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Where do Therapeutic companies stand in combating COVID-19 ?

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Global companies are on a mission to battle Coronavirus through their efforts to invent Novel Therapies, Vaccines and expedited Clinical researches

Coronavirus pandemic has been a global threat to both healthcare and economy across the world. More than 200 countries and territories have confirmed coronavirus cases, pushing billions of people into lockdown as health services struggle to cope.

As of today, 6 April 2020 the virus has infected 1,27,6302 people with around 69,526 reported deaths globally. Though WHO announced the enrolment of Spain and Norway for initial clinical trials, the struggle is still on the bar. US FDA approved certain quick solutions as vaccines or therapies for the immediate fight against the virus. The regulator on March 29 granted an emergency use authorization to hydroxychloroquine sulfate and chloroquine phosphate to treat COVID-19 patients. The emergency rules require patients to receive doses of the drugs donated to the U.S. federal stockpile by drug manufacturers.

In the U.S., many of the companies that are initiating development have received funding from two organizations: the Biomedical Advanced Research and Development Authority (BARDA) and the National Institute of Allergy and Infectious Diseases (NIAID). Some companies have also received funding from Coalition for Epidemic Preparedness Innovations (CEPI), a global organization funding to vaccine makers. Other companies are funding trials by themselves or through partnerships with other life sciences companies.

Here are some of the companies developing treatments or vaccines in the U.S. for COVID-19:

Company BioNTech SE and Pfizer Inc.

Type: Vaccine; **Stage:** Preclinical; **Name:** BNT162; **Announced**: 17 March

Pfizer announced that it would help develop and distribute BioNTech SE's COVID-19 vaccine candidate, though the deal excludes China. BioNTech plans to put the vaccine candidate into clinical trials in late April, in Germany and the U.S. It is testing the vaccine in collaboration with Shanghai Fosun Pharmaceutical Group Co. Ltd. in China.

Company: CytoDyn Inc.

Type: Treatment; **Stage:** Phase 2 clinical trial; **Name:** leronlimab; **Announced**: 31 March

CytoDyn, a preclinical biotechnology company based in Vancouver, said that the FDA is allowing a mid-stage trial for its experimental drug leronlimab for COVID-19 patients. The investigational therapy has been proposed as a treatment for mild-to-moderate respiratory complications that occur in patients with the disease.

Company: Dynavax Technologies Corp.

Type: Adjuvant platform for vaccines; **Announced**: March

Dynavax, the biopharmaceutical company announced that it's making its adjuvant technology available to companies developing COVID-19 vaccines through a partnership with CEPI. Dynavax's adjuvant technology can help provide an increased immune response to a vaccine.

Company: Gilead Sciences Inc.

Type: Treatment; **Stage:** Phase 3 clinical trials; **Name:** remdesivir

Gilead, a drugmaker is conducting a randomized, controlled clinical trial in Wuhan along with U.S. trials to test remdesivir as a treatment for mild-to-moderate forms of pneumonia in coronavirus patients. The trial was given the go-ahead by China's FDA in February. However, on 28 March Gilead halted due to an overwhelming number of applications after providing the investigational therapy to 1,000 patients.

Company: GlaxoSmithKline

Type: Pandemic adjuvant platform for vaccines; **Name:** AS03 Adjuvant System; **Announced**: 3 Feb

GSK announced that the CEPI-funded University of Queensland will have access to the British drugmaker's vaccine adjuvant platform technology, which is believed to both strengthen the response of a vaccine and limit the amount of vaccine needed per dose. On Feb. 24, GSK said that Clover Biopharmaceuticals Inc., a Chinese biotechnology company, is also using its adjuvant technology in combination with its vaccine candidate, COVID-19 S-Trimer, in preclinical studies.

Company: Heat Biologics Inc.

Type: Vaccine; **Stage:** Preclinical; **Announced**: 17 March

Heat Biologics has previously announced that it is developing a vaccine for the coronavirus with the University of Miami Miller School of Medicine and its vaccine candidate has been added to the WHO's "draft landscape" of 41 candidate vaccines. The company also recently joined the Alliance for Biosecurity, which may help it "secure government funding to support its rapid development, production, and distribution" of its COVID-19 vaccine, according to Maxim Group analysts.

Company: Inovio Pharmaceuticals Inc.

Type: DNA-based vaccine; **Stage:** Preclinical; **Name:** INO-4800

Inovio, an immunotherapies and vaccines developer and a $9 million CEPI grantee proposed INO-4800 for COVID-19 treatment after its preclinical testing and small-scale manufacturing. The company plans to begin clinical trials in the U.S. with 30 participants in April along with plans to launch human trials in China and South Korea, and says that it has a total of 3,000 doses prepared for the trials in the three countries. Inovio said it expects to have the first results from the trial in the fall and to have 1 million doses of the vaccine ready for additional clinical trials or emergency use by the end of the year. Inovio on 12 March announced a $5 million grant from the Bill & Melinda Gates Foundation to test a delivery device for its vaccine candidate. In late March, Inovio said that Ology Bioservices Inc., a contract development and manufacturing organization, had received an $11.9 million contract from the Department of Defense to support future potential manufacturing of Inovio's vaccine candidate for military personnel.

