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Personalized Stem Cells, Inc (“PSC”), a human adipose-derived stem cell company, has received FDA approval for a New Drug (IND) application for use of a person's own adipose-derived stem cells to treat their osteoarthritis. The first clinical trial, expected to begin in August, uses stem cells as a treatment of osteoarthritis in the knee.

This is the first of several planned clinical trials which will enable qualified PSC-enrolled physicians to provide FDA compliant, regulated quality cell therapy to patients suffering from osteoarthritis. PSC plans to conduct a series of FDA approved clinical trials starting with uses in orthopedics and expanding to other medical conditions in the future.

PSC is working with the FDA to provide alternatives to unregulated, in-clinic stem cell processing and unapproved "regenerative" therapies. The current environment of in-office, unregulated manufacturing of stem cells by physicians has come under serious regulatory action by the FDA, FTC, and the Federation of State Medical Boards. It is clear that the only allowed use of stem cells will be through legitimate FDA clinical trials with manufacturing in a controlled FDA inspected, GMP compliant facility.

PSC was founded by Robert Harman, DVM, MPVM and Michael Dale, both of whom also co-founded VetStem Biopharma and are both experienced serial entrepreneurs.

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“This first clinical trial will not only provide an approved method for treatment of knee arthritis, but it will also demonstrate that it is possible to work within the FDA regulatory guidelines to bring advanced stem cell therapy to the public. We have made remarkable progress in obtaining our first approval in less than one year after forming the company,” says Mr. Dale.

PSC has enrolled a limited number of clinical sites around the U.S. to provide treatment of knee osteoarthritis using stem cells. The physicians in this first clinical trial are among the most experienced stem cell physicians in the country. Contact PSC for clinical trial information, clinical trial site locations, or investment information.

About Personalized Stem Cells, Inc.
Personalized Stem Cells was formed in 2018 to advance and legitimize human regenerative medicine. This privately held biopharmaceutical enterprise, based near San Diego (California), offers qualified physicians who enroll, an FDA compliant autologous stem cell product (from patient’s own fat tissue) for use in FDA approved clinical trials. PSC is driving development and adoption of stem cell and regenerative medicine within the FDA-IND process by providing quality manufactured, safety tested cells, and well-defined clinical trials. PSC has licensed a portfolio of over 70 issued patents in the field of regenerative medicine.