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INTEGRATED BIOPHARMA
AND PHARMA SOLUTION

COVID-19

(Update collated on -19-Jun-2020)

COVID-19: Frontrunners in Treatment

	Q1 2020	Q2 2020	Q3 2020	Q4 2020	2021+
Remdesivir		Phase III Study shows that it Cuts hospital stays by 31% compared to placebo.	USFDA Authorization for Emergency Use		
Ritonovir/ Lopinavir		Phase II Study shows positive results for combination therapy with Ribavirin and IFN-beta			
Favipiravir		2 Chinese trials in Favipiravir do not show clinically significant improvement in patients	Avigan's (Fujifilm) trial final results expected in Jul		
Sarilumab		Interim result of Regeneron trial of 457 patients shows promise for only Critical Patients and not Severe patients			
Tocilizumab		Roche Study demonstrates significant decrease in mortality	Data from Italian RCT showed that Actemra was not effective in early stage patients		
Convalescent Plasma therapy	FDA Authorization for Emergency Use	Multiple RCTs initiated	Data from Chinese study does not provide evidence for benefit (*CT was terminated prematurely for other reasons)		
Stem cell therapy		ADSCC shows positive results for 73 patients	Mesoblast Phase III trial initiated		
Hydroxy-chloroquine		3 observation studies at NY, France and Albany for +2,500 patients shows no significant benefit of HCQ	US FDA withdraw the emergency use authorization / Oxford trial discontinues HCQ arm		
Dexamethasone		Positive preliminary results of the Oxford Recovery trial	UK Govt. authorization for Use	Oxford Trial Interim results expected	

Positive Preliminary CT Data

Preliminary CT Data

Other Preclinical/Supportive Data

Approval Withdrawn

Early Access Approval

Trial Status

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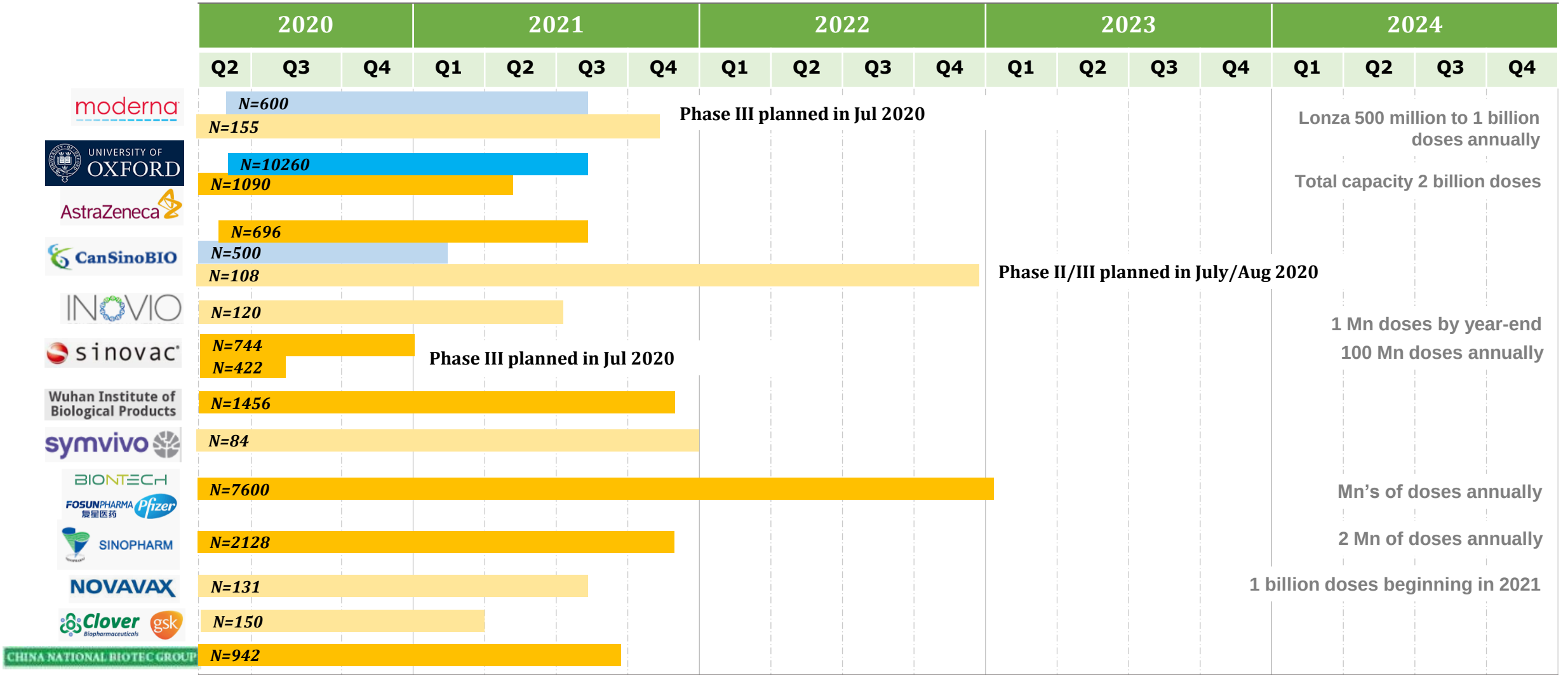
COVID-19: 15* Vaccine Candidates in Clinical Development

** For 3 Vaccine candidates, trials approval granted, study details awaited*



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COVID-19: Progress Snapshot

Remdesivir

- Gilead Phase III trial Findings
  - The study demonstrated that patients in the 5-day Remdesivir treatment group were 65 percent more likely to have clinical improvement at Day 11 compared with those in the standard of care group (OR 1.65 [95% CI 1.09-2.48]; p=0.017)
  - No new safety signals were identified with Remdesivir across either treatment group. Gilead plans to submit the full data for publication in a peer-reviewed journal in the coming weeks
- Remdesivir granted emergency use authorization by USFDA last month, also received approval by Japanese health regulators and DCGI (Won't be available till Jul 20 in Indian Market as regulators waiting crucial safety data from Gilead)
- FDA warns of potential drug interaction with Remdesivir. Co-administration of Remdesivir and Chloroquine phosphate or hydroxychloroquine sulfate is not recommended as it may result in reduced antiviral activity
- Gilead signs non-exclusive voluntary licensing agreements with four generic pharma firms -- Cipla, Jubilant Life Sciences, Hetero and Mylan to manufacture and distribute Remdesivir in 127 countries

Lopinavir/Ritonavir

- A small Phase II study conducted in Hong Kong demonstrated that Early triple antiviral therapy (Lopinavir/ Ritonavir, Ribavirin and IFN-beta Combination) was safe and superior to Lopinavir–ritonavir alone in alleviating symptoms and shortening the duration of viral shedding and hospital stay in patients with mild to moderate COVID-19. Future clinical study of a double antiviral therapy with interferon beta-1b as a backbone however is warranted (NCT04276688)
- Another study in China with 125 subjects demonstrated that LPV/r or Arbidol mono therapy present little benefit for improving the clinical outcome of patients hospitalized with mild/moderate COVID-19 over supportive care as no clinically significant difference in primary and secondary endpoints (NCT04252885)

