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INTEGRATED BIOPHARMA
AND PHARMA SOLUTION

COVID-19

(Update collated on 6-Apr-2020)

COVID-19 has many names; Coronavirus, Covid-19 or SARS-CoV-2. Worldwide pandemic triggered by this virus has prompted an unprecedented amount of research and experimentation in finding therapeutic treatments for Covid-19 and a vaccine to prevent the next seasonal wave, given that Covid-19 isn't going away anytime soon. Academic researchers, non-profits, companies, health organizations and governments are co-operating in ways and under timeframes unimaginable only 8 weeks ago. Potential "cures" and "wonder drugs" ricochet around the globe faster than anyone can follow. Healthcare professionals are using hypothesis about mechanisms of action and are relying on small observational studies to make treatment decisions in real-time. These decisions being made to save rapidly deteriorating patients are also to prevent stable patients from entering rapid decline which is a hallmark of Covid-19.

We at Integrated Biopharma and Pharma Solutions and SBLehrer LLC will be summarizing the data coming from ongoing trials around the world. Unfortunately the 24 hours news cycle can only focus on the sound bites and the latest disagreements between policy markets and the medical community. We continue to hear of "anecdotal" evidence vs. "real science", however without the time to fully explore what is actually working. Our goal here is to highlight the actual work and results from studies around the world to aid in decision-making.

We start with summarizing the actual clinical trials being conducted across the world for therapeutic solutions to treat Covid-19 patients. As of April 06, 2020, we count 41 trials with specific inclusion/exclusion criteria on patients with 34 separate treatments being tested in 21 countries around the world. You will be able to see specific treatment arms, the planned number of patients and expected timelines. We also are building a comprehensive database of various vaccine approaches. To date we count 62 proposed vaccines with many more being discussed.

No one group looking at this can track all the trials. Most tend to or can focus only on a few countries and will likely miss work that occurs outside of well-known medical centers. Frequently the best learning happens away from the glare of the spotlight. Please help us in making this as complete as possible. Reply to this post with trials that we are missing.

Every 2 weeks we will send out an update including any learning's we find along the way.

Hopefully in the next few weeks life will start to move away from the current "stay at home" and "social distancing" approach in managing the pandemic given we have no other tools to use today. We will probably witness the world slowly getting back to a new "normal". And the 24 hour news cycle will start to shift. However this work will continue. The world needs to be ready when new hot spots re-emerge.

Thanks for joining us on this journey



COVID-19 Management

Prophylaxis

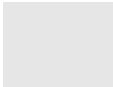
- Repurposing of existing drugs
 - antiviral drugs
 - anti malarial drugs

Treatment

- Repurposing of existing drug
- Vaccine

COVID-19 Development Snapshot (Prophylaxis)

Company	Drug	Status	Location
Pulmotect, Inc. (US)	PUL-042 [combination drug agonists of Toll-like receptors]	Phase II CT ongoing, target completion Oct 2020	US
National Institute of Respiratory Diseases, Mexico/Sanofi (France)	Hydroxychloroquine	Phase III ongoing, target completion Mar 2021	Mexico



COVID-19 Development Snapshot (Treatment)

Company	Drug	Status	Location
Shanghai Zhongxi Pharmaceuticals Co. Ltd (China)	Hydroxychloroquine Sulfate	Phase IV CT ongoing, target completion Jun 2020	China
FUJIFILM Toyama Chemical Co. Ltd (Japan)	Avigan® (favipiravir) (approved in JP as anti-flu drug)	Phase III ongoing in the US, Target completion Jul 2020	US
Bio-Thera Solutions, Ltd* (China)	Adalimumab [humanized anti-human recombinant monoclonal IgG1 antibody]	Phase IV CT ongoing, target completion Aug 2020	China
Shenyang Tonglian Group Co., Ltd. (China)	<ul style="list-style-type: none"> Carrimycin lopinavir/ritonavir tablets or Arbidol or chloroquine phosphate 	Phase IV CT ongoing, target completion Feb 2021	China
Asclepis Pharmaceuticals Co., Ltd. (China)	Ganovo (Danoprevir)+ritonavir+/-Interferon nebulization	Phase IV CT completed on Mar 2020 [Results not Posted]	China
Asclepis Pharmaceuticals Co., Ltd. (China)	ASC09 [protease inhibitor to treat HIV type-1 infections] /ritonavir, lopinavir/ritonavir	Phase III CT ongoing, target completion Jun 2020	China
Gilead Sciences (US)	Remdesivir [antiviral compound]	Phase III CT ongoing, target completion May 2020	US, Germany, Hong Kong, Italy, Korea, Spain, Singapore, Switzerland, Taiwan
Gilead Sciences (US)	Remdesivir [antiviral compound]	Phase III CT ongoing, target completion May 2020	US, Germany, Hong Kong, Iran, Italy, Korea, Spain, Singapore, Switzerland, Taiwan

COVID-19 Development Snapshot (Treatment)

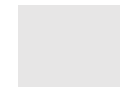
Company	Drug	Status	Location
OncoImmune, Inc. (US)	CD24Fc [biological immuno-modulator]	Phase III CT ongoing, target completion May 2022	US
Hoffmann-La Roche (Switzerland)	Tocilizumab [humanized anti-interleukin-6 (IL-6) receptor mAb]	Phase III CT ongoing, target completion Sep 2021	Not Listed
Ache Laboratorios Farmaceuticos S.A. (Brazil)	Dexamethasone	Phase III CT ongoing, target completion Aug 2020	Brazil
Vanda Pharmaceuticals (US)	Tradipitant [Neurokinin 1 receptor antagonists]	Phase III CT ongoing, target completion Aug 2020	Not Listed
Ansun Biopharma, Inc. (US)	DAS181 [Virus internalization inhibitors]	Phase III CT ongoing, target completion Dec 2021	US, Australia, Taiwan, Korea
Pulmotect, Inc. (US)	PUL-042 [combination drug agonists of Toll-like receptors]	Phase II CT ongoing, target completion Oct 2020	US
National Institute of Respiratory Diseases, Mexico/Sanofi (France)	Hydroxychloroquine	Phase III CT ongoing, target completion Mar 2021	Mexico
Sanofi (France)/ Regeneron Pharmaceuticals (US)	Sarilumab [Interleukin 6 receptor antagonists]	Phase II/III CT ongoing, target completion Jun 2021	France, Canada, Germany, Israel, Italy, Japan, Russia, Spain
Swedish Orphan Biovitrum (Sweden)	Emapalumab [human anti-interferon gamma (IFN γ) mAb], Anakinra [recombinant non-glycosylated human interleukin-1 receptor antagonist]	Phase II/III CT ongoing, target completion Sep 2020	Italy

COVID-19 Development Snapshot (Treatment)

Company	Drug	Status	Location
Regeneron Pharmaceuticals (US)/Sanofi (France)	Sarilumab [Interleukin 6 receptor antagonists]	Phase II/III CT ongoing, target completion Mar 2021	US
InflaRx GmbH (Germany)	IFX-1 [anti-human C5a monoclonal antibody]	Phase II/III CT ongoing, target completion Dec 2020	Netherlands
WHO/AbbVie (US)	Lopinavir/ritonavir	Phase II CT ongoing, target completion May 2022	Canada
Synaigen Research Limited (UK)	Inhaled SNG001 (IFN β -1a for nebulization)	Phase II CT ongoing, target completion Mar 2021	UK
NeuroRx, Inc. (US)/ Relief Therapeutics Holding SA (Switzerland)	Aviptadi	Phase II CT ongoing, target completion Sep 2020	US, Israel
Can-Fite BioPharma (Israel)	Piclidenoson [novel, first-in-class, A3 adenosine receptor agonist]	Phase II CT ongoing, target completion Jul 2020	Israel
Mallinckrodt (UK)	Inhaled Gaseous Nitric Oxide (gNO)	Phase II CT ongoing, target completion Mar 2021	Canada
JinYu Bio-Technology Co.,LTD. (China)	Tocilizumab [humanized anti-interleukin-6 (IL-6) receptor mAb]	Phase II CT ongoing, target completion May2020	China
Sanofi (France)	Hydroxychloroquine	Phase I CT ongoing, target completion May 2020	US
Azidus Brasil (Brazil)	Hydroxychloroquine (HCQ) and azithromycin (AZT)	Early Phase I CT ongoing, target completion Jun 2020	Not Listed

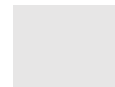
COVID-19 Development Snapshot (Treatment)

Company	Stem Cells	Status	Location
Azidus Brasil (Brazil)	NestCell® Mesenchymal Stem Cell I.V.	Phase I CT ongoing, target completion Jun 2020	Brazil
Cellular Biomedicine Group Ltd. (US)	Aerosol Inhalation of Exosomes Derived From Allogenic Adipose Mesenchymal Stem Cells	Phase I CT ongoing, target completion Jul 2020	China
CAR-T (Shanghai) Biotechnology Co., Ltd.	Dental Pulp Mesenchymal Stem Cells	Early Phase I CT ongoing, target completion Jul 2021	Not Listed
Jiangxi Mayo Biotechnologies Co. Ltd (China)	Natural killer cells combined with cord derived mesenchymal stem cells	Phase I CT ongoing, target completion Aug 2020	China
Stem Cells Arabia (Jordan)	Wharton's Jelly-Mesenchymal Stem Cells	Phase I CT ongoing, target completion Sep 2020	Jordan
Chongqing Sidemu Biotechnology Technology Co.,Ltd. (China)	NKG2D-ACE2 CAR-NK Cells Secreting IL15 Superagonist and GM-CSF-neutralizing scFv [NKG2D is an activating receptor of NK cells]	Phase I/II CT ongoing, target completion Sep 2020	China
Tuohua Biological Technology Co. Ltd (China)	Umbilical Cord(UC)-Derived Mesenchymal Stem Cells(MSCs)	Phase II CT ongoing, target completion Sep 2020	China
Tianhe Stem Cell Biotechnologies Inc. (US)	Stem Cell Educator-Treated Mononuclear Cells	Phase II CT ongoing, target completion Nov 2020	Not Listed
VCANBIO Cell & Gene Engineering Corp Ltd. (China)	Mesenchymal Stem Cell	Phase I CT ongoing, target completion Dec 2021	China
Pluristem (USA)	PLX cells [allogeneic mesenchymal-like cells]	Proof of Concept Completed	US



COVID-19 Development Snapshot (Vaccines)

Company	Vaccine	Status	Location
CanSino Biologics Inc. (China)	Recombinant Novel Coronavirus Vaccine (Adenovirus Type 5 Vector)	Phase I CT ongoing, target completion Dec 2022	China
National Institute of Allergy and Infectious Diseases (partner NIH and Moderna) (US)	novel lipid nanoparticle (LNP)-encapsulated mRNA-based vaccine	Phase I CT ongoing, target completion Jun 2021	US
Inovio (partner, Gates foundation)	INO-4800 DNA vaccine	Phase 1 approved by FDA	US
Karolinska Institute (Sweden) / Cobra Biologics (OPENCORONA Project)	DNA vaccine with electroporation	Preclinical	-
Osaka University (Japan) / AnGes (Japan)/ Takara Bio (Japan)	DNA plasmid vaccine	Preclinical	-
Takis/Applied DNA Sciences (US) /Evvivax (Italy)	DNA vaccine	Preclinical	-
Zydus Cadila (India)	DNA plasmid vaccine	Preclinical	-
Sinovac (China)	Inactivated + alum	Preclinical	-
Beijing Institute of Biological Products (China) /Wuhan Institute of Biological Products (China)	Inactivated	Preclinical	-
Osaka University (Japan) / BIKEN/ NIBIOHN	Inactivated	Preclinical	-
Codagenix (US) /Serum Institute of India (India)	Deoptimized live attenuated vaccines	Preclinical	-
GeoVax (US) /BravoVax (China)	Non-Replicating Viral Vector - MVA encoded VLP	Preclinical	-

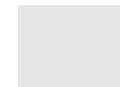


COVID-19 Development Snapshot (Vaccines)

