

LAST UPDATED: SEPTEMBER 25, 2020

# RA CAPITAL'S COVID-19 MAP:

## Map Update Log

RACAPITAL

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# VACCINE UPDATES

## VERSION 8 UPDATES: SEPTEMBER 25, 2020

### NEW PROGRAMS ADDED (2):

1. **SpyBiotech / Serum Institute of India**
2. **Meissa Vaccines (MV-014-210)**

### UPDATES TO EXISTING PROGRAMS (20):

1. **Novavax/Emergent BioSolutions:** *Novavax reported Ph1/2 RCT data for two doses (5 ug and 25 ug) of NVX-CoV2373 + 50 ug of its Matrix-M adjuvant. Neutralizing antibody titers were the highest produced by any vaccine candidate to date (3906 GMT, assessed by a stringent 100% inhibition live virus assay) and the tolerability profile was largely superior to other published COVID vaccine candidates, as well as common marketed common flu vaccines. The Ph2 portion of trial started August 2020. Novavax was awarded \$1.6B from Operation Warp Speed to support large-scale manufacturing of candidate NVX-CoV2373 by FUJIFILM Diosynth Biotechnologies and fund a pivotal 30K volunteer Ph3 RCT to begin September 2020, with data plausibly January 2021, submission Feb 2021, and launch March 2021. Together with their acquisition of Cyrus Poonawalla Group, Novavax is guiding to having 100M doses ready by late 2020 and reach 1B doses/year run rate by YE21. The company recently entered an exclusive licensing agreement with the Serum Institute of India to support an additional 1B doses for India and low- and middle-income countries, a partnership with Takeda to support the production of over 250M annually for Japan, a development and supply agreement with SK Bioscience for global manufacturing of the antigen component and vaccine supply for South Korea, an agreement with the UK government to purchase 60M doses (and run a Ph3 in the UK as part of an expanded collaboration with FUJIFILM Diosynth Biotechnologies, starting 3Q20), and an agreement in principle with Canada to supply up to 76M doses.*
2. **University of Queensland/CSL Behring:** *This technology leverages a molecular clamp to stabilize the viral antigen. Ph1 trials started 3Q20, with data expected by YE20 before initiation of a large scale Ph3 study. The program has multiple additional partners (Cytiva, Viroclinics Xplore, Lonza, and Thermo Fisher Scientific) and recently announced an agreement with the Australian government to supply 51M doses. CSL expects the first doses to be available MY21 with capacity for up to 100M doses YE21.*
3. **Sanofi:** *Sanofi guided to producing 100M-600M vaccine doses between YE20 and 2H21, and then scaling up to 1B doses annually by YE21. However, since protection requires 2 doses this is enough to vaccinate only 50M-300M people. Sanofi was recently awarded \$2.1B by Operation Warp Speed to supply the US with 100M doses in 2021 with the option for up to 500M doses. Similarly, Sanofi has entered agreements with the UK to supply up to 60M doses and has finalized negotiations with the EU to supply up to 300M doses in 2021. Ph1/2 testing launched September 2020, with data expected December 2020 and the initiation of a Ph3 trial shortly thereafter, with possible regulatory approval 1H21. Early data showing the minimum dose needed to achieve protective immunity will be critical to determine how quickly Sanofi could make a dent in global vaccine need.*
4. **Sinovac Biotech (PiCoVacc):** *Inactivated vaccine candidate for which preliminary Ph2 data were recently reported and demonstrated induction of neutralizing antibodies in above 90% of volunteers. Preclinically, NHP challenge experiment for SARS-CoV-2 demonstrated protection without enhancement, though doses seemed too high for efficient manufacturing. This program is run by the Chinese government and entered into a collaboration with the Brazilian Institute to initiate a Ph3 trial (committing 60M-100M doses through this agreement), in addition to a supply deal with Indonesia (committing 40M doses). Although immunogenicity data from this trial have not yet been published, this vaccine candidate was granted emergency use authorization in China August 2020 and intends to launch a Ph1/2 pediatric trial shortly. Sinovac*

currently has the capacity to produce ~100M doses annually and is aiming to triple capacity to ~300M doses largely for domestic supply in 2021.

