**Sharp HealthCare COVID-19**

**Inpatient Treatment Clinical Trials**

**Updated January 12, 2021**

**Mild to Moderate**

**None at this time**

**Moderate**

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| **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 |
| **IRB #**  **Hospitals** | **Study** | **Primary Inclusion Criteria** | **Primary Exclusion Criteria** | **Investigators** | **Contact** | **Notes** |
| **2010901** | **Industry Alliance Platform Trial to Assess the Efficacy and Safety of Multiple Candidate Agents for the Treatment of COVID-19 in Hospitalized Patients (Sub-protocol Number COV-01-004)** | -18+  -Grade 5 (hospitalized, not requiring supplemental oxygen) on 8-pt ordinal scale | -Stage 4 severe chronic kidney disease or req. dialysis  -QTc interval > 500ms  - active TB  -participation in another clinical trial for COVID-19  -active uncontrolled systemic bacterial or fungal infection  **GROUP 2: AMGEN**  -current tx w/apremilast or other similar agent  -cytochrome P450 (CYP)3A inducers within 1 week  -hypersensitivity to apremilast  **GROUP 3: TAKENDA**  -hypersensitivity to lanadelumab  -previous (<90 days) or current use of immunodulators  -known or suspected venous thromboembolism  -previous (<90days) or current use of pKal inhibitor or bradykinin receptor blocker  **Group 4 – UCB**  **--**unresolved/suspected infection w/N.meningitis or past hx N. meningitis | SCV: Meyer | Beatriz Alvarez  balvarez@  balboaunited.org | Open to Enrollment |

**Moderate to Severe**

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| **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+ < 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 |
| **IRB #**  **Hospitals** | | **Study** | **Primary Inclusion Criteria** | **Primary Exclusion Criteria** | **Investigators** | **Contact** | **Notes** |
| **2010901**  SCV | | **Industry Alliance Platform Trial to Assess the Efficacy and Safety of Multiple Candidate Agents for the Treatment of COVID-19 in Hospitalized Patients (Sub-protocol Number COV-01-004)** | -18+  -Grade 3 (hospitalized, on noninvasive ventilation or high-flow oxygen devices) or Grade 4 (hospitalized, requiring supplemental oxygen) on 8-pt ordinal scale | -Stage 4 severe chronic kidney disease or req. dialysis  -QTc interval > 500ms  - active TB  -participation in another clinical trial for COVID-19  -active uncontrolled systemic bacterial or fungal infection  **GROUP 2: AMGEN**  -current tx w/apremilast or other similar agent  -cytochrome P450 (CYP)3A inducers within 1 week  -hypersensitivity to apremilast  **GROUP 3: TAKENDA**  -hypersensitivity to lanadelumab  -previous (<90 days) or current use of immunodulators  -known or suspected venous thromboembolism  -previous (<90days) or current use of pKal inhibitor or bradykinin receptor blocker  **Group 4 – UCB**  **--**unresolved/suspected infection w/N.meningitis or past hx N. meningitis | SCV: Meyer | Beatriz Alvarez  balvarez@  balboaunited.org | Open to Enrollment |

**Severe**

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| **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  - 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 |
| **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**  ***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 |
| **IRB #**  **Hospital** | **Study** | **Primary Inclusion Criteria** | **Primary Exclusion Criteria** | **Investigators** | **Contact** | **Notes** |
| **2008902** | **A Randomized Double Blind, Placebo-Controlled Study of Auxora for the Treatment of Severe COVID-19 Pneumonia (CARDEA)** | -18+-  + < 72hrs prior to randomization  - one of; fever, cough, sore throat, malaise, headache, muscle pain dyspnea, confusion, respiratory distress  - SpO2 <92% room air  -PaO2/FiO2 <300 w/low flow oxygen  -if SpO2 >97% must be receiving 7L or more supplemental oxygen  -presence of a respiratory infiltrate or abnormality consistent with pneumonia documented by CXR or CT | -expected survival < 7 days  - do not intubate order  -home mechanical ventilation except CPAP/BIPAP for sleep disorder  -PaO2/FiO2 < 100 at screening or 24 hours prior to screening  -High flow supplemental oxygen using a high flow nasal cannula  - Noninvasive positive pressure ventilation  - Invasive mechanical ventilation via endotracheal intubation or tracheostomy  -ECMO  -Shock defined by use of vasopressors  - Multiple organ dysfunction or failure  - Positive influenza A or B  - Pathogens detected by respiratory panel  - Hx or organ or hematologic transplant, HIV, Active Hep B or C  - Current TX with chemotherapy, immunosuppressive medications or immunotherapy, hemodialysis or peritoneal dialysis  - HX of VTE, DVT, PE w/in 12 weeks or recurrent VTE  - Pregnant  - Allergy to eggs or any excipients of study drug | SMH: Lawrie, El Ghazal  SCV: | Cary Murphy, RN  Cary.murphy@  sharp.com | Open to enrollment |

