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IBPS

INTEGRATED BIOPHARMA
AND PHARMA SOLUTION

COVID-19

(Update collated on 24-May-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.

We are currently tracking worldwide 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.

- **Anti-virals:** The big new was Emergency Use Approval by US FDA and Japanese Approval for Remdesivir which showed Remdesivir cut hospital stays by 31 percent compared to a placebo. Gilead Sciences also reached agreement with several leading Generic Drug Manufacturers to ramp up production worldwide. Equally impressive is progress seen in trials with other anti-virals such as Lopinavir/ Ritonavir in combo with an old antiviral Ribavirin and INF-Beta and separate trials with Favipiravir show promising initial results. One imagines this will look like HIV/AIDS where a combination of anti-virals depending on whether given early or later in disease progression. More trial data is needed to determine which anti-viral works best throughout the course of Covid19 infection.
- **Hydroxychloroquine**: Hydroxychloroquine was the early front-runner of a viable treatment. Recent data is showing limited efficacy. Given the drug has know Long QT/ Ventricular tachycardia side effect, it is not generally safe for everyone to use. US FDA amended its Emergency Use Approval for use only when in a hospital setting where side effects can be managed. Robust clinical trials are ongoing to determine where best to use Hydroxychloroquine for treating Covid19
- **Stem cells** continue to show positive signs. Three additional trials showed very high recovery rates with severe patients. Almost 100 patients have seen significant improvement with use of stem cells
- **Biopharmaceuticals for auto-immune disease** slowing down the "cytokine storm" to show positive signs using various IL antagonists was an early leading approach with the assumption the "cytokine storm" was causing patients to rapidly decline. Trial data to date is very mixed with some promising data in severe patients. Similar to Anti-virals more trials will be needed to see when to best use these drugs and the associated benefits.
- In the **Vaccine** world there was lots of early data showing various vaccine candidates appeared safe and subjects developed SARS-Cov-2 antibodies/spike protein Antibodies. Moderna and CanSino Biologics had the most promising human data, although very limited in scope. Equally important, basically all leading Vaccine Candidates are lining up the necessary manufacturing capacity to manufacture "at risk". The goal is to have 100's of millions of doses of vaccine available by early 2021 if any leading candidate continues to show promise. While most will fail, Governments led by the US are funding this production to ensure rapid distribution of any vaccine demonstrating safety and efficacy

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.

COVID-19: Frontrunners in Treatment

Treatment Developments & Timeline

	Q1 2020	Q2 2020	Q3 2020	Q4 2020	2021+
Remdesivir	Phase III Study shows that it Cuts hospital stays by 31% compared to placebo.		FDA Authorization for Emergency Use		
Ritonovir/ Lopinavir	Phase II Study shows positive results for combination therapy with Ribavirin and IFN-beta				
Favipiravir	Russian Study with 40 patients shows 65% patient tested –ve for coronavirus at 10th day		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		Chinese Observation study also shows positive data		
Convalescent Plasma therapy	FDA Authorization for Emergency Use		Multiple RCTs to be initiated		
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		Oxford Trial early results expected	

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Preliminary Clinical Trial Data | Other Preclinical/Supportive Data | Early Access Approval | Trial Status

