Methods. We identified KTR with COVID-19 between 3/1/2020 and 4/30/2021. Patients were excluded if they had multiorgan transplant or hospital-acquired COVID-19. Data were analyzed by Cox regression with mAb administration as time-dependent variable, and the day of symptom onset as baseline.

Results. We studied 95 KTR; 20 received mAb. Comorbidities and immunosuppression were balanced between the two groups. mAb administration was associated with a significant decrease in hospitalizations or ER visits (15 vs. 76%, P< 0.001). This association remained significant after adjustment for confounders and by analyzing mAb administration as a time-dependent variable (Table: adj. HR 0.2, P=0.04). No KTR who received mAb died or required mechanical ventilation. Black or Hispanic KTR were less likely to receive mAb and more likely to be admitted to the hospital or visit the ER (Table).

Table

Analysis / Parameter	Univariate			Multivariate		
	HR	95% CI	P	HR	95% CI	P
Age (years)	1.022	1.004-1.041	**0.019**	1.023	1.003-1.044	**0.024**
mAb	0.115	0.036-0.368	**0.009**	0.216	0.050-0.929	**0.040**
Chronic kidney disease	2.456	1.243-4.855	**0.010**	2.087	1.043-4.176	**0.038**
Black race	2.168	1.186-3.964	**0.012**	1.881	0.959-3.689	0.066
Hispanic ethnicity	1.701	1.003-2.883	**0.049**	2.029	1.111-3.703	**0.021**

Factors significantly associated with hospitalization or ER visit.

Conclusion. In our KTR population, mAb therapy for COVID-19 may have helped decrease hospitalizations and ER visits. Healthcare inequities, including access to investigational treatments, were exacerbated by the COVID-19 pandemic. Acknowledging the nonconcurrent control group as a limitation, we found a strong signal for benefit from mAb treatment. Antiviral mAb are a promising therapeutic modality for immunosuppressed patients.

Disclosures. **Dimitrios Farmakiotis, M.D.**, **Astellas** (Grant/Research Support)**Merck** (Grant/Research Support)**Viracor** (Grant/Research Support)

40. Lenzilumab Efficacy and Safety in Newly Hospitalized COVID-19 Subjects: Results From a Phase 3 Randomized Double-Blind Placebo-Controlled Trial

Zelalem Temesgem, MD[1]; Charles Burger, MD[1]; Jason Baker, MD[2]; Christopher Polk, MD[3]; Claudia R. Libertin, MD[4]; Colleen F. Kelley, MD, MPH[5]; Vincent Marconi, MD[6]; Robert Orenstein, DO[7]; Victoria Catterson, PhD[8]; William Aronstein, MD, PhD[9]; Cameron Durrant, MD[10]; Dale Chappell, MD[10]; Omar Ahmed, PharmD[10]; Gabrielle Chappell, MSc[10]; Andrew Badley, M.D.[1]; for the LIVE-AIR Study Group, n/a[10]; [1]Mayo Clinic, Rochester, MN; [2]Hennepin Healthcare Research Institute, Minneapolis, Minnesota; [3]Atrium Health, Charlotte, North Carolina; [4]Mayo Clinic, Jacksonville, Jacksonville, FL; [5]Emory University, Decatur, GA; [6]Atlanta VA, Atlanta, GA; [7]Mayo Clinic in Arizona, Phoenix, AZ; [8]BioSymetrics, Inc, New York, New York [9]CTI, Clinical Trial Services, Inc, Covington, Kentucky; [10]Humanigen, Inc, Burlingame,, California

