dysphagia. Of these patients only 2.4% (n=2) were found to have oropharyngeal dysphagia on clinical assessment.

This preliminary study emphasises the importance of the SLT role within the Multi-Disciplinary Team; to identify whether these symptoms warrant further assessment. This study also highlights the benefits of access to instrumental assessment to prevent patient morbidity and inform diagnostic management.

Further prospective studies with larger patient cohorts may help to understand patient-reported symptoms of dysphagia further, and continue to inform clinical decision-making.

Developing treatments for COVID-19

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LENZILUMAB EFFICACY AND SAFETY IN NEWLY HOSPITALIZED COVID-19 SUBJECTS: RESULTS FROM THE LIVE-AIR PHASE 3 RANDOMIZED DOUBLE-BLIND PLACEBO-CONTROLLED TRIAL

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Background Severe COVID-19 pneumonia results from a hyperinflammatory immune response (cytokine storm, CS), characterized by GM-CSF mediated activation and trafficking of myeloid cells, leading to elevations of downstream inflammatory chemokines (MCP-1, IL-8, IP-10) and cytokines (IL-6, IL-1). CS leads to fever, hypotension, coagulopathy, respiratory failure, ARDS, and death. Lenzilumab is a novel Humaneered[®] anti-human GM-CSF monoclonal antibody that binds GM-CSF and prevents signaling through its receptor. The LIVE-AIR Phase 3 randomized, double-blind, placebo-controlled trial investigated the efficacy and safety of lenzilumab to improve the likelihood of ventilator-free survival (referred to herein as survival without ventilation, SWOV), beyond standard supportive care, in hospitalized subjects with severe COVID-19.

Methods Subjects with COVID-19 (n=520), ≥18 years, and ≤94% oxygen saturation on room air and/or requiring supplemental oxygen, but not invasive mechanical ventilation, were randomized to receive lenzilumab (600 mg, n=261) or placebo (n=259) via three intravenous infusions administered 8 hours apart. Subjects were followed through Day 28 following treatment.

Results Baseline demographics were comparable between the two treatment groups: male, 64.7%; mean age, 60.5 years; mean BMI, 32.5 kg/m²; median CRP, 79 mg/L; CRP was <150 mg/L in 78% of subjects. The most common comorbidities were hypertension (65.6%), obesity (55.1%), diabetes (53.4%), chronic kidney disease (14.0%), and coronary artery disease (13.6%). Subjects received steroids (93.7%), remdesivir (72.4%), or both (69.1%). Lenzilumab improved the likelihood of SWOV by 54% in the mITT population (HR: 1.54; 95%CI: 1.02–2.32, p=0.0403). SWOV also relatively improved by 92% in the predefined subgroup of subjects who

received both corticosteroids and remdesivir (1.92; 1.20–3.07; nominal p=0.0067). 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). Serious adverse events were reported in 24.7% and 29.6% of the lenzilumab and placebo patients, respectively. Compared with placebo, lenzilumab produced no infusion-related reactions, and no attributable serious adverse events; including, hematologic or liver enzyme abnormalities, pulmonary alveolar proteinosis, or increased incidence of infection.

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

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C-REACTIVE PROTEIN AS A BIOMARKER FOR IMPROVED EFFICACY OF LENZILUMAB IN COVID-19 PATIENTS: RESULTS FROM THE LIVE-AIR TRIAL

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Background The hyperinflammatory cytokine storm (CS) of COVID-19 is mediated by GM-CSF leading to release of downstream inflammatory chemokines, cytokines, and markers of systemic inflammation (C-reactive protein, CRP). The LIVE-AIR study demonstrated that lenzilumab, an anti-GM-CSF monoclonal antibody in patients hospitalized with COVID-19, safely improved the likelihood of achieving the primary endpoint, survival without ventilation (SWOV) by 1.54-fold (HR: 1.54; 95%CI: 1.02–2.32, p=0.0403) compared with placebo. An exploratory analysis in patients with CRP<150 mg/L and age<85 years was conducted to determine lenzilumab efficacy when administered prior to advanced inflammation.

Methods LIVE-AIR was a phase 3 randomized, double-blind, placebo-controlled trial. Patients with COVID-19 (n=520), ≥18 years, and ≤94% oxygen saturation on room air and/or requiring supplemental oxygen, but not invasive mechanical ventilation (IMV), were randomized to receive lenzilumab (600 mg, n=261) or placebo (n=259) via three intravenous infusions administered 8 hours apart. Participants were followed through Day 28 following treatment.

Results Overall, baseline demographics were comparable between treatment groups: male, 64.7%; mean age, 60.5 years; mean BMI, 32.5 kg/m²; median CRP, 79 mg/L; CRP was <150 mg/L in 78% of participants. Participants received steroids (93.7%), remdesivir (72.4%), or both (69.1%). Lenzilumab (n=159) improved the likelihood of SWOV by 3.04-fold in participants with CRP<150 mg/L and age<85 years (3.04; 1.68–5.51, nominal p=0.0003) compared with placebo (n=178). Response to lenzilumab was observed in the first through third quartiles of baseline CRP (<41 mg/L, HR:8.33;