Sharp HealthCare COVID-19

Inpatient Treatment Clinical Trials

Updated September 25, 2020

Mild to Moderate

IRB # Hospitals	Study	Primary Inclusion Criteria	Primary Exclusion Criteria	Investigators	Contact	Notes
2003902 SMH SGH SCV	**COVID-ARB**	-Mild to moderate respiratory symptoms, ---SBP ≥110mmHg; Screen within 3 days of COVID-19 test	-Severe allergy to any ARB or ACE inh, in ICU, home meds include ACE or ARB; CrCl < 30ml/min	SMH:Sakoulas SGH: Haddad SCV: Shao	Matthew Geriak, PharmD; matthew.geriak@sharp.com; Cary Murphy, RN cary.murphy@ sharp.com	Open to Enrollment

Moderate

IRB # Hospitals	Study	Primary Inclusion Criteria	Primary Exclusion Criteria	Investigators	Contact	Notes
2006903 SMH SCV	**MS200569-0026A Phase II, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Safety and Efficacy of M5049 in Hospitalized Participants with COVID-19 Pneumonia**	- ≥18 and ≤ 70 -Not on vent or ECMO -SpO2 < 94% in room air AND able to maintain a PaO2/FiO2 ≥ 150 with a max FiO2 0.4	-Clinically significant cardiovascular disease -Hx of uncontrolled illness prior to SARS-CoV-2 infection, within the past 3 months -Hx of the following: -HIV -Untreated hepatitis -Recurrent herpes -tuberculosis (TB)	SMH:El Ghazal SCV: Shao	Adriana Valdez-Hernandez Adriana.valdez-hernandez@ sharp.com	Open to Enrollment

Moderate to Severe

IRB # Hospital	Study	Primary Inclusion Criteria	Primary Exclusion Criteria	Investigators	Contact	Notes
2005901 SGH **2005902** SCV	**GA42496 a phase II, randomized, double-blind, placebo-controlled, multicenter study to evaluate the safety and efficacy of MSTT1041A or UTTR1147A in patients with severe covid-19 pneumonia**	-18+ -Hospitalized and positive for COVID19 pneumonia by RT PCR and Chest Xray/Scan -SpO2 <93% or PaO2/FiO2 <300mmHg	-Progression to death is imminent within 24hrs; -High-dose corticosteroids within 72hrs - pregnant or breastfeeding -Not participating in another drug trial including CCP	SGH: Overcash SCV: Waters	Shandel Odom sodom@estudysite.com Rosalynn Landazuri rlandazuri@estudysite.com	Open to Enrollment
2005903 SGH **2005904** SCV	**CMAS825F12201: A Phase 2, randomized, placebo-controlled, participant and investigator blinded, multi-center study to assess efficacy and safety of MAS825 for the treatment of SARS-CoV-2 infected patients with COVID-19 pneumonia and impaired respiratory function**	-18-80 -SARS-CoV-2 diagnosis by PCR within 7 days prior to randomization -Hospitalized with COVID-19 induced pneumonia evidenced by chest Xray/CTscan/MRI within 5 days prior to randomization -SpO2 <=93% or PaO2/FiO2<300mmHg	-APACHEII >=10 (acute physiology score+age points+chronic health points. Increasing score associated with increasing risk of hospital death) -weight 45-120kg -No other bacterial, fungal, viral or other infection -Progression to death is not imminent within next 24 hours -Not intubated at randomization	SGH: Overcash SCV: Waters	Erica Sanchez esanchez@estudysite.com Dalia Tover dtover@estudysite.com	Open to Enrollment
2006902 SMH SGH SCV	**GAM10-10: Efficacy and Safety of Octagon 10% Therapy in COVID-19 Patients with Severe Disease Progression**	18+ -Resting $Sp0_2$ of <93% requiring oxygen supplementation PaO2/FiO2 ratio < 300 mmHg	-History of allergic reaction to IVIG -Recent TEE -Underlying medical condition that can lead to hypercoagulable states and hyperviscosity - Hx of IgA deficiency - Vented - rec'd CCP - rec'd IVIG products - Anti-interleukin agents Interferons	SMH:Sakoulas, Willms, Salem, SGH:Haddad	Cary Murphy, RN cary.murphy@sharp.com Matthew Geriak, PharmD Matthew.geriak@sharp.com	Open to Enrollment

