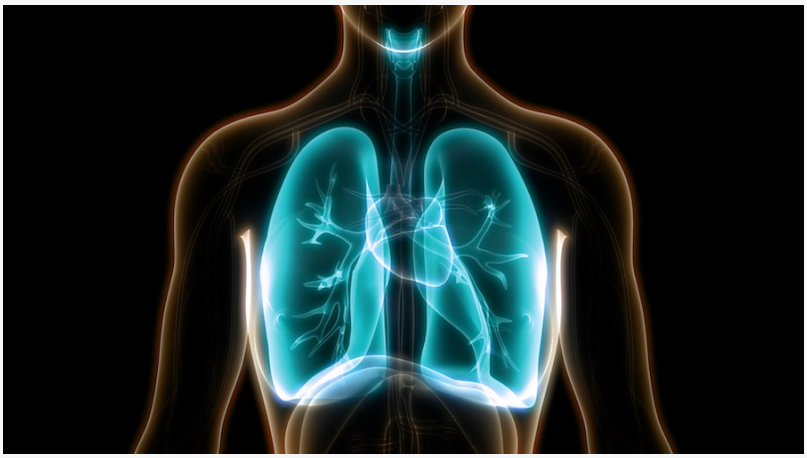
Personalized Stem Cells Receives FDA Approval to Treat COVID-19 Patients

Personalized Stem Cells, Inc. receives FDA approval to treat COVID-19 patients with stem cells.



POWAY, CALIFORNIA, US, July 22, 2020 /EINPresswire.com/ -- Personalized Stem Cells, Inc. (PSC) has received FDA approval for an Investigational New Drug (IND) application for the treatment of COVID-19 patients with stem cells. The first trial is named "CoronaStem 1" and will provide treatment for 20 hospitalized COVID-19 patients in California.

PSC applied for this IND with the FDA in April 2020 at the request of the White House Coronavirus Task Force. The expedited IND was submitted under the newly formed FDA Coronavirus Therapeutic Accelerator Program (CTAP), which helps to expedite the launch of FDA clinical trials for promising COVID-19 therapies. PSC Medical Director, Dr. Christopher Rogers, stated, "With nearly 3.9 million cases and over 140,000 deaths in the United States, PSC is ready to step up to the plate and launch this first study to evaluate what we believe is one of the most promising therapies. Stem cells have the potential to reduce the most serious complications of coronavirus infection."

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> *Dr. Christopher Rogers, PSC Medical Director*

PSC recently published a landmark peer-reviewed scientific article on the rationale behind using stem cells to treat COVID-19. With the rapid upswing in positive cases, it is more important than ever to get new therapeutics into testing and approved. PSC hopes to rapidly complete the CoronaStem 1 study and then proceed into a larger Phase 2 clinical trial and potentially into FDA compassionate use programs to reach more patients. PSC has already scaled up production of stem cells in its San Diego FDA-inspected stem cell manufacturing facilities in order to be ready to treat patients.

PSC CEO, Dr. Bob Harman, stated, “Stem cell doses are ready for clinical trial use in hospitalized patients now. Our physician partners will begin treating patients in the coming weeks.” The first trial will be conducted in a limited number of patients who are hospitalized for COVID-19 as outlined in the FDA submission, however FDA Expanded Use programs or Emergency Use Authorization could allow for many more patients to be treated. PSC is not soliciting patients for enrollment at this time due to the limited number of hospitals to be included in the CoronaStem 1 study.

PSC wants to acknowledge Allan Camaisa (CEO) and the team at Calidi Biotherapeutics for providing the stem cell lines used to manufacture the CoronaStem cells. Their generous help has allowed PSC to move forward rapidly. PSC also thanks the staff at sister company and CRO, VetStem Biopharma, for the manufacturing and regulatory support that made this approval a reality.

For those interested in more information about becoming involved with PSC, please click here.

About Personalized Stem Cells, Inc.
Personalized Stem Cells was formed in 2018 to advance human regenerative medicine based up the research of its parent company, VetStem Biopharma, Inc. This privately held biopharmaceutical enterprise, based near San Diego (California), offers qualified physicians who enroll, a GMP compliant stem cell product for use in approved clinical trials. PSC has licensed a portfolio of patents and applications in the field of regenerative medicine including patents for treating COVID-19 and related lung diseases.

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