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First Study Testing Cell Therapy for Rotator Cuff Surgery Launches at HSS

Scott A. Rodeo, MD, a sports medicine surgeon and clinician-scientist at Hospital for Special Surgery (HSS) has launched a clinical trial of an experimental engineered cell therapy that aims to promote better healing of rotator cuff tears after surgery.

The rotator cuff is a collection of muscles and tendons at the shoulder joint that allows it to move. Overuse from repetitive overhead activities like swimming, tennis, or pitching a baseball, or acute injuries, can cause tears in the muscles or tendons of the rotator cuff.

"Arthroscopic shoulder surgery for rotator cuff tears is effective for relieving pain, restoring function and improving quality of life, but up to 25% of patients show incomplete or failed healing on imaging," says Dr. Rodeo. "The frequency of incomplete or failed healing is more pronounced in patients over the age of 60. That matters because more people today want to stay active as they age."

Many tissues in the body, including muscles and tendons, harbor stem cells that have the ability to form new tissues. The new clinical trial will test whether injecting an experimental cell therapy into both the muscle and the tendon of an injured rotator cuff will stimulate stem cell activity and promote better repair.

The engineered cell therapy product is E-CEL UVEC®, produced by San Diego based Angiocrine Bioscience, Inc. The investigational product consists of endothelial cells derived from the walls of the blood vessels of human umbilical cords that have been genetically modified to maintain their stability and their regenerative properties. The US Food and Drug Administration has granted the cell therapy Investigational New Drug (IND) status.

In a previous basic science study led by Dr. Rodeo, the cell therapy showed accelerated healing and an increase in the strength of the tendon attachment at the repair site, with no observable side effects, compared to surgery alone.

In the new clinical trial, patients with full-thickness rotator cuff tears who undergo arthroscopic surgical repair will receive two injections of the cell therapy: one into the tendon and one into the adjacent muscle. The study is open-label, meaning that all volunteers will know that they received the cell therapy.

The primary objective of the trial is to evaluate the safety of the cell therapy over 12 months. Dr. Rodeo and his research team will use blood tests to check whether the experimental cells

have migrated away from the rotator cuff repair site. The investigators will also evaluate patients' symptoms as well as shoulder strength, motion and healing as measured by MRI, ultrasound and patients' reports about their progress.

"Improving patients' symptoms with standard rotator cuff surgery is good, but strength improvements are less predictable," Dr. Rodeo says. "Identification of new ways to improve healing and muscle function would represent a significant advance in the treatment of rotator cuff tendon tears."

"We continue to enjoy working with Dr. Rodeo and his team on this long-term collaborative effort and look forward to providing support for this exciting new therapeutic application of E-CEL UVEC cells," commented Paul Finnegan, MD, Angiocrine's CEO.

The study opened September 1, 2019, with the goal of recruiting up to 20 patients ages 45 to 70 with full-thickness rotator cuff tears confirmed by physical examination and MRI. Eligible participants must already have tried and failed standard non-operative approaches, including a minimum of three months of physical therapy, oral anti-inflammatory medications, or a steroid injection.

For more information about the clinical trial (NCT04057833), please contact Camila Carballo, PhD, at carballoc@hss.edu or Daniel Edon, MS, at edond@hss.edu.

About HSS

HSS is the world's leading academic medical center focused on musculoskeletal health. At its core is Hospital for Special Surgery, nationally ranked No. 1 in orthopedics (for the tenth consecutive year), No. 3 in rheumatology by *U.S. News* & World Report (2019-2020), and named a leader in pediatric orthopedics by *U.S. News & World Report* "Best Children's Hospitals" list (2019-2020). Founded in 1863, the Hospital has one of the lowest infection rates in the country and was the first in New York State to receive Magnet Recognition for Excellence in Nursing Service from the American Nurses Credentialing Center four consecutive times. The global standard total knee replacement was developed at HSS in 1969. An affiliate of Weill Cornell Medical College, HSS has a main campus in New York City and facilities in New Jersey, Connecticut and in the Long Island and Westchester County regions of New York State. In addition, HSS will be opening a new facility in Florida in early 2020. In 2018, HSS provided care to 139,000 patients and performed more than 32,000 surgical procedures, and people from all 50 U.S. states and 80 countries travelled to receive care at HSS. There were more than 37,000 pediatric visits to the HSS Lerner Children's Pavilion for treatment by a team of interdisciplinary experts. In addition to patient care, HSS leads the field in research, innovation and education. The HSS Research Institute comprises 20 laboratories and 300 staff members focused on

leading the advancement of musculoskeletal health through prevention of degeneration, tissue repair and tissue regeneration. The HSS Global Innovation Institute was formed in 2016 to realize the potential of new drugs, therapeutics and devices. The HSS Education Institute is the world's leading provider of education on musculoskeletal health, with its online learning platform offering more than 600 courses to more than 21,000 medical professional members worldwide. Through HSS Global Ventures, the institution is collaborating with medical centers and other organizations to advance the quality and value of musculoskeletal care and to make world-class HSS care more widely accessible nationally and internationally. www.hss.edu.

About Angiocrine Bioscience, Inc.

Angiocrine Bioscience is an innovative, early clinical stage biotechnology company harnessing the power of engineered endothelial cells to heal and rejuvenate patients with serious medical conditions. The company is developing a line of engineered endothelial cell (E-CEL®) therapies for treating numerous life-threatening hematology and oncology conditions, as well as, in the field of organ and tissue regeneration. The core technology is founded on breakthroughs in vascular biology and stem cell research honed from decades of research by Professor Shahin Rafii and his laboratory at the Ansary Stem Cell Institute at Weill Cornell Medical College in New York City. Angiocrine Bioscience is at the front line in the next great medical revolution of utilizing living cells to improve the health and quality of life for patients in need.