IRB # Hospital	Study	Primary Inclusion Criteria	Primary Exclusion Criteria	Investigators	Contact	Notes
2007903 SMH SGH SCV	**A Randomized Double-Blind, Placebo-Controlled, Parallel-Group Phase 3 Study of Baricitinib in Patients with COVID-19 Infection: 14V-MC-KHAA**	-18+ -PCR+ $\leq$ 72 hours -Sp02 < 94 or Pa02/Fi02 ratio <300mmHg ->UNL (CRP, D-Dimer, LDH, Ferritin)	-receiving cytotoxic or biologic tx - washout req'd for: B-cell, TNF inhibitors, JAK inhibitors -rec'd CCP or IVIG - corticosteroids > 20 mg/day for 14 days -TB -bacterial, fungal, viral or other non-COVID infection - Live vaccine w/in 4 wk -ECMO -current malignancy -VTE, PE w/in 12 wks -neutropenia -lymphopenia -ALT or AST > 5 times ULN -eGFR <30mL/min/1,73m2	SMH: Lawrie, El Ghazal SGH: Haddad SCV: Shao	Cary Murphy, RN Cary.murphy@sharp.com	Open to Enrollment

Severe

IRB # Hospital	Study	Primary Inclusion Criteria	Primary Exclusion Criteria	Investigators	Contact	Notes
2007904 SMH SGH SCV	**Phase 2/3 clinical study with mavrilimumab (KPL-301), an anti-GM-CSF inhibitor, for patients hospitalized with severe COVID-19 pneumonia and systemic hyper-inflammation**	-18+ -COVID+ w/in 14days -Bilateral pneumonia - Fever ≥ 100 - one of the following: Ferritin > 500ng/mL CRP>5 mg/dL D-Dimer >1,000 LDH > 250 U/L Intubated or non-intubated	-Onset of sx> 14 days -hosp > 7 days - Need ECMO - Hx of PAP - Hx of immunodef. -Hx solid organ or bone marrow transplant -current systemic immune-modulating RX -current cytotoxic chemotherapy - Severe asthma, COPD - LVEF < 35% - TB - bacterial or fungal infection - SARs, MERS -Chronic liver disease - QTcF ECG ≥ 450ms -chronic or recent (7days) corticosteroid use >10mg/day	SMH:Lawrie, Willms	Cary Murphy, RN Cary.murphy@sharp.com	Open to Enrollment
2006901 SGH SCV	**WA42511 REMDACTA, A phase III, randomized, double-blind, multicenter study to evaluate the efficacy and safety of Remdesivir plus Tocilizumab compared with Remdesivir plus Placebo in hospitalized patients with severe covid-19 pneumonia**	-18+ -Hospitalized with Covid-19 pneumonia confirmed per positive PCR and evidenced by CXR or CT scan -Requiring >6 L/min supplemental O2 to maintain SpO2 >93% -Can be intubated (not required)	-Allergies to TCZ or other monoclonal antibodies, or hypersensitivity to remdesivir - Active TB infection; bacterial, fungal, viral, or other infection (besides Covid-19) - Tx with TCZ within last 3 months -Concurrent tx with other agents or possible direct-acting antiviral activity against SARS-CoV-2 within 24hrs prior to dosing - GFR <30 mL/min -ALT/AST >5 ULN - ANC <1,000 - Platelets <50,000 - body weight <40kg; pregnant or breastfeeding	SGH and SCV: Overcash		Open to Enrollment

2007904 SMH SGH SCV	**Phase 2/3 clinical study with mavrilimumab (KPL-301), an anti-GM-CSF inhibitor, for patients hospitalized with severe COVID-19 pneumonia and systemic hyper-inflammation** ***COHORT 1***	-18+ - + COVID test w/in 14 days of randomization -Bilateral pneumonia on x-ray or CT -fever ≥100.4°F or ≥38.2°C -ferritin>500mg/mL or CRP > 5mg/dL or D-dimer>1,000ng/mL or LDH>250U/L - receiving non-invasive ventilation/ oxygenation to maintain SpO2 ≥ 92% and non-intubated	-hosp > 7 days prior to rand. -need for invasive mechanical ventilation -need for ECMO -live vaccine w/in 4 weeks -chronic or recent corticosteroid use > 10mg/day -serious or concomitant illness that in the opinion of the investigator precludes subject enrolling in trial – e.g., hx of PAP, immunodeficiency, solid organ or bone marrow transplant, current use of mavrilimumab, active cancer within 10 years (except basal and squamous of skin)or in situ carcinoma of cervix now cured, severe, uncontrolled pulmonary disease other than COVID-19, left ventricular systolic dysfunction, active TB, uncontrolled bacterial or fungal infection, SARS or MERS (per investigator opinion), chronic liver disease. - recent tx with cell-depleting biological therapies within 12 mos., anakinra, anti-IL-6 receptor within 8 wks, cyclosporine A, azathioprine, cyclophosphamide, MMF, CCP or other immunosuppressant w/in 4 weeks prior to randomization.	SMH: Lawrie, Willms SGH: SCV:	Cary Murphy, RN Cary.murphy@Sharp.com	Open to Enrollment