5. **SpyBiotech / Serum Institute of India:** A Ph1/2 study has been initiated in Australia. This platform uses a proprietary SpyCatcher/SpyTag “superglue” technology to display the Spike protein on the surface of Hepatitis B surface antigen VLPs.
6. **Vaxine Pty/Medy-Tox/Oxford Expression Technologies:** Small, Australian biotech company leveraging its proprietary adjuvant (Advax-CpG55.2) and its previous experience developing a SARS-CoV1 vaccine candidate to develop COVAX-19. They are partnered with South Korea’s Medy-Tox and the UK’s Oxford Expression Technologies to develop this program. Unclear clinical timelines or manufacturing scale.
7. **Medigen/NIAID/Dynavax:** Ph1 testing is expected to start September 2020. The company plans to finish the preclinical development and CMC by Fall 2020 to proceed with clinical trials to be done by June 2021. Concurrently, manufacturing and scale-up are planned to provide up to 200M doses by YE21. This program recently entered a partnership with Vaxess Technologies to develop a combination COVID-19 + seasonal influenza microneedle patch vaccine.
8. **Sinopharm Group/Wuhan Institute of Biological Products/Beijing Institute of Biological Products:** Inactivated vaccine sponsored by the China National Pharmaceutical Group that entered Ph1/2 testing in April 2020. Early data from this trial demonstrated that participants generate relatively low levels of neutralizing antibodies (121-250 GMT with a low stringency PRNT50 assay), although they did not have a human convalescent comparator arm to benchmark these results to. The company has guided to supplying 200M doses annually. Initiated a Ph3 trial in the UAE enrolling up to 15K volunteers. In September 2020, the UAE granted Emergency Use Authorization for this vaccine candidate before clinical trials are complete, becoming the first program to be granted approval by a foreign country.
9. **Valneva:** Valneva expects to enter clinical studies by YE20 with potential regulatory approval 2H21. They have recently reached an agreement with the UK to provide 60M doses 2H21 (purchased for 470M euros), with options for an additional 130M doses 2022-2025, which will be manufactured at its facilities in Livingston, Scotland and Solna, Sweden. Dynavax will supply its adjuvant for this agreement. Valneva has a marketing and distribution agreement for Seqirus’ quadrivalent seasonal influenza vaccines in Austria. This prior relationship provides possible access to MF59 and discussions are ongoing.
10. **Vaxart/Emergent Biosolutions/Kindred Biosciences:** Vaxart announced FDA clearance of their COVID-19 vaccine candidate IND in September 2020 and expect additional preclinical data to be released October 2020. They have a development agreement with Emergent BioSolutions to prepare bulk cBMP oral COVID-19 vaccine. Vaxart has also contracted KindredBio to manufacture its lead vaccine candidate at a large scale. Selected by Operation Warp Speed to participate in a NHP challenge study
11. **Meissa Vaccines (MV-014-210):** Meissa’s COVID-19 vaccine candidate, MV-014-210, was derived by modifying the company’s RSV LAV candidate, MV-012-968, and replacing the RSV glycoproteins with a functioning SARS-CoV-2 Spike protein. This platform offers potential advantages for global deployment and clinical trials are expected to begin early 2021.
12. **Vaxess Technologies/Medigen:** MIMIX platform allows for combination of multiple antigens (COVID and Flu) for the development of a pentavalent, single dose, self-applied vaccine. Vaxess recently announced a partnership with Medigen to use their COVID-19 vaccine candidate for this combination patch. Their microneedle technology is silk-based and the antigen is room temperature stable. It is unlikely that this program will contribute to the first wave of COVID vaccines. A more likely market is for future seasonal vaccine cycles.
13. **ASTRAZENECA/Vaccitech/ University of Oxford (AZD1222):** Clinical trials for this vaccine candidate have resumed after a clinical hold was triggered by a possible case of transverse myelitis. Although AstraZeneca has not released any medical details about this situation, they do report that an independent review deemed the safety signal was not likely associated to the vaccine itself, although there is insufficient evidence to say for certain. AstraZeneca has signed agreements to provide hundreds of millions of doses to be delivered starting YE20 (100M UK, 300M US, 400M

Serum Institute of India to provide for poorer countries, 300M CEPI/GAVI, and 300M EU). They also reached a licensing deal with Chinese firm BioKangtai for 200M doses annually. Early data from a Ph1/2 RCT trial enrolling >1,000 patients showed that AZD1222 produced neutralizing antibodies at best on par with human convalescent control, which may not be enough to provide sterilizing immunity but could protect from severe disease. This trial is large enough that, if over the next several months when 4% of people might be expected to become infected, it might demonstrate vaccine efficacy if it cuts the infection rate in half (e.g., 20 unvaccinated patients getting sick vs. 10 vaccinated patients). However, with all the social distancing measures, 4% prevalence of COVID-19 might be an unreasonably high attack rate to model, and therefore it will take a larger study to prove efficacy; Oxford is preparing to run with an additional trial with 5,000 subjects. Recognized by Operation Warp Speed (OWS) as one of five vaccine candidates most likely to work.

14. **Cansino Biologics (Ad5-nCoV):** Publication of Ph1 trial results demonstrated that ~50% of participants have pre-existing immunity to Ad5, which greatly impedes immunogenicity and makes this vaccine candidate less relevant for the broader population. Low levels of neutralizing antibodies were reproduced in their expanded Ph2 cohort, signaling that this vaccine may not provide strong protection. The company plans to start Ph3 trials soon in Russia, Brazil, Saudi Arabia, and Chile. China has approved this vaccine for military use and while current in-house manufacturing capacity sits at 80M doses annually, a new factory under construction in China will allow the production of 100-200M doses/year starting 1H21. In August the National Research Council of Canada announced that collaboration with CanSino ended upon delays in vaccine shipments. At the same time, CanSino has entered talks with several countries to get emergency use authorization for its COVID-19 candidate. Concurrently, they are initiating a Ph1 trial to two-dose regimen for this vaccine after concerns were raised by the scientific community about the limited efficacy of this vaccine.
15. **Gamaleya Research Institute:** Russian program with very little publicly available information. They started Ph1 trials 2Q20 for their adenovirus based vaccine and recently announced this candidate is expected to get conditional registration on August 12th, only requiring trials on another 1,600 people with production likely to start in September. This program recently published Ph1 data, placing neutralizing antibody titers in a similar range as AstraZeneca's vaccine candidate (1:40 vs 1:30). However, a global group of scientists have called into question the reliability of these data after highly unlikely data patterns were identified throughout the publication.
16. **Moderna Therapeutics/Lonza (mRNA-1273):** Moderna published Ph1 data testing 25/100/250 ug doses and reported levels of neutralizing antibodies for the 100 ug dose at 14 days after the boost that were ~4X greater than levels in their human convalescent sera control. Early Ph1 data in elderly patients suggest neutralizing titers levels do not drop off in older patients, which is supported by work from their RSV program. While Moderna is testing 50/100 ug doses in a 600-patient Ph2 trial, they will move forward with the 100 ug for a 30K volunteer Ph3 trial July 2020 (with total \$955M support from BARDA) due to reactogenicity concerns with the 250 ug dose. Moderna has guided to supplying 500M - 1B doses annually (20M by YE20) and has committed 100M to the US (with the option of an additional 400M), 80M to the EU, and 40M to Japan. Recognized by Operation Warp Speed (OWS) as one of five vaccine candidates most likely to work.
17. **BioNTech/Pfizer (BNT162):** Interim data from Ph1/2 trials in Germany and the US demonstrated that the modRNA vaccine candidate 162b1 (RBD, 30 ug prime/boost) induced neutralizing antibodies levels ~3-4x greater than levels with human convalescent sera control. However, the company will move forward with a new lead candidate 162b2 (full length spike, 30 prime/boost ug) for their Ph2b/3 RCT starting July (recently expanded to enroll 44K volunteers), which elicited a broader T cell response in elderly volunteers while maintaining similar neutralizing antibody titers and a better reactogenicity profile. They are guiding to manufacturing 100M doses by YE20, scaling up to 2B doses in 2021 with the recent acquisition of a GMP facility in Germany and manufacturing supply agreements with the UK (60M), the US (100M-600M), the EU (200M), and Japan (120M). Recognized by Operation Warp Speed (OWS) as one of five vaccine candidates most likely to work and awarded 375M euros by the German Federal Ministry of Education and Research to advance vaccine development.
18. **CureVac:** Expects to start Ph1 clinical trials in summer 2020. Received regulatory clearance to begin trials in Germany and Belgium; if successful they could progress to Ph2 trials in August 2020. The company announced that they are in advanced talks with the EU to supply 225M doses of their vaccine candidate MY21, with an option for 180M more. Recently awarded 252M euros by the German Federal Ministry of Education and Research to advance vaccine

development.