**Vented**

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| **IRB #**  **Hospital** | **Study** | **Primary Inclusion**  **Criteria** | | **Primary Exclusion**  **Criteria** | | **Investigators** | | **Contact** | | | **Notes** | |
| **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 | |
| **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**  ***COHORT 2*** | -18+  -Vented w/in 48 hours  -Bilateral pneumonia on x-ray or CT  -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 | |
| **IRB #**  **Hospital** | **Study** | **Primary Inclusion Criteria** | | **Primary Exclusion Criteria** | | **Investigators** | | **Contact** | | | **Notes** | |
| **2010902**  SMH | **COVID IVIG-Vent - A Pilot Study of the use of IVIG in patients with Severe COVID-19 infections requiring Mechanical Ventilation to assess their Biological Responses to IVIG Therapy** | -18+  -confirmed COVID+  -initiation of first dose IVIG w/in 72 hours of vent | | -bacterial pneumonia or bacteremia  -severe allergy to IVIG  -hypersensitivity to corn  -uncontrolled hypertension (SPB>180mm HG or DBP > 120mmHg)  -participating in another treatment trial  -advanced dementia  -severe renal disease (CrCl<20mL/min)  -active cancer malignancy  -active tx w/chemo or immunotherapy  -congestive heart failure (EF<25%)  -prior exposure to other investigational product (e.g., CCP, tociluzimab)  - venous or arterial thrombosis <90 days prior  - receiving cytotoxic or bio tx such as TNF inhibitors, anti-interleukin-1 (IL-1), anti –IL-6, t or b cell therapies, interferon, JAK inhibitor for any indication at study entry | | SMH: Sakoulas | | MacKenzie Habib  Mackenzie.habib@sharp.com | | | Open to enrollment | |
| **IRB #**  **Hospital** | **Study** | | **Primary Inclusion Criteria** | | **Primary Exclusion Criteria** | | **Investigators** | | **Contact** | **Notes** | |
| **2010901** | **Industry Alliance Platform Trial to Assess the Efficacy and Safety of Multiple Candidate Agents for the Treatment of COVID-19 in Hospitalized Patients (Sub-protocol Number COV-01-004)** | | -18+  -Grade 2 (hospitalized, on invasive mechanical ventilation or ECMO) on 8-pt ordinal scale | | -Stage 4 severe chronic kidney disease or req. dialysis  -QTc interval > 500ms  - active TB  -participation in another clinical trial for COVID-19  -active uncontrolled systemic bacterial or fungal infection  **GROUP 2: AMGEN**  -current tx w/apremilast or other similar agent  -cytochrome P450 (CYP)3A inducers within 1 week  -hypersensitivity to apremilast  **GROUP 3: TAKENDA**  -hypersensitivity to lanadelumab  -previous (<90 days) or current use of immunodulators  -known or suspected venous thromboembolism  -previous (<90days) or current use of pKal inhibitor or bradykinin receptor blocker  **Group 4 – UCB**  **--**unresolved/suspected infection w/N.meningitis or past hx N. meningitis | | SCV: Meyer | | Beatriz Alvarez  balvarez@  balboaunited.org | Open to Enrollment | |

**Closed to Enrollment**

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| **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** | **38** |
| **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**  SCOR  SCV  SGH  SMH | **MAYO Expanded Access to Convalescent Plasma for the Treatment of Patient with COVID-19** | All SHC Physicians | **8/31/20** | **211** |
| **2003902**  SMH  SGH  SCV | **COVID-ARB** | Matthew Geriak, PharmD | **10/20/20** | **34** |
| **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** | SGH: Overcash  SCV: Waters | **12/9/20** | **13**  **43** |
| **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** | SGH: Overcash  SCV: Waters | **12/9/20** | **11**  **6** |
| **2006902**  SMH  SGH  SCV | **GAM10-10: Efficacy and Safety of Octagam 10% Therapy in COVID-19 Patients with Severe Disease Progression** | Sakoulas | **1/1/21** | **38** |