



IBPS

INTEGRATED BIOPHARMA
AND PHARMA SOLUTION

COVID-19

(Update collated on 24-Apr-2020)

IBPS and SBLehrer LLC are releasing the next update of clinical efforts for treatments and vaccines for **Covid19**. As we stated when we started this effort, Our goal is to highlight the actual work and results from studies around the world to aid in decision making, not follow the 24 hour news cycle hype.

Of the +1500 trials registered on various clinical websites we are currently tracking the progress on the following

- Prophylaxis treatment of Covid19 for at risk Population like Medical staff
- Treatment options for Infected Patients
- Vaccines for Healthy People

Several major development occurred since our last update.

- **Hydroxychloroquine**: Initial reports from France and the US show hydroxychloroquine in combination with Azithromycin showed promise. Governments around the world are stockpiling the drug. US FDA authorized use for patients who were not enrolled in clinical trials. Trials in Brazil and the US with hydroxychloroquine were recently stopped due to significant cardiac side effects, a known side effect of the drug. FDA on April 24th, advised doctors against prescribing hydroxychloroquine or the related drug chloroquine to coronavirus patients outside of the hospital setting as it appears to be causing some serious and potentially life-threatening side effects. A small trial of 30 subjects has demonstrated despite its small sample size that hydroxychloroquine treatment is significantly associated with viral load reduction/disappearance in COVID-19 patients and its effect is reinforced by azithromycin. Another small study in China is also exhibiting positive preliminary outcomes
- **Remdesivir**: Similar to Hydroxychloroquine, Remdesivir has had its own roller coaster in the last 2 weeks. Worldwide equity markets rose more than 10% after initial promising compassionate use results on ~120 patients were released. New data issued by WHO from a Chinese study which had to stop recruiting after the drug failed to show any effect caused major headlines around the world. Meanwhile Gilead has further increased its enrollment numbers for 2 trials which are currently ongoing and expected to end in May-2020.
- **Stem cells** are showing positive signs. Two small studies showed very high recovery rates with severe patients
- In the **Vaccine** world which is currently the most promising of all alternatives under development, WHO currently tracked 71 vaccines in development across the globe of which 8 have moved into clinical phase

We look to update this summary in the next two weeks. As before, please help us by adding any information you see missing from the summary.

Thanks for your help in this journey

COVID-19: Progress Snapshot

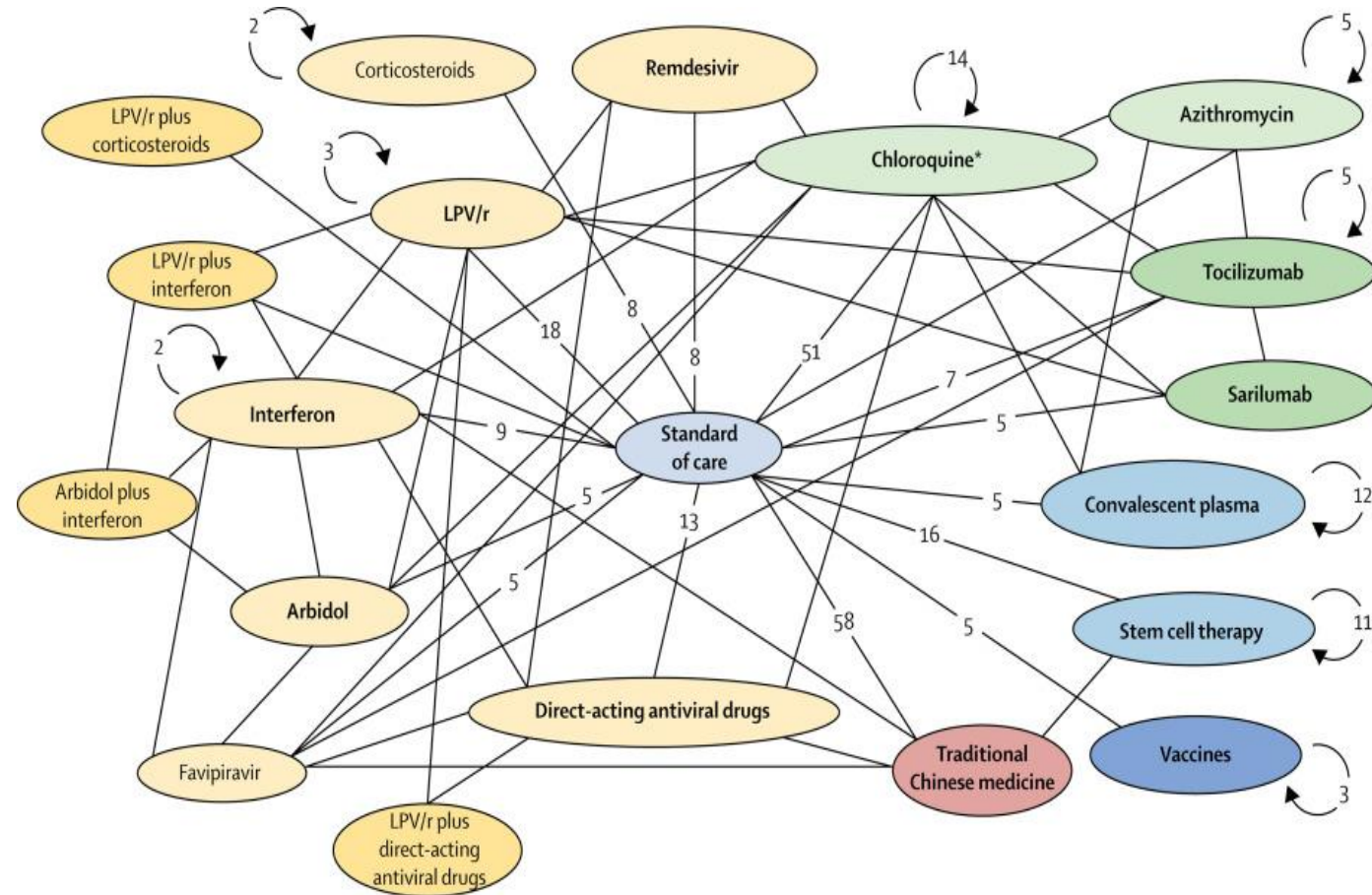
As of April 24, 2020, +1500 clinical trials have been registered at the various international and national clinical trial registry sites.