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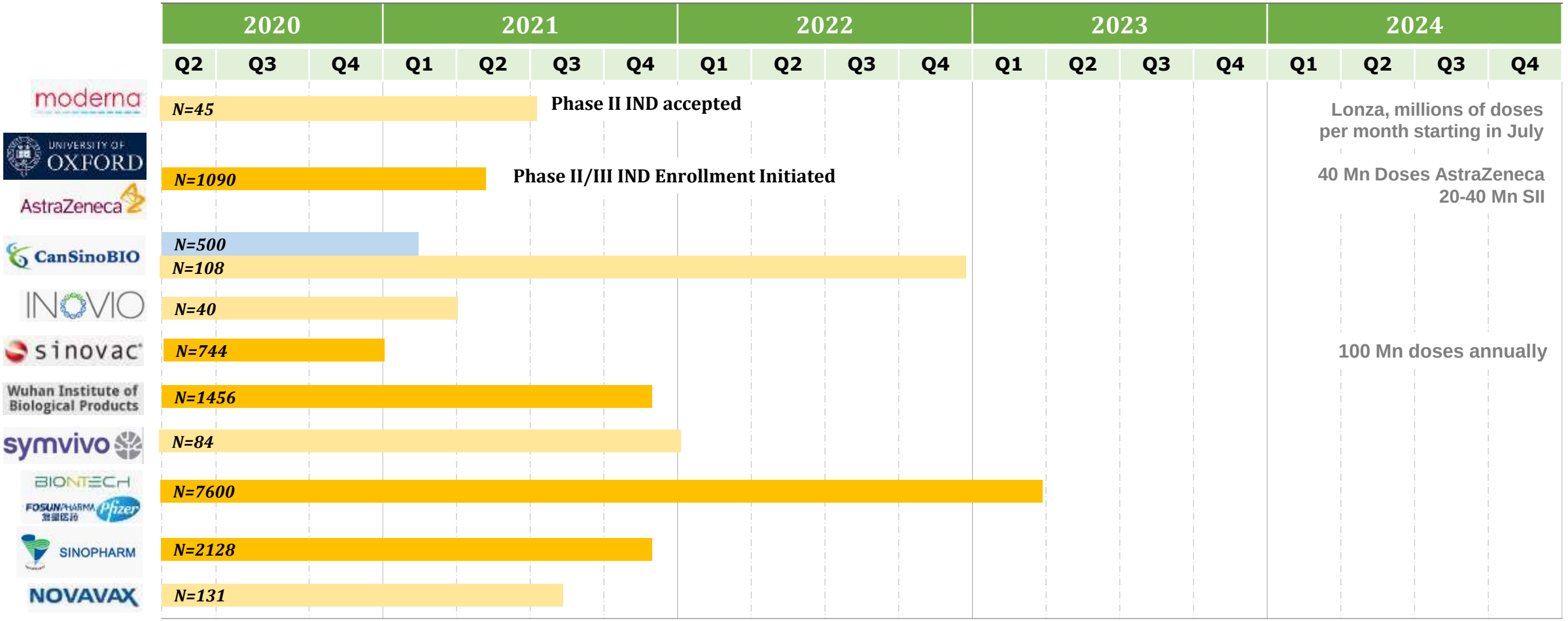
COVID-19: 10 Vaccine Candidates in Clinical Development

Clinical Development Timeline



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COVID-19: Progress Snapshot

Remdesivir

- Gilead trial Findings
  - Remdesivir cut hospital stays by 31 percent compared to a placebo.
  - Top line results released state that Study Demonstrates Similar Efficacy with 5-Day and 10-Day Dosing Durations of Remdesivir
  - Further results expected by end of this month

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)

Favipiravir

- ChemRar Group and The Russian Direct Investment Fund (RDIF) have reported positive data from a multi-centre clinical trial of Favipiravir in patients hospitalized due to Covid-19. During the randomised, open, comparative trial, 40 patients were treated with the drug. Of these patients, 65% tested negative for coronavirus following five days of treatment, two times higher compared to those on standard therapy. By day 10, the number of patients whose tests returned negative results reached 35 out of 40. The findings are said to be consistent with data from studies performed in China, which also revealed a decrease in the disease duration from 11 days to four-five days.
- Stride Pharma recently received regulatory approval and will being Clinical trial shortly. Glenmark Pharma initiated clinical trial.

