

Brazilian Approval for Phase 2 COVID-19 Clinical Trial Using Stem Cells Manufactured by Performance Cell Manufacturing

Sorrento Therapeutics received Brazilian approval for a Phase 2 COVID-19 clinical trial using stem cells manufactured by Performance Cell Manufacturing.

POWAY, CALIFORNIA, US, June 8, 2021 /EINPresswire.com/ -- [Performance Cell Manufacturing](#) was contracted to manufacture stem cells for multiple clinical trials to treat COVID-19 induced acute respiratory distress syndrome (ARDS). The most recent clinical trial approval comes from the Brazilian Health Regulatory Agency (Anvisa), who authorized a Phase 2 COVID-19 stem cell clinical trial. Adipose derived stem cell company, [Personalized Stem Cells, Inc.](#) (PSC), developed the drug and first clinical trial, which they subsequently licensed to Sorrento Therapeutics (Nasdaq: SRNE, "Sorrento").



The new trial will be a Phase 2 pivotal, multi-center, randomized, controlled study to evaluate the safety and efficacy of allogeneic mesenchymal stem cell therapy for the treatment of ARDS as a result of COVID-19 infection. Sorrento expects to enroll 100 patients in the new study, with 33 placebo and 67 treated patients. The stem cell treatments will be administered every other day for a total of three infusions.

Approval for the Phase 2 trial came shortly after the completion of the FDA approved Phase 1b study which was conducted in California at UCSF Fresno. In that study, ten patients who were hospitalized and required oxygen supplementation, were all discharged from the hospital shortly after completing treatment with stem cells. In addition, there were no infusion related adverse events reported in any of the patients. These promising results helped secure approval for the Phase 2 study in Brazil.

The stem cell platform and FDA approval for the Phase 1b clinical trial were secured by Personalized Stem Cells shortly after COVID-19 was declared a global pandemic. Personalized

Stem Cells granted global rights to its adipose derived allogeneic mesenchymal stem cell (MSC) program, including the COVID-19 therapy candidate, to Sorrento in October 2020.

[About Performance Cell Manufacturing](#)

Performance Cell Manufacturing is the contract development and manufacturing division of VetStem Biopharma, Inc. PCM utilizes unique expertise acquired over the past 15 years of cell therapy development and manufacturing. The PCM team is focused on responding to the needs of cell therapy companies and applying technical, regulatory, and cGMP quality experience in order to form long term development and manufacturing relationships.

Michael Dale, Director of Business Development

Performance Cell Manufacturing

+1 858-218-8670

[email us here](#)

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