research Study Investigator, Research Grant or Support) **Yaoxing Huang, PhD**, **Merck & Co., Inc.** (Grant/Research Support, Scientific Research Study Investigator, Research Grant or Support) **Yang Luo, PhD**, **Merck & Co., Inc.** (Grant/Research Support, Scientific Research Study Investigator, Research Grant or Support) **Daria Hazuda, PhD**, **Merck & Co., Inc.** (Employee, Shareholder) **David D. Ho, MD**, **Merck & Co., Inc.** (Grant/Research Support, Scientific Research Study Investigator, Research Grant or Support) **David D. Ho, MD**, Brii Biosciences (Individual(s) Involved: Self): Consultant; Merck (Individual(s) Involved: Self): Research Grant or Support; RenBio (Individual(s) Involved: Self): Consultant, Founder, Other Financial or Material Support, Shareholder; WuXi Biologics (Individual(s) Involved: Self): Consultant

544. Using Active Surveillance to Identify Monoclonal Antibody Candidates Among COVID-19 Positive Veterans, Atlanta VA Healthcare System

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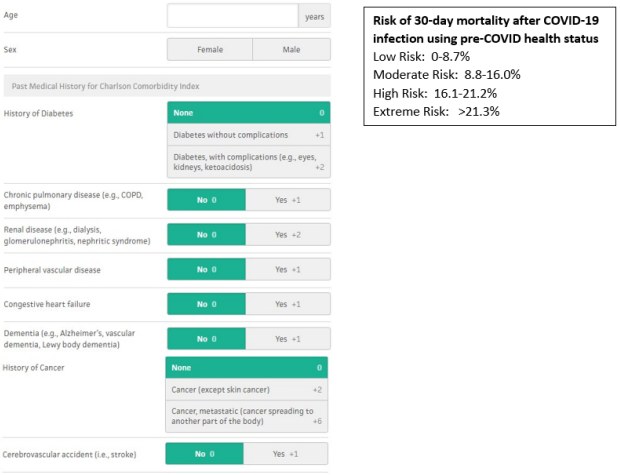
Session: P-24. COVID-19 Treatment

Background. Monoclonal antibody (Mab) infusions have reduced hospitalization and mortality among higher risk patients with mild to moderate COVID-19 symptoms. Using an interdisciplinary team approach, we created a clinical team to proactively screen and outreach patients with COVID-19 to equitably offer Mab.

Methods. From December 28, 2020 - May 3, 2021, a clinical team consisting of an Infectious disease pharmacist and physician, reviewed each outpatient with a positive SARS-CoV-2 PCR test at the Atlanta VA Healthcare System (AVAHCS) daily. The clinical team used the published Emergency Use Authorization criteria to determine eligibility. Eligible patients were prioritized using the Veterans Health Administration (VACO) Index for COVID-19 Mortality, which estimates the risk of 30-day mortality after COVID-19 infection using pre-COVID-19 health status (Figure 1). Eligible patients were contacted via telephone to confirm eligibility and obtain verbal consent. We performed SARS-CoV-2 IgG antibody tests when possible prior to Mab infusion, but results did not preclude Mab receipt. Telehealth follow-up occurred at 1- and 7-days post infusion.

Figure 1. Veterans Health Administration COVID-19 (VACO) Index for COVID-19 Mortality



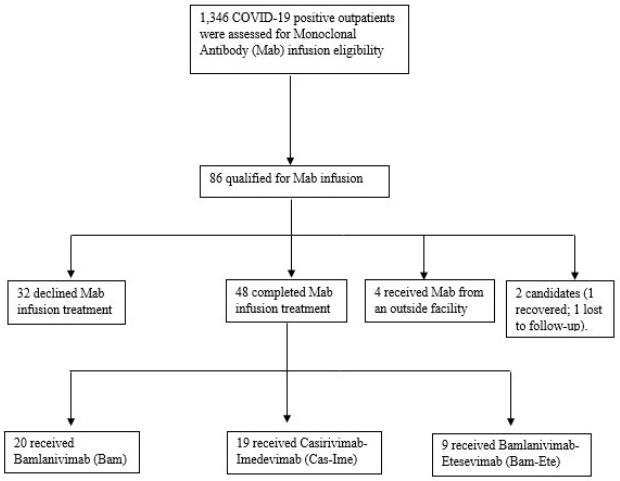
Overview of the elements of the VACO index, part 1 of 2.

Figure 1 continued. Veterans Health Administration COVID-19 (VACO) Index for COVID-19 Mortality

Overview of the elements of the VACO index, part 2 of 2.

Results. In total, 1,346 COVID-19 patients were identified; 86 (6%) patients were eligible, and 48/86 (55%) received Mab infusions (Figure 2). The median time from symptom-onset to positive COVID-19 PCR test result was 6 days (0-9) and the median time from positive COVID-19 PCR test result to Mab infusion was 2 days (0-8). SARS-CoV-2 IgG antibodies were detected in 4 of 24 (17%) patients tested. The most common comorbidities were hypertension (73%) and diabetes, (42%) (Table). Five (10%) patients required hospitalization for worsening COVID-19 symptoms post infusion. No deaths occurred.