COVID-19: Progress Snapshot

Hydroxychloroquine

- In a randomised controlled trial in China (ChiCTR2000029868) it was found that administration of hydroxychloroquine did not result in a significantly higher probability of negative conversion than standard of care alone in patients admitted to hospital with mainly persistent mild to moderate Covid-19. Adverse events were higher in hydroxychloroquine recipients than in non-recipients
- In an observational study of 84 patients researchers in France assessed the effectiveness and safety of hydroxychloroquine compared with standard care in adults admitted to hospital with pneumonia due to covid-19 who needed oxygen. Of 181 patients, 84 received hydroxychloroquine within 48 hours of admission and 97 did not (control group). They found no meaningful differences between the groups for transfer to intensive care, death within 7 days, or developing acute respiratory distress syndrome within 10 days
- Further a multinational registry analysis of the use of hydroxychloroquine (HCQ) or chloroquine (CQ) with or without a macrolide for treatment of COVID-19 was also performed
  - Of 96,032 patients. 15.6% were in treatment group (CQ+Macrolide[25%], CQ [12%], HCQ[20%], HCQ+Macrolide[41%]) and 84.4% were in control group.
  - 11% patient died, mortality in each group was control group (9·3%), HCQ (18·0%), HCQ+Macrolide (23·8%), CQ (16·4%), and CQ+macrolide (22·2%) were each independently associated with an increased risk of in-hospital mortality. Compared with the control group (0·3%), HCQ(6·1%), HCQ+macrolide (8·1%), CQ(4·3%), and CQ+Macrolide (6·5%) were independently associated with an increased risk of de-novo ventricular arrhythmia during hospitalisation
  - The study was unable to confirm a benefit of hydroxychloroquine or chloroquine, when used alone or with a macrolide, on in-hospital outcomes for COVID-19. Each of these drug regimens was associated with decreased in-hospital survival and an increased frequency of ventricular arrhythmias when used for treatment of COVID-19.
- An observational study carried by University of Albany's School of Public Health of +1,400 patients and another one conducted by National Institutes of Health in New York of 1,376 consecutive patients data stated that they **did not observe a significant benefit/ any potential benefit or harm from the drug**. Both studies added a rigorous, randomized clinical trial was needed to be conclusive.

COVID-19: Progress Snapshot

Biologics Therapy

- Sarilumab (Kevzara): In a Randomized trial of 457 hospitalized patients showed promise for treating the sickest coronavirus patients in a clinical trial but wasn't beneficial for patients with less-advanced disease, prompting the companies to stop testing the medicine in that group (NCT04315298).
- Tocilizumab
  - Early data from a clinical trial in France has demonstrated encouraging profile of Roche unit Genentech's rheumatoid arthritis drug tocilizumab (Actemra) to treat seriously ill Covid-19 patients. During the trial, the drug was able to 'significantly' decrease the number of deaths or life support interventions when compared to a control group.
  - A recent observational study from China reported that Tocilizumab treatment in severe COVID-19 cases resulted in improvement in COVID-19 symptoms, peripheral oxygen saturation, and lymphopenia within a few days. A substantial remission of lung lesion opacity in chest CT scan was observed in 95% of patients (19 of 20) after 5 days of treatment, and all patients were discharged after an average of 15.1 days of hospital stay
- Convalescent Plasma therapy continues to show some positive impacts in CN, US and in India. RCT 's initiated
- Certain positive news on Stem cell therapy
  - A team of doctors and researchers at the Abu Dhabi Stem Cell Center (ADSCC) administered the treatment in the UAE to 73 COVID-19 patients, who were all 'successfully treated and cured', without any 'immediate side effects', according to a statement by the United Arab Emirates (UAE) health ministry
  - 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. Phase III ongoing.
  - 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.

COVID-19: Progress Snapshot

Vaccine Development

- The most promising areas so far. At least 10 have moved to clinical phase and 108 are in the pre-clinical phase (*Source: WHO list released on 15 May 2020*)
- Different approaches taken for vaccine development are attenuated virus development, using viral peptides, RNA and DNA vaccines.
- Frontrunners among these 10 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 III is expected to begin in July this year
  - 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). Target completion Jan 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 40Mn doses

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	Not Yet Recruiting
National Institute of Respiratory Diseases, Mexico/Sanofi (France)	Hydroxychloroquine	Phase III ongoing, target completion Mar 2021, N=400 (NCT04318015)	Mexico	Recruiting
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=600 (NCT04343248)	-	• Not Yet Recruiting • Not Yet Recruiting • NCT04359680 – Health Workers - Not Yet Recruiting
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 May 2020, N=6000 (NCT04292899) • Phase III CT ongoing, target completion May 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	Top line results released state that Study Demonstrates Similar Efficacy with 5-Day (N=200) Vs. 10-Day (N=197) Dosing Durations of Remdesivir. • Time to clinical improvement for 50% of subjects= 10 days Vs. 11 days • Clinical recovery at 14th day = 64.5% (129/200) Vs. 53.8% (106/197) • Clinical outcomes varied by geography. Outside of Italy, the overall mortality rate at Day 14 was 7 percent (n=23/320) across both treatment groups, with 64 percent (n=205/320) of patients experiencing clinical improvement at Day 14 and 61 percent (n=196/320) of patients discharged from the hospital. Further details expected by End of May
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 538/1063 were given Remdesivir Vs. 521/1063 on placebo. • Median recovery time (11 days vs. 15 days) • Kaplan-Meier estimates of mortality by 14 days (7.1% Vs. 11.9%) • SAE reported by (21.1% Vs. 27%)
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: Danoprevir+Ritonavir, Favipiravir, 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 ongoing, target completion May 2020, N=40 (NCT04345276)	China	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
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. • Recruitment Complete • Recruiting