Company	Vaccine	Status	Location
Janssen Pharmaceutical Companies (Belgium)	Ad26 Non-Replicating Viral Vector (alone or with MVA boost)	Preclinical	-
DZIF – German Center for Infection Research (Germany)	Non-Replicating Viral Vector, MVA-S encoded	Preclinical	-
Altimmune (US)	Non-Replicating Viral Vector, adenovirus-based NasoVAX expressing SARS2-CoV spike protein	Preclinical	-
Greffex (US)	Ad5 S, Non-Replicating Viral Vector (GREVAX™ platform)	Preclinical	-
Vaxart (US)	Non-Replicating Viral Vector, Oral Vaccine platform	Preclinical	-
AdaptVac (PREVENT-nCoV consortium) (Denmark)	Protein Subunit, Capsid-like Particle	Preclinical	-
ExpreS2ion (Denmark)	Drosophila S2 insect cell expression system VLPs	Preclinical	-
WRAIR/USAMRIID (US)	Protein Subunit, S protein	Preclinical	-
National Institute of Infectious Disease (Japan)	Protein Subunit, S protein +Adjuvant	Preclinical	-
Osaka University / BIKEN/ National Institutes of Biomedical Innovation (Japan)	Protein Subunit, VLP-recombinant protein + Adjuvant	Preclinical	-
Clover Biopharmaceuticals Inc.(China) /GSK (UK) /Dynavax (US)	Protein Subunit, Native like Trimeric subunit Spike Protein vaccine	Preclinical	-
Univ. of Pittsburgh (US)	Protein Subunit, microneedle arrays S1 subunit	Preclinical	-
Vaxil Bio (Canada)	Protein Subunit, Peptide	Preclinical	-

COVID-19 Development Snapshot (Vaccines)

Company	Vaccine	Status	Location
Biological E Ltd (India)	Protein Subunit, Adjuvanted protein subunit (RBD)	Preclinical	-
Flow Pharma Inc (US)	Protein Subunit, Peptide	Preclinical	-
AJ Vaccines (Denmark)	Protein Subunit, S protein	Preclinical	-
Generex (Canada) /EpiVax (US)	Protein Subunit, Ii-Key peptide	Preclinical	-
EpiVax (US) /Univ. of Georgia (US)	Protein Subunit, S protein	Preclinical	-
Sanofi Pasteur (France)	Protein Subunit, S protein (baculovirus production)	Preclinical	-
Novavax (US)	VLP-recombinant protein nanoparticle vaccine + Matrix M	Preclinical	-
Heat Biologics/Univ. Of Miami (US)	Protein Subunit, gp-96 backbone	Preclinical	-
University of Queensland (Australia) /GSK (UK) /Dynavax (US)	Protein Subunit, Molecular clamp stabilized Spike protein	Preclinical	-
Baylor College of Medicine (US)	Protein Subunit, S1 or RBD protein	Preclinical	-
iBio (US)/CC-Pharming (China)	Protein Subunit, Subunit protein, plant produced	Preclinical	-
Saint-Petersburg scientific research institute of vaccines and serums (Russia)	Recombinant protein, nanoparticles (based on S-protein and other epitopes)	Preclinical	-
Innovax/Xiamen Univ. (China) /GSK (UK)	Protein Subunit, COVID-19 XWG-03 truncated S (spike) proteins	Preclinical	-



COVID-19 Development Snapshot (Vaccines)

Company	Vaccine	Status	Location
VIDO-InterVac, University of Saskatchewan (Canada)	Protein Subunit, Adjuvanted microsphere peptide	Preclinical	-
OncoGen (Malaysia)	Protein Subunit, Synthetic Long Peptide Vaccine candidate for S and M proteins	Preclinical	-
Zydus Cadila (India)	Replicating Viral Vector, Measles Vector	Preclinical	-
Institute Pasteur (France)/Themis/Univ. of Pittsburg Center for Vaccine Research (US)	Replicating Viral Vector, Measles Vector	Preclinical	-
DZIF – German Center for Infection Research (Germany)	Live attenuated virus, Measles Virus (S, N targets)	Preclinical	-
Tonix Pharma/Southern Research (US)	Replicating Viral Vector, Horsepox vector expressing S protein	Preclinical	-
University of Hong Kong	Replicating Viral Vector, Influenza vector expressing RBD	Preclinical	-
IAVI/Batavia (US)	Replicating Viral Vector, VSV vector expressing S protein	Preclinical	-
Fudan University/ Shanghai JiaoTong University/RNACure Biopharma (China)	RNA, LNP-encapsulated mRNA cocktail encoding VLP	Preclinical	-
Fudan University/ Shanghai JiaoTong University/RNACure Biopharma (China)	RNA, LNP-encapsulated mRNA encoding RBD	Preclinical	-
University of Tokyo/ Daiichi-Sankyo (Japan)	RNA, LNP-encapsulated mRNA	Preclinical	-
China CDC/Tongji University/Stermina	RNA, mRNA	Preclinical	-
Arcturus/Duke-NUS (Singapore)	RNA, mRNA	Preclinical	-
BioNTech (Germany) /Fosun Pharma (China)/ Pfizer (US)	RNA, mRNA	Preclinical	-

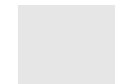
COVID-19 Development Snapshot (Vaccines)

Company	Vaccine	Status	Location
Imperial College London (UK)	RNA, saRNA	Preclinical	-
Curevac (Germany)	RNA, mRNA	Preclinical	-
Medicago Inc. (Canada)	VLP, Plant-derived VLP	Preclinical	-
Imophoron Ltd and Bristol University's Max Planck Centre (UK)	VLP, ADDomer™ multiepitope display	Preclinical	-
ReiThera (Italy)	Not Listed	Preclinical	-
BioNet Asia (Thailand)	Not Listed	Preclinical	-
ImmunoPrecise (Canada)	Not Listed	Preclinical	-
MIGAL Galilee Research Institute (Israel)	Not Listed	Preclinical	-
Doherty Institute (Australia)	Not Listed	Preclinical	-
Tulane University (US)	Not Listed	Preclinical	-



COVID-19 Clinical Trials - Prophylaxis

Organization	Drug	Remarks	Phase
Pulmotect, Inc. (US)	PUL-042 [novel combination of two synthetic molecules (Pam2 and ODN) that are agonists of Toll-like receptors]	New Drug in clinical development	Ongoing (Not Yet Recruiting) (Phase II)
			Study = Adults Exposed to SARS-CoV-2 and test negative for SARS-CoV-2 infection (NCT04313023) Enrolment = 200 No. of Arms = Two Type = Randomized, Parallel, Quadruple Masking, placebo Controlled Intervention = PUL-042 Inhalation Solution to be given by nebulization Outcome = Prevention of incidence Endpoint = Primary : Difference in the incidence of infection with SARS-CoV-2 (Up to 14 Days) Dose = Arm 1 : 20.3 µg Pam2 : 29.8 µg ODN/mL (50 µg PUL-042) PUL-042 Inhalation Solution to be given by nebulization on study days 1, 3, 6, and 10 Arm2 : Placebo Location = Not Listed, Likely US Estimated Start Date = Apr 2020 Estimated End Date = Oct 2020
National Institute of Respiratory Diseases, Mexico/Sanofi (France)	Hydroxychloroquine	Phase I/II not applicable as this is an approved drug	Ongoing (Not Yet Recruiting) Phase III
			Study = HealthCare workers in contact with of COVID-19 patients (NCT04318015) (PHYDRA Trial) Enrolment = 400 No. of Arms = Four Type = Randomized, Parallel, Triple Blind, Quadruple masking, placebo Controlled Intervention = Hydroxychloroquine Outcome = Prevention of incidence Dose = Arm 1 (High Risk) : 200mg per day for 60 days, Arm 2 (High Risk) : Placebo, Arm 3 (Low Risk) : 200mg per day for 60 days, Arm 4 (Low Risk) : Placebo Location = Mexico Estimated Start Date = Apr 2020 Estimated End Date = Mar 2021



COVID-19 Clinical Trials – Treatment

Organization	Drug	Remarks	Phase
Shanghai Zhongxi Pharmaceuticals Co. Ltd (China)	Hydroxychloroquine Sulfate	Phase I/II not applicable as this is an approved drug	Ongoing (Not Recruiting) Phase IV
			Study = Mild/normal/severe novel coronavirus pneumonia patients (COVID-19) (ChiCTR2000029868) Enrolment = 360 No. of Arms = Two Type = Randomized controlled, open label, multicenter trial Outcome = Efficacy and Safety Endpoints = Viral nucleic acid testing performed, Adverse Event's monitored Arm 1 : Standard treatment according to the guideline recommendation combined with: Day 1 to day 3: oral hydroxychloroquine sulfate tablets (100mg / tablet, 200mg / tablet), 400mg each time, 3 times a day; Day 4 to day 14/21: oral hydroxychloroquine sulfate tablets (100mg / tablet, 200mg / tablet), 400mg each time, 2 times a day Arm 2 : Standard treatment according to the guideline recommendation. Treatment period: 14 days for mild/normal type, 21 days for severe type Location = China Start Date = Feb 2020 Estimated End Date = Jun 2020
FUJIFILM Toyama Chemical Co. Ltd (Japan)	Avigan® (favipiravir) (approved in JP as anti-flu drug)	Phase I/II not applicable as this is an approved drug	Ongoing (Not Recruiting) Phase III
			Study = Adult subjects with COVID-19-moderate type. (NCT04336904) Enrolment = 100 No. of Arms = Two Type = Randomized controlled, open label Outcome = Efficacy and Safety Endpoints = Duration of treatment, negative RTPCR, aggravation of pneumonia Arm 1 1800mg, BID; Day 2 and thereafter: 600mg, TID, for a maximum of 14 days. Arm 2 : Placebo Location = US Start Date = Mar 2020 Estimated End Date = Jul 2020

COVID-19 Clinical Trials – Treatment

Organization	Drug	Remarks	Phase
Bio-Thera Solutions, Ltd* (China) *Donated for this trial	Adalimumab	Approved mAb, it is a humanized anti-human recombinant monoclonal IgG1 antibody	Ongoing (Not Yet Recruiting) Phase IV
			Study = Severe and Critical novel coronavirus pneumonia patients (COVID-19) (ChiCTR2000030089) Enrolment = 60 No. of Arms = Two Type = Randomized controlled, open label Outcome = Efficacy and Safety Endpoints = Primary : Time to Clinical Improvement Secondary : All-cause mortality, Time for body temperature to return to normal, Time of improvement in respiratory symptoms, Proportion of severe to light, Days in Hospital, Duration of non-invasive / invasive ventilation, Frequency of serious adverse events, Inflammatory factors Dose = Not Listed Arm 1 : Conventional treatment + Adalimumab Arm 2 : Conventional treatment Location = China Estimated Start Date = Feb 2020 Estimated End Date = Aug 2020

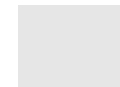


COVID-19 Clinical Trials – Treatment

Organization	Drug	Remarks	Phase
Shenyang Tonglian Group Co., Ltd. (China)	<ul style="list-style-type: none"> Carrimycin lopinavir/ritonavir tablets or Arbidol or chloroquine phosphate 	Approved Drugs	Ongoing (Not Yet Recruiting) Phase IV
			<p>Study = Patients With COVID-19 (NCT04286503)</p> <p>Enrolment = 520</p> <p>No. of Arms = Two</p> <p>Type = Randomized, Parallel, Open Label</p> <p>Outcome = Efficacy and Safety</p> <p>Endpoints =</p> <p>Primary: Fever to normal time (day) [Time Frame: 30 days], Pulmonary inflammation resolution time (HRCT) (day) [Time Frame: 30 days], Negative conversion (%) of 2019-nCoV RNA in gargle (throat swabs) at the end of treatment [Time Frame: 30 days]</p> <p>Secondary: Not Listed</p> <p>Dose = Not Listed</p> <p>Arm 1 : Carrimycin + basic treatment</p> <p>Arm 2 : lopinavir/ritonavir tablets or Arbidol or chloroquine phosphate + basic treatment</p> <p>Location= China</p> <p>Estimated Start Date = Feb 2020</p> <p>Estimated End Date = Feb 2021</p>