COVID-19: Progress Snapshot

Favipiravir

- In 2 China studies it was found that
  - Study was conducted by First Hospital Affiliated to Zhejiang University's Medical School (China) using combination of Baloxavir Marboxil or Favipiravir in 30 subjects. Findings do not support that adding either baloxavir or favipiravir under the trial dosages to the existing standard treatment (ChiCTR2000029544)
  - Study was conducted by Zhongnan Hospital of Wuhan University (China) using Favipiravir, Arbidol in 240 patients. Among patients with COVID-19, Favipiravir, compared to Arbidol, did not significantly improve the clinically recovery rate at Day 7. Favipiravir significantly improved the latency to relief for pyrexia and cough. Adverse effects caused Favipiravir are mild and manageable(ChiCTR2000030254)
- For Glenmark Pharmaceuticals Phase III CT results in 150 subjects are expected in Jul/Aug 2020. FUJIFILM Phase III data is also awaited

Hydroxychloroquine

- The Food and Drug Administration (FDA) on Monday 15 June announced to withdraw the emergency use authorization (EUA) for chloroquine and hydroxychloroquine (HCQ) as treatment for severe COVID-19 patients. After reviewing new information from large clinical trials, the FDA now believes that the suggested dosing regimens "are unlikely to produce an antiviral effect," FDA chief scientist Denise Hinton said in a letter announcing the decision
- UK Suspends Hydroxychloroquine Trial For COVID-19. The Medicines and Healthcare products Regulatory Agency (MHRA) said it was following "emerging concerns" about the use of the drug, and also cited a UK trial which found no meaningful mortality benefit in patients hospitalized with COVID-19.
- A Randomized controlled trial in 821 volunteers found that after high-risk or moderate-risk exposure to Covid-19, hydroxychloroquine did not prevent illness compatible with Covid-19 or confirmed infection when used as post-exposure prophylaxis within 4 days after exposure. (NCT04308668)

COVID-19: Progress Snapshot

Other Candidates/Approaches

- **Dexamethasone** in the preliminary results of the Oxford Recovery trial (NCT04381936) shows promising results which show that if patients who have Covid-19 and are on ventilators or are on oxygen are given dexamethasone, it will save lives, and it will do so at a remarkably low cost. UK has authorized the use of anti-inflammatory drug dexamethasone for the treatment of Covid-19
- Preliminary Data Suggests **Low-Dose Radiation** May Be Successful Treatment For Severe Covid-19. Human medical trials have begun on severely ill COVID-19 patients using low-doses of radiation. The first results on a very small group at Emory University Hospital were and the results were quite extraordinary in 5 patients who were requiring supplemental oxygen. These patients were given a single low-dose of radiation (1.5 Gy) to both lungs, delivered by a front and back beam configuration. Within 24 hours, four of the patients showed rapid improvement in oxygenation and mental status (more awake, alert and talkative) and were being discharged from the hospital 12 days later.
- A Phase II study conducted by AstraZeneca for **Acalabrutinib** with 140 subjects came out with Positive preliminary response, 11/19 patients receiving oxygen from an external source and 8/19 had been on ventilators . Within 1-3 days 8/11 patients came off the external oxygen support and were discharged. 6/8 patients came off the ventilators while 2/8 died owing to sepsis and renal failure (NCT04346199)
- Another Phase II study conducted by CalciMedicai for **Auxora [CM4620 Injectable Emulsion] in 120 subjects** also shared positive topline data from an interim analysis which showed that Auxora + SOC reduced ventilator use and improved time to recovery in treated patients compared to standard of care alone for in COVID-19 patients with severe pneumonia (NCT04345614)
- A different French study showed Anakinra reduced both need for invasive mechanical ventilation in the ICU and mortality among patients with severe forms of COVID-19, without serious side-effects. Confirmation of efficacy will require controlled trials

Biologics Therapy

- A Phase III study conducted by Humanigen for **Lenzilumab** (Granulocyte macrophage colony stimulating factor antagonists) in 238 subjects reported positive data, rapid clinical improvement with a median time to recovery and discharge of five days and 100% survival to the data cut-off date (NCT04351152).
- A Phase II/III study conducted by InflaRx **for IFX-1 [anti-human C5a monoclonal antibody]** in 130 subjects showed Positive interim results from the first 30 patients. Upon review of the safety data. Independent DSMB recommended continuation of the trial into the Phase III part. (NCT04333420)

COVID-19: Progress Snapshot

Biologics Therapy

- Russia has approved use of **Levilimab** based on data from a Phase III study conducted by BIOCAD. Trial data supports that levilimab therapy can significantly reduce death risk among patients (NCT04397562)
- A Phase II Italian study in 126 patients concluded that **Tocilizumab** didn't help patients with early-stage COVID-19 pneumonia (EudraCT: 2020-001110-38)
- In a Phase III study by OncoImmune using **CD24Fc [biological immuno-modulator]** in 230 subjects the preliminary results for first 70 patients are promising as well (NCT04317040)
- Convalescent Plasma therapy shows mixed results, multiple RCT's being initiated in CN, US and in India
  - Between March 28 and April 14, Houston Methodist Hospital in Texas enrolled 25 people with severe or life threatening COVID-19 into a preliminary study to investigate the safety of the therapy. Nine of the participants (36%) showed an improvement in their condition after 7 days, and 19 (76%) had improved or been discharged after 14 days. There were no adverse events that the researchers could attribute to the therapy
  - However recent study results from China indicated that among patients with severe or life-threatening COVID-19, convalescent plasma therapy added to standard treatment, compared with standard treatment alone, did not result in a statistically significant improvement in time to clinical improvement within 28 days. Interpretation is limited by early termination of the trial, which may have been underpowered to detect a clinically important difference. (ChiCTR2000029757)
- Some news on Stem cell therapy
  - A Phase I/II study conducted by I-Mab Biopharma in 144 subjects for TJ003234 (Anti-GM-CSF Monoclonal Antibody) showed of 24 patients randomized to receive 1 or the 2 doses of TJM2 or a placebo. a correlation between clinical improvement and reduced levels of some disease related cytokines was observed (NCT04341116**)**