Drs. Meghan Lewis, Linda Sher, Michael Bowdish, Noah Wald-Dickler, Subarna Biswas, Lydia Lam, Khang Vo, Roy Poblete, May M. Lee, Douglass Hutcheon from the University of Southern California (USC) Keck and LAC Medical Centers; Drs. Zelalem Temesgen, and Andrew D. Badley, MD from the Mayo Clinic, Rochester MN; Drs. Charles D. Burger and Claudia R. Libertin from Mayo Clinic, Jacksonville FL; Dr. Jason Baker from Hennepin Healthcare Research Institute Minneapolis, MN; Dr. Victoria Catterson from BioSymetrics, Inc., New York, NY; Dr. William S. Aronstein from CTI, Covington, KY; Drs. Cameron Durrant, Dale Chappell, Omar Ahmed, and Gabrielle Chappell from Humanigen, Inc., Burlingame, CA; Drs. Robert Orenstein and Roberto Patron from Mayo Clinic Arizona, Drs. Colleen F. Kelley, John Gharbin, Caitlin Moran, Sheetal Kandiah, Valeria Cantos, Paulina Rebolledo, Carlos del Rio, Jeffrey Lennox, Carmen Polito, Paulina Rebolledo, Anandi Sheth from Emory University Medical Center and Grady Memorial Hospital; Drs. Anup Patel, Homero Paniagua from St. Barnabas Medical Center; Dr. Seife Yohannes from MedStar Washington Hospital Center; Drs. Alpesh Amin, Richard Lee, Miki Watanabe, Lanny Hsieh from the University of California-Irvine Medical Center; Drs. Martin Cearras, Amay Parikh, Jason Sniffen, Wilfred Onyia from AdventHealth Orlando; Drs. Vincent C. Marconi, Christopher Polk, Michael Boger, Lisa Davidson, Kiran Gajurel, Michael Leonard, Lewis McCurdy, Nestor Quezada, Mindy Sampson, Zainab Shahid, Stephanie Strollo, David Weinrib, Sara Zulfigar from Atrium Health; Drs. Cheryl McDonald, John Hollingsworth, John Burk, Joshua Berg, Daniel Barbaro, Andrew Miller, Lakshmi Sambathkumar, Stuart McDonald, Obinna Okoye from Texas Health Harris Methodist Hospital Fort Worth; Drs. Juan Pulido, Jennifer Fulton, William Gill from Baptist Health Research Institute Jacksonville; Drs. Richard Zuckerman, Lionel Lewis from Dartmouth-Hitchcock Medical Center; Dr. Chaitanya Mandapakala from St. Elizabeth Medical Center; Drs. Matthew Robinson, Brian Metzger from St. David's Medical Center; Drs. Maqsood Alam, Chrisoula Politis from Mercy Medical; Drs. Anne Frosch, Linh Ngo from Hennepin Healthcare; Drs. Fernando Carvalho Neuenschwander, Estevão Figueiredo, Gualter Cançado, Gustavo Araujo, Lucas Guimarães from Hospital Vera Cruz (NUPEC) in Brazil; Drs. Ricardo Diaz, Natalia Bacellar, Celso Silva, Paulo Ferreira, from Escola Paulista de Medicina (UNIFESP) in Brazil; Dr. Marina Andrade Lima, Caroline Uber Ghisi, Camila Anton, Ricardo Albaneze from Hospital Dia do Pulmãoin Brazil; Dr. Daniel Wagner de Castro Lima Santos, Ana Caroline Iglessias, Marianna Lago, Paula Pietrobom, Maysa Alves from Hospital São Luiz do Jabaquara (IDOR) in Brazil; Drs. Juvencio José Duailibe Furtado, Leopoldo Trevelin, Valeria Telles, Francini Correa from Hospital Heliópolis in Brazil; Drs. Fabiano Ramos, Marina de A. R. Da Silva, Rebeca C. Lacerda Garcia, Ana Elizabeth G. Maldonado, Ana Carolina M. Beheregaray, Ana Maria T. Ortiz from Hospital São Lucas (PUCRS); Drs. Kleber Luz, Eveline Pipolo Milan, Janine Soares de Castro, Matheus José Barbosa Moreira, Renata Bezerra Onofre, Tácito do Nascimento Jácome, Victor Barreto Garcia, Victor Matheus Rolim de Souzafrom Centro de Pesquisas Clínicas de Natal (CPCLIN) in Brazil; Drs. Felipe Dal Pizzol, Cristiane Ritter, Marcelo B. Vinhas from Sociedade Literaria e Caritativa Santo Agostinho (SLCSA) in Brazil; Drs. Adilson Joaquim Westheimer Cavalcante, Julia Minghini, Loni Dorigo, Marina Salgado Miranda from Centro Multidisciplinar de Estudos Clínicos (CEMEC) in Brazil; Drs. Martti Anton Antila, Rebeca Brugnolli, Henrikki Antila from Consultoria Médica e Pesquisa Clínica (CMPC) in Brazil

Session: O-08. COVID-19 Treatment & Diagnostics

Background. Severe coronavirus disease 2019 (COVID-19) often results from the immune-mediated cytokine storm, triggered by granulocyte macrophage-colony stimulating factor (GM-CSF), potentially leading to respiratory failure and death. Lenzilumab, a novel anti-human GM-CSF monoclonal antibody, neutralizes GM-CSF and demonstrated potential to improve clinical outcomes in a matched case-cohort study of patients with severe COVID-19 pneumonia. This Phase 3 randomized, double-blind, placebo-controlled trial investigated the efficacy and safety of lenzilumab to improve the likelihood of survival without invasive mechanical ventilation (SWOV), beyond available treatments.