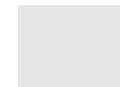
COVID-19 Clinical Trials – Treatment

Organization	Drug	Remarks	Phase
Asclepis Pharmaceuticals Co., Ltd. (China)	Ganovo (Danoprevir)+ritonavir+/-Interferon nebulization	Approved Drugs	Completed (No Results Posted) Phase IV
			<p>Study = 2019-nCoV infected patients (NCT04291729)</p> <p>Enrolment = 11</p> <p>No. of Arms = One</p> <p>Type= Open Label</p> <p>Outcome = Efficacy and Safety</p> <p>Endpoints =</p> <p>Primary: Rate of composite adverse outcomes [Time Frame: 14 days] Defined as SPO2≤ 93% without oxygen supplementation, PaO2/FiO2 ≤300mmHg or a respiratory rate ≥30 breaths per min without supplemental oxygen</p> <p>Secondary: Time to recovery [Time Frame: 14 days], Rate of no fever [Time Frame: 14 days], Rate of no cough [Time Frame: 14 days], Rate of no dyspnea [Time Frame: 14 days], Rate of no requiring supplemental oxygen [Time Frame: 14 days], Rate of undetectable New coronavirus pathogen nucleic acid [Time Frame: 14 days], Rate of mechanical ventilation [Time Frame: 14 days], Rate of ICU admission [Time Frame: 14 days], Rate of serious adverse event [Time Frame: 14 days]</p> <p>Dose = Ganovo one tablet (100mg / tablet) at a time, twice a day, up to 14 days. Ritonavir one tablet(100mg / tablet) at a time, twice a day, up to 14 days. With or without spray inhalation of interferon, 50µg / time for adults, twice a day up to 14 days.</p> <p>Location= China</p> <p>Start Date = Feb 2020</p> <p>End Date = Mar 2020</p>



COVID-19 Clinical Trials – Treatment

Organization	Drug	Remarks	Phase
Ascleptis Pharmaceuticals Co., Ltd. (China)	ASC09 (protease inhibitor to treat HIV type-1 infections) /ritonavir, lopinavir/ritonavir	ASC09 is under clinical development for HIV-therapy, phase IIb clinical trial is expected to be initiated in 2020	Ongoing (No Yet Recruiting) Phase III
			<p>Study = 2019-nCoV infected patients (NCT04261907)</p> <p>Enrolment = 160</p> <p>No. of Arms = Two</p> <p>Type= Randomized, Open Label</p> <p>lopinavir/ritonavir</p> <p>Outcome = Efficacy and Safety</p> <p>Endpoints =</p> <p>Primary: The incidence of composite adverse outcome [Time Frame: 14 days], Defined as(one of them) $SpO_2 \leq 93\%$ without oxygen supplementation, $PaO_2/FiO_2 \leq 300\text{mmHg}$ or $RR \geq 30$ breaths per.</p> <p>Secondary: Time to recovery [Time Frame: 14 days], Rate of no fever [Time Frame: 14 days], Rate of no cough [Time Frame: 14 days], Rate of no dyspnea [Time Frame: 14 days], Rate of no requiring supplemental oxygen [Time Frame: 14 days], Rate of undetectable viral RNA [Time Frame: 14 days], Rate of mechanical ventilation [Time Frame: 14 days], Rate of ICU admission [Time Frame: 14 days], Time and rate of laboratory indicators related to disease improvement to return to normal [Time Frame: 14 days]</p> <p>Dose =</p> <p>Arm 1 : ASC09/ritonavir(300mg/100mg tablet), one tablet each time, twice daily, for 14 days, +conventional standardized treatment</p> <p>Arm 2 : Lopinavir/ritonavir tablets(200mg / 50mg tablet), two tablets each time, twice daily, for 14 days, +conventional standardized treatment</p> <p>Location= China</p> <p>Estimated Start Date = Feb 2020</p> <p>Estimated End Date = Jun 2020</p>



COVID-19 Clinical Trials – Treatment

Organization	Drug	Remarks	Phase
Gilead Sciences (US)	Remdesivir	Remdesivir is an antiviral compound under Clinical Development for Ebola (Phase II)	Ongoing (Recruiting) Phase III
			<p>Study = Participants With Severe Coronavirus Disease (COVID-19) (NCT04292899)</p> <p>Enrolment = 400</p> <p>No. of Arms = Two</p> <p>Type = Randomized, Parallel, Open Label</p> <p>Outcome = Safety and Antiviral Activity</p> <p>Endpoints =</p> <p>Primary: Proportion of Participants With Normalization of Fever (Temperature < 36.6 °C armpit, < 37.2 °C oral, or < 37.8 °C rectal sustained for at least 24 hours) and Oxygen Saturation Through Day 14 (peripheral capillary oxygen saturation (SpO2) > 94% sustained for at least 24 hours)</p> <p>Secondary: Proportion of Participants With Treatment Emergent Adverse Events Leading to Study Drug Discontinuation [Time Frame: First dose date up to 10 days]</p> <p>Dose =</p> <p>Arm 1: RDV 200 mg on Day 1 followed by RDV 100 mg on Days 2, 3, 4, and 5. + SOC</p> <p>Arm 2: RDV 200 mg on Day 1 followed by RDV 100 mg on Days 2, 3, 4, 5, 6, 7, 8, 9, and 10 + Standard of Care (SOC)</p> <p>Location = US, Germany, Hong Kong, Italy, Korea, Spain, Singapore, Switzerland, Taiwan</p> <p>Start Date = Mar 2020</p> <p>Estimated End Date = May 2020</p>



COVID-19 Clinical Trials – Treatment

Organization	Drug	Remarks	Phase
Gilead Sciences (US)	Remdesivir	Remdesivir is an antiviral compound under Clinical Development for Ebola (Phase II)	Ongoing (Recruiting) Phase III
			Study = Participants With Moderate Coronavirus Disease (COVID-19) (NCT04292730) Enrolment = 600 No. of Arms = Three Type = Randomized, Parallel, Open Label Outcome = Safety and Antiviral Activity Endpoints = Primary: Proportion of Participants Discharged by Day 14 [First dose date or randomization date up to 14 days] Secondary: Proportion of Participants With Treatment Emergent Adverse Events Leading to Study Drug Discontinuation [First dose date up to 10 days] Dose = Arm 1: RDV 200 mg on Day 1 followed by RDV 100 mg on Days 2, 3, 4, and 5 + Standard of Care (SOC) Arm 2: RDV 200 mg on Day 1 followed by RDV 100 mg on Days 2, 3, 4, 5, 6, 7, 8, 9, and 10 + SOC Arm 3: SOC Location = US, Germany, Hong Kong, Iran, Italy, Korea, Spain, Singapore, Switzerland, Taiwan Start Date = Mar 2020 Estimated End Date = May 2020



COVID-19 Clinical Trials – Treatment

Organization	Drug	Remarks	Phase
OncoImmune, Inc. (US)	CD24Fc is a biological immuno-modulator	CD24Fc is in clinical development (Phase II/III) for leukemia patients	Ongoing (Not Yet Recruiting) Phase III
			<p>Study = Adult subjects with severe COVID 19 and absolute lymphocyte counts $\leq 800/\text{mm}^3$ in peripheral blood (NCT04317040)</p> <p>Enrolment = 230</p> <p>No. of Arms = Two</p> <p>Type= Randomized, Parallel, Quadruple Masking, Double-blind, Placebo-controlled, Multi-site</p> <p>Outcome = Safety and Efficacy</p> <p>Endpoints = Primary: Improvement of COVID-19 disease status on NIAID ordinal scale [Time Frame: 14 days]</p> <p>Secondary: Conversion rate of clinical status at Day 8 [Time Frame: 7 days], Conversion rate of clinical status at Day 15 [Time Frame: 14 days], Hospital discharge time [Time Frame: 14 days], All cause of death [Time Frame: 14 days], Duration of mechanical ventilation [Time Frame: 14 days], Duration of pressors [Time Frame: 14 days], Duration of ECMO [Time Frame: 14 days], Duration of oxygen therapy [Time Frame: 14 days], Length of hospital stay [Time Frame: 14 days], Absolute lymphocyte count [Time Frame: 14 days]</p> <p>Dose = Arm1: Single dose at Day 1, CD24Fc, 480mg, diluted to 100ml with normal saline, IV infusion in 60 minutes)</p> <p>Arm 2: Placebo: Single dose at Day 1, normal saline solution 100ml, IV infusion in 60 minutes.</p> <p>Location= US</p> <p>Estimated Start Date = May 2020</p> <p>Estimated End Date = May 2022</p>

COVID-19 Clinical Trials – Treatment

Organization	Drug	Remarks	Phase
Hoffmann-La Roche (Switzerland)	Tocilizumab	Approved mAb, it is a humanized anti-interleukin-6 (IL-6) receptor monoclonal antibody	Ongoing (Not Yet Recruiting) Phase III
			<p>Study = Patients With Severe COVID-19 Pneumonia (COVACTA) (NCT04320615)</p> <p>Enrolment = 330</p> <p>No. of Arms =Two</p> <p>Type = Randomized, Parallel, Double Masking, Double-Blind, Placebo-Controlled</p> <p>Outcome = Safety and Efficacy</p> <p>Endpoints = Primary: Clinical Status Assessed Using a 7-Category Ordinal Scale Secondary: 1. Time to Clinical Improvement (TTCI), Defined as a National Early Warning Score 2 (NEWS2) of ≤ 2 Maintained for 24 Hours [Up to 60 days], 2. Time to Improvement of at Least 2 Categories Relative to Baseline on a 7-Category Ordinal Scale of Clinical Status [Up to 60 days], 3. Incidence of Mechanical Ventilation [Up to 60 days], 4. Ventilator-Free Days to Day 28 [Up to Day 28], 5. Organ Failure-Free Days to Day 28 [Up to Day 28], 6. Incidence of ICU Stay [Up to 60 days], 7. Duration of ICU Stay [Up to 60 days], 8. Time to Clinical Failure [From first dose to time of death, mechanical ventilation, ICU admission, or study withdrawal (whichever occurs first, for up to 60 days)], 9. Mortality Rate [Days 7, 14, 21, 28, and 60], 10. Time to Hospital Discharge [Up to 60 days], 11. Duration of Time on Supplemental Oxygen [Up to 60 days], 12. Percentage of Participants with Adverse Events [Up to 60 days], 13. COVID-19 (SARS-CoV-2) Viral Load Over Time [Up to 60 days], 14. Time to Reverse-Transcriptase Polymerase Chain Reaction (RT-PCR) Virus Negativity [Up to 60 days], 15. Proportion of Participants with Post-Treatment Infection [Up to 60 days], 16. Serum Concentration of IL-6 [Up to 60 days], 17. Serum Concentration of sIL-6R [Up to 60 days], 18. Serum Concentration of Ferritin [Up to 60 days], 19. Serum Concentration of C-Reactive Protein [Up to 60 days], 20. Serum Concentration of TCZ [Up to 60 days]</p> <p>Dose = Arm1: 1 I.V infusion of TCZ, dosed at 8 mg/kg, up to a maximum dose 800 mg. Up to 1 additional dose may be given if clinical symptoms worsen or show no improvement.Arm 2: 1 IV infusion of placebo matched to TCZ</p> <p>Location= Not Listed</p> <p>Estimated Start Date = Apr 2020</p> <p>Estimated End Date = Sep 2021</p>

