

# Pipeline: Investigational Therapies for COVID-19

Currently, there are no antivirals licensed by the FDA to treat patients with COVID-19. While no specific treatment for coronavirus 2019 (COVID-19) is currently available, several therapies are being investigated globally.\*

## Antivirals

AbbVie: the Company is collaborating with select health authorities and institutions to determine the antiviral activity of lopinavir/ritonavir (Kaletra) against COVID-19.

AIM ImmunoTech: developing Ampligen, a broad-spectrum antiviral that will be tested as a potential treatment for COVID-19 in Japan. A significant survival effect was observed in a trial evaluating mice infected with the earlier Severe Acute Respiratory Syndrome (SARS) coronavirus.

Gilead: developing remdesivir, a broad-spectrum antiviral agent that is being investigated in a double-blinded, placebo-controlled study sponsored by the National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health (NIH). In addition, Gilead is initiating two phase 3 trials to evaluate the safety and efficacy of remdesivir in adults diagnosed with COVID-19, following a rapid review and acceptance by the Food and Drug Administration (FDA) of the investigational new drug filing for the novel antiviral.

## Immunotherapies and Other Investigational Therapies

Algernon Pharmaceuticals: developing ifenprodil, an N-methyl-d-aspartate (NDMA) receptor glutamate receptor antagonist, which is being prepared for US clinical trials for COVID-19 based on results of an animal study that showed the investigational therapy significantly reduced acute lung injury and improved survivability in H5N1 infected mice.

CEL-SCI: developing an immunotherapy using LEAPS, a patented T cell modulation peptide epitope delivery technology, to stimulate protective cell-mediated T cell responses and reduce viral load.

Innovation Pharmaceuticals: developing brilacidin, a defensin-mimetic, that mimics the human innate immune system and causes disruption of the membrane of pathogens, leading to cell death. It has already been tested in humans in phase 2 trials for other indications.



Mesoblast Limited: investigating remestemcel-L, an allogeneic mesenchymal stem cell (MSC) product candidate, as a treatment for patients with acute respiratory distress syndrome caused by COVID-19. Remestemcel-L, which is comprised of culture-expanded MSCs derived from the bone marrow of an unrelated donor, is administered in a series of intravenous infusions and is believed to have immunomodulatory properties to counteract inflammatory processes.

Q BioMed: partnering with Mannin Research to develop a potential treatment that addresses vascular leakage and endothelial dysfunction, which may potentially help patients with severe cases of COVID-19.

Takeda: developing an anti-SARS-CoV-2 polyclonal hyperimmune globulin (H-IG) to treat high-risk individuals with COVID-19 (TAK-888). Pathogen-specific antibodies from plasma will be collected from recovered patients (or vaccinated donors in the future) and will be transferred to sick patients to improve the immune response to the infection and increase the chance of recovery.

Tiziana: developing TZLS-501, which has been shown to rapidly deplete circulating levels of interleukin-6 (IL-6) in the blood, a key driver of chronic inflammation. Excessive production of IL-6 is believed to be associated with severe lung damage observed with COVID-19 infections.

## **Vaccines**

Altimune Inc: developing a single-dose, intranasal vaccine against COVID-19 using its proprietary NasoVAX technology. The vaccine is moving toward animal testing.

Applied DNA Sciences: collaborating with Takis Biotech to develop a DNA vaccine candidate using PCR-based DNA (“LinearDNA”) manufacturing systems; preclinical testing in animals are expected to begin in the second quarter of 2020.

Codagenix Inc: co-developing a live-attenuated vaccine with the Serum Institute of India using viral deoptimization.

GlaxoSmithKline: collaborating with Clover Biopharmaceuticals to develop a protein-based coronavirus vaccine candidate (COVID-19 S-Trimer) using Clover’s proprietary technology (Timer-Tag©) and combining it with GSK’s pandemic adjuvant system.

Inovio Pharmaceuticals: developing a DNA vaccine (INO-4800) to address COVID-19; human trials to begin in the US in April.



Johnson & Johnson: partnering with the Biomedical Advanced Research and Development Authority (BARDA) to develop a vaccine using Janssen's AdVac® and PER.C6® technology, which provide the ability to rapidly upscale production of an optimal vaccine candidate.

Moderna Inc: vials of the Company's mRNA vaccine (mRNA-1273) have been shipped to the National Institute of Allergy and Infectious Diseases to be used in a phase 1 study in the US.

Novavax: currently evaluating multiple recombinant nanoparticle vaccine candidates in animal models; initiation of phase 1 testing is expected in late spring of 2020. The COVID-19 vaccine candidates will likely include the saponin-based Matrix-M™ adjuvant to enhance immune responses.

Sanofi: collaborating with BARDA to develop a vaccine using Sanofi's recombinant DNA platform. The DNA sequence encoding the antigen will be combined into the DNA of the baculovirus expression platform and used to produce large quantities of the coronavirus antigen which will be formulated to stimulate the immune system to protect against the virus.