COVID-19: Progress Snapshot

Vaccine Development

- The most promising areas so far. At least 15 have moved to clinical phase and 124 are in the pre-clinical phase (*Source: WHO list released on 9 Jun 2020*).
- Different approaches taken for vaccine development are attenuated virus development, using viral peptides, RNA and DNA vaccines.
- Frontrunners among these 15 candidates are CanSino Biologics Inc. (China), Moderna and Oxford
  - Moderna has a RNA-based vaccine is currently called mRNA-1273 which uses an alternative approach when compared to the traditional vaccines. Vaccine has demonstrated positive results in Phase I and it was found to be safe and well tolerated. Phase 2 is ongoing and Phase 3 placebo controlled study for 100 µg with 30,000 volunteers expected to start in July, study design has been finalized
  - 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) where vaccine appears to be safe and triggers an immune response in healthy adults, vaccine has progressed to phase II in 500 subjects (ChiCTR2000031781) in China with Target completion Jan 2021. Company has also initiated a Phase I/II trial of 696 subjects (NCT04398147) in Canada with Target completion Aug 2021
  - Oxford University uses a weakened strain of the common cold virus, known as adenovirus which causes infections in Chimpanzees which has been combined to genetical material of the spike protein of SARS-CoV-2. The vaccine candidate was developed within 3 months and showed promising results in animal trials. However, recent reports have confirmed that the potential vaccine 'ChAdOx1 nCoV-19', 'was not able to prevent infection in rhesus macaque monkeys. As of now, the vaccine seems to be partially effective as it protected the animals from developing viral pneumonia but could not stop the COVID-19 infection. Oxford university initiated Phase II/III recruitment and has partnered up with AstraZeneca for production of 400Mn doses and received more than $1 billion in funding from the U.S. government BARDA

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	Recruiting
National Institute of Respiratory Diseases, Mexico/Sanofi (France)	Hydroxychloroquine	Phase III ongoing, target completion Mar 2021, N=400 (NCT04318015)	Mexico	Recruiting
University of Minnesota (US)	Hydroxychloroquine	Phase III completed, N=821 (NCT04308668)	US, Canada	Study conducted for post exposure prophylaxis with primary outcome of incidence of either laboratory-confirmed Covid-19 or illness compatible with Covid-19 within 14 days. Of 821 asymptomatic participants. 87.6% of the participants reported a high-risk exposure to a confirmed Covid-19 contact. The incidence of new illness compatible with Covid-19 did not differ significantly between participants receiving hydroxychloroquine (49 of 414 [11.8%]) and those receiving placebo (58 of 407 [14.3%]); the absolute difference was −2.4 percentage points (95% confidence interval, −7.0 to 2.2; P=0.35). Side effects were more common with hydroxychloroquine than with placebo (40.1% vs. 16.8%), but no serious adverse reactions were reported

COVID-19 Development Snapshot (Prophylaxis)

Company	Drug	Status	Location	Remarks
Cadila Pharmaceuticals (India)	Suspension of heat killed (autoclaved) Mycobacterium	Phase III ongoing, target completion May 2021, N=4000 (NCT04353518)	-	Not Yet Recruiting
Romark Laboratories L.C. (US)	Nitazoxanide (NTZ) for Pre- or Post Exposure Prophylaxis	• Phase III ongoing, target completion Aug 2020, N=800 (NCT04359680) • Phase III ongoing, target completion Aug 2020, N=800 (NCT04343248)	-	• Recruiting • Recruiting • NCT04359680 – Health Workers
Plan Nacional sobre el Sida (PNS)	• Emtricitabine/tenofovir disoproxil • Hydroxychloroquine	Phase III ongoing, target completion Jul 2020, N=4000 (NCT04334928)	Spain	Recruiting
Hope Biosciences (US)	• Allogeneic adipose-derived mesenchymal stem cells • Autologous Mesenchymal Stem Cell Therapy	• Phase II CT ongoing, target completion Apr 2021, N=100 (NCT04348435) • Phase II CT ongoing, target completion Dec 2020, N=56 (NCT04349631)	US	• Enrolling by invitation • Enrolling by invitation

COVID-19 Development Snapshot (Treatment: Remdesivir)

Company	Drug	Status	Location	Remarks
Gilead Sciences (US)	Remdesivir [antiviral compound]*	• Phase III CT ongoing, target completion Jun 2020, N=6000 (NCT04292899) • Phase III CT ongoing, target completion Jun 2020, N=1600 (NCT04292730)	• US, Germany, Hong Kong, Italy, Korea, Spain, Singapore, Switzerland, Taiwan • US, Germany, Hong Kong, Iran, Italy, Korea, Spain, Singapore, Switzerland, Taiwan	Study Treatment of patients with severe disease with 5 days of Remdesivir led to similar clinical improvements as a 10-day course. patients in the 5-day. Remdesivir treatment group was 65% more likely to have clinical improvement at Day 11 compared with those in the SOC group (OR 1.65 [95% CI 1.09-2.48]; p=0.017). Remdesivir was generally well-tolerated in both the 5-day and 10-day treatment groups. Most common adverse events occurring in more than 5 percent of patients in both treatment groups were nausea (5-day: 10% / 10-day: 9% / SOC: 3%), diarrhea (5-day: 5% / 10-day: 5% / SOC: 7%) and headache (5-day: 5% / 10-day: 5% / SOC: 3%).
Gilead Sciences (US)	Remdesivir [antiviral compound]*	Phase III CT ongoing, target completion Apr 2023, N=1063 (NCT04280705)	US, Denmark, Germany, Greece, Korea, Spain, Singapore, Mexico, Japan, UK	Recruiting Preliminary results from the 1059 patients (538 assigned to Remdesivir and 521 to placebo). - Patients who received Remdesivir had a median recovery time of 11 days (95% confidence interval [CI], 9 to 12), as compared with 15 days (95% CI, 13 to 19) in those who received placebo (rate ratio for recovery, 1.32; 95% CI, 1.12 to 1.55; P<0.001). - Kaplan-Meier estimates of mortality by 14 days were 7.1% with Remdesivir and 11.9% with placebo (hazard ratio for death, 0.70; 95% CI, 0.47 to 1.04). - Serious adverse events were reported for 114 of the 541 patients in the Remdesivir group who underwent randomization (21.1%) and 141 of the 522 patients in the placebo group who underwent randomization (27.0%).
Capital Medical University	Remdesivir [antiviral compound]*	Phase III CT **Terminated** (NCT04257656)	China	• Reason for Termination: The epidemic of COVID-19 has been controlled well in China, no eligible patients can be enrolled at present

*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: Favipiravir)

Company	Drug	Status	Location	Remarks
FUJIFILM Toyama Chemical Co. Ltd (Japan)	• Hydroxychloroquine (HCQ) • Favipiravir	Phase III CT ongoing, target completion Mar 2021, N=450 (NCT04373733)	UK	Not yet recruiting
	Avigan® (favipiravir) (approved in JP as anti-flu drug)	• Phase III ongoing, Target completion Jul 2020, N=100 (NCT04336904) • 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. • Active, Not Recruitment • Recruiting
Glenmark Pharmaceuticals Ltd (India)	Favipiravir	Phase III CT ongoing, target completion May 2021, N=150 (CTRI/2020/05/025114)	India	Recruiting Results expected between the months of July and August
The First Hospital Affiliated to Zhejiang University's Medical School (China)	• Baloxavir • Favipiravir	CT completed on May 2020, N=30 (ChiCTR2000029544)	China	Findings do not support that adding either baloxavir or favipiravir under the trial dosages to the existing standard treatment
Zhongnan Hospital of Wuhan University (China)	• Favipiravir • Arbidol	CT completed on Mar 2020, N=240 (ChiCTR2000030254)	China	Among patients with COVID-19, Favipiravir, compared to Arbidol, did not significantly improve the clinically recovery rate at Day 7. Favipiravir significantly improved the latency to relief for pyrexia and cough. Adverse effects caused Favipiravir are mild and manageable