19. **Takis Biotech/Applied DNA Sciences:** *Ph1 trials to begin in Italy late 2021; their manufacturing capacity is currently unclear. The company has recently announced the launch of a veterinary trial to study the immune response in companion felines of humans.*
20. **Merck/Institut Pasteur/University of Pittsburgh:** *Consortium headed by the Institute Pasteur and backed by CEPI. The University of Pittsburgh will develop a candidate, while Merck (which acquired Themis) is responsible for supporting the clinical trial and manufacturing. Ph1 dosing has started in Belgium September 2020.*

## VACCINES: VERSION 7 UPDATES: SEPTEMBER 4, 2020

### NEW PROGRAMS ADDED (1):

#### 1. Baylor College of Medicine/Biological E

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### UPDATES TO EXISTING PROGRAMS (16):

- Novavax/Emergent BioSolutions:** The Ph2 portion of trial started August 2020. The company recently entered an exclusive licensing agreement with the Serum Institute of India to support minimum of 1B doses for India and low- and middle-income countries, a partnership with Takeda to support the production of over 250M annually for Japan, a development and supply agreement with SK Bioscience for global manufacturing of the antigen component and vaccine supply for South Korea, and an agreement with the UK government to purchase 60M doses (and run a Ph3 in the UK as part of an expanded collaboration with FUJIFILM Diosynth Biotechnologies, starting 3Q20)
- Sinovac Biotech (PiCoVacc):** Although immunogenicity data from this trial have not yet been published, this vaccine candidate was granted emergency use authorization in China August 2020. Recently entered a supply deal with Indonesia to supply 40M doses by 1Q21.
- VBI Vaccines/National Research Council of Canada:** VBI selected two lead candidates to take into Ph1/2 YE20 that generated robust neutralizing antibody titers in mice.
- Baylor College of Medicine/Biological E:** Baylor College of Medicine recently licensed their subunit vaccine candidate to Biological E to help manufacture and develop. Unspecified clinical timelines. Biological E expects to manufacture hundreds of million doses annually.
- VIDO-InterVac at the University of Saskatchewan:** VIDO-InterVac was awarded \$23M by the Canadian government to accelerate COVID-19 vaccine development and the University of Saskatchewan was awarded another \$3.6M. Recently partnered with Dalton Pharma and Biodextris for manufacturing and fill-finish. Clinical trials are expected to start 4Q20.
- Sinopharm Group/Wuhan Institute of Biological Products/Beijing Institute of Biological Products:** Early data from this trial demonstrated that participants generate relatively low levels of neutralizing antibodies (121-250 GMT with a low stringency PRNT50 assay), although they did not have a human convalescent comparator arm to benchmark these results to.
- Bharat Biotech International (Covaxin):** They reported that this vaccine has a "positive" reactogenicity profile and are collecting sera to study immunogenicity.
- Valneva:** Valneva has a marketing and distribution agreement for Seqirus' quadrivalent seasonal influenza vaccines in Austria. This prior relationship provides possible access to MF59 and discussions are ongoing. Valneva is also testing Dynavax's adjuvant.
- JNJ/Emergent Biosolutions:** the company is guiding that the Ph2 portion will initiate the first week of September in Europe. Ph3 is planned to enroll up to 60K participants in South America.
- ReiThera/Leukocare/Univercells:** European Consortium developing a vaccine candidate that entered the clinic August 2020 in Italy.
- Cansino Biologics (Ad5-nCoV):** In August the National Research Council of Canada announced that collaboration with

*CanSino ended upon delays in vaccine shipments. At the same time, CanSino has entered talks with several countries to get emergency use authorization for its COVID-19 candidate*

- 12. Moderna Therapeutics/Lonza (mRNA-1273):** *Early Ph1 data in elderly patients suggest neutralizing titers levels do not drop off in older patients. Moderna has guided to supplying 500M - 1B doses annually and has committed 100M to the US (with the option of an additional 400M), 80M to the EU, and 40M to Japan.*
- 13. BioNTech/Pfizer (BNT162):** *However, the company will move forward with a new lead candidate 162b2 (full length spike, 30 prime/boost ug) for their Ph2b/3 RCT starting July, which elicited a broader T cell response in elderly volunteers while maintaining similar neutralizing antibody titers and a better reactogenicity profile.*
- 14. CureVac:** *The company announced that they are in advanced talks with the EU to supply 225M doses of their vaccine candidate MY21, with an option for 180M more.*
- 15. Translate Bio/Sanofi:** *Sanofi recently doubled down on a \$425M commitment to fund Translate Bio's mRNA vaccine, with a trial to start November 2020.*
- 16. Generex/EpiVax (il-key platform):** *They recently announced an agreement with Bintai Kinden to advance the development and commercialization of their vaccine candidate for Malaysia.*