So far, Randomised clinical trials that have been published have investigated the efficacy of

- **Lopinavir – Ritonavir compared with standard of care,**
- **Hydroxychloroquine compared with best supportive care**
- **Hydroxychloroquine versus Hydroxychloroquine combined with azithromycin**
- **Favipiravir compared with Arbidol, and**
- **Lopinavir – Ritonavir compared with Arbidol**

300+ trials are aimed to investigate of the above drugs and promising therapies such as

- **Remdesivir**
- **IL-6 inhibitors (Tocilizumab and Sarilumab)**
- **Convalescent plasma therapy**
- **Stem-cell transfusion**
- **Vaccine candidates**
- **Several other well known direct acting Antivirals, and traditional Chinese medicines**



Source: Lancet

COVID-19: Progress Snapshot

Remdesivir

- The Trial carried out in CN by capital medical university (NCT04257656) failed to show any effect in the first full trial, it has been revealed. Initial report suggested Remdesivir was stopped early in 18 (11.6%) patients because of adverse effects, compared with 4 (5.1%) in the control group.
- The other two big trials which are being carried out (NCT04292899 and NCT04292730) have shown 17/40 patients who were treated have been discharged (32-severe condition and 7 moderately severe) at site in Tacoma AND 21/32 patients who were treated have been discharged (29 were in severe condition and 3 were moderate)

Lopinavir/Ritonavir

- First 400 patients study done in Canada (NCT04330690) indicates no benefit in COVID 19 (Mar. 2020, published in NEJM). Many other are ongoing.

Hydroxychloroquine (an anti-malarial drug)

- A non-placebo control trial (N=30) showed (EU Clinical Trials Register, number 2020-000890-25) despite its small sample size our survey shows that hydroxychloroquine treatment is significantly associated with viral load reduction/disappearance in COVID-19 patients and its effect is reinforced by azithromycin. **This was the basis of many undergoing clinical trials** (we have recorded N=15 key trials in this category)
- Another study by Shanghai Public Health Clinical Center claims positive preliminary outcomes, COVID-19 nucleic acid of throat swabs was negative in 13 (86.7%) cases in the HCQ group and 14 (93.3%) cases in the control group but again in a small sample size N=30 (NCT04261517)

Other

- Fujifilm claims Phase III Study (NCT04336904) shows 91% of the patients who took **favipiravir** had lung improvement, versus 62% of patients who did not get the medication. Note that these outcomes may only apply for patients with no symptoms or mild symptoms of COVID-19.

COVID-19: Progress Snapshot

Biologics Therapy

- Roche/Genentech sponsored trial on Tocilizumab [humanized anti-interleukin-6 (IL-6) receptor mAb] a Hospital report improved symptoms in 75% patients for Phase III study. Multiple trials are ongoing by many sponsors with Tocilizumab.
- Convalescent Plasma therapy created some positive impacts in CN, US and in India.
- Certain positive news on Stem cell therapy
 - A study by Mesoblast Limited (Australia) indicates use of Allogeneic mesenchymal stem cell product candidate remestemcel-L showed 83% survival in ventilator-dependent COVID-19 patients (10/12) with moderate/severe ARDS treated with two infusions of cell therapy within 5 days under emergency compassionate use. IND filed for further studies.
 - Pluristem (USA) demonstrated in proof of concept study (N=7 subjects) that 4/6 patients showed improvements, 3/6 in advanced stages are weaning off from ventilators. Further studies planned.