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

Company	Drug	Status	Location	Remarks
Ascletis 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 completed on Apr 2020, N=10 (NCT04345276)	China	
Guangzhou 8th People's Hospital (China)	• Lopinavir and Ritonavir Tablets • Arbidol • SOC	Phase IV CT ongoing, target completion Jul 2020, N=125 (NCT04252885)	China	Recruiting LPV/r or arbidol mono therapy present little benefit for improving the clinical outcome of patients hospitalized with mild/moderate COVID-19 over supportive care as no clinically significant difference in primary and secondary endpoints
Wuhan Jinyintan Hospital (China)	• Lopinavir and Ritonavir Tablets	CT ongoing, target completion Jan 2021, N=160 (ChiCTR2000029308)	China	Recruiting Mortality at 28 days was similar in the lopinavir–ritonavir group and the standard-care group (19.2% vs. 25.0%; difference, −5.8 percentage points; 95% CI, −17.3 to 5.7) In hospitalized adult patients with severe Covid-19, no benefit was observed with lopinavir–ritonavir treatment beyond standard care

COVID-19 Development Snapshot (Treatment: Lopinavir/Ritonavir)

Company	Drug	Status	Location	Remarks
Shenyang Tonglian Group Co., Ltd. (China)	• Carrimycin • lopinavir/ritonavir tablets or Arbidol or chloroquine phosphate	Phase IV CT ongoing, target completion Feb 2021, N=520 (NCT04286503)	China	Not yet recruiting
Ascletis 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	Not yet recruiting
The University of Hong Kong (Hong Kong)	• Lopinavir/ Ritonavir, Ribavirin and IFN-beta Combination	Phase II CT completed, N=127 (NCT04276688)	Hong Kong	Completed 86/127: Combination Therapy, 41/127 Control group Median number of days from symptom onset to start of study treatment was 5 days (IQR 3–7). The combination group had a significantly shorter median time from start of study treatment to negative nasopharyngeal swab (7 days [IQR 5–11]) than the control group (12 days [8–15]; No difference in AE's between 2 groups was found
WHO/ AbbVie (US)	Lopinavir/ritonavir	Phase II CT ongoing, target completion May 2022, N=2900 (NCT04330690)	Canada	NEJM published initial data that shows no benefit in COVID 19 (Mar. 2020) Recruiting
Asan Medical Center (Korea)	• Lopinavir/ritonavir • Hydroxychloroquine sulfate	Phase II **Terminated** (NCT04307693)	Korea	Reason for Termination: No patients were further enrolled since mid-Apr 2020

COVID-19 Development Snapshot (Treatment: Hydroxychloroquine)

Company	Drug	Status	Location	Remarks
Fondation Méditerranée Infection (FMI) - IHU Méditerranée Infection	Hydroxychloroquine	Phase III ongoing , target completion Mar 2021, 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	• Recruitment completed • 109/150 patients had negative conversion well before 28 days (56 standard of care; 53 standard of care + HCQ) • Adverse events were recorded in 7/80 (9%) hydroxychloroquine non-recipients and in 21/70 (30%) hydroxychloroquine recipients
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=2250 (NCT04304053)	Spain	Active Not Recruiting
Novartis (Switzerland)	• Hydroxychloroquine (HCQ) • HCQ + azithromycin	Phase III ongoing , target completion Jul 2020, N=444 (NCT04358081)	US	Recruiting
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)	• Hydroxychloroquine Sulfate • Hydroxychloroquine Sulfate + Azithromycin	Phase III CT ongoing, target completion Nov 2020, N=500 (NCT04361461)	Brazil	Not yet recruiting
National Institute of Respiratory Diseases, Mexico/Sanofi (France)	Hydroxychloroquine	Phase III CT ongoing, target completion Mar 2021, N=500 (NCT04315896)	Mexico	Recruiting
University of Washington (US)/ Bill and Melinda Gates Foundation	Hydroxychloroquine Sulfate	Phase II/III CT ongoing, target completion Oct 2020, N=2000 (NCT04328961)	Brazil	Recruiting
UnitedHealth Group (US)	Hydroxychloroquine	Phase II CT ongoing, target completion Jun 2021, N=850 (NCT04353037)	US	Recruiting
Bukwang Pharmaceutical (Korea)	• Clevudine • Hydroxychloroquine	Phase II CT ongoing, target completion Dec 2020, N=60 (NCT04347915)	-	Recruiting
Sanofi (France)	Hydroxychloroquine	Phase I CT suspended, previous target completion Aug 2020, N=210 (NCT04333654)	US, France	Suspended (Sponsor decision pending further evaluation of information related to benefit-risk)
Azidus Brasil (Brazil)	Hydroxychloroquine (HCQ) and azithromycin (AZT)	Early Phase I CT suspended, previous target completion Jun 2020, N=400 (NCT04329572)	Not Listed	Suspended (Azidus, the CRO hired for this study by Prevent Senior has lost the interest to conduct this study.)
Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A. (Greece)	Chloroquine Phosphate	Phase II CT ongoing, target completion Apr 2021, N=60 (NCT04344951)	Greece	Recruiting

COVID-19 Development Snapshot (Treatment: Other Candidates)

Company	Drug	Status	Location	Remarks
Tongji Hospital (China)	Ruxolitinib combined with mesenchymal stem cell	CT ongoing , target completion Dec 2020, N=70 (ChiCTR2000029580)	China	Recruiting Ruxolitinib did not significantly accelerate the clinical improvement in patients of severe COVID-19. However, those on Ruxolitinib had a "numerically faster clinical improvement
Novartis (Switzerland)	Ruxolitinib	Phase III ongoing , target completion Oct 2020, N=402 (NCT04362137)	Not Listed	Recruiting For compassionate Use in Severe/Very Severe COVID-19 Illness
Incyte Corporation (US)	Ruxolitinib	• Phase II CT Withdrawn (NCT04354714) • Phase III ongoing , target completion Jul 2020, N=500 (NCT04377620)	• US • US	• Reason for Withdrawal: Could not make FDA required changes • Recruiting
Fundación de investigación HM (Spain)	Ruxolitinib plus simvastatin	Phase II CT ongoing, target completion May 2020, N=94 (NCT04348695)	Spain	Recruiting
University Health Network, Toronto (Canada)	Ruxolitinib	CT ongoing , target completion Jan 2021, N=64 (NCT04331665)	Canada	Not yet recruiting
AstraZeneca (UK)	Acalabrutinib	Phase II CT ongoing, target completion Nov 2020, N=140 (NCT04346199)	Spain	Recruiting Positive preliminary response, 11/19 patients receiving oxygen from an external source and 8/19 had been on ventilators . Within 1-3 days 8/11 patients came off the external oxygen support and were discharged. 6/8 patients came off the ventilators while 2/8 died owing to sepsis and renal failure