## VACCINES: VERSION 6 UPDATES: AUGUST 14, 2020

### NEW PROGRAMS ADDED (2):

#### SUBUNIT VACCINES:

1. **Kentucky Bioprocessing**
2. **Covaxx**

### UPDATES TO EXISTING PROGRAMS (22):

#### SUBUNIT VACCINES:

1. **Novavax/Emergent Biosolutions (NVX-CoV2373):** Novavax reported Ph1/2 RCT data for two doses (5 ug and 25 ug) of NVX-CoV2373 + 50 ug of its Matrix-M adjuvant. Neutralizing antibody titers were the highest produced by any vaccine candidate to date (3906 GMT, assessed by a stringent 100% inhibition live virus assay) and the tolerability profile was largely superior to other published COVID vaccine candidates, as well as common marketed common flu vaccines. The company recently entered an exclusive licensing agreement with the Serum Institute of India to support minimum of 1B doses for India and low- and middle-income countries, as well as a partnership with Takeda to support the production of over 250M annually for Japan.
2. **Medicago:** Leveraging a plant-based vaccine production platform.
3. **VBI Vaccines/National Research Council of Canada:** VBI was recently awarded CAD \$56M by the Canadian government to accelerate vaccine developments efforts through Ph2 testing. The initiation of clinical studies is expected by YE20.
4. **Sanofi:** Sanofi was recently awarded \$2.1B by Operation Warp Speed to supply the US with 100M doses in 2021 with the option for up to 500M doses. Similarly, Sanofi has entered agreements with the UK to supply up to 60M doses and is in negotiations with the EU to supply up to 300M doses in 2021. Ph1/2 testing is expected to begin September 2020, with Ph3 to start YE20 and possible regulatory approval 1H21.
5. **Biological E:** Ph1 testing is expected to start September 2020. The company claims it has the manufacturing capacity to produce 80M-100M doses/month with this platform, although little information about this program is available within the public domain.
6. **IMV:** Ph2 by YE20. They have recently been granted CAD \$4.15M by the Canadian government to progress their candidate DPX-COVID-19 through Ph1.
7. **Intravacc/EpiVax/CimCure/Celonic Group:** The program plans to be in the clinic in 2021, and has recently entered a research agreement with Celonic Group (CDMO), although the manufacturing capacity of this joint venture is unclear.
8. **Medigen/NIAID/Dynavax:** Ph1 testing is expected to start 4Q20.

#### WHOLE VIRUS VACCINES:

9. **Sinovac Biotech (PiCoVacc):** This program is run by Chinese government and recently entered into a collaboration with the Brazilian Institute to initiate a Ph3 trial, committing to share 60M-100M doses through this agreement. Sinovac currently has the capacity to produce ~100M doses annually and is aiming to triple capacity to ~300M doses largely for domestic supply in 2021.
10. **Bharat Biotech International (Covaxin):** Recently entered Ph2 clinical testing.



**11. Valneva:** Valneva expects to enter clinical studies by YE20 with potential regulatory approval 2H21. They have recently reached an agreement with the UK to provide up to 100M doses of its inactivated whole virus candidate, which will be manufactured at its facilities in Livingston, Scotland and Solna, Sweden.

### ADENOVIRUS VECTOR VACCINES:

**12. JNJ/Emergent Biosolutions:** While their lead candidate failed to provide sterilizing immunity in an NHP model, it did provide protection from severe disease. Ph1/2 trial started July 2020. 100M doses pledged to the US and negotiations for 200M to the EU.

**13. AstraZeneca/Vaccitech/ University of Oxford (AZD1222):** Faster into clinical development than JNJ. They also reached a licensing deal with Chinese firm BioKangtai for 200M doses annually. Early data from a Ph1/2 RCT trial enrolling >1,000 patients showed that AZD1222 produced neutralizing antibodies at best on par with human convalescent control, which may not be enough to provide sterilizing immunity but could protect from severe disease.

**14. Cansino Biologics (Ad5-nCoV):** Low levels of neutralizing antibodies were reproduced in their expanded Ph2 cohort, signaling that this vaccine may not provide strong protection.

**15. Gamaleya Research Institute:** Russian program with very little publicly available information. They started Ph1 trials 2Q20 for their adenovirus based vaccine and recently announced this candidate is expected to get conditional registration on August 12th, only requiring trials on another 1,600 people with production likely to start in September. Although – concerningly – the world has seen no clinical data from this program, this could be the first registered COVID-19 vaccine.

**16. Altimune (AdCOVID)/Vigene Biosciences/UAB:** Ph1 set to start 4Q20 with topline safety and serology data expected 2021. The company is scaling up manufacturing to reach 100M doses annually with Vigene Biosciences.

### MRNA VACCINES:

**17. Moderna Therapeutics/Lonza (mRNA-1273):** While Moderna is testing 50/100 ug doses in a 600-patient Ph2 trial, they will move forward with the 100 ug for a 30K volunteer Ph3 trial July 2020 (with total \$955M support from BARDA) due to reactogenicity concerns with the 250 ug dose.

**18. BioNTech/Pfizer (BNT162):** Interim data from Ph1/2 trials in Germany and the US demonstrated that the modRNA vaccine candidate 162b1 (RBD, 30 ug prime/boost) induced neutralizing antibodies levels ~2x greater than levels with human convalescent sera control. However, the company will move forward with a new lead candidate 162b2 (full length spike, 30 prime/boost ug) for their Ph2b/3 RCT starting July, which elicited a broader T cell response in elderly volunteers. They are guiding to manufacturing 100M doses by YE20, scaling up to 1.3B doses in 2021 with recent manufacturing agreements with the UK (60M), the US (100M-600M), and Japan (120M).

**19. Arcturus/Duke University:** They announced a Ph1/2 clinical trial to begin 3Q20 in Singapore and a recent partnership with Catalent will help them scale up to 100M doses in 2021.

### DNA VACCINES:

**20. Inovio/Beijing Advaccine Biotechnology (INO-4800):** Recent data from an NHP challenge model demonstrated that INO-4800 did not provide complete protection in the lungs or nasal cavity against COVID-19, which is a weak signal moving into clinical trials.

**21. Zydus Cadila:** Initiated a Ph2 trial 3Q20 and guiding towards 100M doses annually starting 2Q21.

### MEASLES VECTOR:

**22. Merck/Institut Pasteur/University of Pittsburgh:** The University of Pittsburgh will develop a candidate, while Merck (which acquired Themis) is responsible for supporting the clinical trial and manufacturing. The company plans to enter clinical testing 3Q20.