COVID-19 Development Snapshot (Treatment: Danoprevir+Ritonavir, Favipiravir, 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
Glenmark Pharmaceuticals Ltd (India)	Favipiravir	Phase III CT ongoing, target completion May 2021, N=150 (CTRI/2020/05/025114)	India	Not yet recruiting Results expected between the months of July and August
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
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) 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	• 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=3040 (NCT04304053)	Spain	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 + Azythromycin	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 ongoing, target completion Aug 2020, N=210 (NCT04333654)	US, France	Recruiting
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	Recruiting

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	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	Not yet recruiting
Eli Lilly and Company (US) / National Institute of Allergy and Infectious Diseases (NIAID)	Baricitinib	Study Planned	US, Europe, Asia	Expected to start phase I Apr 2020 and results by Jul 2020

COVID-19 Development Snapshot (Treatment: Other Candidates)

Company	Drug	Status	Location	Remarks
Laboratorio Elea S.A.C.I.F. y A. (Argentina)	Telmisartan	Phase II CT ongoing, target completion Oct 2020, N=400 (NCT04355936)	Argentina	Not yet recruiting
AstraZeneca (UK)	Dapagliflozin	Phase III CT ongoing, target completion Dec 2020. N=900 (NCT04350593)	US	Recruiting, For Respiratory Failure in Patients
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	• Not yet 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=290 (NCT04327401)	Brazil	Recruiting
NeuroRx, Inc. (US)/ Relief Therapeutics Holding SA (Switzerland	Aviptadi	Phase II CT ongoing, target completion Sep 2020, N=144 (NCT04311697)	US, Israel	Enrolling by invitation
NeuroRx, Inc. (US)	Inhaled Aviptadil	Phase II/III CT ongoing, target completion Oct 2020, N=144 (NCT04360096)	-Not listed	Not yet recruiting
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

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	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)	-	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	Not yet 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)	-	Not Yet Recruiting
CalciMedica, Inc. (US)	CM4620 Injectable Emulsion	Phase II CT ongoing, target completion Sep 2020, N=120 (NCT04345614)	US	Recruiting
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
Theravance Biopharma (Cayman Islands)	TD-0903	Phase I CT ongoing, target completion Jun 2020, N=54 (NCT04350736)	UK	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 Apr 2021, N=400 (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 • Not yet recruiting
Hoffmann-La Roche (Switzerland)	Tocilizumab [anti interleukin-6 receptor humanized monoclonal antibody]	• Phase III CT ongoing, target completion Sep 2020, N=330 (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 • 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=500 (IRCT20150303021315N17)	Iran	
Humanigen, Inc. (US)	Lenzilumab (Granulocyte macrophage colony stimulating factor antagonists)	Phase III ongoing, Target completion Sep 2020, N=238 (NCT04351152)	-	Recruiting
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
Kinevant Sciences GmbH (Switzerland)	Gimsilumab	Phase II CT ongoing, target completion Oct 2020, N=270 (NCT04351243)	US	Recruiting
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 • Recruiting
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

COVID-19 Development Snapshot (Treatment: Biologics)