COVID-19 Clinical Trials – Treatment

Organization	Drug	Remarks	Phase
Ache Laboratorios Farmaceuticos S.A. (Brazil)	Dexamethasone	Approved Drug	Ongoing (Not Yet Recruiting) Phase III
			<p>Study = COVID-19 Patients with Acute Respiratory Distress Syndrome (ARDS) (NCT04327401) (CODEX)</p> <p>Enrolment = 290</p> <p>No. of Arms = Two</p> <p>Type= Randomized, Parallel, Open Label</p> <p>Outcome = Efficacy</p> <p>Endpoints =</p> <p>Primary: Ventilator-free days [Time Frame: 28 days after randomization]</p> <p>Secondary: Evaluation of the clinical status [Time Frame: 15 days after randomization], All-cause mortality [Time Frame: 28 days after randomization], Mechanical ventilation duration [Time Frame: 28 days after randomization], Sequential Organ Failure Assessment (SOFA) Score [Time Frame: Score at 48 hours, 72 hours and 7 days after randomization]</p> <p>Dose = Arm1: dexamethasone [20mg IV 1x/day for 5 days, followed by 10mg IV 1xd for 5 days] + standard treatment (according to the treatment protocol for 2019-nCoV infection) Arm 2: Standard treatment</p> <p>Location= Brazil</p> <p>Estimated Start Date = Apr 2020</p> <p>Estimated End Date = Aug 2020</p>



COVID-19 Clinical Trials – Treatment

Organization	Drug	Remarks	Phase
Vanda Pharmaceuticals (US)	Tradipitant	Tradipitant is a Neurokinin 1 receptor antagonists under clinical development (Phase II/Phase III) for Pruritus and Gastroparesis	Ongoing (Not Yet Recruiting) Phase III
			<p>Study = Severe or Critical COVID-19 Infection (NCT04326426)</p> <p>Enrolment = 300</p> <p>No. of Arms = Two</p> <p>Type= Randomized, Parallel, Triple Masking, Double-blind, Placebo-controlled</p> <p>Outcome = Efficacy</p> <p>Endpoints =</p> <p>Primary: Proportion of participants with normalization of fever and oxygen saturation by day 14 [Time Frame: 14 days or discharge]</p> <p>Secondary: Treatment and prevention of inflammatory lung injury as measured by change in baseline of interleukin-6 (IL-6) [Time Frame: 14 days or discharge], Rate of Decline of COVID-19 viral load assessed by RT-PCR from nasopharyngeal samples [Time Frame: 14 days or discharge], In-hospital mortality [Time Frame: 14 days or discharge], Mean change in NEWS2 score from baseline [Time Frame: 14 days or discharge], Understand the effect of genetics for treatment response through whole genome sequence of the participant and the COVID-19 virus [Time Frame: 14 days or discharge], Reduction from baseline of NRS for cough [Time Frame: 14 days or discharge]</p> <p>Dose = Arm1: Tradipitant 85 mg PO BID Arm 2: 2 capsules of matching placebo</p> <p>Location= Not Listed</p> <p>Estimated Start Date = Apr 2020</p> <p>Estimated End Date = Aug 2020</p>

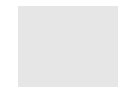


COVID-19 Clinical Trials – Treatment

Organization	Drug	Remarks	Phase
Ansun Biopharma, Inc. (US)	DAS181	Virus internalization inhibitors under clinical development (Phase III) for Para-influenza virus infections	Ongoing (Recruiting) Phase III
			<p>Study = Patients With severe COVID-19 Infection (Sub study: DAS181 for COVID-19): RCT Study (NCT03808922)</p> <p>Enrolment = 250</p> <p>No. of Arms = Four</p> <p>Type= Randomized, Parallel, Quadruple Masking, placebo-controlled</p> <p>Outcome = Efficacy and Safety</p> <p>Endpoints = Primary: Percent of subjects who Return to Room Air (RTRA) (main study) [Time Frame: by Day 28], Percent of subjects with improved COVID-19 Clinical Status Scale (sub-study) [Time Frame: Day 14]</p> <p>Secondary: All-cause mortality rate (main study) [at Day 28], Percent of subjects who Return to Room Air (RTRA) (main study) [by Day 21], Time to RTRA (main study) [Days 10, 14, 21, 28], Percent of subjects who achieve clinical stability (main study) [by Day 28], Percent of subjects discharged (without mortality and hospice) (main study) [by Days 14, 21, 28 and 35], Time to first hospital discharge (without hospice) (main study) [through Day 35], Total number of inpatient days (main study) [up to Day 35], Baseline SAD-RV infection-related mortality rate (main study) [at Day 28], Baseline SAD-RV infection-related mortality rate (main study) [at Day 35], All-cause mortality rate (main study) [at Day 35], Change in pulmonary function (FEV1% predicted) (main study) [Day 1, 7, 14 and 28], Time to improved COVID19 clinical status (Sub-study) [Day 5, 10, 21 and 28], Time to RTRA [Day 10, 14, 21 and 28], Time to Clinical stability [Day 14, 21 and 28], Time to SARS-CoV-2 RNA in the respiratory specimens being undetectable [Day 5, 10, 14, 21 and 28], Time to Clinical deterioration [Day 5, 10, 14, 21 and 28], Time to Discharge from hospital (without readmission before Day 28), [Day 14, 21 and 28], Time to Death (all causes) [Day 14, 21 and 28]</p> <p>Dose = Arm1: DAS181 4.5mg nebulized qd x 7 OR 10 days Arm 2: Placebo nebulized qd x 7 OR 10 days Arm 3: DAS181 4.5mg nebulized qd x 7 OR 10 days ≥ 40kg DAS181 2.5mg nebulized qd x 7 OR 10 days < 40kg Arm4: DAS181 4.5mg nebulized q12h/day x 7 OR 10 days</p> <p>Location= US, Australia, Taiwan, Korea</p> <p>Start Date = May 2019</p> <p>Estimated End Date = Dec 2021</p>

COVID-19 Clinical Trials – Treatment

Organization	Drug	Remarks	Phase
Pulmotect, Inc. (US)	PUL-042 [novel combination of two synthetic molecules (Pam2 and ODN) that are agonists of Toll-like receptors]	New Drug in clinical development	Ongoing (Not Yet Recruiting) Phase II
			Study = Adults Positive for SARS-CoV-2 Infection (NCT04312997) Enrolment = 100 No. of Arms = Two Type = Randomized, Parallel, Quadruple Masking, placebo Controlled Outcome = Efficacy and Safety Endpoints = Primary: Severity of COVID-19: Ordinal Scale for Clinical Improvement (score 1-8) Secondary: All cause mortality Dose = Arm 1: 20.3 µg Pam2 : 29.8 µg ODN/mL (50 µg PUL-042) PUL-042 Inhalation Solution to be given by nebulization on study days 1, 3, 6, and 10 Arm2: Placebo (Sterile normal saline for inhalation) Location = US Estimated Start Date = Apr 2020 Estimated End Date = Oct 2020
National Institute of Respiratory Diseases, Mexico/Sanofi (France)	Hydroxychloroquine	Phase I/II not applicable as this is an approved drug	Ongoing (Not Yet Recruiting) Phase III
			Study = Patients with severe respiratory COVID-19 disease (NCT04315896) (HYDRA) Enrolment = 500 No. of Arms = Two Type = Randomized, Parallel, Quadruple masking, placebo controlled, Double blinded Outcome = Safety and Efficacy Dose = Arm 1: Hydroxychloroquine tablet 200mg every 12 hours for 10 days Arm 2: Placebo Location = Mexico Estimated Start Date = Mar 2020 Estimated End Date = Mar 2021



COVID-19 Clinical Trials – Treatment

Organization	Drug	Remarks	Phase
Sanofi (France)/ Regeneron Pharmaceuticals (US)	Sarilumab	Approved mAb, it is an Interleukin 6 receptor antagonists	Ongoing (Recruiting) (Phase II/III)
			Study = Hospitalized Patients With COVID19 (NCT04327388/EudraCT Number: 2020-001162-12) Enrolment = 460 No. of Arms = Three Type = Randomized, Double-blind, Placebo Controlled, Quadruple Masking, Parallel Assignment Outcome = Safety and Efficacy Endpoints = Primary: Phase 2: Time to resolution of fever for at least 48 hours without antipyretics or until discharge, whichever is sooner [Baseline to Day 29], Phase 3: Percentage of patients reporting each severity rating on the 7-point ordinal scale [Baseline to Day 15] Secondary: Phase2 and 3: Evaluate clinical efficacy of sarilumab compared to the control arm by clinical severity, Evaluate changes in the National Early Warning Score 2 (NEWS2), Evaluate duration of predefined symptoms and signs (if applicable), Evaluate duration of supplemental oxygen dependency (if applicable), Evaluate incidence of new mechanical ventilation use during the study, Evaluate the duration of new mechanical ventilation use during the Study, Evaluate proportion of patients requiring rescue medication during the 28-day period, Evaluate need for admission into ICU, Evaluate duration of hospitalization (days), Evaluate 28-day mortality rate, Secondary safety objectives of study are to evaluate safety of sarilumab through hospitalization (up to day 29) Dose = Dose not listed Arm1: Sarilumab Dose 1 given one time on Day 1 Arm 2: Sarilumab Dose 1 given one time on Day 1 Arm 3: Matching placebo given intravenously one time on Day 1 Location = France, Canada, Germany, Israel, Italy, Japan, Russia, Spain Start Date = Mar 2020 Estimated End Date = Jun 2021

COVID-19 Clinical Trials – Treatment

Organization	Drug	Study	Remarks	Phase
Swedish Orphan Biovitrum (Sweden)	Emapalumab, Anakinra	Status	Emapalumab is a approved human anti-interferon gamma (IFN γ) monoclonal antibody, Anakinra is an approved recombinant non-glycosylated human interleukin-1 receptor antagonist	Ongoing (Not Yet Recruiting) (Phase II/III)
		Design		<p>Study = Patients With COVID-19 Infection (NCT04324021)</p> <p>Enrolment = 54</p> <p>No. of Arms = Three</p> <p>Type= Randomized, Parallel, Open Label</p> <p>Outcome = Safety and Efficacy in Reducing Hyper-inflammation and Respiratory Distress in in Patients With SARS-CoV-2 Infection</p> <p>Endpoints = Primary: Proportion of patients not requiring invasive mechanical ventilation or Extracorporeal membrane oxygenation (ECMO) [up to 15 days] Secondary: Time to mechanical ventilation from date of Randomization, Change from baseline in Modified Early Warning system score and in partial pressure of oxygen/fraction of inspired oxygen (PaO₂/FiO₂) [Time Frame: Baseline, Day 15], Change from baseline in 1. resting peripheral capillary oxygen saturation (SpO₂), 2. pH in hemogasanalysis, 3. carbon dioxide tension (pCO₂) in hemogasanalysis, 4. oxygen tension (pO₂) in hemogasanalysis, 5. potassium in hemogasanalysis, 6. sodium in hemogasanalysis, 7. chloride in hemogasanalysis, 8. lactic acid in hemogasanalysis, 8. hemoglobin in hemogasanalysis, 9. baseline in oxygen supplementation, 10. Ferritin, 11. lactate dehydrogenase (LDH), 12. D-dimers, 13. White Blood Cells with differential counts, 14. Red Blood Counts, 15. Hemoglobin , 16. Platelet count, 17. Fibrinogen, 18. Complement factors C3/C4, 19. Prothrombin time, 20. Cardiac troponin, 21. aspartate aminotransferase (AST), 22. alanine aminotransferase (ALT), 23. total bilirubin levels, 24. C-Reactive Protein and 25. Creatinine from Baseline [Time Frame: Baseline, 3 assessments every Days 4, 7, 10, 13 and 15], Change of findings of high-resolution computed tomography (CT) scan of the chest [Time Frame: Screening, Day 15], Overall survival [Time Frame: Weeks 6 and 10], Time to hospital discharge [Time Frame: Weeks 6 and 10]</p> <p>Dose = Arm1: Emapalumab i.v infusion every 3rd day for a total 5 infusions. Day 1: 6mg/kg. Days 4, 7, 10 and 13: 3 mg/kg Arm 2: Anakinra i.v infusion four times daily for 15 days. 400 mg/day in total, divided into 4 doses given every 6 hours Arm 3: Standard of care according to local practice</p> <p>Location= Italy</p> <p>Estimated Start Date = Mar 2020</p> <p>Estimated End Date = Sep 2020</p>