## VACCINES: VERSION 5 UPDATES: JULY 22, 2020

### NEW PROGRAMS ADDED (6):

1. **Anhui Zhifei Longcom Biopharmaceutical/ Institute of Microbiology, Chinese Academy of Sciences**
2. **Vaccine Pty Ltd/Medytox**
3. **Institute of Medical Biology , Chinese Academy of Medical Sciences**
4. **Bharat Biotech International**
5. **Verndari Inc**
6. **People's Liberation Army (PLA) Academy of Military Sciences/Walvax Biotech**

### UPDATES TO EXISTING VACCINE PROGRAMS (18):

1. **Novavax/Emergent Biosolutions (NVX-CoV2373):** Recognized by Operation Warp Speed (OWS). Partnered with BARDA.
2. **ExpreS2ion Biotechnology/AdaptVac/Bavarian Nordic:** Partnered with Bavarian Nordic A/S, Europe's largest independent vaccine developer, this program is expected to start Ph1 trials in December 2020 with early data available 2021
3. **Medicago:** Phase 1 testing started July 2020 and Ph2/3 is expected to start October 2020 with possible approval 2H21
4. **Saiba/AGC Biologics:** Recently partnered with AGC biologics to manufacture and distribute at national scale.
5. **Sanofi:** Company guided to producing 100M-600M vaccine doses between YE20 and 2H21, and then scaling up to 1B doses annually YE21.
6. **Clover Biopharmaceuticals:** Expanded CEPI partnership with additional funding.
7. **University of Queensland/CSL Behring:** Phase 1 Trials started 3Q20.
8. **Sinopharm Group/Wuhan Institute of Biological Products/Beijing Institute of Biological Products:** Recently initiated Phase 3 trial in the UAE enrolling up to 15k volunteers.
9. **JNJ/Emergent Biosolutions:** Ph1 trial to start in July 2020 and the company is guiding that a Ph3 trial could start as early as September 2020. Recently signed a \$480M, five-year manufacturing agreement with Emergent Biosolutions to manufacture its COVID-19 vaccine.
10. **ASTRAZENECA/Vaccitech/ University of Oxford (AZD1222):** Signed agreements to provide hundreds of millions of doses to be delivered starting YE20 (100M UK, 300M US, 400M Serum Institute of India to provide for poorer countries, 300M CEPI/GAVI, and 300M EU).
11. **Cansino Biologics (Ad5-nCoV):** Publication of Ph1 trial results demonstrated that ~50% of participants have pre-existing immunity to Ad5, which greatly impedes immunogenicity and makes this vaccine candidate less relevant for the broader population.
12. **Gamaleya Research Institute:** Recently announced that Ph3 trials could start as early as mid-August 2020.
13. **Moderna/Lonza (mRNA-1273):** Moderna published Ph1 data testing 25/100/250 ug doses and reported levels of neutralizing antibodies for the 100 ug dose at 14 days after the boost that were ~4X greater than levels in their human convalescent sera control.

- 14. BioNTech/Pfizer (BNT162):** *Interim data from this study demonstrated that the modRNA vaccine candidate 162b1 (30 ug prime/boost) induced neutralizing antibodies levels ~2x greater than levels with human convalescent sera control. The company will move forward with a dose between 10 and 30 ug for their Ph2b/3 starting July.*
- 15. Inovio/Beijing Advaccine Biotechnology (INO-4800):** *From the Ph1 trial, 94% (34/36) volunteers seroconverted but no additional data have been released. A Ph2/3 trial is expected to start late summer.*
- 16. Zydus Cadila:** *Initiated a Ph1 trial 3Q20 and guiding towards 100M doses annually starting 2Q21.*
- 17. Osaka University/AnGes/Takara:** *Initiated a Ph1 trial and are focused on the Japanese domestic market with approval projected for MY21*
- 18. BioNet-Asia:** *Ph1 testing is projected to start November 2020 with 10,000 doses.*

## VACCINES: VERSION 4 UPDATES: JULY 2, 2020

### NEW PROGRAMS ADDED (6):

1. **VBI Vaccines/National Research Council of Canada**
2. **Gamaleya Research Institute**
3. **Memgen (MemVax)**
4. **Ntx**
5. **eTheRNA**
6. **University of Tokyo/Daiichi-Sankyo**

### UPDATES TO EXISTING VACCINE PROGRAMS (13):

1. **Sanofi:** Phase 1/2 trial moved up to September and the goal is to have it fully licensed by June 2021.
2. **Clover Biopharmaceuticals:** Initiated Phase 2 2Q20. Preliminary results are expected in August 2020.
3. **University of Queensland/CSL:** Guiding to 100 million doses YE20 with recent CSL collaboration.
4. **Sinovac:** Preliminary study results announced.
5. **Sinopharm/Wuhan/Beijing Institute of Biological Products:** 100% Seroconversion rate reported from phase 1/2. nAbs not reported. Aiming to produce 200M doses a year.
6. **Vaxart/Emergent Biosolutions/KindredBio:** Vaxart has been selected to participate in a NHP challenge study, organized by OWS.
7. **Moderna/Lonza (mRNA-1273):** Agreement with Catalent to provide vial filling, packaging capacity, and additional 24/7 staffing requirements to support an initial 100M doses 3Q20.
8. **CureVac:** CureVac received regulatory clearance to begin Phase 1 trials in Germany and Belgium.
9. **Translate Bio/Sanofi**
10. **Imperial College London:** Initiated Phase 1 June 2020.
11. **Inovio/Beijing Advaccine Biotechnology (INO-4800):** Inovio receives \$71M contract from DoD to manufacture intradermal DNA delivery device. Guiding to report Phase 1 clinical trial results in late June.
12. **Genexine/Binex (GX-19):** Initiated Phase 1/2 trials in June and guiding towards data September 2020.
13. **Entos Pharma/Epivax/Fusogenix:** Initiated Phase 1/2 trials with data expected in September and the final product expected YE21.