Figure 2. Overview of COVID-19 Monoclonal Antibody (Mab) infusion Process



Summary of Mab Infusion Screening Process

Table. Patient Characteristics of Monoclonal (Mab) Infusion Recipients (N = 48)

	Number (%)
Age ≥65	19 (40)
Male	41 (85)
Race/Ethnicity – no. (%)	
Black	30 (63)
White	17 (35)
Other	1 (2)
BMI ≥ 35 – no. (%)	19 (40)
Monoclonal Ab Infusion Type	
Bamlanivimab (Bam)	20 (42)
Bamlanivimab-Etesevimab (Bam-Ete)	9 (19)
Casirivimab-Imedevimab (Cas-Ime)	19 (40)
Initial symptom onset to Infusion	
Median, days (range)	6 (0-9)
Positive test result to Infusion	
Median, days (range)	2 (0-8)
Reported Side Effects at 1 day	8 (17)
Nausea	2
Pruritis	2
Multiple[1]	2
Diarrhea	1
Dyspnea	1
Reported Side Effects at 7 days	7 (15)
Dyspnea	5
Nausea	1
Multiple[2]	1
Hospitalized due to worsening COVID-19 symptoms	5 (10)
Risk Factors	
Hypertension (HTN)	35 (73)
Diabetes	20 (42)
Chronic Respiratory Disease (CRD)	14 (29)
Cardiovascular Disease (CVD)	8 (17)
Age ≥ 55 + HTN	27 (56)
Age ≥ 55 + CRD	10 (21)
Age ≥ 55 + CVD	6 (13)
SARS-CoV-2 IgG detected	4 (17)

1. Two patients reported multiple side effects: (1) pruritis, rash, dyspnea; and (2) dyspnea and fever.
2. One patient reported multiple side effects: nausea, vomiting, diarrhea.

Descriptive Statistics and Findings of Study Data, part 1 of 2

Table continued. Patient Characteristics of Monoclonal (Mab) Infusion Recipients (N = 48)

Descriptive Statistics and Findings of Study Data, part 2 of 2

Conclusion. This approach of combining laboratory surveillance and active screening minimized delay in symptoms onset to Mab infusion, thereby optimizing outpatient treatment of COVID-19 disease. Our approach successfully treated a more diverse patient population compared to clinical trials. Mab infusions overall was well tolerated with few hospitalizations and no deaths in this cohort.

Disclosures. **All Authors**: No reported disclosures

545. A Retrospective Review of 30-day Mortalities in Solid-Organ Transplant Recipients (SOT) versus Non-Transplant Patients (NTP) Receiving Remdesivir (REM) and Dexamethasone (DEX) for COVID-19 Pneumonia

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Session: P-24. COVID-19 Treatment

Background. Treating COVID-19 infection in SOT is challenging due to long-term use of immunosuppressive agents. REM is the only FDA-approved anti-viral for SARS-COV-2 infection. DEX showed decrease in mortality in the Recovery Trial. COVID-19 treatment guidelines for SOT patients are the same as NTP despite limited literature on those outcomes. Our primary objective was to determine if 30-day mortality was different between SOT and NTP matched cohorts using these 2 drugs. The secondary objectives included comparisons of length of stay (LOS), days on mechanical ventilation (DMV), and the use of other treatment modalities.

Methods. We retrospectively collected data for hospitalized SOT and NTP, 18 years and older, with pcr-confirmed SARS-CoV-2 infection receiving REM and DEX from May 1, 2020, to October 10, 2020, at Mayo Clinic Florida. IRB approval was obtained. Descriptive statistics were used to analyze the data. Continuous variables were summarized as mean (standard deviation) or median (range) where appropriate, while categorical variables were reported as frequency (percentage).

Results. Of 80 patients who met the inclusion criteria, 28 were SOT, and 52 were NTP. The SOT cohort was subcategorized below:

Characteristics	Number of SOT (n = 28)
Transplant Type	
Kidney n (%)	15 (53.7)
Lung n (%)	3 (10.7)
Liver n (%)	2 (7.1)
Heart n (%)	6 (21.4)
Multi-organ n (%)	2 (7.1)

SOT patients were significantly younger than NTP ($p < .001$). Further, SOT patients had significantly longer LOS ($p = 0.043$) and more COVID-19 modalities (75% vs. 36.5%, $p = 0.002$) compared to NTP. Among the 28 SOT patients, 2 of them died within 30 days of admission, and among the 52 NTP patients, 7 of them died within 30 days. The 30-d survival estimate for SOT group is 92.9% (95% CI: 83.8% - 100.0%) and for NTP group is 86.5% (95% CI: 77.7% - 96.3%). The log-rank test was not significant between the groups (p=0.37), but the NTP has a worse survival curve from the figure below.

SOT-NTP Survival Curve