COVID-19 Clinical Trials – Treatment

Organization	Drug	Study	Remarks	Phase
Regeneron Pharmaceuticals (US)/Sanofi (France)	Sarilumab	Status	Approved mAb, it is an Interleukin 6 receptor antagonists	Ongoing (Recruiting) (Phase II/III)
		Design		Study = Hospitalized COVID-19 patients (NCT04315298) Enrolment = 400 No. of Arms =Three Type = Randomized, Parallel Assignment, Quadruple Masking, Double-Blind, Placebo-Controlled, Single dose Outcome = Safety and Efficacy Endpoints = Primary: Time to resolution of fever for at least 48 hours without antipyretics for 48 hours, Percentage of patients reporting each severity rating on a 6-point ordinal scale ranging from Not Hospitalized to Death, Secondary: 1. Time to improvement in oxygenation for at least 48 hours [Up to day 29], 2. Mean change in 6-point ordinal scale [Up to day 29], 3. Clinical status using 6-point ordinal scale [Up to day 29], 4. Time to improvement in one category from admission using 6-point ordinal scale [Up to day 29], 5. Time to resolution of fever for at least 48 hours without antipyretics by clinical severity [Up to day 29], 6. Time to resolution of fever for at least 48 hours without antipyretics by baseline IL-6 levels [Up to day 29], 7. Time to improvement in oxygenation for at least 48 hours by clinical severity [Time Frame: Up to day 29, 8. Time to improvement in oxygenation for at least 48 hours by baseline IL-6 levels [Up to day 29], 9. Time to resolution of fever and improvement in oxygenation for at least 48 hours [Up to day 29], 10. Time to change in National Early Warning Score 2 (NEWS2) scoring system [Up to day 29], 11. Time to score of <2 maintained for 24 hours in NEWS2 scoring system [Up to day 29], 12. Mean change in NEWS2 scoring system [Up to day 29], 13. Number of days with fever [Up to day 29], 14 Number of patients alive off oxygen [Day 29], 15. Number of days of resting respiratory rate >24 breaths/min [Up to day 29], 16. Number of days with hypoxemia [Up to day 29], 17. Number of days of supplemental oxygen use [Up to day 29], 18. Time to saturation ≥94% on room air [Up to day 29] 19. Number of ventilator free days in first 28 days [Baseline to day 29], 20. Number of patients requiring initiation of mechanical ventilation [Up to day 29], 21. Number of patients requiring non-invasive ventilation [Up to day 29] (Cont.)

COVID-19 Clinical Trials – Treatment

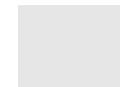
Organization	Drug	Remarks	Phase
Regeneron Pharmaceuticals (US)/Sanofi (France)	Sarilumab	Approved mAb, it is an Interleukin 6 receptor antagonists	Ongoing (Recruiting) (Phase II/III)
			Study = Hospitalized COVID-19 patients (NCT04315298) Secondary: 22. Number of patients requiring use of high flow nasal cannula [Up to day 29], 23. Number of patients admitted into an intensive care unit (ICU) [Up to day 29], 24. Number of days of hospitalization among survivors [Up to day 29], 25. Number of deaths due to any cause [Up to day 60], 26. Incidence of serious adverse events [Up to day 60], 27. Incidence of severe or life-threatening bacterial, invasive fungal, or opportunistic infection [Up to day 29], 28. Incidence of severe or life-threatening bacterial, invasive fungal, or opportunistic infection in patients with grade 4 neutropenia [Up to day 60], 29. Incidence of hypersensitivity reactions [Up to day 29], 30. Incidence of infusion reactions [Up to day 29], 31. Incidence of gastrointestinal perforation [Up to day 60], 32. White blood cell count [Up to day 29 if still hospitalized], 33. Hemoglobin levels [Up to day 29 if still hospitalized], 34. Platelet count [Up to day 29 if still hospitalized], 35. Creatinine levels [Up to day 29 if still hospitalized], 36. Total bilirubin level [Up to day 29 if still hospitalized], 37. Alanine aminotransferase level [Up to day 29 if still hospitalized], 38. Aspartate aminotransferase level [Up to day 29 if still hospitalized] Dose = Arm1: Sarilumab (High Dose, I.V.), Arm 2: Sarilumab (Low Dose, I.V.), Arm 3: placebo Location= US Start Date = Mar 2020 Estimated End Date = Mar 2021
InflaRx GmbH (Germany)	IFX-1, anti-human C5a monoclonal antibody	IFX-1 is in clinical development (Phase II, completed) for Hidradenitis suppurativa	Ongoing (Recruiting) (Phase II/III)
			Study = Patients with Severe COVID-19 PNEUMONIA (PANAMO) (NCT04333420) Enrolment = 130 No. of Arms = Two Type= Randomized, open-label, parallel assignment, adaptive Outcome = Clinical benefit Endpoints = Primary: Change in PaO2/FiO2 [Time Frame: Baseline to Day 5], Relative change (%) from baseline in Oxygenation Index (PaO2 / FiO2) to day 5. Secondary: Patients achieving early response [Time Frame: Baseline to Day 7], Number of patients (%) achieving an Early Response Dose = Not Listed Arm 1: Drug: Best supportive Care (BSC) + IFX-1 Arm2: Best supportive care only Location= Netherlands Start Date = Mar 2020 Estimated End Date = Dec 2020

COVID-19 Clinical Trials – Treatment

Organization	Drug	Study	Remarks	Phase
WHO/ AbbVie (US)	Lopinavir/ritonavir	Status	Approved Drugs	Ongoing (Not Recruiting) Phase II
		Design		<p>Study = Patients of COVID-19 (NCT04330690) SOLIDARITY TRIAL – Canadian Arm</p> <p>Enrolment = 440</p> <p>No. of Arms = Two</p> <p>Type= Adaptive, randomized, open-label, controlled clinical trial</p> <p>Outcome = Safety and Efficacy</p> <p>Endpoints =</p> <p>Primary: Efficacy of Intervention [Time Frame: 29 days] as measured on a 10-point ordinal scale through a proportional odds model</p> <p>Secondary: Time to improvement of one category from admission [up to 60 days], Subject clinical status [up to 60 days], Change in Subject clinical status [up to 60 days], Oxygen free days [up to 29 days], Incidence of oxygen use [up to 29 days], Duration of oxygen use [up to 29 days], Incidence of new mechanical ventilation [up to 29 days], Duration of mechanical ventilation [up to 29 days], Duration of hospitalization [up to 29 days], Mortality [up to 60 days], Cumulative Incidence of Grade 3 and 4 Adverse Events (AEs) and Serious Adverse Events (SAEs) [up to 30 days after last dose of drug administration]</p> <p>Dose = Arm 1: Lopinavir/ritonavir will be administered 400 mg/100 mg orally (or weight based dose adjustment for children) for a 14-day course, or until discharge from hospital, whichever occurs first Arm2: Standard of care</p> <p>Location= Canada</p> <p>Start Date = Mar 2020</p> <p>Estimated End Date = May 2022</p>

COVID-19 Clinical Trials – Treatment

Organization	Drug	Study	Remarks	Phase
Synairgen Research Limited (UK)	Inhaled SNG001 (IFN β -1a for nebulization)	Status	SNG001 is in clinical development (Phase II) for Chronic obstructive pulmonary disease	Ongoing (Unknown) Phase II
		Design		<p>Study = Patients of COVID-19 (EudraCT Number: 2020-001023-14)</p> <p>Enrolment = 400</p> <p>No. of Arms = Two</p> <p>Type= Randomized double-blind placebo-controlled</p> <p>Outcome = Safety and Efficacy</p> <p>Endpoints =</p> <p>Primary: Change in condition measured using the Ordinal Scale for Clinical Improvement during the dosing period, The Ordinal Scale for Clinical Improvement is a World Health Organization recommended scale for use in COVID-19 trials</p> <p>Secondary: Progression to pneumonia as diagnosed by chest x-ray, if no pneumonia is present at time of enrolment, Evolution of pneumonia, as diagnosed by chest x-ray, if pneumonia is present at time of enrolment, Time to clinical resolution ≥ 4 of 5 vital signs (temperature, O2 sats, Resp rate, heart rate, systolic blood pressure), LRT Symptoms (Changes in daily symptoms breathlessness, cough and sputum scale, (BCSS) symptoms score during the study period (including disaggregated scores)), Virus clearance/load, Safety and tolerability, Blood and sputum biomarkers if samples are available</p> <p>Dose = Not Listed</p> <p>Arm 1: Inhaled SNG001 (IFNβ-1a for nebulization)</p> <p>Arm 2: Placebo</p> <p>Location= UK</p> <p>Estimated Start Date = Mar 2020</p> <p>Estimated End Date = Mar 2021</p>



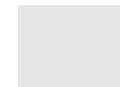
COVID-19 Clinical Trials – Treatment

Organization	Drug	Study	Remarks	Phase
NeuroRx, Inc. (US)/ Relief Therapeutics Holding SA (Switzerland)	Intravenous Aviptadi	Status	Approved Drug	Ongoing (Not Yet Recruiting) Phase II
		Design		<p>Study = Patients With COVID-19 Infection (COVID-AIV) (NCT04311697)</p> <p>Enrolment = 120</p> <p>No. of Arms = Two</p> <p>Type= Randomized, Parallel, Quadruple Masking, placebo-controlled</p> <p>Intervention= Intravenous Aviptadil for COVID-19 Associated Acute Respiratory Distress</p> <p>Outcome = Improvement in blood oxygenation and mortality and safety/futility assessment</p> <p>Endpoints =</p> <p>Primary: Mortality [Time Frame: 5 Days with follow-up through 30 days], Index of Respiratory Distress PaO2:FiO2 ratio [Time Frame: 5 Days with follow-up through the end of telemetry monitoring]</p> <p>Secondary: TNF alpha [Time Frame: 5 Days], Multi-system organ failure free days [Time Frame: 5 days with follow-up through 30 days]</p> <p>Dose = Arm1: Aviptadil IV in escalating doses + maximal intensive care: Patients will be administered Aviptadil IV in escalating doses of 50 pmol, 100 pmol, 150 pmol/kg/hr .</p> <p>Arm 2: Placebo + Maximal intensive care: Patients will first be treated with placebo infusion + maximal intensive care</p> <p>Location= US, Israel</p> <p>Estimated Start Date = Apr 2020</p> <p>Estimated End Date = Sep 2020</p>



COVID-19 Clinical Trials – Treatment

Organization	Drug	Study	Remarks	Phase
Can-Fite BioPharma (Israel)	Piclidenoson is a novel, first-in-class, A3 adenosine receptor agonist (A3AR)	Status	Piclidenoson is in clinical development (Phase III) for Rheumatoid arthritis and Plaque psoriasis	Ongoing (Not Yet Recruiting) Phase II
		Design		<p>Study = Patients With COVID-19 Infection (NCT04333472)</p> <p>Enrolment = 40</p> <p>No. of Arms = Two</p> <p>Type= Randomized, Parallel, Open Label</p> <p>Outcome = Efficacy, Safety and tolerability</p> <p>Endpoints =</p> <p>Primary: Duration of viral shedding in days [Time Frame: 28 days], Time to clinical recovery (TTCR) in days [Time Frame: 28 days], Treatment-emergent adverse events (AEs) [Time Frame: 28 days]</p> <p>Secondary: Requirement for non-invasive or mechanical ventilation [Time Frame: 28 days], Length of hospital stay in days [Time Frame: 28 days], Estimated PaO2/FiO2 ratio on day of discharge [Time Frame: 28 days], All-cause mortality [Time Frame: 28 days], Patients reaching undetectable COVID-19 virus levels in respiratory secretions [Time Frame: 28 days], Duration of symptoms and signs of respiratory infection in days [Time Frame: 28 days], Need for supportive respiratory management [Time Frame: 28 days], Viral load [Time Frame: 28 days], Treatment-emergent serious AEs (SAEs) [Time Frame: 28 days], AEs leading to withdrawal [Time Frame: 28 days], Treatment-emergent abnormalities in clinical laboratory parameters [Time Frame: 28 days]</p> <p>Dose = Arm1: Piclidenoson 2 mg orally every 12 hours for up to 21 days Arm 2: Standard of care</p> <p>Location= Israel</p> <p>Estimated Start Date = Apr 2020</p> <p>Estimated End Date = Jul 2020</p>