## VACCINES: VERSION 3 UPDATES: JUNE 15, 2020

### NEW PROGRAMS ADDED (5):

1. **Abnova/PharmaJet**
2. **Immunity Bio/NantKwest (Ad5COVID-S/N)**
3. **Intravacc/EpiVaxx**
4. **Ntx (multivalent mRNA)**
5. **Vaxess Technologies**

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### UPDATES TO EXISTING VACCINE PROGRAMS (4):

1. **BioNTech/Pfizer (BNT162):** *Recognized by Operation Warp Speed (OWS) as one of five vaccine candidates most likely to work.*
2. **BioNTech/Pfizer (BNT162):** *Recognized by Operation Warp Speed (OWS) as one of five vaccine candidates most likely to work.*
3. **Novavax/Emergent (NVX-CoV2373):** *Moved to human trials*
4. **Moderna/Lonza (mRNA-1273):** *Recognized by Operation Warp Speed (OWS) as one of five vaccine candidates most likely to work.*

**VACCINES:**  
**VERSION 2 UPDATES: MAY 22, 2020**

**NEW PROGRAMS ADDED (7):**

- 1. Bharat Biotech/Thomas Jefferson University**
- 2. Entos Pharma/Epivax/Fusogenix**
- 3. Indian Immunologicals Ltd/Griffith University**
- 4. Medigen Vaccine Biologics Corporation/NIAID/Dynavax**
- 5. Sensei Biotherapeutics**
- 6. Symvivo**
- 7. University of Wisconsin–Madison/FluGen/Bharat Biotech (CoroFlu)**

# THERAPEUTICS UPDATES:

## VERSION 7: SEPTEMBER 15, 2020

### NEW PROGRAMS ADDED (17):

#### TARGET VIRAL REPLICATION:

1. Eli Lilly/AbCellera Biologics (LY-CoV555 + LY-CoV016)
2. AstraZeneca (AZD7442/ AZD8895 + AZD1061)
3. Beigene/Singlomics (BGB DXP593)
4. Immunome (synthetic convalescent plasma)
5. Pfizer (PF-07304814)
6. RA Capital's Incubator

#### TARGET THE IMMUNE RESPONSE:

7. Primmune (PRTX007)
8. Fate Therapeutics (FT-516)

#### TREAT OR PREVENTS ARDS:

9. Kancera AB (AZD-8797/KAND567)
10. Dompe (reparixin)
11. Verona Pharma (ensifentrine)
12. Viela Bio (VIB7734)
13. Boehringer Ingelheim (Ofev/nintedanib)
14. Mereo (alvelestat)

#### PREVENT ORGAN FAILURE:

15. Bayer (Xarelto/rivaroxaban)
16. Daiichi Sankyo (Savaysa/edoxaban)
17. Takeda (Takhzyro/lanadelumab)

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## UPDATES TO EXISTING PROGRAMS (19):

### TARGET VIRAL REPLICATION:

1. **Regeneron/Roche (REGN-COV2/REGN10933+REGN10987):** *Partnered with Roche*
2. **Vir Biotechnology/GSK (VIR-7831/GSK4182136):** *Moved to human trials*
3. **Sorrento Therapeutics (COVI-GUARD/STI-1499):** *Moved to human trials*
4. **Convalescent Plasma:** *Approved for Emergency Use Authorization*
5. **Ansun Biopharma (DAS181):** **FAILED**

### TARGET IMMUNE RESPONSE:

6. **Romark Laboratories (NT-300/nitazoxanide):** *RCT readout moved to 4Q20*
7. **Synairgen (SNG001/Interferon beta 1a):** *RCT readout moved to 1Q21*

### PROTECT THE LUNG FROM INJURY:

8. **Constant Therapeutics (TXA127/Angiotensin 1-7):** *RCT readout moved to 4Q20*

### TREAT OR PREVENT ACUTE RESPIRATORY DISTRESS SYNDROME (ARDS):

9. **(dexamethasone):** *Standard of Care*
10. **Eli Lilly (Olumiant/baricitinib):** *Positive Ph3 Trial*
11. **Pharming (Ruconest/recombinant C1 esterase inhibitor):** *RCT readout moved to 1Q21*
12. **Enlivex Therapeutics (Allocetra):** *RCT readout moved to 4Q20*
13. **AstraZeneca (acalabrutinib):** *RCT readout moved to 4Q20*
14. **BeiGene (Brukinsa/zanubrutinib):** *RCT readout moved to 1Q21*
15. **Sorrento Therapeutics (STI-5656/abivertinib maleate):** *RCT readout moved to 1Q21*
16. **Biohaven (BHV-3500/zavegepant):** *RCT readout moved to 4Q20*
17. **Vanda pharmaceuticals (tradipitant):** *RCT readout moved to 4Q20*
18. **Verastem (Copiktra/ duvelisib):** *RCT readout moved to 1Q21*
19. **Biotest (Trimodulin):** *RCT readout moved to 1Q21*



## **THERAPEUTICS:** **VERSION 6: AUGUST 14, 2020**

### **NEW PROGRAMS ADDED (20):**

#### **TARGET VIRAL REPLICATION:**

1. **Adagio**
2. **Brii Biosciences (BRII-196)**
3. **Brii Biosciences (BRII-198)**
4. **SInocelltech (SCTA01)**

#### **TARGET THE IMMUNE RESPONSE:**

5. **(peginterferon alfa-2b)**

#### **TREAT OR PREVENTS ARDS:**

6. **AbbVie (cenicriviroc)**
7. **Rapa Therapeutics (RAPA-501)**
8. **Denali Therapeutics/ Sanofi (DNL758/SAR443122)**
9. **AI Therapeutics (apilimod mesylate/LAM-002A)**
10. **NeuroActiva (Traneucorin/NA-831)**
11. **Grifols (Gamunex-C)**
12. **Bristol-Myers Squibb (Orencia/abatacept)**
13. **Takeda (Finazyr/icatibant)**
14. **BioAegis (rhu-pGSN)**
15. **Heron (Cinvanti/aprepitant)**
16. **Monopar Therapeutics/ NorthStar Medical Radioisotopes (MNPR-101 radiolabelled)**
17. **Thirty Respiratory (RESP301)**
18. **ReviveMed (bucillamine/REV-002)**
19. **Angion (ANG-3777)**

#### **PREVENT ORGAN FAILURE:**

20. **Reata (bardoxolone methyl)**
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## UPDATES TO EXISTING PROGRAMS (12):