Vaccine Development

- The most promising areas so far. At least 8 have moved to clinical phase and 6 are in the end of pre-clinical phase based on the current information.
- Different approaches taken for vaccine development are attenuated virus development, using viral peptides, RNA and DNA vaccines.
- Oxford university started dosing healthy volunteers using the recombinant adenovirus modified to include the spike or 'S' protein on the surface of SARS-CoV-2 in 510 subjects (NCT04324606). Indian vaccine manufacturer Serum institute of India is a partner for this study. **Target completion in Sep 2020.**
- CanSino Biologics Inc. (China) / PLA China is doing systematic development program using recombinant adenovirus type 5 vector. Based on Phase I data in 108 subjects (NCT04313127, ChiCTR2000030906) they have progressed into phase II in 500 subjects (ChiCTR2000031781). **Target completion Jan 2021.**

COVID-19: Progress Snapshot

Vaccine Development

- National Institute of Allergy and Infectious Diseases (partner NIH and Moderna) (US) started phase 1 study using RNA vaccine in 45 subjects (NCT04283461). **Target completion Jun 2020.**
- A DNA vaccine work started by Inovio (US) partnering with Gates foundation in 40 subjects (NCT04336410). **Target completion April 2021.**
- Sinovac China started phase1/2 trial in 744 subjects using inactivated virus (NCT04352608). **Target completion Dec 2020.**
- Beijing Institute of Biological Products (China) /Wuhan Institute of Biological Products (China) started trial in 744 subjects using inactivated virus (ChiCTR2000031809). **Target completion Nov 2021.** Initial data on 96 subjects shows encouraging titre with adequate safety.
- Symvivo Corporation (Canada) is conducting a vaccine trial using COVID-19 spike protein in 84 subjects (NCT04334980). **Target completion Dec 2021.**
- Another RNA virus vaccine trial is initiated in Germany in 200 subjects by BioNTech (Germany) /Fosun Pharma (China)/ Pfizer (US). **Target completion Dec 2020.**

COVID-19 Management

Prophylaxis

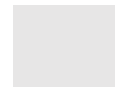
- Repurposing of existing drugs
 - antiviral drugs
 - anti malarial drugs

Treatment

- Repurposing of existing drug
- Vaccine

COVID-19 Development Snapshot (Prophylaxis)

Company	Drug	Status	Location	Remarks
Pulmotect, Inc. (US)	PUL-042 [combination drug agonists of Toll-like receptors]	Phase II CT ongoing, target completion Oct 2020, N=200 (NCT04313023)	US	
National Institute of Respiratory Diseases, Mexico/Sanofi (France)	Hydroxychloroquine	Phase III ongoing, target completion Mar 2021, N=400 (NCT04318015)	Mexico	
Cadila Pharmaceuticals (India)	Suspension of heat killed (autoclaved) Mycobacterium	Phase III ongoing, target completion May 2021, N=4000 (NCT04353518)	-	
Romark Laboratories L.C. (US)	Nitazoxanide (NTZ) for Pre- or Post Exposure Prophylaxis	<ul style="list-style-type: none"> Phase III ongoing, target completion Aug 2020, N=800 (NCT04359680) Phase III ongoing, target completion Aug 2020, N=600 (NCT04343248) 	-	NCT04359680 – Health Workers NCT04343248 – Elderly Residents
Plan Nacional sobre el Sida (PNS)	<ul style="list-style-type: none"> Emtricitabine/tenofovir disoproxil Hydroxychloroquine 	Phase III ongoing, target completion Jul 2020, N=4000 (NCT04334928)	Spain	
Hope Biosciences (US)	<ul style="list-style-type: none"> Allogeneic adipose-derived mesenchymal stem cells Autologous Mesenchymal Stem Cell Therapy 	<ul style="list-style-type: none"> Phase II CT ongoing, target completion Apr 2021, N=100 (NCT04348435) Phase II CT ongoing, target completion Dec 2020, N=56 (NCT04349631) 	US	



COVID-19 Development Snapshot (Treatment: Remdesivir)