COVID-19 Clinical Trials – Treatment

Organization	Drug	Study	Remarks	Phase
Mallinckrodt (UK)	Inhaled Gaseous Nitric Oxide (gNO)	Status	-	Ongoing (Not Recruiting) Phase II
		Design		<p>Study = Adults & Adolescents With Non-Tuberculous Mycobacteria, Burkholderia Spp, Aspergillus Spp and Corona-like Viral (Sub-Study) Infections, Sub-study for Patients With COVID-19 Infection (NCT03331445)</p> <p>Enrolment = 20</p> <p>No. of Arms = One</p> <p>Type= Sequential Assignment, Open Label</p> <p>Outcome = Safety</p> <p>Endpoints =</p> <p>Primary: Measure the safety of 160ppm inhaled nitric oxide delivery in NTM subjects [Time Frame: 26 Days]</p> <p>Secondary: Measure the effect of 160ppm inhaled nitric oxide delivery on lung spirometry in NTM subjects [Time Frame: Day 5,12,19 and 26], Measure the antimicrobial effect of 160ppm inhaled nitric oxide on lung NTM bacterial load in the sputum [Time Frame: Day 19 and 26], Measure the effect of 160ppm inhaled nitric oxide on Quality of Life (CRISS) Score [Time Frame: Day 19 and 26]</p> <p>Dose = Nitric Oxide 0.5 % / Nitrogen 99.5 % Gas for Inhalation, Inhaled Nitric Oxide 160ppm balance air</p> <p>Location= Canada</p> <p>Start Date = Oct 2017</p> <p>Estimated End Date = Mar 2021</p>



COVID-19 Clinical Trials – Treatment

Organization	Drug	Study	Remarks	Phase
JinYu Bio-Technology Co.,LTD. (China)	Tocilizumab	Status	Approved mAb, it is a humanized anti-interleukin-6 (IL-6) receptor monoclonal antibody	Ongoing (Not Yet Recruiting) Phase II
		Design		<p>Study = Cytokine release syndrome (CRS) in new coronavirus pneumonia patients (COVID-19) (ChiCTR2000030196)</p> <p>Enrolment = 60</p> <p>No. of Arms = One</p> <p>Type= Multicenter, single arm, open label</p> <p>Outcome = Efficacy and safety</p> <p>Endpoints =</p> <p>Primary: Cytokine release syndrome (CRS) Remission rate</p> <p>Secondary: AE, SAE, laboratory findings, symptoms, vital signs, ECG, Physical examination, recurrence of CRS, change of IL-1, IL-6, IFN-gama, TNF-alpha</p> <p>Dose = Not Listed, conventional therapy + tocilizumab</p> <p>Location= China</p> <p>Estimated Start Date = Feb 2020</p> <p>Estimated End Date = May 2020</p>



COVID-19 Clinical Trials – Treatment

Organization	Drug	Study	Remarks	Phase
Sanofi (France)	Hydroxychloroquine	Status	Approved Drug	Ongoing (Recruiting) Phase I
		Design		<p>Study = Outpatient Adults With COVID-19 (NCT04333654)</p> <p>Enrolment = 210</p> <p>No. of Arms = Two</p> <p>Type= Randomized, Quadruple Masking, Parallel Assignment, Double-blinded, Placebo-controlled</p> <p>Outcome = Efficacy, Safety and tolerability</p> <p>Endpoints =</p> <p>Primary: Change from baseline to Day 3 in nasopharyngeal SARS-CoV-2 viral load (if quantitative PCR is available) [Time Frame: Baseline to Day 3], Number of participants by PCR result status (positive or negative) (if quantitative PCR is not available) [Time Frame: Baseline to Day 3]</p> <p>Secondary: Change from baseline to Day 5 in nasopharyngeal SARS-CoV-2 viral load [Time Frame: Baseline to Day 5], Number of participants by PCR result status (positive or negative) [Time Frame: Baseline to end of study (Day14)], Number of participants with COVID-19 symptoms by severity [Time Frame: Baseline to end of study (Day14)], Time to resolution of COVID-19 Symptoms [Time Frame: Baseline to end of study (Day14)], Time to resolution of fever [Time Frame: Baseline to end of study (Day14)], Percentage of participants with resolution of fever [Time Frame: Baseline to end of study (Day14)], Percentage of participants hospitalized [Time Frame: Baseline to end of study (Day14)], Number of participants with Adverse Events [Time Frame: Baseline to end of study (Day14)]</p> <p>Dose = Not Listed, Arm 1: Hydroxychloroquine, loading dose on day 1 followed by a daily maintenance dose during 9 days Arm 2: Matching Placebo</p> <p>Location= US</p> <p>Start Date = Mar 2020</p> <p>Estimated End Date = May 2020</p>



COVID-19 Clinical Trials – Treatment

Organization	Drug	Remarks	Phase
Azidus Brasil (Brazil)	Hydroxychloroquine (HCQ) and azithromycin (AZT)	Approved Drugs	Ongoing (Not Yet Recruiting) Early Phase 1
			Study = Hospitalized Patients With Moderate to Severe COVID-19 (NCT04329572) Enrolment = 400 No. of Arms = One Type = Open, Multi-centric, Non Randomized, Exploratory Clinical Trial, Single Group Assignment Intervention = Hydroxychloroquine (HCQ) and azithromycin (AZT) for the Treatment of Acute Respiratory Syndrome (COVID-19) Caused by SARS-CoV-2 Virus Outcome = Efficacy and Safety Endpoints = Primary: Evolution of acute respiratory syndrome, oxygen saturation hemodynamic stability [Time Frame: 28 days] Secondary: Viral load [Time Frame: Day 6], Change in Clinical Condition [Time Frame: 28 days], Evolution of Acute Respiratory Syndrome [Time Frame: 28 days], Hospital discharge [Time Frame: 28 days], Rate of mortality within 28-days [Time Frame: 28 days] Dose = HCQ (400 mg BID on D1 and 400 mg/day on D2 to D5) and AZT (500 mg/ 5 days) on top of standard care Location = Not Listed Estimated Start Date = Apr 2020 Estimated End Date = Jun 2020



COVID-19 Clinical Trials – Treatment (Stem Cells)

Organization	Stem Cells	Remarks	Phase
Pluristem (USA)	PLX cells are allogeneic mesenchymal-like cells that have immunomodulatory properties	Proof of concept completed	Completed
			<p>Study = Proof of concept study in COVID ARDS patients (ICU – Ventilators) have survived, thus far. Six patients completed one week follow up; the seventh patient was treated on April 5, 2020.</p> <p>Enrolment = 7</p> <p>Type= Non Randomized, Open Label</p> <p>Outcome = Efficacy and Safety</p> <p>Results:</p> <ul style="list-style-type: none"> • Four of the six (66%) patients that completed one week follow up demonstrated improvement in respiratory parameters. • Three of the six, or half of the patients that completed one week follow up, are in advanced stages of weaning from ventilators. • Pluristem plans to apply for initiation of a multinational clinical trial for treatment of complications associated with COVID-19.



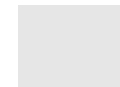
COVID-19 Clinical Trials – Treatment (Stem Cells)

Organization	Stem Cells	Remarks	Phase
Azidus Brasil (Brazil)	NestCell® Mesenchymal Stem Cell I.V.	-	Ongoing (Not Yet Recruiting) Phase I
			<p>Study = Patients With Severe COVID-19 Pneumonia (HOPE) (NCT04315987)</p> <p>Enrolment = 66</p> <p>No. of Arms =Two</p> <p>Type= Non Randomized, Open Label</p> <p>Outcome = Efficacy and Safety</p> <p>Endpoints</p> <p>Primary: Disappear time of ground-glass shadow in the lungs [Time Frame: 28 days]</p> <p>Secondary: Rate of mortality within 28-days, Change of Clinical symptoms including duration of fever and respiratory (At Baseline , Day 3, Day 7, Day 10, Day 14, Day 21, Day 28), Time of nucleic acid turning negative [Time Frame: 28 days], CD4+ and CD8+ T cell count [Time Frame: At Baseline , Day 3, Day 6, Day 10, Day 14, Day 21 and Day 28], Changes of blood oxygen [Time Frame: At Baseline , Day 3, Day 6, Day 10, Day 14, Day 21 and Day 28], Side effects in the treatment group [Time Frame: 28 days]</p> <p>Dose = Arm1: 6 patients conventional treatment plus 3 times of 1×10^6 cells/kg of body weight of NestCell® on Day1, Day3 and Day7</p> <p>Arm 2: In 2 phases. 1st phase, 6 patients receive 1×10^6 cells/kg weight on days 1, 3 and 7 + SOC. Post which Safety Monitoring Board will decide whether to continue the treatment and if the next dose should remain the same or if any change in posology or dose should be done. Then, 60 new subjects will be included in the study and treated according to Safety Monitoring Board recommendation.</p> <p>Location= Brazil</p> <p>Estimated Start Date = Apr 2020</p> <p>Estimated End Date = Jun 2020</p>



COVID-19 Clinical Trials – Treatment (Stem Cells)

Organization	Stem Cells	Remarks	Phase
Tuohua Biological Technology Co. Ltd (China)	Umbilical Cord(UC)-Derived Mesenchymal Stem Cells(MSCs)	-	Ongoing (Recruiting) Phase II
			<p>Study = Patients with 2019-novel Coronavirus(nCOV) Pneumonia (NCT04269525)</p> <p>Enrolment = 10</p> <p>No. of Arms = One</p> <p>Type= Single Group Assignment, Open Label</p> <p>Outcome = Efficacy, Availability and Safety</p> <p>Endpoints =</p> <p>Primary: Oxygenation index [Time Frame: on the day 14 after enrollment]</p> <p>Secondary 28 day mortality [Time Frame: on the day 28 after enrollment], Hospital stay [Time Frame: up to 6 months], 2019-nCoV nucleic acid test [Time Frame: on the day 7,14,28 after enrollment], Improvement of lung imaging examinations [Time Frame: on the day 7,14,28 after enrollment], White blood cell count [Time Frame: on the day 7,14,28 after enrollment], Lymphocyte count [Time Frame: on the day 7,14,28 after enrollment], Lymphocyte percentage [Time Frame: on the day 7,14,28 after enrollment], Procalcitonin [Time Frame: on the day 7,14,28 after enrollment], interleukin(IL)-2 [Time Frame: on the day 7,14,28 after enrollment], IL-4 [Time Frame: on the day 7,14,28 after enrollment], IL-6 [Time Frame: on the day 7,14,28 after enrollment], IL-8 [Time Frame: on the day 7,14,28 after enrollment], IL-10 [Time Frame: on the day 7,14,28 after enrollment], tumor necrosis factor(TNF)-α [Time Frame: on the day 7,14,28 after enrollment], γ-interferon(IFN) [Time Frame: on the day 7,14,28 after enrollment]</p> <p>Dose = Patients will be divided to serious pneumonia group or critical pneumonia group. All subjects will receive UC-MSCs 3.3 * 10⁷ cell number / 50ml / bag, 3 bags each time. And UC-MSCs will be infused intravenously on the 1st, 3rd, 5th, and 7th days after enrollment, 1 time each day</p> <p>Location= China</p> <p>Start Date = Feb 2020</p> <p>Estimated End Date = Sep 2020</p>



COVID-19 Clinical Trials – Treatment (Stem Cells)

