

Alliance for Cell Therapy Now

Advancing Regenerative Medicine and Cell Therapies for Patients in Need

Cell-Based Therapies Show Promise for Seriously Ill Patients with COVID-19

Federal Funding for Large-Scale, Randomized, Controlled Trials is Needed to Confirm Results and Help Bring Safe and Effective Treatments to Patients in Need

Washington, DC (March 24, 2021) – A new [report](#) released by [Alliance for Cell Therapy Now](#), an independent, non-profit organization guided by leaders representing academic and medical institutions, industry innovators, and patients, summarizes clinical studies that are now underway that explore the use of cell-based therapies for seriously ill patients with COVID-19.

According to the [report](#), there are at least 114 clinical studies that explore the use of cell-based therapies for patients with COVID-19, nearly all of which are either Phase 1 or Phase 2 studies. At least 140 review articles have been published over the last 12 months that describe the promise or potential of these therapies for those affected by this deadly disease.

More than 30 million Americans have tested positive for COVID-19 and more than 540,000 individuals have died. While vaccines are making their way to eligible populations and therapies are beginning to emerge, to date, no approved therapy has shown significant benefit for the most severe cases, in which individuals are hospitalized.

Early evidence shows that cell-based therapies—in particular, mesenchymal stromal cells (MSCs)—can play a key role in helping severely ill patients with COVID-19, given their immunomodulatory and anti-inflammatory characteristics.

While early results of clinical studies are promising, large-scale, randomized, placebo-controlled clinical trials, along with cell characterization and optimization and scaling of manufacturing, are needed to confirm early results and help bring safe and effective treatments to patients in need.

The largest barrier to conducting clinical research related to cell-based therapies is the high cost of conducting these studies. The financial barriers associated with clinical trials is particularly problematic for academic and research institutions and small biotechnology companies, who are responsible for nearly all of the clinical trials being conducted for COVID-19 both in the U.S. and abroad.

The Administration recognizes the lack of reliable and accessible treatments for COVID-19 and the need for investment in the development and manufacturing of therapies, as demonstrated both within the January 21, 2021 [Executive Order](#) which outlines policies to accelerate the development of novel therapies to treat COVID-19, and the [American Rescue Plan](#), which formed the basis for the COVID-19 relief package passed by Congress and signed into law by the President in early March 2021.

Congress has authorized nearly \$40 billion in funding for vaccines, therapeutics, and other medical supplies within three COVID-19 relief packages—two of which were passed and signed into law in 2020 and one of which was passed and signed into law earlier this year.

As the Administration establishes its priorities for the billions of dollars in funding authorized by Congress for COVID-19 vaccines and therapeutics, and as Congress considers FY 2022 appropriations, both should assure that a portion of funds for research and development are directed towards cell-based therapies to help patients with COVID-19, as well as other serious and life-threatening conditions.

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About Alliance for Cell Therapy Now

Alliance for Cell Therapy Now (ACT Now) is an independent, non-profit organization guided by leaders representing academic and medical institutions, industry innovators, and patients, that is working to advance safe and effective regenerative medicine and cell therapies for patients in need. See www.allianceforcelltherapynow.org