Methods. Hypoxic patients, hospitalized with COVID-19 (n=520), requiring supplemental oxygen, but not invasive mechanical ventilation, were randomized on Day 0 to receive lenzilumab (1800mg, n=261) or placebo (n=259), and available treatments, including remdesivir and/or corticosteroids; and were followed through Day 28.

Results. Baseline demographics were comparable between groups: male, 64.7%; mean age, 60.5 years; median CRP, 79.0 mg/L. Patients across both groups received steroids (93.7%), remdesivir (72.4%), or both (69.1%). Lenzilumab improved the primary endpoint, likelihood of SWOV in the mITT population, by 1.54-fold (HR: 1.54; 95%CI: 1.02-2.32, p=0.0403). Lenzilumab improved SWOV by 1.91-fold (nominal p=0.0073) and 1.92-fold (nominal p=0.0067) in patients receiving remdesivir or remdesivir and corticosteroids, respectively. A key secondary endpoint of incidence of IMV, ECMO or death was also improved in patients receiving remdesivir (p=0.020) or remdesivir and corticosteroids (p=0.0180). Treatment-emergent serious adverse events were similar across both groups.

Conclusion. Lenzilumab significantly improved SWOV in hypoxic COVID-19 patients upon hospitalization, with the greatest benefit observed in patients receiving treatment with remdesivir and corticosteroids. NCT04351152

Disclosures. **Zelalem Temesgem, MD**, **Humanigen, Inc** (Grant/Research Support) **Jason Baker, MD**, **Humanigen, Inc** (Grant/Research Support) **Christopher Polk, MD**, **Atea** (Research Grant or Support)**Gilead** (Advisor or Review Panel member, Research Grant or Support)**Humanigen** (Research Grant or Support)**Regeneron** (Research Grant or Support) **Claudia R. Libertin, MD**, **Gilead** (Grant/Research Support) **Colleen F. Kelley, MD, MPH**, Gilead Sciences (Individual(s) Involved: Self): Grant/Research Support; Moderna (Individual(s) Involved: Self): Grant/Research Support; Novavax (Individual(s) Involved: Self): Grant/Research Support; Viiv (Individual(s) Involved: Self): Grant/Research Support **Vincent Marconi, MD**, **Bayer** (Consultant, Scientific Research Study Investigator)**Eli Lilly** (Consultant, Scientific Research Study Investigator)**Gilead Sciences** (Consultant, Scientific Research Study Investigator)**ViiV** (Consultant, Scientific Research Study Investigator) **Victoria Catterson, PhD**, **Humanigen, Inc** (Consultant) **William Aronstein, MD, PhD**, **Humanigen, Inc** (Consultant) **Cameron Durrant, MD**, **Humanigen, Inc** (Employee) **Dale Chappell, MD**, **Humanigen, Inc** (Employee) **Omar Ahmed, PharmD**, **Humanigen, Inc** (Employee) **Gabrielle Chappell, MSc**, **Humanigen, Inc** (Consultant) **Andrew Badley, M.D.**, **AbbVie** (Consultant) **for the LIVE-AIR Study Group, n/a**, **Humanigen, Inc** (Grant/Research Support)

41. Assessing Past vs Present COVID-19 Infection: A Survey of Criteria for Discontinuing Precautions in Asymptomatic Patients

Shruti K. Gohil, MD, MPH[1]; Annabelle De St. Maurice, MD[2]; Deborah S. Yokoe, MD, MPH[3]; Deborah S. Yokoe, MD, MPH[3]; Stuart H. Cohen, MD[4]; Francesca J. Torriani, MD[5]; Jonathan Grein, MD[6]; Philip A. Robinson, MD[7]; Shannon C. Mabalot, MPH, CIC[8]; Paula Pedrani, BS[1]; Jessica Park, BS[9]; Richard Platt, MD, MSc[10]; Susan S. Huang, MD, MPH[9]; [1]UC Irvine School of