Company	Drug	Status	Location	Remarks
Gilead Sciences (US)	Remdesivir [antiviral compound]*	Phase III CT ongoing, target completion May 2020, N=6000 (NCT04292899)	US, Germany, Hong Kong, Italy, Korea, Spain, Singapore, Switzerland, Taiwan	<ul style="list-style-type: none"> 17/40 patients who were treated have been discharged (32-severe condition and 7 moderately severe) at site in Tacoma 21/32 patients who were treated have been discharged (29 were in severe condition and 3 were moderate)
Gilead Sciences (US)	Remdesivir [antiviral compound]*	Phase III CT ongoing, target completion May 2020, N=1600 (NCT04292730)	US, Germany, Hong Kong, Iran, Italy, Korea, Spain, Singapore, Switzerland, Taiwan	
Capital Medical University	Remdesivir [antiviral compound]*	Phase III CT, Started Jan 2020; Actual enrollment 237 against estimated enrollment 432; (NCT04257656)	CN	<ul style="list-style-type: none"> Initial report suggested Remdesivir was stopped early in 18 (11.6%) patients because of adverse effects, compared with 4 (5.1%) in the control group

*Key pharma companies including Cipla, Glenmark and Dr. Reddy's, according to the industry sources, have started working on the development of the drug which is under patent protection until 2035

COVID-19 Development Snapshot (Treatment: Danoprevir+Ritonavir, Favipiravir, Lopinavir/Ritonavir)

Company	Drug	Status	Location	Remarks
Ascleitis Pharmaceuticals Co., Ltd. (China)	Ganovo (Danoprevir)+ritonavir+/- Interferon nebulization	Phase IV CT completed on Mar 2020, N=11 (NCT04291729)	China	Results not Posted but The primary endpoint of safety and tolerability is achieved
	Danoprevir+Ritonavir	Phase IV CT ongoing, target completion May 2020, N=40 (NCT04345276)	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, N=520 (NCT04286503)	China	
FUJIFILM Toyama Chemical Co. Ltd (Japan)	Avigan® (favipiravir) (approved in JP as anti-flu drug)	<ul style="list-style-type: none"> Phase III ongoing, Target completion Jul 2020, N=100 (NCT04336904) Phase II ongoing, Target completion Dec 2020, N=50 (NCT04358549) 	US	Phase III Study shows 91% of the patients who took favipiravir had lung improvement, versus 62% of patients who did not get the medication. Note that these outcomes may only apply for patients with no symptoms or mild symptoms of COVID-19.
Ascleitis Pharmaceuticals Co., Ltd. (China)	ASC09 [protease inhibitor to treat HIV type-1 infections] /ritonavir, lopinavir/ritonavir	Phase III CT ongoing, target completion Jun 2020, N=160 (NCT04261907)	China	
WHO/ AbbVie (US)	Lopinavir/ritonavir	Phase II CT ongoing, target completion May 2022, N=440 (NCT04330690)	Canada	NEJM published initial data that shows no benefit in COVID 19 (Mar. 2020)
Asan Medical Center (Korea)	<ul style="list-style-type: none"> Lopinavir/ritonavir Hydroxychloroquine sulfate 	Phase II ongoing , target completion May 2020, N=150 (NCT04307693)	Korea	

COVID-19 Development Snapshot (Treatment: Hydroxychloroquine)

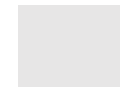
Company	Drug	Status	Location	Remarks
Fondation Méditerranée Infection (FMI) - IHU Méditerranée Infection	Hydroxychloroquine	N=30 at different age group EU Clinical Trials Register, number 2020-000890-25	France	Despite its small sample size our survey shows that hydroxychloroquine treatment is significantly associated with viral load reduction/disappearance in COVID-19 patients and its effect is reinforced by azithromycin.
Shanghai Zhongxi Pharmaceuticals Co. Ltd (China)	Hydroxychloroquine Sulfate	Phase IV CT ongoing, target completion Jun 2020. N=360 (ChiCTR2000029868)	China	
EMS Farmacêutica (Brazil)	Hydroxychloroquine	Phase III CT ongoing, target completion Jul 2020, N=1300 (A27736297878)	Brazil	
Fundacio Lluita Contra la SIDA	Hydroxychloroquine	Phase III ongoing , target completion Jun 2020, N=3040 (NCT04304053)	Spain	
Novartis (Switzerland)	<ul style="list-style-type: none"> Hydroxychloroquine (HCQ) HCQ + azithromycin 	Phase III ongoing , target completion Jul 2020, N=444 (NCT04358081)	US	
Shanghai Public Health Clinical Center (China)	Hydroxychloroquine	Phase III completed, N=30 (NCT04261517)	China	Positive preliminary outcomes, COVID-19 nucleic acid of throat swabs was negative in 13 (86.7%) cases in the HCQ group and 14 (93.3%) cases in the control group

COVID-19 Development Snapshot (Treatment: Hydroxychloroquine)