COVID-19 Development Snapshot (Treatment: Other Candidates)

Company	Drug	Status	Location	Remarks
Eli Lilly and Company (US) / National Institute of Allergy and Infectious Diseases (NIAID)	Baricitinib	Phase III CT ongoing, target completion Sep 2020, N=400 (NCT04421027)	US, Germany, Mexico, Spain	Recruiting First Patient enrolled for the study
Laboratorio Elea S.A.C.I.F. y A. (Argentina)	Telmisartan	Phase II CT ongoing, target completion Oct 2020, N=400 (NCT04355936)	Argentina	Recruiting
AstraZeneca (UK)	Dapagliflozin	Phase III CT ongoing, target completion Dec 2020. N=900 (NCT04350593)	US	Recruiting
Biohaven Pharmaceuticals, Inc. (US)	Vazegepant (Intra-Nasal)	Phase II/III CT ongoing, target completion Sep 2020, N=120 (NCT04346615)	US	Recruiting
Pfizer (US) / University of Oxford (UK) / Bill and Melinda Gates Foundation	Azithromycin	• Phase III CT ongoing, target completion Oct 2020, N=800 (NCT04381962) • Phase III CT ongoing, target completion Sep 2021, N=2271 (NCT04332107)	• - • US	• Recruiting • Recruiting
Bosnalijek D.D (Bosnia and Herzegovina)	Metenkefalin + Tridecactide	Phase II/III CT ongoing, target completion Oct 2020, N=120 (NCT04374032)	Bosnia and Herzegovina	Recruiting
IDIVAL (Spain)	Colchicine	Phase III CT ongoing, target completion Aug 2020, N=1024 (2020-001603-16)	Spain	

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	Not yet recruiting
Ache Laboratorios Farmaceuticos S.A. (Brazil)	Dexamethasone	Phase III CT ongoing, target completion Aug 2020, N=350 (NCT04327401)	Brazil	Recruiting
University of Oxford (UK)	• Lopinavir-Ritonavir • Corticosteroid - Dexamethasone • Hydroxychloroquine • Azithromycin • Biological: Convalescent plasma • Tocilizumab	Phase II/III CT ongoing, target completion Jun 2021, N=12000 (NCT04381936)	UK	Recruiting 11,000 patients enrolled till date, Trial compared outcomes of around 2,100 patients who were randomly assigned to get the steroid, with those of around 4,300 patients who did not get it. The results suggest that one death would be prevented by treatment with dexamethasone among every eight ventilated Covid-19 patients, One death would be prevented among every 25 Covid-19 patients that received the drug and are on oxygen.
NeuroRx, Inc. (US)/ Relief Therapeutics Holding SA (Switzerland	Aviptadil	Phase II CT ongoing, target completion Sep 2020, N=144 (NCT04311697)	US, Israel	Recruiting
NeuroRx, Inc. (US)	Inhaled Aviptadil	Phase II/III CT ongoing, target completion Oct 2020, N=144 (NCT04360096)	-Not listed	Not yet recruiting

COVID-19 Development Snapshot (Treatment: Other Candidates)

Company	Drug	Status	Location	Remarks
Vanda Pharmaceuticals (US)	Tradipitant [Neurokinin 1 receptor antagonists]	Phase III CT ongoing, target completion Aug 2020, N=300 (NCT04326426)	Not Listed	Enrolling by invitation
Karyopharm Therapeutics Inc (US)	Oral Selinexor	• Phase II CT ongoing, target completion Aug 2020, N=80 (NCT04355676) • Phase II CT ongoing, target completion Aug 2020, N=230 (NCT04349098)	• Not Listed • US , Austria, Israel, Spain	• Not yet recruiting • Recruiting
Blade Therapeutics (US)	BLD-2660 (novel, small molecule inhibitor of calpain)	Phase II CT ongoing, target completion Sep 2020, N=120 (NCT04334460)	-	Recruiting
Azidus Brasil (Brazil)	Methotrexate	Phase I/II CT ongoing, target completion Nov 2020, N=42 (NCT04352465)	Brazil	Not yet recruiting
Bausch Health Americas, Inc.	VIRAZOLE®	Phase I CT ongoing, target completion Apr 2021, N=50 (NCT04356677)	-	Not yet recruiting
BioCryst Pharmaceuticals (US) / National Institute of Allergy and Infectious Diseases (NIAID)	Galidesivir	Phase I CT ongoing, target completion May 2021, N=66 (NCT03891420)	Brazil	Recruiting
Algernon Pharmaceuticals (Canada)	Ifenprodil	Phase II/III CT yet to start, target completion Feb 2022, N=462 (NCT04382924)	Australia	Not yet recruiting
Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A. (Greece)	Triiodothyronine	Phase II CT ongoing, target completion May 2021, N=60 (NCT04348513)	Greece	Recruiting

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) • Phase II/III ongoing, Target completion Oct 2020, N=82 (NCT04354389)	• US, Australia, Taiwan, Korea • Italy	• Recruiting • Not yet recruiting • Stage 1 with 22 subjects as Proof of concept
Immunic AG (US)	Vidofludimus calcium	Phase II/III CT ongoing, target completion Oct 2020, N=230 (NCT04379271)	-	Not Yet Recruiting
Abivax S.A. (France)	ABX 464	Phase II/III CT ongoing, target completion Apr 2021, N=1034 (NCT04393038)	France	Recruiting
Chimerix. (US)	Dociparstat	Phase II/III CT ongoing, target completion Mar 2021, N=524 (NCT04389840)	-	Recruiting
CalciMedica, Inc. (US)	Auxora [CM4620 Injectable Emulsion]	Phase II CT ongoing, target completion Sep 2020, N=120 (NCT04345614)	US	Recruiting Has positive topline data from an interim analysis which showed that Auxora + SOC reduced ventilator use and improved time to recovery in treated patients compared to standard of care alone for in COVID-19 patients with severe pneumonia
Pulmotect, Inc. (US)	PUL-042 [combination drug agonists of Toll-like receptors]	Phase II CT ongoing, target completion Oct 2020, N=100 (NCT04312997)	US	Recruiting

COVID-19 Development Snapshot (Treatment: New Molecules)

Company	Drug	Status	Location	Remarks
Theravance Biopharma (Cayman Islands)	TD-0903	Phase I CT ongoing, target completion Jun 2020, N=54 (NCT04350736)	UK	Recruiting
Eli Lilly and Company (US)/ AbCellera Biologics Inc. (Canada)	LY3819253 (Antibody)	• Phase II CT ongoing, target completion Sep 2020, N=400 (NCT04427501) • Phase I ongoing, Target completion Aug 2020, N=40 (NCT04411628)	US	• Recruiting • Recruiting
Eli Lilly and Company (US)/ Junshi Biosciences (China)	JS016 (SARS-CoV-2 neutralizing antibody)	Phase I ongoing, Target completion Unknown	US	Recruiting