Organization	Stem Cells	Remarks	Phase
Tianhe Stem Cell Biotechnologies Inc. (US)	Stem Cell Educator-Treated Mononuclear Cells	-	Ongoing (Not Yet Recruiting) Phase II
			<p>Study = Patients with SARS-CoV-2 infection (NCT04299152) Enrolment = 20 No. of Arms =Two Type= Randomized, Parallel Assignment, Partially masked Outcome = Safety, feasibility, and efficacy Endpoints = Primary: Determine the number of Covid-19 patients who were unable to complete SCE Therapy [Time Frame: 4 weeks] Secondary Examine the percentage of activated T cells after SCE therapy by flow cytometry [Time Frame: 4 weeks], Assess the percentage of Th17 cells after SCE therapy by flow cytometry [Time Frame: 4 weeks], Chest imaging changes by computed tomography (CT) scan of the chest [Time Frame: 4 weeks], Quantification of the SARS-CoV-2 viral load by real time RT-PCR [Time Frame: 4 weeks] Dose = Not listed Arm1: Stem Cell Educator therapy treat patients with SARS-CoV-2 Arm 2: Conventional treatment of patients with SARS-CoV-2 Location= Not Listed Estimated Start Date = Apr 2020 Estimated End Date = Nov 2020</p>



COVID-19 Clinical Trials – Treatment (Stem Cells)

Organization	Stem Cells	Remarks	Phase
Chongqing Sidemu Biotechnology Technology Co.,Ltd. (China)	NKG2D-ACE2 CAR-NK Cells Secreting IL15 Superagonist and GM-CSF-neutralizing scFv (NKG2D is an activating receptor of NK cells. NK cells modified by CAR play)	-	Ongoing (Recruiting) Phase I/II
			<p>Study = Patients with common, severe and critical type COVID-19 (NCT04324996)</p> <p>Enrolment = 90</p> <p>No. of Arms =Five</p> <p>Type= Randomized, Parallel Assignment, Quadruple masked</p> <p>Outcome = Safety, tolerability, and efficacy</p> <p>Endpoints =</p> <p>Primary: Clinical response [Time Frame: Up to 28 days], the efficacy of NKG2D-ACE2 CAR-NK cells in treating severe and critical 2019 new coronavirus (COVID-19) pneumonia</p> <p>Secondary Side effects in the treatment group [Time Frame: Up to 28 days], the safety and tolerability of NKG2D-ACE2 CAR-NK cells in patients with severe and critical 2019 new coronavirus (COVID-19) pneumonia</p> <p>Dose =</p> <p>Arm1: The NK cells are going to be give by intravenous infusion (10E8 cells per kilogram of body weight, once a week)</p> <p>Arm 2: The NK cells secreting super IL15 superagonist are going to be give by intravenous infusion (10E8 cells per kilogram of body weight, once a week)</p> <p>Arm3: The NKG2D CAR-NK cells are going to be give by intravenous infusion (10E8 cells per kilogram of body weight, once a week)</p> <p>Arm 4: The ACE2 CAR-NK cells are going to be give by intravenous infusion (10E8 cells per kilogram of body weight, once a week)</p> <p>Arm5: The NKG2D-ACE2 CAR-NK cells secreting IL15 superagonist and GM-CSF-neutralizing scFv are going to be give by intravenous infusion (10E8 cells per kilogram of body weight, once a week).</p> <p>Location= China</p> <p>Start Date = Mar 2020</p> <p>Estimated End Date = Sep 2020</p>



COVID-19 Clinical Trials – Treatment (Stem Cells)

Organization	Stem Cells	Remarks	Phase
Stem Cells Arabia (Jordan)	Wharton's Jelly- Mesenchymal Stem Cells	-	Ongoing (Recruiting) Phase I
			<p>Study = Patients positively diagnosed with COVID-19 (NCT04313322)</p> <p>Enrolment = 5</p> <p>No. of Arms = One</p> <p>Type= Open Label, Single Group Assignment</p> <p>Outcome = Clinical Outcome</p> <p>Endpoints =</p> <p>Primary: Improvement of clinical symptoms [Time Frame: 3 weeks], Side effects measured by Chest Radiograph [Time Frame: 3 weeks], Results of Real-Time Polymerase Chain Reaction of Viral RNA, Turing negative [Time Frame: 3 weeks]</p> <p>Secondary: Results of Real-Time Polymerase Chain Reaction of Viral RNA, Turing negative [Time Frame: 8 weeks]</p> <p>Dose = WJ-MSCs will be derived from cord tissue of newborns, screened for HIV1/2, HBV, HCV, CMV, Mycoplasma, and cultured to enrich for MSCs.</p> <p>Each patient will be given three IV doses of WJ-MSCs consisting of 1X10e6/kg. WJ-MSCs will be counted and suspended in 25 ml of Saline solution containing 0.5% human serum Albumin, and will be given to patient intravenously. The three doses will be 3 days apart form each other</p> <p>Location= Jordan</p> <p>Start Date = Mar 2020</p> <p>Estimated End Date = Sep 2020</p>



COVID-19 Clinical Trials – Treatment (Stem Cells)

Organization	Stem Cells	Remarks	Phase
VCANBIO Cell & Gene Engineering Corp Ltd. (China)	Mesenchymal Stem Cell	-	Ongoing (Recruiting) Phase I
			<p>Study = Pneumonia Patients Infected With 2019 Novel Coronavirus (NCT04252118)</p> <p>Enrolment = 20</p> <p>No. of Arms = Two</p> <p>Type= Non-Randomized, Parallel Assignment, Open Label</p> <p>Outcome = Efficacy and Safety</p> <p>Endpoints =</p> <p>Primary: Size of lesion area by chest radiograph or CT [Time Frame: At Baseline , Day 3, Day 6, Day 10, Day 14, Day 21, Day 28], Side effects in the MSCs treatment group [Time Frame: At Baseline , Day 3, Day 6, Day 10, Day 14, Day 21, Day 28, Day 90 and Day 180]</p> <p>Secondary: Improvement of Clinical symptoms including duration of fever and respiratory [Time Frame: At Baseline , Day 3, Day 6, Day 10, Day 14, Day 21, Day 28], Time of nucleic acid turning negative [Time Frame: At Baseline , Day 3, Day 6, Day 10, Day 14, Day 21, Day 28, Day 90 and Day 180], Rate of mortality within 28-days [Time Frame: Day 28], CD4+ and CD8+ T cell count [Time Frame: At Baseline , Day 3, Day 6, Day 10, Day 14, Day 21, Day 28, Day 90 and Day 180], Alanine aminotransferase [Time Frame: At Baseline , Day 3, Day 6, Day 10, Day 14, Day 21, Day 28, Day 90 and Day 180], C-reactive protein [Time Frame: At Baseline , Day 3, Day 6, Day 10, Day 14, Day 21, Day 28, Day 90 and Day 180], Creatine kinase [Time Frame: At Baseline , Day 3, Day 6, Day 10, Day 14, Day 21, Day 28, Day 90 and Day 180]</p> <p>Dose =</p> <p>Arm 1: Conventional treatment plus MSCs Participants will receive conventional treatment plus 3 times of MSCs(3.0*10E7 MSCs intravenously at Day 0, Day 3, Day 6)</p> <p>Arm 2 : Conventional treatment</p> <p>Location= China</p> <p>Start Date = Jan 2020</p> <p>Estimated End Date = Dec 2021</p>



COVID-19 Clinical Trials – Treatment (Stem Cells)

Organization	Stem Cells	Remarks	Phase
Jiangxi Mayo Biotechnologies Co. Ltd (China)	Natural killer cells combined with cord derived mesenchymal stem cells	-	Ongoing (Not Yet Recruiting) Phase I
			<p>Study = Patients With Severe Novel Coronavirus Pneumonia (COVID-19) (ChiCTR2000030944)</p> <p>Enrolment = 20</p> <p>No. of Arms =Two</p> <p>Type= Open Label, multi-centre and controlled</p> <p>Outcome = Safety, tolerance and efficacy</p> <p>Endpoints =</p> <p>Primary: Changes of serum inflammatory factors, Patient death risk, Drug related adverse reactions and events</p> <p>Dose = Not Listed</p> <p>Arm1: Natural killer cells combined with cord derived mesenchymal stem cells</p> <p>Arm 2: current clinical treatment of sNCP</p> <p>Location= China</p> <p>Estimated Start Date = Mar 2020</p> <p>Estimated End Date = Aug 2020</p>



COVID-19 Clinical Trials – Treatment (Stem Cells)

Organization	Stem Cells	Remarks	Phase
Cellular Biomedicine Group Ltd. (US)	Aerosol Inhalation of the Exosomes Derived From Allogenic Adipose Mesenchymal Stem Cells	-	Ongoing (Not Yet Recruiting) Phase I
			<p>Study = Treatment of Severe Patients With Novel Coronavirus Pneumonia (NCT04276987)</p> <p>Enrolment = 30</p> <p>No. of Arms = One</p> <p>Type= Single Group Assignment, Open Label</p> <p>Outcome = Efficacy and Safety</p> <p>Endpoints</p> <p>Primary: Adverse reaction (AE) and severe adverse reaction (SAE) [Up to 28 days], Time to clinical improvement (TTIC) [Up to 28 days]</p> <p>Secondary: Number of patients weaning from mechanical ventilation within 28 days, Duration (days) of ICU monitoring within 28 days, Duration (days) of vasoactive agents using within 28 days, Duration (days) of mechanical ventilation supply among survivors, Number of patients with improved organ failure within 28 days, Rate of mortality within 28 days</p> <p>Dose = 5 times aerosol inhalation of MSCs-derived exosomes (2.0*10E8 nano vesicles/3 ml at Day 1, Day 2, Day 3, Day 4, Day 5) + Conventional treatment</p> <p>Location= China</p> <p>Estimated Start Date = Feb 2020</p> <p>Estimated End Date = Jul 2020</p>



COVID-19 Clinical Trials – Treatment (Stem Cells)

Organization	Stem Cells	Remarks	Phase
CAR-T (Shanghai) Biotechnology Co., Ltd.	Dental Pulp Mesenchymal Stem Cells	-	Ongoing (Not Yet Recruiting) Early Phase I
			<p>Study = Patients of novel coronavirus with induced severe pneumonia (NCT04302519)</p> <p>Enrolment = 24</p> <p>No. of Arms = One</p> <p>Type= Single Group Assignment, Open Label</p> <p>Endpoints =</p> <p>Primary: Disappear time of ground-glass shadow in the lungs [Time Frame: 14 days]</p> <p>Secondary: Absorption of Lung shadow absorption by CT Scan-Chest [Time Frame: 7, 14, 28 and 360 days]</p> <p>Absorption of Lung shadow absorption by CT Scan-Chest [Time Frame: 7, 14, 28 and 360 days] by using Kaplan-meier method, Changes of blood oxygen [Time Frame: 3, 7 and 14 days] by using T-test</p> <p>Dose = Slowly and quietly drop 50 mL of normal saline, then the endodontic mesenchymal stem cell injection of 1.0x10⁶ cells /kg (after 60 min), and then 50 mL of normal saline. 1. 3, 7 days to increase the injection of mesenchymal stem cells</p> <p>Location= Not Listed</p> <p>Estimated Start Date = Mar 2020</p> <p>Estimated End Date = Jul 2021</p>