Company	Drug	Status	Location	Remarks
Apsen Farmaceutica S.A. (Brazil)	<ul style="list-style-type: none"> Hydroxychloroquine Sulfate Hydroxychloroquine Sulfate + Azithromycin 	Phase III CT ongoing, target completion Nov 2020, N=500 (NCT04361461)	Brazil	
National Institute of Respiratory Diseases, Mexico/Sanofi (France)	Hydroxychloroquine	Phase III CT ongoing, target completion Mar 2021, N=500 (NCT04315896)	Mexico	
University of Washington (US)/ Bill and Melinda Gates Foundation	Hydroxychloroquine Sulfate	Phase II/III CT ongoing, target completion Oct 2020, N=2000 (NCT04328961)	Brazil	
UnitedHealth Group (US)	Hydroxychloroquine	Phase II CT ongoing, target completion Jun 2021, N=850 (NCT04353037)	US	
Bukwang Pharmaceutical (Korea)	<ul style="list-style-type: none"> Clevudine Hydroxychloroquine 	Phase II CT ongoing, target completion Dec 2020, N=60 (NCT04347915)	-	
Sanofi (France)	Hydroxychloroquine	Phase I CT ongoing, target completion May 2020, N=210 (NCT04333654)	US, France	
Azidus Brasil (Brazil)	Hydroxychloroquine (HCQ) and azithromycin (AZT)	Early Phase I CT suspended, target completion Jun 2020, N=400 (NCT04329572)	Not Listed	
Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A. (Greece)	Chloroquine Phosphate	Phase II CT ongoing, target completion Apr 2021, N=60 (NCT04344951)	Greece	

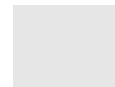
COVID-19 Development Snapshot (Treatment: Other Candidates)

Company	Drug	Status	Location	Remarks
Novartis (Switzerland)	Ruxolitinib	Phase III ongoing , target completion Jun 2020, N=402 (NCT04362137)	Not Listed	For compassionate Use in Severe/Very Severe COVID-19 Illness
Incyte Corporation (US)	Ruxolitinib	Phase II CT ongoing, target completion Dec 2021, N=25 (NCT04354714)	US	
Fundación de investigación HM (Spain)	Ruxolitinib plus simvastatin	Phase II CT ongoing, target completion May 2020, N=94 (NCT04348695)	Spain	
University Health Network, Toronto (Canada)	Ruxolitinib	CT ongoing , target completion Jan 2021, N=64 (NCT04331665)	Canada	
AstraZeneca (UK)	Acalabrutinib	Phase II CT ongoing, target completion Sep 2020, N=428 (NCT04346199)	Spain	
Eli Lilly and Company (US) / National Institute of Allergy and Infectious Diseases (NIAID)	Baricitinib	Study Planned	US, Europe, Asia	Expected to start I Apr 2020 and results by Jul 2020
Laboratorio Elea S.A.C.I.F. y A. (Argentina)	Telmisartan	Phase II CT ongoing, target completion Oct 2020, N=400 (NCT04355936)	Argentina	
AstraZeneca (UK)	Dapagliflozin	Phase III CT ongoing, target completion Dec 2020. N=900 (NCT04350593)	US	For Respiratory Failure in Patients
Biohaven Pharmaceuticals, Inc. (US)	Vazegepant (Intra-Nasal)	Phase II/III CT ongoing, target completion Jul 2020, N=120 (NCT04346615)	US	



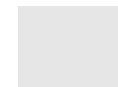
COVID-19 Development Snapshot (Treatment: Other Candidates)

Company	Drug	Status	Location	Remarks
Can-Fite BioPharma (Israel)	Piclidenoson [novel, first-in-class, A3 adenosine receptor agonist]	Phase II CT ongoing, target completion Jul 2020, N=40 (NCT04333472)	Israel	
Ache Laboratorios Farmaceuticos S.A. (Brazil)	Dexamethasone	Phase III CT ongoing, target completion Aug 2020, N=290 (NCT04327401)	Brazil	
NeuroRx, Inc. (US)/ Relief Therapeutics Holding SA (Switzerland)	Aviptadi	Phase II CT ongoing, target completion Sep 2020, N=120 (NCT04311697)	US, Israel	
NeuroRx, Inc. (US)	Inhaled Aviptadil	Phase II/III CT ongoing, target completion Oct 2020, N=144 (NCT04360096)	-Not listed	
Vanda Pharmaceuticals (US)	Tradipitant [Neurokinin 1 receptor antagonists]	Phase III CT ongoing, target completion Aug 2020, N=300 (NCT04326426)	Not Listed	
Karyopharm Therapeutics Inc (US)	Oral Selinexor	<ul style="list-style-type: none"> Phase II CT ongoing, target completion Aug 2020, N=80 (NCT04355676) Phase II CT ongoing, target completion Aug 2020, N=230 (NCT04349098) 	<ul style="list-style-type: none"> Not Listed US, Austria, Israel, Spain 	
Blade Therapeutics (US)	BLD-2660 (novel, small molecule inhibitor of calpain)	Phase II CT ongoing, target completion Sep 2020, N=120 (NCT04334460)	-	



