News Release

For Immediate Release:   
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**PENNSYLVANIA COMPANY RECEIVES FDA APPROVAL TO BEGIN STEM CELL CLINICAL TRIALS**

INDIANA, PA – a Western Pennsylvania-based group of doctors and researchers who make up Antria Inc., have received approval by the U.S. Food and Drug Administration to begin testing the use of stem cells during certain plastic surgery procedures. Antria is the first company to gain approval to work with autologous adipose derived stem cells for elective facial cosmetic surgery.

Dr. Leonard Maliver, CEO of Antria, is pleased with the latest development. “It was a long road that seemed to take forever, but through perseverance and a good working relationship with the FDA, we eventually were given the ok to move forward,” he states.

In the United States, ethical concerns have kept many researchers from pursing stem cell treatments. Stem cells have been controversial because often the cells are taken from human embryos. Antria uses what are called adult stem cells, derived from an adult rather than an embryo, and they take them from one of the more abundant features of the human body: fat.

Dr. Shah Rahimian, President of Research and Development of Antria, says that researchers have looked to take adult stem cells from bone marrow. But the process, he said, results in fewer stem cells with fewer possibilities. There are 400 times as many stem cells in body fat than in bone marrow, he adds. Antria’s cell preparation process extracts, isolates, and purifies stromal vascular fraction (SVF) and is an excellent method in activating the stem cells.

Dr. Maliver and Dr. Rahimian have developed a process to remove adult stem cells from a patient’s fat tissue, condense and activate them, then insert them back into the same patient. This could eventually lead to using stem cells to form new blood vessels and to grow new cartilage in injured joints and limbs.

For now, the clinical trial approved by the FDA is simpler: to improve facial augmentation procedures. Under currently approved practices, when a plastic surgeon uses fat tissue as filler for a procedure, the lack of oxygen to the fat cells can cause them to die off and shrink over time. Stem cells should be able to form new blood vessels, restoring oxygen to the fat cells, keeping them viable.

The first phase of the trial involves six patients and will attempt to prove that using stem cells will not cause harm. All six patients have completed the process and Maliver says the results are very promising. The process involves removing fat tissue through liposuction; separating the stem cells from the fat cells; condensing and activating them; then inserting them back into the tissue that will be used in the facial augmentation. From start to finish the procedure takes less than two hours. Future phases will attempt to prove the stem cells actually work and will explore other ways they can be used. Dr. Maliver hopes they will end with FDA approval for their procedure and the reagents they use.

"We think that by using the stem cells, we can find cures for many, many diseases," Dr. Rahimian says. “The possibilities are really endless. We believe that stem cells will create a revolution in medicine, just like antibiotics did.”

Antria was formed in 2010 and, while applying to the FDA, conducted pre-clinical trials testing the fat-derived stem cells in test tubes to show how they change and grow. They have also developed a chemical proprietary reagent used to activate the stem cells that they hope to eventually sell as a kit to other companies.

Currently the company is run out of Dr. Maliver’s office with much of the laboratory work done at Indiana Regional Medical Center and Windber Research Institute. Dr. Maliver and Dr. Rahimian would like to build a new facility in Indiana from which to operate.

Dr. Maliver graduated medical school from Thomas Jefferson Medical School in 1980 and later completed his urological residency program in 1985 at Einstein-Montefiore Medical Center in Bronx, New York. Currently, he is an active staff member and board-certified urologist at Indiana Regional Medical Center. Dr. Maliver’s medical background and business experience allows Antria to effectively apply Antria Cell Preparation Process to various disease pathologies affecting patients worldwide.

Dr. Rahimian graduated medical school from the University of Istanbul in 2000 where he subsequently pursued and later received his PhD in public health. In the last 10 years, Rahimian has served as a senior scientist and general surgeon at Istanbul University, vice president and director of clinical research at Ilumina Clinical Associates, and a consultant for the biomedical industry throughout North America, Asia, and Europe. Currently, he is dedicated to move forward with the mission of Antria, which is to treat patients suffering from rare and common diseases using cell-based therapies. Dr. Rahimian’s past medical background and expertise will place the clinical research organization at the forefront of utilizing emerging therapeutic treatments in the field of regenerative medicine.

Dr. Francis Johns, a board certified plastic surgeon and a member of the American Society of Plastic Surgeons, has performed the surgeries in his Greensburg, PA, office, located at 400 Oakbrook Commons.

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