## TARGET VIRAL REPLICATION:

1. **Bausch Health (Virazole/ribavirin):** *RCT readout moved to 4Q20*
2. **JNJ (Prezcobix/darunavir + cobicistat):** **FAILED**
3. **Ascletis (ASC09 + ritonavir):** *Completed trial*
4. **Karyopharm (Xpovio/selinexor):** *Completed trial*
5. **(azithromycin + hydroxychloroquine):** **FAILED**
6. **(azithromycin + chloroquine):** **FAILED**

## TARGET IMMUNE RESPONSE:

7. **Synairgen (SNG001/Interferon beta 1a):** *Completed trial*

## PROTECT THE LUNG FROM INJURY:

8. **Constant Therapeutics (TXA127/Angiotensin 1-7):** *RCT readout moved to 4Q20*

## TREAT OR PREVENT ACUTE RESPIRATORY DISTRESS SYNDROME (ARDS):

9. **Roche (Actemra/tocilizumab):** **FAILED**
10. **Cytodyn (Ieronlimab):** *RCT readout moved to 4Q20*
11. **Abbvie/JNJ (Imbruvica/ibrutinib):** *RCT readout moved to 1Q21*
12. **Amgen (Otezla/apremilast):** *RCT trial started, readout date is 4Q20*
13. **Aerpio Pharmaceuticals (razuprotafib):** *RCT trial started, readout date is 4Q20*

## THERAPEUTICS: VERSION 5: JULY 22, 2020

### NEW PROGRAMS ADDED (10):

1. **Arrowhead Pharmaceuticals (ARO-COV)**
2. **Rigel (Tavlesse/fostamatinib)**
3. **Merck KGaA (M5049)**
4. **Equillium/Biocon (itolizumab)**
5. **Apeptico (solnatide)**
6. **Roche (Pulmozyme/dornase alfa)**
7. **Chrysalis (TP508)**
8. **Akebia Therapeutics (vadadustat)**
9. **Chiesi (Curosurf/poractant alfa)**
10. **Sedana Medical (IsoConDa/isoflurane)**

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### UPDATES TO EXISTING THERAPEUTICS PROGRAMS (3):

1. **Celltrion:** *Moved to Human Trials. RCT readout expected 4Q20*
2. **EUSA Pharma (Sylvant/siltuximab):** *RCT readout expected 4Q20*
3. **InflaRx (IFX-1):** *RCT readout expected 4Q20*

## THERAPEUTICS: VERSION 4 UPDATES: JULY 2, 2020

### NEW PROGRAMS ADDED (45):

1. Aridis (AR-701)
2. Formycon
3. Alphamab/Institut Pasteur Shanghai
4. pHion Therapeutics (PTX-G1)
5. Mithra Pharmaceuticals (estetrol)
6. (favipiravir)
7. Gilead (remdesivir) inhaled
8. PTC Therapeutics (PTC299)
9. Geneone (GLS-1200)
10. SaNOtize (NORS)
11. Union (UNI911/nicloasamide)
12. Leidos/Orgenesis (ranpirnase)
13. NPO Petrovax (polyoxidonium/azoximer bromide)
14. (ramipril)
15. Novoteris/Mallinckrodt (Thiolanox)
16. Actelion (Ventavis/iloprost)
17. Diffusion (trans sodium crocetinate)
18. Merck (MK-5475)
19. Novartis (MAS825)
20. (infiximab)
21. Syndax (axatilimab/SNDX-6352)
22. AVM (AVM0703/dexamethasone)
23. Cytocom/Immune Therapeutics (Lodonal/low dose naltrexone)
24. Dimerix (DMX-200)
25. Argenx (ARGX-117)
26. Caladrius (CLBS119)
27. Stemedica Cell Technologies (CLBS119)
28. Celltex (AdMSCs)
29. Hope Biosciences
30. Aspire (ACT-20)
31. Pluristem (PLX-PAD)
32. Sorrento Therapeutics (STI-5656/abivertinib maleate)
33. Fulcrum (Iosmapimod)
34. Aclaris (ATI-450)
35. Verastem (Copiktra/ duvelisib)
36. Laurent (LAU-7b/fenretinide)
37. Edesa (EB05)
38. (ulinastatin)
39. Implicit (IC14)
40. Ampio Pharmaceuticals (Ampion)
41. Palatin (PL8177)
42. CSL Behring (garadacimab/CSL312)
43. Boehringer Ingelheim (Aggrenox)
44. Fulcrum Pharma/SIRS Therapeutics (FX06)
45. Amarin (Vascepa/icosapent ethyl)

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### UPDATES TO EXISTING THERAPEUTICS PROGRAMS (6):

1. Tychan (TY027): *Moved to human trials*
2. Pharmstandard (Arbidol/umifenovir): **FAILED**
3. (lopinavir + ritonavir): **FAILED**
4. Genoscience Pharma (GNS561): **SUSPENDED**
5. (chloroquine): **FAILED**
6. (interferon beta-1b): *Completed Phase 2 trial*
7. Sanofi/Regeneron (Kevzara/sarilumab): **FAILED**

## THERAPEUTICS: VERSION 3 UPDATES: JUNE 15, 2020

### NEW PROGRAMS ADDED (43):

1. Abbvie/Harbour BioMed (47D11)
2. AB Science (masitinib + isoquercetin)
3. Aerpio Pharmaceuticals (razuprotafib)
4. Agenus (AgenT-797)
5. Altimune (T-COVID)
6. Anivive (GC376)
7. Apogenix (asunercept)
8. Applied Therapeutics (AT-001)
9. ARCA Biopharma
10. Ashvattha (OP-101)
11. Atriva (ATR-002)
12. Biocad (levilimab/BCD-089)
13. Biophytis (Sarconeos/BIO101)
14. BLife Therapeutics (AP-003/Interferon  $\alpha$ 2b)
15. Brii Biosciences/Tsinghua University/3rd People's Hospital of Shenzhen
16. Cellenkos (CK0802)
17. Cerecor (CERC-002)
18. Edesa Biotech/NovImmune (EB06)
19. Enlivex (Allocetra)
20. Ennaid Therapeutics/Catalent (ENU200)
21. Ensysce (nafamostat)
22. Exvastat (imatinib)
23. Faron (Traumakine/interferon beta-1a)
24. Fibrogen (pamrevlumab)
25. GSK (otilimab)
26. IDBiologics/Vanderbilt University
27. INmune Bio (XPro1595) Yumab
28. Leading BioSciences (LB1148/tranexamic acid)
29. MedinCell (ivermectin)
30. Nichi-Iko/Daiichi Sankyo/University of Tokyo/RIKEN (nafamostat)
31. Octapharma (Octagam/Immune Globulin Intravenous)
32. Partner Therapeutics (Leukine/sargramostim)
33. PhaseBio (PB1046)
34. PureTech (LYT-100 /deupirfenidone)
35. RedHill (Yeliva/opaganib)
36. Renibus (RBT-9)
37. resTORbio (RTB101)
38. Sun Pharma (nafamostat)
39. Trevana (TRV027)
40. Tychen (TY027)
41. UCB (zilucoplan)
42. Veru (VERU-111)
43. Yumab