COVID-19 Clinical Trials - Vaccine

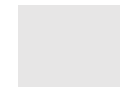
Organization	Vaccine	Remarks	Phase
CanSino Biologics Inc. (China)	Recombinant Novel Coronavirus Vaccine (Adenovirus Type 5 Vector)	New Vaccine	Ongoing (Recruiting) Phase 1
			<p>Study = Healthy Adults (NCT04313127) Enrolment = 108 No. of Arms = Three Type= Non-Randomized, Sequential, Open Label, Dose-escalating Outcome = Safety, reactogenicity and immunogenicity Endpoints = Primary: Safety indexes of adverse reactions [Time Frame: 0-7 days post-vaccination] Secondary: Occurrence of adverse events post-vaccination [Time Frame: 0-28 days post-vaccination], Occurrence of serious adverse events post-vaccination [Time Frame: 0-28 days, within 6 months post-vaccination], Occurrence of abnormal changes of laboratory safety examinations [Time Frame: pre-vaccination, day 7 post-vaccination], Geometric mean titer (GMT) of S-specific antibodies against 2019 novel coronavirus tested by ELISA in serum[Time Frame: day14,28 month 3,6 post-vaccination], GMT of S-specific antibodies against 2019 novel coronavirus tested by pseudoviral neutralization test method in serum [Time Frame: day14,28 month 6 post-vaccination], seropositivity rates of S-specific antibodies against 2019 novel coronavirus tested by ELISA in serum [Time Frame: day14,28, month 3,6 post-vaccination], seropositivity rates of S-specific antibodies against 2019 novel coronavirus tested by pseudoviral neutralization test method in serum [Time Frame: day14,28 month 6 post-vaccination], Geometric mean fold increase (GMI) of S-specific antibodies against 2019 novel coronavirus tested by ELISA in serum [Time Frame: day14,28, month 3,6 post-vaccination], GMI of S-specific antibodies against 2019 novel coronavirus tested by pseudoviral neutralization test method in serum [Time Frame: day14,28, month 6 post-vaccination], Geometric mean concentration of anti-Ad5 vector neutralizing antibody responses [Time Frame: day、 14,28, month3,6 post-vaccination], GMI of anti-Ad5 vector neutralizing antibody responses [Time Frame: day、 14,28, month3,6 post-vaccination], specific cellular immune responses[Time Frame: day 14, 28,month 6 post-vaccination] Dose = Arm 1: Low-Dose: Subjects received one dose of 5E10 vp Ad5-nCoV at 18 to 60 years old Arm2: Middle-Dose :Subjects received one dose of 1E11 vp Ad5-nCoV at 18 to 60 years old Arm 3: High-dose Group: Subjects received one dose of 1.5E11vp Ad5-nCoV at 18 to 60 years old Location= China Start Date = Mar 2020 Estimated End Date = Dec 2022</p>

COVID-19 Clinical Trials - Vaccine

Organization	Vaccine	Remarks	Phase
National Institute of Allergy and Infectious Diseases (NIAID) (US)/ Co-developed by NIH and Moderna (US)	mRNA-1273 [novel lipid nanoparticle (LNP)-encapsulated mRNA-based vaccine]	New Vaccine	Ongoing (Recruiting) Phase 1
			<p>Study = Healthy Adults (NCT04283461) Enrolment = 45 No. of Arms = Three Type= Non-Randomized, Sequential, Open Label, Dose-Ranging Outcome = Safety and immunogenicity Endpoints = Primary: Frequency of solicited local reactogenicity adverse events (AEs) [Time Frame: Through 7 days post-vaccination], Frequency of any medically-attended adverse events (MAAEs) [Time Frame: Day 1 to Day 394], Frequency of any new-onset chronic medical conditions (NOCMCs) [Time Frame: Day 1 to Day 394], Frequency of any serious adverse events (SAEs) [Time Frame: Day 1 to Day 394], Frequency of any unsolicited adverse events (AEs) [Time Frame: Through 28 days post-vaccination], Frequency of solicited systemic reactogenicity adverse events (AEs) [Time Frame: Through 7 days post-vaccination], Grade of any unsolicited adverse events (AEs) [Time Frame: Through 28 days post-vaccination], Grade of solicited local reactogenicity adverse events (AEs) [Time Frame: Through 7 days post-vaccination], Grade of solicited systemic reactogenicity adverse events (AEs) [Time Frame: Through 7 days post-vaccination] Secondary: Geometric mean fold rise (GMFR) in IgG titer from baseline [Time Frame: Day 1 to Day 57], Geometric mean titer (GMT) of antibody [Time Frame: Day 57], Percentage of subjects who seroconverted [Time Frame: Day 1 to Day 57]: Seroconversion is defined as a 4-fold change in antibody titer from baseline Dose = Arm 1: 25 mcg of mRNA-1273 administered through 0.5 mL intramuscular injection in the deltoid muscle on Days 1 and 29. n=15 (4 sentinel, 11 non-sentinel) Arm2: 100 mcg of mRNA-1273 administered through 0.5 mL intramuscular injection in the deltoid muscle on Days 1 and 29. n=15 (4 sentinel, 11 non-sentinel) Arm 3: 250 mcg of mRNA-1273 administered through 0.5 mL intramuscular injection in the deltoid muscle on Days 1 and 29. n=15 (4 sentinel, 11 non-sentinel) Location= US Start Date = Mar 2020 Estimated End Date = Jun 2021</p>

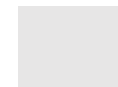
COVID-19 Clinical Trials - Vaccine

Organization	Phase I	Phase II	Phase III	Remarks
Inovio Pharmaceuticals (US)/Gates foundation	IND approved, N=40	-	-	Trial to start at Philadelphia's Perelman School of Medicine at the University of Pennsylvania, or the Center for Pharmaceutical Research in Kansas City
Karolinska Institute (Sweden) / Cobra Biologics (OPENCORONA Project)	-	-	-	Preclinical (DNA vaccine with electroporation)
Osaka University (Japan) / AnGes (Japan)/ Takara Bio (Japan)	-	-	-	Preclinical (DNA plasmid vaccine)
Takis/Applied DNA Sciences (US) /Evvivax (Italy)	-	-	-	Preclinical (DNA vaccine)
Zydus Cadila (India)	-	-	-	Preclinical (DNA plasmid vaccine)
Sinovac (China)	-	-	-	Preclinical (Inactivated + alum)
Beijing Institute of Biological Products (China) /Wuhan Institute of Biological Products (China)	-	-	-	Preclinical (Inactivated)
Osaka University (Japan) / BIKEN/ NIBIOHN	-	-	-	Preclinical (Inactivated)
Codagenix (US) /Serum Institute of India (India)	-	-	-	Preclinical (Deoptimized live attenuated vaccines)
GeoVax (US) /BravoVax (China)	-	-	-	Preclinical (Non-Replicating Viral Vector - MVA encoded VLP)
Janssen Pharmaceutical Companies (Belgium)	-	-	-	Preclinical [Ad26 Non-Replicating Viral Vector (alone or with MVA boost)]
DZIF – German Center for Infection Research (Germany)	-	-	-	Preclinical (Non-Replicating Viral Vector, MVA-S encoded)
Altimune (US)	-	-	-	Preclinical (Non-Replicating Viral Vector, adenovirus-based NasoVAX expressing SARS2-CoV spike protein)



COVID-19 Clinical Trials - Vaccine

Organization	Phase I	Phase II	Phase III	Remarks
Greffex (US)	-	-	-	Preclinical [Ad5 S, Non-Replicating Viral Vector (GREVAX™ platform)]
Vaxart (US)	-	-	-	Preclinical (Non-Replicating Viral Vector, Oral Vaccine platform)
AdaptVac (PREVENT-nCoV consortium) (Denmark)	-	-	-	Preclinical (Protein Subunit, Capsid-like Particle)
ExpreS2ion (Denmark)	-	-	-	Preclinical (Drosophila S2 insect cell expression system VLPs)
WRAIR/USAMRIID (US)	-	-	-	Preclinical (Protein Subunit, S protein)
National Institute of Infectious Disease (Japan)	-	-	-	Preclinical (Protein Subunit, S protein +Adjuvant)
Osaka University / BIKEN/ National Institutes of Biomedical Innovation (Japan)	-	-	-	Preclinical (Protein Subunit, VLP-recombinant protein + Adjuvant)
Clover Biopharmaceuticals Inc.(China) /GSK (UK) /Dynavax (US)	-	-	-	Preclinical (Protein Subunit, Native like Trimeric subunit Spike Protein vaccine)
Univ. of Pittsburgh (US)	-	-	-	Preclinical (Protein Subunit, microneedle arrays S1 subunit)
Vaxil Bio (Canada)	-	-	-	Preclinical (Protein Subunit, Peptide)
Biological E Ltd (India)	-	-	-	Preclinical [Protein Subunit, Adjuvanted protein subunit (RBD)]
Flow Pharma Inc (US)	-	-	-	Preclinical (Protein Subunit, Peptide)
AJ Vaccines (Denmark)	-	-	-	Preclinical (Protein Subunit, S protein)
Generex (Canada) /EpiVax (US)	-	-	-	Preclinical (Protein Subunit, li-Key peptide)
EpiVax (US) /Univ. of Georgia (US)	-	-	-	Preclinical (Protein Subunit, S protein)



COVID-19 Clinical Trials - Vaccine

Organization	Phase I	Phase II	Phase III	Remarks
Sanofi Pasteur (France)	-	-	-	Preclinical [Protein Subunit, S protein (baculovirus production)]
Novavax (US)	-	-	-	Preclinical (VLP-recombinant protein nanoparticle vaccine + Matrix M)
Heat Biologics/Univ. Of Miami (US)	-	-	-	Preclinical (Protein Subunit, gp-96 backbone)
University of Queensland (Australia) /GSK (UK) /Dynavax (US)	-	-	-	Preclinical (Protein Subunit, Molecular clamp stabilized Spike protein)
Baylor College of Medicine (US)	-	-	-	Preclinical (Protein Subunit, S1 or RBD protein)
iBio (US)/CC-Pharming (China)	-	-	-	Preclinical (Protein Subunit, Subunit protein, plant produced)
Saint-Petersburg scientific research institute of vaccines and serums (Russia)	-	-	-	Preclinical [Recombinant protein, nanoparticles (based on S-protein and other epitopes)]
Innovax/Xiamen Univ. (China) /GSK (UK)	-	-	-	Preclinical (Protein Subunit, COVID-19 XWG-03 truncated S (spike) proteins)
VIDO-InterVac, University of Saskatchewan (Canada)	-	-	-	Preclinical (Protein Subunit, Adjuvanted microsphere peptide)
OncoGen (Malaysia)	-	-	-	Preclinical (Protein Subunit, Synthetic Long Peptide Vaccine candidate for S and M proteins)
Zydus Cadila (India)	-	-	-	Preclinical (Replicating Viral Vector, Measles Vector)
Institute Pasteur (France)/Themis/Univ. of Pittsburg Center for Vaccine Research (US)	-	-	-	Preclinical (Replicating Viral Vector, Measles Vector)
DZIF – German Center for Infection Research (Germany)	-	-	-	Preclinical [Live attenuated virus, Measles Virus (S, N targets)]
Tonix Pharma/Southern Research (US)	-	-	-	Preclinical (Replicating Viral Vector, Horsepox vector expressing S protein)
University of Hong Kong	-	-	-	Preclinical (Replicating Viral Vector, Influenza vector expressing RBD)

COVID-19 Clinical Trials - Vaccine

Organization	Phase I	Phase II	Phase III	Remarks
IAVI/Batavia (US)	-	-	-	Preclinical (Replicating Viral Vector, VSV vector expressing S protein)
Fudan University/ Shanghai JiaoTong University/RNACure Biopharma (China)	-	-	-	Preclinical (RNA, LNP-encapsulated mRNA cocktail encoding VLP)
Fudan University/ Shanghai JiaoTong University/RNACure Biopharma (China)	-	-	-	Preclinical (RNA, LNP-encapsulated mRNA encoding RBD)
University of Tokyo/ Daiichi-Sankyo (Japan)	-	-	-	Preclinical (RNA, LNP-encapsulated mRNA)
China CDC/Tongji University/Stermina	-	-	-	Preclinical (RNA, mRNA)
Arcturus/Duke-NUS (Singapore)	-	-	-	Preclinical (RNA, mRNA)
BioNTech (Germany) /Fosun Pharma (China)/ Pfizer (US)	-	-	-	Preclinical (RNA, mRNA)
Imperial College London (UK)	-	-	-	Preclinical (RNA, saRNA)
Curevac (Germany)	-	-	-	Preclinical (RNA, mRNA)
Medicago Inc. (Canada)	-	-	-	Preclinical (VLP, Plant-derived VLP)
Imophoron Ltd and Bristol University's Max Planck Centre (UK)	-	-	-	Preclinical (VLP, ADDomer™ multiepitope display)
ReiThera (Italy)	-	-	-	Preclinical
BioNet Asia (Thailand)	-	-	-	Preclinical
ImmunoPrecise (Canada)	-	-	-	Preclinical
MIGAL Galilee Research Institute (Israel)	-	-	-	Preclinical
Doherty Institute (Australia)	-	-	-	Preclinical
Tulane University (US)	-	-	-	Preclinical

Thank You