Company: Johnson & Johnson

Type: Vaccine; **Name:** To be named; **Announced**: 11 Feb

J&J was working with BARDA to test its vaccine candidate, with each organization providing $1 billion for research and development and the public-health organization funding the Phase 1 trials. Similar to GSK, J&J's AdVac and PER. C6 technologies are used to improve the development process for a vaccine. J&J has started preclinical testing on multiple candidates in collaboration with Beth Israel Deaconess Medical Center in Boston, and by 30 March it had identified a lead vaccine candidate. The company is scaling up its vaccine manufacturing capabilities in the U.S. and abroad to bring an affordable vaccine to the public on a not-for-profit basis for emergency pandemic use. J&J had partnered with BARDA on a project that aims to screen existing antiviral medications, including experimental or approved therapies, which may be effective against COVID-19.

The company aims to put its lead vaccine candidate in Phase 1 clinical trial in September 2020 and it may have investigational doses of the vaccine available by early 2021 for emergency use.

Company: Moderna Inc.

Type: RNA-based vaccine; **Stage:** Phase 1; **Name:** mRNA-1273

Moderna received funding from CEPI in January to develop an mRNA vaccine against COVID-19. On 24 Feb, it said it had shipped the first batch of mRNA-1273 to the NIAID for a Phase 1 clinical trial in the U.S.

Company: Novavax Inc.

Type: Vaccines; **Phase:** Preclinical; **Announced**: 26 Feb

Novavax, a preclinical biotechnology company, had several vaccine candidates in preclinical animal studies and plans to initiate a Phase I clinical study by June. In March the company received $4 million from CEPI to develop a COVID-19 vaccine and that Emergent BioSolutions Inc. would support contract development and manufacture for the experimental vaccine.

Company: Regeneron Pharmaceuticals Inc.

Type: Treatment; **Stage:** Preclinical; **Name:** To be named; **Announced**: 4 Feb

Regeneron announced it is working on developing monoclonal antibodies to treat COVID-19. The company's VelocImmune platform uses genetically-engineered mice with humanized immune systems in preclinical testing. The company aims to have hundreds of thousands of prophylactic doses ready for human testing by the end of August 2020.

Companies: Regeneron Pharmaceuticals and Sanofi

Type: Treatment; **Stage:** Phase 2/3?clinical trial; **Name:** Kevzara; **Announced**: 16 March

The FDA previously approved Kevzara, a treatment developed by Regeneron and Sanofi, as a therapy for rheumatoid arthritis in 2017. A Phase 2/3 clinical trial was started in mid-March to test Kevzara on COVID-19 patients in seven countries, including the U.S.

Company: Roche Holding AG

Type: Treatment; **Stage:** Phase 3; **Name:** Actemra

Roche's Actemra was first approved in 2010 as a rheumatoid arthritis drug. The Swiss drugmaker has initiated a Phase 3 clinical trial evaluating Actemra to treat COVID-19 patients. Roche expects to begin enrolling around 330 patients in early April, in the U.S. and elsewhere in the world. The company plans to examine patient mortality and need for mechanical ventilation or an intensive care unit stay among other primary and secondary endpoints. The trial is in partnership with BARDA.

Companies: Sanofi and Translate Bio Inc.

Type: Vaccines; **Stage:** Preclinical; **Name:** To be named; **Announced**: 18 Feb

Sanofi is working with BARDA to test a preclinical vaccine candidate for COVID-19 using its recombinant DNA platform. Sanofi Pasteur acquired this candidate through its 2017 acquisition of Protein Sciences for $750 million. The French drugmaker previously worked with the organization on flu vaccines. Sanofi announced a separate program with Translate Bio Inc. on 27 March to develop an mRNA vaccine. Sanofi aims to put a vaccine into a Phase 1 clinical trial between March 2021

and August 2021.

Company: Takeda Pharmaceutical Company Ltd

Type: Treatment; **Stage:** Preclinical; **Name:** TAK-888; **Announced**: 4 March

The Japanese drugmaker announced its attempt to test hyperimmune globulins for people who are at high risk for infection. As part of its research, Takeda said it would need access to plasma from people who have recovered from COVID-19 or those who have received a vaccine if one is developed. Dr Rajeev Venkayya, president of Takeda's vaccine business, is the co-lead of the company's COVID-19 response team. Takeda plans to examine whether other therapies, both experimental or with regulatory approval, may have treatment potential.

Company: Vaxart Inc.

Type: Vaccine; **Stage:** Preclinical; **Announced**: 31 Jan

Vaxart was one of the first companies to announce plans to develop a vaccine. In March the clinical-stage company announced that Emergent BioSolutions will help develop and manufacture its oral vaccine candidate. The company plans to start a Phase 1 clinical trial in the U.S. in the second half of 2020. As of 31 March, it had five vaccine candidates for preclinical testing.

Company: Vir Biotechnology Inc and Biogen Inc.

Type: Treatment; **Stage:** Preclinical; **Announced**: 25 Feb

Vir announced its collaboration with Shanghai-based WuXi Biologics to test monoclonal antibodies as a treatment for COVID-19. If the treatment is approved, WuXi will commercialize it in China, while Vir will have marketing rights for the rest of the world. The preclinical company is run by George Scangos, the former CEO of Biogen. It later announced a partnership with Biogen to help develop and manufacture its monoclonal antibodies as a potential treatment for COVID-19. Biogen will handle clinical manufacturing of Vir's antibodies, the company said. Vir later announced a research agreement with Generation Bio as part of its COVID-19 antibody development program.