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### UPDATES TO EXISTING THERAPEUTICS PROGRAMS (6):

1. AbCellera/Eli Lilly (LY-CoV555): *moved to human trials*
2. (dexamethasone): **EFFECTIVE**
3. (hydroxychloroquine): **FAILED**
4. Junshi Biosciences/Eli Lilly (JS016): *moved to human trials*
5. Merck/Ridgeback Biotherapeutics (EIDD-2801): *moved to phase 2*
6. Regeneron (REGN-COV2/REGN10933 + REGN10987) + BARDA: *moved to phase 1*

## THERAPEUTICS: VERSION 2 UPDATES: MAY 22, 2020

### NEW PROGRAMS ADDED (41):

1. Abbvie/JNJ (Imbruvica/ibrutinib)
2. Abivax (ABX-464)
3. Acer Therapeutics (emetine)
4. Alderya (ADX-1612)
5. Alderya (ADX-629)
6. (almitrine)
7. Amgen (Otezla/apremilast)
8. (amiodarone)
9. Amyndas (AMY-101)
10. Apellis (APL-9)
11. BeiGene (Brukinsa/zanubrutinib)
12. Bristol-Myers Squibb (BMS-986253)
13. Bukwang (clevudine)
14. Can-Fite (CF101/piclidenoson)
15. Clear Creek Bio (brequinar)
16. CTI Biopharma (Enpaxiq/pacritinib)
17. eFFECTOR (eFT226/zotatifin)
18. Emergent BioSolutions (COVID-EIG)
19. Evelo (EDP1815)
20. (Futhan/nafamostat mesylate)
21. IGM Biosciences/Atreca/Beigene
22. Immunic (IMU-838)
23. ImmunityBio (N-803)
24. Innate Pharma (IPH5401/avdoralimab)
25. (ivermectin)
26. JNJ (Plivensia/sirukumab)
27. Kaleido Biosciences (KB109)
28. Molecular Partners
29. Oryzon Genomics (vafidemstat)
30. (prazosin)
31. RevImmune (CYT107)
32. Roche (MTPS9579A/astegolimab)
33. Roche (UTTR1147A)
34. Romark (NT-300/nitazoxanide)
35. R-Pharm/Cromos Pharma (olokizumab)
36. R-Pharm/Cromos Pharma (RPH-104)
37. Sorrento (COVI-GUARD/STI-1499)
38. Sorrento (COVI-SHIELD)
39. (telmisartan)
40. (valsartan)
41. (verapamil)

# DIAGNOSTICS UPDATES:

## VERSION 3 UPDATES: SEPTEMBER 21, 2020

### NEW PROGRAMS ADDED (6):

#### COVID DIAGNOSTICS TESTS:

1. Roche Molecular Systems, Inc. (cobas SARS-CoV-2 & Influenza A/B Nucleic Acid Test for use on the cobas Liat System)
2. Visby Medical, Inc. (Visby Medical COVID-19)

#### QUANTATIVE PLATFORMS:

3. University of Arizona Genetics Core for Clinical Services (COVID-19 ELISA pan-Ig Antibody Test)
4. Shenzhen New Industries Biomedical Engineering Co., Ltd. (MAGLUMI 2019-nCoV IgM/IgG)

#### QUALITATIVE LATERAL FLOW ASSAYS:

5. TBG Biotechnology Corp. (TBG SARS-CoV-2 IgG / IgM Rapid Test Kit)
6. Sugentech, Inc. (SGTi-flex COVID-19 IgG)

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### UPDATES TO EXISTING THERAPEUTICS PROGRAMS (3):

1. **Example: Labcorp (Pixel):** *There are 21 kits for home collection with EUA approval.*
2. **Example: Thermo Fisher (SARS-Cov-2):** *There are over 100 kits released under the EUA program. CLIA labs will often use one of these detection kits in combination with other general purpose extraction kits and instruments to validate an assay and get an EUA for their lab.*
3. **Example: Phosphorus Diagnostics LLC (Phosphorus COVID-19 RT-qPCR Test):** *There are over 50 labs with EUA approval.*

## DIAGNOSTICS UPDATES: VERSION 2 UPDATES: SEPTEMBER 4, 2020

### NEW PROGRAMS ADDED (7):

#### COVID SCREENING TESTS:

1. Abbott Diagnostics Scarborough, Inc. (BinaxNOW COVID-19 Ag Card)
2. Quidel Corporation (Sofia SARS Antigen FIA)
3. Becton Dickinson and Company (BD) (BD Veritor System for Rapid Detection of SARS-CoV-2)
4. LumiraDx UK Ltd. (LumiraDx SARS-CoV-2 Ag Test)

#### COVID DIAGNOSTICS TESTS:

5. Helix OpCo LLC (dba Helix) (Helix COVID-19 NGS Test)

#### QUANTATIVE PLATFORMS:

6. bioMérieux SA (VIDAS SARS-CoV-2 IgG)
7. BioCheck, Inc. (BioCheck SARS-CoV-2 IgG and IgM Combo Test)
8. Beijing Wantai Biological Pharmacy Enterprise Co., Ltd. (WANTAI SARS-CoV-2 Ab ELISA)

#### QUALITATIVE LATERAL FLOW ASSAYS:

9. Biocan Diagnostics Inc. (Tell Me Fast Novel Coronavirus (COVID-19) IgG/IgM Antibody Test)