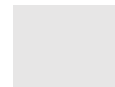
COVID-19 Development Snapshot (Treatment: Other Candidates)

Company	Drug	Status	Location	Remarks
Azidus Brasil (Brazil)	Methotrexate	Phase I/II CT ongoing, target completion Nov 2020, N=42 (NCT04352465)	Brazil	
Bausch Health Americas, Inc.	VIRAZOLE®	Phase I CT ongoing, target completion Apr 2021, N=50 (NCT04356677)	-	
BioCryst Pharmaceuticals (US) / National Institute of Allergy and Infectious Diseases (NIAID)	Galidesivir	Phase I CT ongoing, target completion May 2021, N=66 (NCT03891420)	Brazil	
Algernon Pharmaceuticals (Canada)	Ifenprodil	Pre-IND Application with U.S. FDA	-	
Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A. (Greece)	Triiodothyronine	Phase II CT ongoing, target completion May 2021, N=60 (NCT04348513)	Greece	



COVID-19 Development Snapshot (Treatment: New Molecules)

Company	Drug	Status	Location	Remarks
Ansun Biopharma, Inc. (US)	DAS181 [Virus internalization inhibitors] (Initial development was against influenza virus)	Phase III CT ongoing, target completion Dec 2021, N=250 (NCT03808922)	US, Australia, Taiwan, Korea	
		Phase II/III ongoing, Target completion Jul 2020, N=82 (NCT04354389)	Italy	Stage 1 with 22 subjects as Proof of concept
CalciMedica, Inc. (US)	CM4620 Injectable Emulsion	Phase II CT ongoing, target completion Sep 2020, N=120 (NCT04345614)	US	
Pulmotect, Inc. (US)	PUL-042 [combination drug agonists of Toll-like receptors]	Phase II CT ongoing, target completion Oct 2020, N=100 (NCT04312997)	US	
Theravance Biopharma (Cayman Islands)	TD-0903	Phase I CT ongoing, target completion Jun 2020, N=54 (NCT04350736)	UK	

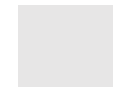


COVID-19 Development Snapshot (Treatment: Biologics)

Company	Drug	Status	Location	Remarks
Bio-Thera Solutions, Ltd* (China)	Adalimumab [humanized anti-human recombinant monoclonal IgG1 antibody]	Phase IV CT ongoing, target completion Aug 2020, N=60 (ChiCTR2000030089)	China	
AryoGen pharmed Co. (Iran)	Tocilizumab [humanized anti-interleukin-6 (IL-6) receptor mAb]	Phase III CT ongoing, target completion Jul 2020, N=500 (IRCT20150303021315N17)	Iran	
Genentech, Inc. (US)	Tocilizumab	Phase III CT ongoing, target completion Aug 2020, N=300 (NCT04356937)	US	
Hoffmann-La Roche (Switzerland)	Tocilizumab	<ul style="list-style-type: none"> Phase III CT ongoing, target completion Sep 2021, N=330 (NCT04320615) Phase II CT ongoing, target completion Oct 2020, N=100 (NCT04335071) 	<ul style="list-style-type: none"> US, Canada, Denmark, France, Germany, Italy, Netherlands, Spain, UK Switzerland 	A Hospital report improved symptoms in 75% patients for Phase III study
JinYu Bio-Technology Co.,LTD. (China)	Tocilizumab	Phase II CT ongoing, target completion May2020, N=60 (ChiCTR2000030196)	China	
Regeneron Pharmaceuticals (US)/Sanofi (France)	Sarilumab [Interleukin 6 receptor antagonists] , an anti-arthritis drug	Phase II/III CT ongoing, target completion Mar 2021, N=400 (NCT04315298)	US	
		Phase II/III CT ongoing, target completion Jun 2021, N=460 (NCT04327388)	France, Canada, Germany, Israel, Italy, Japan, Russia, Spain	

COVID-19 Development Snapshot (Treatment: Biologics)