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	Not yet recruiting
Regeneron Pharmaceuticals (US)/Sanofi (France)	Sarilumab [Interleukin 6 receptor antagonists] , an anti-arthritis drug	• Phase II/III CT ongoing, target completion Jul 2021, N=2500 (NCT04315298) • Phase III CT ongoing, target completion Aug 2020, N=400 (NCT04327388)	• US • France, Canada, Germany, Israel, Italy, Japan, Russia, Spain	• Recruiting • Recruiting (Phase II/III), preliminary results show study met primary end point of rapidly lowered C-reactive protein (CRP) in critical patients but not in severe patients
Genentech, Inc. (US)	Tocilizumab [anti interleukin-6 receptor humanized monoclonal antibody]	• Phase III CT ongoing, target completion Aug 2020, N=300 (NCT04356937) • Phase III CT ongoing, target completion Oct 2020, N=379 (NCT04372186)	• US • -	• Not yet recruiting • Recruiting
Hoffmann-La Roche (Switzerland)	Tocilizumab [anti interleukin-6 receptor humanized monoclonal antibody]	• Phase III CT ongoing, target completion Sep 2020, N=450 (NCT04320615) • Phase II CT ongoing, target completion Oct 2020, N=100 (NCT04335071)	• US, Canada, Denmark, France, Germany, Italy, Netherlands, Spain, UK • Switzerland	A Hospital report improved symptoms in 75% patients for Phase III study • Active Not Recruiting • Recruiting
JinYu Bio-Technology Co.,LTD. (China)	Tocilizumab [anti interleukin-6 receptor humanized monoclonal antibody]	Phase II CT ongoing, target completion May2020, N=60 (ChiCTR2000030196)	China	Not yet recruiting

COVID-19 Development Snapshot (Treatment: Biologics)

Company	Drug	Status	Location	Remarks
AryoGen pharmed Co. (Iran)	Tocilizumab [humanized anti-interleukin-6 (IL-6) receptor mAb]	Phase III CT ongoing, target completion Jul 2020, N=85 (IRCT20150303021315N17)	Iran	Recruiting
Instituto Nazionale Per Lo Studio E La Cura Dei Tumori - Fondazione "G. Pascale" (Italy)	Tocilizumab [humanized anti-interleukin-6 (IL-6) receptor mAb]	Phase II CT ongoing, target completion unknown, N=330 (EudraCT: 2020-001110-38)	Italy	Recruiting Actemra failed to help patients with early-stage COVID-19 pneumonia
Humanigen, Inc. (US)	Lenzilumab (Granulocyte macrophage colony stimulating factor antagonists)	Phase III ongoing, Target completion Sep 2020, N=238 (NCT04351152)	-	Recruiting Reports positive data, rapid clinical improvement with a median time to recovery and discharge of five days and 100% survival to the data cut-off date.
Swedish Orphan Biovitrum (Sweden)	Emapalumab [human anti-interferon gamma (IFNγ) mAb), Anakinra [recombinant non-glycosylated human interleukin-1 receptor antagonist]	Phase II/III CT ongoing, target completion Sep 2020, N=54 (NCT04324021)	Italy	Recruiting

COVID-19 Development Snapshot (Treatment: Biologics)

Company	Drug	Status	Location	Remarks
Kinevant Sciences GmbH (Switzerland) / Roivant Sciences, Inc (Switzerland)	Gimsilumab	Phase II CT ongoing, target completion Oct 2020, N=270 (NCT04351243)	US	Recruiting 56 patients enrolled to date, independent Data Monitoring Committee (DMC) unanimously recommended that the trial continue after a pre-specified safety assessment evaluating data from the first 10% of randomized subjects after six days of follow-up
CytoDyn, Inc. (US)	Leronlimab	• Phase II CT ongoing, target completion Apr 2021, N=390 (NCT04347239) • Phase II CT ongoing, target completion Apr 2021, N=75 (NCT04343651)	US	• Recruiting • Recruitment Completed, data expected in next 2 weeks
Bristol-Myers Squibb (US)	Anti-Interleukin-8	Phase II CT ongoing, target completion Sep 2022, N=138 (NCT04347226)	US	Recruiting
Laboratoire français de Fractionnement et de Biotechnologies (France)	Clairyg (Polyvalent Immunoglobulin)	Phase III CT ongoing, target completion Aug 2020, N=138 (NCT04350580)	France	Recruiting

COVID-19 Development Snapshot (Treatment: Biologics)

Company	Drug	Status	Location	Remarks
Eli Lilly and Company (US)	LY3127804 [mAb, Angiopoietin 2 inhibitor]	Phase II ongoing , target completion Jul 2020, N=200 (NCT04342897)	US	Recruiting 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	Recruiting Positive interim results from the first 30 patients. Twenty-eight-day all-cause mortality in the IFX-1 treatment group was 13% (2 out of 15) versus 27% (4 out of 15) in the control group. SAE rates were comparable between groups, but the rate of pulmonary embolisms reported as SAEs was substantially lower in the IFX-1 treatment group. Upon review of the safety data. Independent DSMB recommended continuation of the trial into the Phase III part.
Apeiron Biologics (Austria)	Recombinant Human Angiotensin-converting Enzyme 2 (rhACE2)	Phase II CT ongoing, target completion Nov 2020, N=200 (NCT04335136)	Austria, Denmark, Germany	Recruiting
Novartis Pharmaceuticals (Switzerland)	Canakinumab [human anti-IL-1β monoclonal antibody]	Phase III ongoing, Target completion Nov 2020, N=450 (NCT04362813)	US, Spain, Germany, UK	Recruiting

COVID-19 Development Snapshot (Treatment: Biologics)

Company	Drug	Status	Location	Remarks
Biocad (Russia)	Levilimab [human anti-IL-6R monoclonal antibody]	Phase III ongoing, Target completion Apr 2021, N=204 (NCT04397562)	Russia	Recruitment Completed Russia approved Levilimab for use. Data shows that levilimab therapy can significantly reduce death risk among patients
Alexion Pharmaceuticals (US)	Ravulizumab [complement component 5 (C5) inhibitor, human monoclonal antibody]	Phase III ongoing, Target completion Feb 2021, N=270 (NCT04369469)	-	Not yet recruiting
Navarrabiomed - fundación miguel servet (Spain)	• Anakinra [recombinant non-glycosylated human interleukin-1 receptor antagonist] • Hydroxychloroquine	Phase III ongoing, Target completion Jul 2020, N=180 (2020-001825-29)	Spain	-
IDIVAL (Spain)	Methylprednisolone	Phase IV CT ongoing, target completion May 2022, N=200 (2020-001934-37)	Spain	Pragmatic trial inserted in real practice during a pandemic COVID-19
Cadila Pharmaceuticals (India)	Suspension of heat killed (autoclaved) Mycobacterium	Phase III ongoing, target completion Apr 2021, N=480 (NCT04358809)	-	Not Yet Recruiting

