Personalized Stem Cells Announces Stem Cell Knee Arthritis FDA-Approved Phase 1/2a Clinical Trial Results

Personalized Stem Cells, Inc. announces the final results of its FDA-approved Phase 1/2a stem cell clinical trial for knee osteoarthritis.

POWAY, CALIFORNIA, US, March 30, 2021 /EINPresswire.com/ -- Personalized Stem Cells, Inc (PSC), a clinical stage biopharma cell therapy company, announces the results of its single knee osteoarthritis phase 1/2a clinical trial. The final study report has been submitted to the FDA for review and in support of a full scale randomized controlled trial to be conducted later this year.

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> *Dr. Bob Harman, PSC CEO*

Safety was the primary objective of this study and there were no serious adverse events reported. The efficacy of the experimental cell therapy in knee osteoarthritis was measured by the Knee Injury and Osteoarthritis Outcome Score (KOOS) and showed that 79.3% of the patients improved above the "minimal important change" (MIC) with an average improvement over baseline of 2.2 times the MIC. The KOOS measures pain, other symptoms, daily function, sports, and knee related quality of life outcome sub-scales.

PSC Founder and CEO, Dr. Bob Harman, stated, "We are pleased at the strong safety profile and efficacy results in this FDA-approved clinical study of stem cell therapy for knee osteoarthritis. The 15 years of veterinary experience with adipose derived stem cell therapy of our parent company, VetStem Biopharma, provided the basis for our FDA study submission and approval and provided valuable insights into the study design and conduct." There were 39 participants in the study enrolled across seven sites in the US.

The cellular drug used is autologous (patient-derived) mesenchymal stem cells from fat tissue. This study was unique in that the patients were treated with their own stem cells, which were harvested from a small lipoaspiration and then manufactured in an FDA-inspected laboratory.

The cells were quality tested and then released back to the physician investigator for injection. Each patient also had a sample of their cells stored at PSC for possible future use. This cell banking offering is a key component that will allow patients access to their cells for other approved studies without any further fat collection.

Dr. Harman stated, “Despite the challenges resulting from a global pandemic, we are proud to have reached this milestone in our first FDA approved clinical trial. This data supports our progress in the larger placebo-controlled clinical study.”

In addition to a Phase 2 knee trial, PSC plans to pursue FDA approval for a stem cell clinical trial to treat traumatic brain injury (concussion) in 2021. Stem cell therapy may provide answers and tools to address the chronic debilitation experienced by TBI victims. Recent studies have found that stem cells have demonstrated the ability to regenerate damaged nerve tissues which may lead to an improvement in disabilities and thereby quality of life. In addition, our collaborative clinical trial of stem cells for COVID-19 is providing great safety data on the use of adipose stem cells by the intravenous route.

About Personalized Stem Cells, Inc.
Personalized Stem Cells was formed in 2018 to advance human regenerative medicine by securing FDA approval for autologous stem cells for serious diseases with limited treatment options. This privately held biopharmaceutical enterprise, based near San Diego (California), is conducting clinical trials and developing stem cell products in the areas of orthopedics, pain, and traumatic brain injury. PSC has licensed a portfolio of patents and applications in the field of regenerative medicine which includes patent applications covering treatment of lung diseases including COVID-19.

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