Vented

IRB # Hospital	Study	Primary Inclusion Criteria	Primary Exclusion Criteria	Investigators	Contact	Notes
2007902 SCV SGH SMH	**18424-369A Phase 3 randomized, double-blind, placebo-controlled, multi-center study to assess the efficacy and safety of ruxolitinib in patients with COVID-19-induced ARDS who require invasive mechanical ventilation (RUXCOVID-DEVENT)**	-18+ -COVID+ < 3 weeks -Vented - Pa02/Fi02 of < 300mmhg w/in 6 hrs of randomization - bilateral or diffuse pulmonary infiltrates on chest x-ray or CT scan	- sensitivity to drugs in same class - severely impaired renal function - uncontrolled bacterial, fungal or other infection besides COVID-19 -TB -Unlikely to survive 24h -ECMO	SCV: Shao SGH: Haddad SMH: El Ghazal	Adriana Valdez-Hernandez Adriana.valdez-hernandez@sharp.com	Open to Enrollment
2006901 SCV SGH	**WA42511 REMDACTA, A phase III, randomized, double-blind, multicenter study to evaluate the efficacy and safety of Remdesivir plus Tocilizumab compared with Remdesivir plus Placebo in hospitalized patients with severe covid-19 pneumonia**	-18+ -Hospitalized with Covid-19 pneumonia confirmed per positive PCR and evidenced by CXR or CT scan -Requiring >6 L/min supplemental O2 to maintain SpO2 >93% -Can be intubated (not required)	-Allergies to TCZ or other monoclonal antibodies, or hypersensitivity to remdesivir - Active TB infection; bacterial, fungal, viral, or other infection (besides Covid-19) - Tx with TCZ within last 3 months -Concurrent tx with other agents or possible direct-acting antiviral activity against SARS-CoV-2 within 24hrs prior to dosing - GFR <30 mL/min -ALT/AST >5 ULN - ANC <1,000 - Platelets <50,000 - body weight <40kg; pregnant or breastfeeding	SGH and SCV: Overcash		Open to Enrollment
2007901 SMH	**Covid-19 trial of the use of Attune Medical esophageal cooling/warming device to treat ventilated Covid-19 patients with core warming**	-18+ -Vented -Max baseline temp w/in 12hr <38.3 - Has LAR	- No LAR - Contraindication to Core Warming - Pregnant - 40 kg body mass - DNR status- acute stroke, post-cardiac arrest or MS	SMH: Willms, Salem	Kyra Cloutier Kyra.cloutier@sharp.com	Open to Enrollment

2007904 SMH SGH SCV	**Phase 2/3 clinical study with mavrilimumab (KPL-301), an anti-GM-CSF inhibitor, for patients hospitalized with severe COVID-19 pneumonia and systemic hyper-inflammation** ***COHORT 2***	-18+ -Vented w/in 48 hours -Bilateral pneumonia on x-ray or CT -fever ≥100.4 -ferritin>500mg/mL or CRP > 5mg/dL or D-dimer>1,000ng/mL or LDH>250U/L	hosp > 7 days prior to rand. -need for invasive mechanical ventilation -need for ECMO -live vaccine w/in 4 weeks -chronic or recent corticosteroid use > 10mg/day -serious or concomitant illness that in the opinion of the investigator precludes subject enrolling in trial – e.g., hx of PAP, immunodeficiency, solid organ or bone marrow transplant, current use of mavrilimumab, active cancer within 10 years (except basal and squamous of skin)or in situ carcinoma of cervix now cured, severe, uncontrolled pulmonary disease other than COVID-19, left ventricular systolic dysfunction, active TB, uncontrolled bacterial or fungal infection, SARS or MERS (per investigator opinion), chronic liver disease. - recent tx with cell-depleting biological therapies within 12 mos., anakinra, anti-IL-6 receptor within 8 wks, cyclosporine A, azathioprine, cyclophosphamide, MMF, CCP or other immunosuppressant w/in 4 weeks prior to randomization	SMH: Lawrie, Willms SGH: SCV:	Cary Murphy, RN Cary.murphy@Sharp.com	Open to Enrollment

Closed to Enrollment

IRB # Hospital	Study	Principal Investigator	Date Closed	Number enrolled at SHC
2004901 SCV SGH SMH	**WA42380 A Randomized, Double-Blind, Placebo-Controlled, Multicenter Study To Evaluate The Safety And Efficacy Of Tocilizumab In Patients With Severe COVID-19 Pneumonia**	Michael Waters, MD	**5/26/20**	**27**
2004902 SMH SGH	**COVID-IVIG: Randomized Open Label Study of Standard of Care Plus Intravenous Immunoglobulin (IVIG) Compared to Standard of Care Alone in the Treatment of COVID-19 Infection**	George Sakoulas, MD	**6/18/20**	**34**
2005905 SCV	**COVID-019, protocol ml42528. A randomized, double-blind, placebo-controlled, multicenter study to evaluate the efficacy and safety of tocilizumab in hospitalized patients with covid-19 pneumonia EMPACTA**	Michael Waters, MD	**7/20/20**	**10**
2005701	**MAYO Expanded Access to Convalescent Plasma for the Treatment of Patient with COVID-19**	All SHC Physicians	**8/31/20**	**211**