COVID-19 Development Snapshot (Treatment: Biologics)

Company	Drug	Status	Location	Remarks
Chinese Academy of Medical Sciences (China)	Convalescent Plasma	CT ongoing, target completion Feb 2021, N=200 (ChiCTR2000029757)	China	Recruiting 103 patients randomized, 101 (98.1%) completed the trial. Clinical improvement occurred within 28 days in 51.9% (27/52) of the convalescent plasma group vs. 43.1% (22/51) in the control group (difference, 8.8% [95% CI, −10.4% to 28.0%]; hazard ratio [HR], 1.40 [95% CI, 0.79-2.49]; P = .26). There was no significant difference in 28-day mortality (15.7% vs. 24.0%; OR, 0.65 [95% CI, 0.29-1.46]; P = .30) or time from randomization to discharge (51.0% vs. 36.0% discharged by day 28; HR, 1.61 [95% CI, 0.88-2.93]; P = .12). Convalescent plasma treatment was associated with a negative conversion rate of viral PCR at 72 hours in 87.2% of the convalescent plasma group vs. 37.5% of the control group (OR, 11.39 [95% CI, 3.91-33.18]; P < .001).
Indian Council of Medical Research (ICMR) (India)	Convalescent Plasma	Phase II CT ongoing, target completion Oct 2020, N=452 (CTRI/2020/04/024775)	India	Not yet recruiting
OncoImmune, Inc. (US)	CD24Fc [biological immuno-modulator]	Phase III CT ongoing, target completion Dec 2020, N=230 (NCT04317040)	US	First 70 patients have been randomized and received either CD24Fc or placebo as the treatment for severe COVID-19. After reviewing the safety data, the Institutional Review Board has approved continuing enrollment while interim analysis occurs. The mortality rate so far is 5%, which is considered low among severe and critical COVID-19 patients. The preliminary results show that the safety of the drug is outstanding

COVID-19 Development Snapshot (Treatment: Biologics)

Company	Drug	Status	Location	Remarks
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	Recruiting
Synairgen Research Limited (UK)	Inhaled SNG001 (IFNβ-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 Dec 2021, N=164 (NCT04344600)	US	Recruiting
Iltoo Pharma (France)	Interleukin 2 (Ld-IL2)	Phase II CT ongoing, target completion Aug 2020, N=30 (NCT04357444)	France	Not yet recruiting
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	Recruiting 24 patients were randomized to receive 1 or th2 2 doses of TJM2 or a placebo. a correlation between clinical improvement and reduced levels of some disease related cytokines was observed
BioAegis Therapeutics Inc. (US)	Recombinant human plasma gelsolin	Phase II CT ongoing, target completion Sep 2020, N=60 (NCT04358406)	-	Not yet recruiting

COVID-19 Development Snapshot (Treatment: Stem Cell)

Company	Stem Cells	Status	Location	Remarks
Mesoblast Limited (Australia)	Allogeneic mesenchymal stem cell product candidate remestemcel-L	Phase III CT ongoing, target completion Apr 2022, N=300 (NCT04371393)	US	Recruiting Early Data to be available by July
Athersys, Inc (US)	MultiStem® Therapy	Phase II/III CT ongoing, target completion Aug 2022, N=400 (NCT04367077)	US	Recruiting
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	Recruiting
Tianhe Stem Cell Biotechnologies Inc. (US)	Stem Cell Educator-Treated Mononuclear Cells	Phase II CT ongoing, target completion Nov 2020, N=20 (NCT04299152)	Not Listed	Not yet recruiting
Citospin (Spain)	Mesenchymal Stromal Cells	Phase II CT ongoing, target completion Dec 2020, N=24 (NCT04361942)	Spain	Recruiting
Hope Biosciences (US)	Allogeneic adipose-derived mesenchymal stem cells	Phase II CT ongoing, target completion Oct 2020, N=100 (NCT04362189)	US	Not yet recruiting
Azidus Brasil (Brazil)	NestCell® Mesenchymal Stem Cell I.V.	Phase I CT ongoing, target completion Aug 2020, N=90 (NCT04315987)	Brazil	Not yet recruiting
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	Not yet recruiting

COVID-19 Development Snapshot (Treatment: Stem Cell)

Company	Stem Cells	Status	Location	Remarks
Stem Cells Arabia (Jordan)	Wharton's Jelly-Mesenchymal Stem Cells	Phase I CT ongoing, target completion Sep 2020, N=5 (NCT04313322)	Jordan	Recruiting
VCANBIO Cell & Gene Engineering Corp Ltd. (China)	Mesenchymal Stem Cell	Phase I CT ongoing, target completion Dec 2021, N=20 (NCT04252118)	China	Recruiting
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	Not yet recruiting
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	Not yet recruiting
Pluristem (Israel)	PLX cells [allogeneic mesenchymal-like cells]	Phase II CT ongoing, target completion Sep 2021, N=140 (NCT04389450)	US	Recruiting

COVID-19 Development Snapshot (Vaccines)

Company	Vaccine	Status	Location	Remarks
National Institute of Allergy and Infectious Diseases (partner NIH and Moderna] (US) *[WarpSpeed]*	novel lipid nanoparticle (LNP)-encapsulated mRNA-based vaccine	• Phase II ongoing, target completion Aug 2021, N=600 (NCT04405076) • Phase I CT ongoing, target completion Nov 2021, N=155 (NCT04283461)	• US • US	• Phase 3 placebo controlled study for 100 µg with 30,000 volunteers expected to start in July, study design is finalized • Moderna partners with Lonza for production of 500 million and 1 billion doses annually • Phase II: Enrollment of 1st 300-subject cohort of the phase 2 is now complete, 13 days after the dosing of the first subject. It has also fully enrolled a sentinel cohort of 50 people aged 55 years and older. If the vaccine looks safe in that population, Moderna will go on to enroll 300 people aged 55 years and older. All participants will receive either placebo or a 50-µg or 100-µg shot of mRNA-1273. Each participant will receive two shots 28 days apart and will be followed up 12 months after the second dose. • Phase I showed that 100 µg is the optimal dose • Vaccine was generally safe and well tolerated
Oxford University (UK) / AstraZeneca (AZ) / Serum Institute of India (SII) *[WarpSpeed]*	Chimpanzee adenovirus modified to include the spike or 'S' protein on the surface of SARS-CoV-2	• Phase II/III CT ongoing, target completion Aug 2021, N=10260 (NCT04400838) • Phase I/II CT ongoing, target completion May 2021, N=1090 (NCT04324606)	• UK • UK, India	• Next Phase II/III 10,000 to be dosed in May/Jun has started recruitment. AZ could progress to late-stage trials by mid-year, possibly with a 30,000-person Phase 3 study in UK, US and Brazil • Small monkey study offer caution where vaccine provided protection against pneumonia but didn't eliminate coronavirus in the nose • Oxford partners up with AstraZeneca for production of 400 Mn doses • AstraZeneca receiving more than $1 billion in funding from the U.S. government BARDA

