Conclusion. SOT group was younger, had longer LOS, and more COVID-related modalities. The 30-d survival estimate for SOT group is 92.9% and for NTP group is 86.5%, but the survival curve for NTP was worse likely secondary to age. Use of REM & DEX in SOT recipients is a valid recommendation.

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546. Therapeutic Effect of Regdanvimab in Patients with Mild to Moderate COVID-19: Day 28 Results from a Multicentre, Randomised, Controlled Pivotal Trial

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Session: P-24. COVID-19 Treatment

Background. Regdanvimab is a monoclonal antibody with activity against SARS-CoV-2. A Phase 2/3 study with two parts is currently ongoing and data up to Day 28 of Part 1 is available while the data from 1315 patients enrolled in Part 2 are expected in June 2021.

Methods. This phase 2/3, randomized, parallel-group, placebo-controlled, double-blind study with 2 parts is aimed to assess the therapeutic efficacy of regdanvimab in outpatients with mild to moderate COVID-19, not requiring supplemental oxygen therapy. Patients aged >18 with the onset of symptoms within 7 days were eligible to be enrolled.

Results. In Part 1, 307 patients (101, 103, and 103 patients in the regdanvimab 40 mg/kg, regdanvimab 80 mg/kg, and placebo groups, respectively) were confirmed to have COIVD-19 by RT-qPCR at Day 1 (or Day 2). Regdanvimab significantly reduced the proportion of patients who required hospitalization or supplemental oxygen therapy compared to placebo (8.7% in the placebo vs. 4.0% in the regdanvimab 40 mg/kg). The difference in events rate was even larger in patients who met the high-risk criteria and confirmed a 66.1% reduction in patients receiving regdanvimab 40 mg/kg (Table 1). The median time to clinical recovery was shortened by 2.9 days (7.18 days for regdanvimab 40 mg/kg and 10.03 days for placebo; high-risk). Also, greater reductions from baseline viral load were shown in regdanvimab groups (Figure 1). The safety results confirmed that the regdanvimab was safe and well-tolerated. Occurrence of adverse events (Table 2) and results of other safety assessments were generally comparable among the 3 groups. The overall rate of infusion-related reaction was low and no serious adverse events or deaths were reported. The anti-drug antibody positive rate was low in the regdanvimab groups (1.4% in regdanvimab vs. 4.5% in placebo), and no antibody-dependent enhancement was reported.

Table 1. Proportion of Patients with Clinical Symptoms Requiring Hospitalization, Oxygen Therapy, or Experiencing Mortality due to SARS-CoV-2 Infection up to Day 28

	Regdanvimab 40 mg/kg	Regdanvimab 80 mg/kg	All Regdanvimab Doses	Placebo
All patients	4/101 (4%)	5/103 (4.9%)	9/204 (4.4%)	9/103 (8.7%)
Patients at high risk*	3/70 (4.3%)	5/76 (6.6%)	8/146 (5.5%)	9/71 (12.7%)

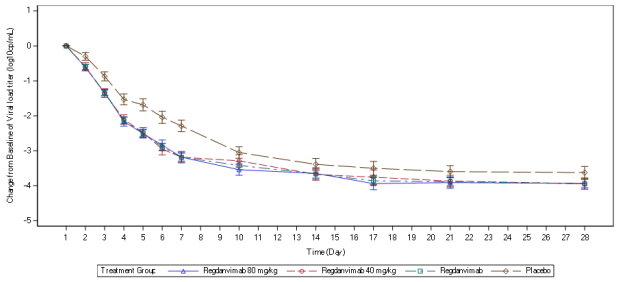
* High risk patients were defined as patients with 1 or more of the following risk factors: Age >50 years; BMI > 30 kg/m^2; Cardiovascular disease, including hypertension; Chronic kidney disease, including those on dialysis; Chronic lung disease, including asthma; Chronic metabolic disease, including diabetes; Chronic liver disease; and Immunosuppressed, based on investigator's assessment.

Note: Criterion of Hospitalisation is ≥24 hours of acute care. Criteria of oxygen therapy are at least 24 hours of supplemental oxygen care and SpO_2 measure in room air before applying supplemental oxygen showing ≤94%.

Table 2. Summary of Safety Results up to Day 28

Number of patients (%)		Regdanvimab 40 mg/kg (N=105)	Regdanvimab 80 mg/kg (N=110)	All Regdanvimab Doses (N=215)	Placebo (N=110)
Treatment-emergent adverse events (TEAEs)	Total	31 (29.5)	27 (24.5)	58 (27.0)	34 (30.9)
	Related	7 (6.7)	5 (4.5)	12 (5.6)	5 (4.5)
Treatment-emergent serious adverse events	Total	0	0	0	0
TEAEs classified as infusion-related reaction	Related	1 (1.0)	0	1 (0.5)	2 (1.8)

Figure 1. Mean (±SE) Change from Baseline for Viral Titre (in log_{10}cp/ml) from RT-qPCR



Conclusion. Results from the first part of the study indicate that regdanvimab may lower the rate of hospitalisation or requirement of oxygen supplementation, with the greatest benefit noted in patients at high-risk of progressing to severe COVID-19. The second part of the study remains ongoing and blinded. Therefore, results for the primary endpoint are forthcoming and will be presented at IDWeek.

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547. Risk Factors Associated with 30-Day Mortality in a Large Cohort of Patients who Received Remdesivir and Corticosteroids for Severe COVID-19

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Session: P-24. COVID-19 Treatment

Background. Remdesivir (RDV), an antiviral agent, is approved by Food and Drug Administration (FDA) for the treatment of patients (pts) admitted with SARS-COV-2 infection (COVID-19). Earlier RDV studies (such as ACCT-1) prior to widespread use of corticosteroids (CS), showed a 30-day mortality of 11%. Advanced age, obesity, and certain comorbidities are known risk factors for death in COVID-19, but whether these risks vary in pts treated with RDV and CS is unknown. As of March 20, 2020 CS were routinely used for the treatment of pts admitted with COVID19 in our health care system. The objective of this study was to identify risk factors associated with 30 -Day mortality in a cohort of pts admitted with COVID-19 and who received RDV and CS.

Methods. This retrospective cohort study evaluated pts admitted to a health system in South East Michigan with COVID-19 between March and November 2020 who received ≥1 dose RDV. Demographics, comorbidities, and characteristics including quick sequential organ failure assessment (qSOFA) score were collected and compared between patients who died versus survived. Primary outcome was 30 day mortality. Secondary outcomes were risk factors for death using logistic regression and time-to-event analysis.

Results. A total of 1,591 pts received RDV and were included in the study; median age 67 years, 56% male and 18% Black. RDV use increased after emergency use authorization and FDA approval (Fig 1). Death within 30 days occurred in 15.3%. Patients who died were older males with higher rates of hypertension, kidney disease, diabetes, and were more likely to have qSOFA ≥2 on arrival (Table 1). In a multivariable logistic model, advanced age, male gender, pulmonary disease, CKD, obesity, and qSOFA≥2 were independent predictors of death (Figure 2). Among these, age and qSOFA≥2 were the most important risk factors (Figure 2).