Company	Drug	Status	Location	Remarks
Bristol-Myers Squibb (US)	Anti-Interleukin-8	Phase II CT ongoing, target completion Sep 2022, N=138 (NCT04347226)	US	Recruiting
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 Oct 2020, N=450 (NCT04362813)	US, Spain, Germany, UK	Recruiting
Biocad (Russia)	Levilimab [human anti-IL-6R monoclonal antibody]	Phase III ongoing, Target completion Apr 2021, N=204 (NCT04397562)	Russia	Recruiting
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
Laboratoire français de Fractionnement et de Biotechnologies (France)	Clairyg (Polyvalent Immunoglobulin)	Phase III CT ongoing, target completion Aug 2020, N=138 (NCT04350580)	France	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 Jun 2021, N=164 (NCT04344600)	US	Not yet recruiting
Iltoo Pharma (France)	Interleukin 2 (Ld-IL2)	Phase II CT ongoing, target completion Jul 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
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
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
BioAegis Therapeutics Inc. (US)	Recombinant human plasma gelsolin	Phase II CT ongoing, target completion Sep 2020, N=60 (NCT04358406)	-	Not yet recruiting
OncoImmune, Inc. (US)	CD24Fc [biological immuno-modulator]	Phase III CT ongoing, target completion May 2022, N=230 (NCT04317040)	US	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
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 Jun 2020, N=66 (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 (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
National Institute of Allergy and Infectious Diseases (partner NIH and Moderna] (US)	novel lipid nanoparticle (LNP)-encapsulated mRNA-based vaccine	• Phase II IND accepted, N=600 • Phase I CT ongoing, target completion Jun 2021, N=45 (NCT04283461)	US	• After two doses all participants evaluated to date across the 25 µg and 100 µg dose cohorts seroconverted with binding antibody levels at or above levels seen in convalescent sera • Elicited neutralizing antibody titer levels in all eight initial participants across the 25 µg and 100 µg dose cohorts, reaching or exceeding neutralizing antibody titers generally seen in convalescent sera • Vaccine was generally safe and well tolerated • Phase 3 study between 25 µg and 100 µg; expected to start in July
Oxford University (UK) / AstraZeneca / Serum Institute of India (SII)	Chimpanzee adenovirus modified to include the spike or 'S' protein on the surface of SARS-CoV-2	• Phase II/III Enrollment initiated • Phase I/II CT ongoing, target completion May 2021, N=1090 (NCT04324606)	UK, India	• 1,000 subjects dosed till now • Next Phase II/III 10,000 to be dosed in May/Jun has started recruitment • 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 40 Mn doses
CanSino Biologics Inc. (China) / PLA China	Recombinant Novel Coronavirus Vaccine (Adenovirus Type 5 Vector)	• Phase I CT ongoing, target completion Dec 2022, N=108 (NCT04313127 / ChiCTR2000030906) • Phase II CT ongoing, target completion Jan 2021, N=500 (ChiCTR2000031781)	China	• Phase 1 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

COVID-19 Development Snapshot (Vaccines)

Company	Vaccine	Status	Location	Remarks
Inovio (US) (partner, Gates foundation)	INO-4800 DNA vaccine	Phase I CT ongoing, target completion Apr 2021, N=40 (NCT04336410)	US	• Demonstrates generation of robust neutralizing antibodies and T cell responses against SARS-CoV-2 in Preclinical Models • Preliminary safety and immune responses data from Phase 1 clinical trial expected in June • Multiple animal challenge study data expected in coming weeks • Phase II/III efficacy trial planned to start in July/August pending regulatory approval
Sinovac (China)	Inactivated + alum	Phase I/II CT ongoing, target completion Dec 2020, N=744 (NCT04352608)	China	• Post preliminary observation of the safety profile of CoronaVac in the Phase I study, the Phase II clinical trial commenced in May • Preclinical studies demonstrates the vaccine candidate is safe and provides protection to rhesus macaques (monkeys) through an animal challenge study • 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 (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 • 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	Not yet begun Recruiting
BioNTech (Germany) /Fosun Pharma (China)/ Pfizer (US)	RNA, mRNA	Phase I/II CT ongoing, target completion Mar 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
Beijing Institute of Biological Products/Sinopharm (China)	Inactivated	Phase I/II CT ongoing, target completion Nov 2021, N=2128 (ChiCTR2000032459)	China	Recruiting ongoing
Novavax (US)	VLP-recombinant protein nanoparticle vaccine + Matrix M	Phase I CT ongoing, target completion Jul 2021, N=131 (NCT04368988)	-	Preliminary results expected in July
CureVac (Germany)	RNA, mRNA	Preclinical	-	• 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 • Plans to launch phase I/IIa clinical trial this June

COVID-19 Development Snapshot (Vaccines)

Company	Vaccine	Status	Location	Remarks
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)	Ad26 Non-Replicating Viral Vector (alone or with MVA boost)	Preclinical	-	• Company pledged $1 billion in partnership with the U.S BARDA • Expects to start a Phase I clinical study this Sep. • Company has capacity to produce 600 - 900 Mn doses by Apr 2021
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

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