

## COVID-19 Emergency Stem Cell Treatment Collaboration in San Diego

Personalized Stem Cells, Inc. and Calidi Biotherapeutics collaborate to rapidly bring a stem cell therapy into clinical trials for COVID-19 patients.

POWAY, CALIFORNIA, USA, April 13, 2020 /EINPresswire.com/ -- The scientific community is racing



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Dr. Bob Harman

to bring new COVID-19 treatments to critical patients. Stem cell therapy is one of the few approaches that directly treats the lung inflammation caused by COVID-19 in these seriously ill patients in the ICU. The goal is reduction in ICU time, reduced ventilator needs, and improvement in survival. Personalized Stem Cells, Inc. (PSC) and Calidi Biotherapeutics have teamed up to accelerate the production of stem cells for treatment of COVID-19 patients.

Several biotechnology companies have announced future clinical trials of proposed treatments, but Israeli and Chinese doctors have already published strikingly positive outcomes from treating COVID-19 patients with stem cells. Israel just announced results of compassionate treatment of seven COVID-19 patients with stem cells showing 100% recovery. Similar results are reported in China from PSC's collaborators in Wuhan and Beijing. PSC is using this front-line hospital experience from Chinese physicians to create the best treatment protocol possible for its U.S. clinical trials.

PSC was asked by the White House Task Force to apply to the FDA for expedited review of their IND application for treating COVID-19 patients with stem cells. PSC submitted its emergency assistance application to the FDA March 30th and its formal IND submission this week. PSC has FDA-inspected stem cell manufacturing facilities that are already in production of stem cell doses for clinical trials and compassionate use.

"Stem cell doses can be released for clinical trial use in May, depending on FDA clinical trial approval," said Dr. Bob Harman, CEO of PSC. The first trial will be conducted in San Diego, California in a limited number of patients hospitalized locally, but compassionate use could allow for many more patients to be treated.

Calidi Biotherapeutics is a San Diego oncology company that provided the stem cell lines to PSC, giving PSC a running start in the stem cell drug manufacturing process. "We are proud to have provided these pre-tested stem cell lines for PSC to accelerate their manufacturing to provide stem cells to patients afflicted with COVID-19," said Calidi CEO Allan Camaisa. "We have a long-standing relationship with Calidi and were already in the manufacturing process since January with these disease-screened stem cell lines. Calidi's generosity and collaboration saved us valuable weeks in this race to get stem cells into clinical trials," says Dr. Harman.

After this initial FDA trial is started, PSC will apply to FDA for a wider compassionate use approval and could also ship cells internationally. PSC is already ramping its manufacturing but is constrained by capital for critical supplies used in making these cells. "With adequate capital (investors or philanthropy), we could manufacture stem cell treatments for up to 8,000 patients per month," said Dr. Harman.

PSC is an essential services company and is running at full speed. "Our team is following our very rigorous personal protection program to keep our employees safe, while executing the mission with amazing passion to bring these stem cells to critical patients. I am humbled every day and work all the harder to support our team in this mission. As always, small business is ready to shoulder any task. This is a war and we are using every resource possible to support the front-line doctors trying to save patients' lives every day. We are even hiring new stem cell manufacturing technicians, doing our part to keep the economy running," says Dr. Harman.

## About Personalized Stem Cells, Inc.

Personalized Stem Cells was formed in 2018 to advance human regenerative medicine. 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 lung disease.

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