Company	Drug	Status	Location	Remarks
Humanigen, Inc. (US)	Lenzilumab (Granulocyte macrophage colony stimulating factor antagonists)	Phase III ongoing, Target completion Sep 2020, N=238 (NCT04351152)	-	
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, N=54 (NCT04324021)	Italy	
Kinevant Sciences GmbH (Switzerland)	Gimsilumab	Phase II CT ongoing, target completion Oct 2020, N=270 (NCT04351243)	US	
CytoDyn, Inc. (US)	Leronlimab	<ul style="list-style-type: none"> Phase II CT ongoing, target completion Apr 2021, N=390 (NCT04347239) Phase II CT ongoing, target completion Apr 2021, N=75 (NCT04343651) 	US	
Eli Lilly and Company (US)	LY3127804 (mAb, Angiopoietin 2 inhibitor)	Phase II ongoing , target completion Jul 2020, N=200 (NCT04342897)	US	To check if progression to ARDS can be reduced
InflaRx GmbH (Germany)	IFX-1 [anti-human C5a monoclonal antibody]	Phase II/III CT ongoing, target completion Dec 2020, N=130 (NCT04333420)	Netherlands	
Bristol-Myers Squibb (US)	Anti-Interleukin-8	Phase II CT ongoing, target completion Sep 2022, N=138 (NCT04347226)	US	
Apeiron Biologics (Austria)	Recombinant Human Angiotensin-converting Enzyme 2 (rhACE2)	Phase II CT ongoing, target completion Nov 2020, N=200 (NCT04335136)	Austria, Denmark, Germany	

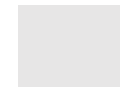


COVID-19 Development Snapshot (Treatment: Biologics)

Company	Drug	Status	Location	Remarks
Laboratoire français de Fractionnement et de Biotechnologies (France)	Clairyg (Polyvalent Immunoglobulin)	Phase III CT ongoing, target completion Aug 2020, N=138 (NCT04350580)	France	
Synairgen Research Limited (UK)	Inhaled SNG001 (IFN β -1a for nebulization)	Phase II CT ongoing, target completion Mar 2021, N=400 (EudraCT Number: 2020-001023-14)	UK	
Eiger BioPharmaceuticals (US)	Peginterferon lambda alfa-1a subcutaneous injection	Phase II CT ongoing, target completion Jun 2021, N=164 (NCT04344600)	US	
Iltoo Pharma (France)	Interleukin 2 (Ld-IL2)	Phase II CT ongoing, target completion Jul 2020, N=30 (NCT04357444)	France	
I-Mab Biopharma Co. Ltd. (China)	TJ003234 (Anti-GM-CSF Monoclonal Antibody)	Phase I/II CT ongoing, target completion Sep 2020, N=144 (NCT04341116)	US	
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, N=90 (NCT04324996)	China	
Indian Council of Medical Research (ICMR) (India)	Convalescent Plasma	Put under Accelerated Approval by SEC on 13-Apr-20, A Phase II trial	India	One case of recovery in a critical patient
BioAegis Therapeutics Inc. (US)	Recombinant human plasma gelsolin	Phase II CT ongoing, target completion Sep 2020, N=60 (NCT04358406)	-	
OncoImmune, Inc. (US)	CD24Fc [biological immuno-modulator]	Phase III CT ongoing, target completion May 2022, N=230 (NCT04317040)	US	

COVID-19 Development Snapshot (Treatment: Stem Cell)

Company	Stem Cells	Status	Location	Remarks
Tuohua Biological Technology Co. Ltd (China)	Umbilical Cord(UC)-Derived Mesenchymal Stem Cells(MSCs)	Phase II CT ongoing, target completion Sep 2020, N=10 (NCT04269525)	China	
Tianhe Stem Cell Biotechnologies Inc. (US)	Stem Cell Educator-Treated Mononuclear Cells	Phase II CT ongoing, target completion Nov 2020, N=Not Listed (NCT04299152)	Not Listed	
Citospin (Spain)	Mesenchymal Stromal Cells	Phase II CT ongoing, target completion Dec 2020, N=24 (NCT04361942)	Spain	
Hope Biosciences (US)	Allogeneic adipose-derived mesenchymal stem cells	Phase II CT ongoing, target completion Oct 2020, N=110 (NCT04362189)	US	
Azidus Brasil (Brazil)	NestCell® Mesenchymal Stem Cell I.V.	Phase I CT ongoing, target completion Jun 2020, N=66 (NCT04315987)	Brazil	
Jiangxi Mayo Biotechnologies Co. Ltd (China)	Natural killer cells combined with cord derived mesenchymal stem cells	Phase I CT ongoing, target completion Aug 2020, N=20 (ChiCTR2000030944)	China	
Stem Cells Arabia (Jordan)	Wharton's Jelly-Mesenchymal Stem Cells	Phase I CT ongoing, target completion Sep 2020, N=5 (NCT04313322)	Jordan	
VCANBIO Cell & Gene Engineering Corp Ltd. (China)	Mesenchymal Stem Cell	Phase I CT ongoing, target completion Dec 2021, N=20 (NCT04252118)	China	
Cellular Biomedicine Group Ltd. (US)	Aerosol Inhalation of Exosomes Derived From Allogenic Adipose Mesenchymal Stem Cells	Phase I CT ongoing, target completion Jul 2020, N=30 (NCT04276987)	China	



