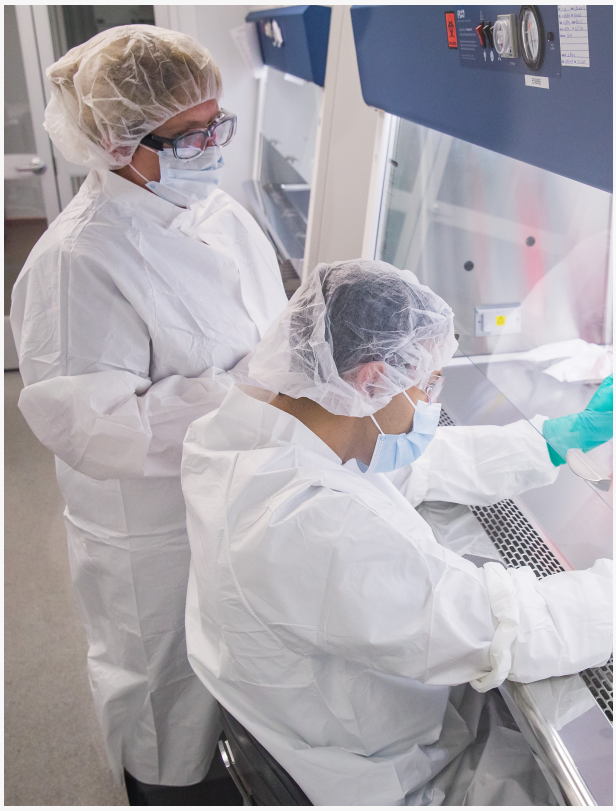
CoronaStem 1 Trial - Personalized Stem Cells Files for Expedited FDA Approval to Treat COVID-19 Patients

Personalized Stem Cells, Inc. filed an FDA request for accelerated review of its COVID-19 stem cell treatment IND application.



POWAY, CALIFORNIA, USA, April 21, 2020 /EINPresswire.com/ -- Personalized Stem Cells, Inc. (PSC) and its parent company, VetStem Biopharma, have filed an expedited review request for an Investigational New Drug (IND) application with the FDA for the treatment of COVID-19 patients with stem cells. The first trial is named “CoronaStem 1” and will provide treatment for twenty hospitalized COVID-19 patients with serious complications.

Recent news stories from Israel, China, and the U.S. show promising effectiveness of stem cells to treat the major medical lung issues of COVID-19 patients. PSC Medical Director, Dr. Christopher Rogers, stated, “I believe this is the most promising therapy being explored by medical scientists at this time and stem cells may potentially reduce the most serious complications of coronavirus infection.”

The FDA has a new program called the Coronavirus Therapeutic Accelerator Program (CTAP) to help expedite the launch of FDA clinical trials for promising COVID-19 therapies. PSC was asked by the White House Coronavirus Task Force to apply to the FDA CTAP program for expedited review of their IND application. 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.

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> *Dr. Christopher Rogers, PSC Medical Director*

PSC CEO, Dr. Bob Harman, stated, “Stem cell doses will be ready for clinical trial use in May, depending on FDA approval.” The first trial will be conducted in a limited number of patients hospitalized for COVID-19 as outlined in the FDA submission, but compassionate use approval 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. Additional information can be found on the PSC website.

More stem cell technicians and critical supplies are needed to further ramp up production of stem cells. Calidi Biotherapeutics has collaborated with PSC by providing needed cell lines and supplies to speed stem cell manufacturing, but money is also needed to pay the doctors, nurses, hospitals, imaging technicians, laboratories and others involved in performing the medical procedures for the clinical trial. PSC is a small company with dedicated employees who are working full time and stepping up to the challenge to rapidly bring stem cells to the fight against COVID-19, but we need everyone's help in this war.

PSC is reaching out to philanthropic groups such as the Gates Foundation and government granting groups, but more importantly, to the public. PSC has partnered with The San Diego Foundation, a 501c3 organization, to take in donations of any size to be focused on providing as many stem cell doses to as many COVID-19 patients as possible. The use of a 501c3 foundation allows the donations to be tax deductible, and the Foundation has generously offered to handle these donations with no management fees. Dr. Harman stated, "Everyone wants to help, and this is something very tangible that you can do. We are raising this additional capital to be able to provide stem cell therapy to a wider population and potentially to underserved groups."

Click here to make a donation.

For those interested in investment information for 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 lung disease.

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