COVID-19 Development Snapshot (Vaccines)

Company	Vaccine	Status	Location	Remarks
CanSino Biologics Inc. (China) / PLA China	Recombinant Novel Coronavirus Vaccine (Adenovirus Type 5 Vector)	• Phase I/II CT ongoing, target completion Aug 2021, N=696 (NCT04398147) • Phase II CT ongoing, target completion Jan 2021, N=500 (ChiCTR2000031781) • Phase I CT ongoing, target completion Dec 2022, N=108 (NCT04313127 / ChiCTR2000030906)	• Canada • China • China	• Phase I Study: Vaccine is tolerable and immunogenic at 28 days post-vaccination. Humoral responses against SARS-CoV-2 peaked at day 28 post-vaccination in healthy adults, and rapid specific T-cell responses were noted from day 14 post-vaccination • Receives approval from Health Canada for human trial • CanSino likely to partner with Vancouver-based Precision NanoSystems Inc. to co-develop another potential vaccine
Inovio (US) (partner, Gates foundation)	INO-4800 DNA vaccine	Phase I CT ongoing, target completion Jul 2021, N=120 (NCT04336410)	US	• Demonstrates generation of robust neutralizing antibodies and T cell responses against SARS-CoV-2 in Preclinical Models • Completed dosing in a 40-patient Phase 1 trial, preliminary safety and immune responses data from Phase 1 clinical trial expected in late June • Multiple animal challenge study data expected in coming weeks • Phase II/III efficacy trial planned to start in July/August pending regulatory approval
Beijing Institute of Biological Products (China) /Wuhan Institute of Biological Products (China)	Inactivated	Phase I/II CT ongoing, target completion Nov 2021, N=1456 (ChiCTR2000031809)	China	• Trial enter 2nd phase, Not Yet Recruiting • Vaccine has shown good safety results for 96 patient dosed

COVID-19 Development Snapshot (Vaccines)

Company	Vaccine	Status	Location	Remarks
Sinovac (China)	Inactivated + alum	• Phase I/II CT ongoing, target completion Dec 2020, N=744 (NCT04352608) • Phase I/II CT ongoing, target completion Jul 2020, N=422 (NCT04383574)	• China • China	• Phase III study with 9000 volunteers in Brazil expected to start in Jul 2020 • Post preliminary observation of the safety profile of CoronaVac in the Phase I study, the Phase II clinical trial commenced in May • Sinovac Secures $15 Million in Funding to Accelerate COVID-19 Vaccine Development • Construction of Manufacturing plant with commercial production capacity of up to 100 million doses annually underway
Beijing Institute of Biological Products/Sinopharm (China)	Inactivated	Phase I/II CT ongoing, target completion Nov 2021, N=2128 (ChiCTR2000032459)	China	• Recruiting ongoing • Demonstrated potent protection in animal studies. pilot-scale production of the vaccine induces high levels of neutralising antibody concentrations in mice, rats, guinea pigs, rabbits and non-human primates including cynomolgus monkeys and rhesus macaques • Vaccine exhibits high productivity and good genetic stability for manufacturing as well
Clover Biopharmaceuticals Inc. (China) /GSK (UK) /Dynavax (US)	Protein Subunit, Native like Trimeric subunit Spike Protein Vaccine	Phase I CT ongoing, target completion Mar 2021, N=150 (NCT04405908)	-	• Not yet recruiting
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	Not yet begun Recruiting

COVID-19 Development Snapshot (Vaccines)

Company	Vaccine	Status	Location	Remarks
BioNTech (Germany) /Fosun Pharma (China)/ Pfizer (US) *[WarpSpeed]*	RNA, mRNA	Phase I/II CT ongoing, target completion Jan 2023, N=7600 (NCT04368728/EudraCT:2020-001038-36)	Germany, US	• Trial has begun dosing subjects • In the first stage of testing, close to 200 people aged between 18-55 are being tested, while in the next phase, another 160 people (possibly from higher-risk categories) will be tested and evaluated • BioNTech has scored a €100 million financing agreement to help fund production in Europe
Novavax (US)	VLP-recombinant protein nanoparticle vaccine + Matrix M	Phase I CT ongoing, target completion Jul 2021, N=131 (NCT04368988)	Australia	Recruiting ongoing, Preliminary immunogenicity and safety results expected in July.
China National Biotec Group/ Chinese Center for Disease Control and Prevention/ Chinese Academy of Medical Sciences (China)	Inactivated	Phase I/II CT ongoing, target completion Sep 2021, N=942 (NCT04412538)	China	• Recruiting ongoing
CureVac (Germany)	RNA, mRNA	Approved to launch Phase I CT, N=168	Belgium	• Preclinical results: Vaccine generated "high levels" of virus-neutralizing titers in animal models with a potential to induce a strong immunologic response to neutralize SARS-CoV-2
Imperial College London (UK) / Morningside Ventures (China)	RNA, sRNA	Clinical Phase I/II set to start this week	-	• Planning to start Phase I/II trials on June 15
Gamaleya Research Institute (Russia)	-	CT ongoing, N=76	Russia	Two forms of vaccine (liquid and powder) developed

COVID-19 Development Snapshot (Vaccines)

Company	Vaccine	Status	Location	Remarks
Novartis (Switzerland) / Massachusetts Eye and Ear Hospital (US)	Non-Replicating Viral Vector, Adeno-associated virus vector (AAVCOVID)	Preclinical	-	• Phase I trials are set to begin in late 2020
IAVI/Merck (US) *[WarpSpeed]*	Replicating Viral Vector, Replication competent VSV chimeric virus technology (VSVΔG) delivering the SARSCoV- 2 Spike (S) glycoprotein.	Preclinical	-	
Sanofi Pasteur (France) / GSK (UK)	Protein Subunit, S protein (baculovirus production)	Preclinical	-	• Plan to start clinical trials in the second half of 2020 • Can produce up to 600 million doses next year
Zydus Cadila (India)	• Replicating Viral Vector, Measles Vector • DNA, DNA plasmid vaccine	• Preclinical • Preclinical	-	Viable vaccine could be expected by end of 2021
Janssen Pharmaceutical Companies (Belgium) *[WarpSpeed]*	Ad26 Non-Replicating Viral Vector (alone or with MVA boost)	Preclinical	-	• Fast tracked Phase I /II clinical study by 2months, expected to begin in late Jul. • Company pledged $1 billion in partnership with the U.S BARDA • Company has capacity to produce 600 - 900 Mn doses by Apr 2021

COVID-19 Development Snapshot (Vaccines)

Company	Vaccine	Status	Location	Remarks
Bharat Biotech (India) / Thomas Jefferson University (US)	Non-Replicating Viral Vector, Recombinant deactivated rabies virus containing S1	Preclinical	-	Animals dosed, results expected next month
Bharat Biotech (India) / University of Wisconsin-Madison (US) / FluGen (US)	Intra-nasal drop vaccine	Preclinical	-	Human trials expected to begin in 4 months

Thank You