COVID-19 Development Snapshot (Treatment: Stem Cell)

Company	Stem Cells	Status	Location	Remarks
CAR-T (Shanghai) Biotechnology Co., Ltd.	Dental Pulp Mesenchymal Stem Cells	Early Phase I CT ongoing, target completion Jul 2021, N=24 (NCT04302519)	Not Listed	
Mesoblast Limited (Australia)	Allogeneic mesenchymal stem cell product candidate remestemcel-L	IND submitted to USFDA	-	83% survival in ventilator-dependent COVID-19 patients (10/12) with moderate/severe ARDS treated with two infusions of cell therapy within 5 days under emergency compassionate use
Pluristem (USA)	PLX cells [allogeneic mesenchymal- like cells]	Proof of Concept Completed, N=7(COVID ARDS patients)	US	4/6 patients showed improvements, 3/6 in advanced stages are weaning off from ventilators

COVID-19 Development Snapshot (Vaccines)

Company	Vaccine	Status	Location	Remarks
Oxford University (UK) / Serum Institute of India (SII)	Chimpanzee adenovirus modified to include the spike or 'S' protein on the surface of SARS-CoV-2	Phase I/II CT ongoing, target completion May 2021, N=510 (NCT04324606)	UK, India	SII to begin human trials. In 2 weeks SII could produce 5 Mn doses/month. Viable vaccine expected to be available by Sep 2020
CanSino Biologics Inc. (China) / PLA China	Recombinant Novel Coronavirus Vaccine (Adenovirus Type 5 Vector)	<ul style="list-style-type: none"> Phase I CT ongoing, target completion Dec 2022, N=108 (NCT04313127 / ChiCTR2000030906) Phase II CT ongoing, target completion Jan 2021, N=500 (ChiCTR2000031781) 	China	Based on preliminary safety data from Phase 1 (primary endpoint was to look at adverse reactions 7 days post injection), CanSino moves into Phase 2
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, N=45 (NCT04283461)	US	First patient dosed Mar 16, 2020, moves into 2 nd round of dosing on 23-Apr-2020 Expected to start Phase 2 in Spring or early summer of 2020
Inovio (US) (partner, Gates foundation)	INO-4800 DNA vaccine	Phase I CT ongoing, target completion Apr 2021, N=40 (NCT04336410)	US	Received grant from CEPI and Bill & Melinda Gates, Company promises to manufacture 1 Mn doses this year
Sinovac (China)	Inactivated + alum	Phase I/II CT ongoing, target completion Dec 2020, N=744 (NCT04352608)	China	
Beijing Institute of Biological Products (China) /Wuhan Institute of Biological Products (China)	Inactivated	Phase I CT ongoing, target completion Nov 2021, N=1456 (ChiCTR2000031809)	China	Vaccine has shown good safety results for 96 patient dosed

COVID-19 Development Snapshot (Vaccines)

Company	Vaccine	Status	Location	Remarks
Symvivo Corporation (Canada)	bacTRL-Spike (containing colony-forming-units of live Bifidobacterium longum)	Phase I CT ongoing, target completion Dec 2021, N=84 (NCT04334980)	Canada	
BioNTech (Germany) / Fosun Pharma (China) / Pfizer (US)	RNA, mRNA	Phase I/II approved in Germany, N=200	Germany	For a viable vaccine, can produce Millions of doses by end of 2020
Clover Biopharmaceuticals Inc.(China) / GSK (UK) / Dynavax (US)	Protein Subunit, Native like Trimeric subunit Spike Protein vaccine	Preclinical	-	A highly purified form expected to be available in 6-8 weeks for performing pre clinical studies
Sanofi Pasteur (France)	Protein Subunit, S protein (baculovirus production)	Preclinical	-	Expects to have a candidate for in vitro tests available in 6 months and could be ready to test in humans in 12-18 months
Novavax (US)	VLP-recombinant protein nanoparticle vaccine + Matrix M	Preclinical	-	Phase I expected in late spring of 2020
Bharat Biotech (India) / University of Wisconsin-Madison (US) / FluGen (US)	Intra-nasal drop vaccine	Preclinical	-	Human trials expected to begin in 4 months
Zydus Cadila (India)	Replicating Viral Vector, Measles Vector	Preclinical	-	Viable vaccine could be expected by end of 2021
Janssen Pharmaceutical Companies (Belgium)	Ad26 Non-Replicating Viral Vector (alone or with MVA boost)	Preclinical	-	Expects to start a Phase 1 clinical study within approximately 8-12 Months. 1 st batches of vaccine to be available by early 2021

Thank You