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Histogenics Begins Phase III Study of NeoCart® Implant for Knee Repair

WALTHAM, MASSACHUSETTS, July 8, 2010 — Histogenics Corporation, a privately held tissue engineering company, announced that it has launched the pivotal Phase III study to evaluate the effectiveness of the NeoCart® autologous tissue implant in repairing knee cartilage injury.

This Phase III clinical program is the largest active study of cartilage repair in the US, comprising 245 patients at about 25 sites across the country. This prospective randomized study is the only large-scale study in the US to evaluate the potential clinical superiority of a neocartilage repair tissue implant (NeoCart) over the current standard, microfracture surgery. In microfracture surgery, small holes are made in the bone to allow a blood clot to fill the defect. With the NeoCart technique, the defect is repaired using neocartilagenous tissue made from the patient's own cells. The Phase III Study outcomes include pain relief and restoration of knee function.

"This is a condition that we see frequently, and we believe NeoCart offers the potential for an improved treatment option for our patients," said principal investigator Riley J. Williams III, M.D., Associate Attending Orthopedic Surgeon and Director of the Institute for Cartilage Repair, Hospital for Special Surgery, New York, who enrolled the first patient in late June. "We are pleased to participate in a study that could lead to a new standard therapy for a growing medical problem: cartilage injuries."

Dennis Crawford, M.D., Ph.D. (Surgical Director of Sports Medicine, Oregon Health & Science University, Portland OR), a principal investigator in the Phase I, II and III NeoCart trials, notes the relative simplicity of the NeoCart procedure and the clinical performance after NeoCart treatment. "The technique of surgically applying the Neocart is performed in less than an hour and without sutures. As such, it is completed as an outpatient procedure and has a recovery time analogous to simple knee arthroscopy. Physicians are anxious for new clinical tools with which to treat the problem of articular cartilage damage, and we are pleased to be a part of a large-scale study to further evaluate the potential of NeoCart."

Also participating in the trial is the OrthoCarolina Research Institute, led by James Fleischli, M.D., Chief of Orthopaedic Surgery at Mercy Hospital, and Dana Piasecki, M.D., Charlotte, North Carolina.

"Enrolling the first patients in this study is a milestone," said F. Ken Andrews, Histogenics President and Chief Executive Officer. "Demonstrating superiority of NeoCart over microfracture would open the door for potentially thousands of patients each year to take advantage of this new therapy." Based on numerous studies of knee arthroscopies, it is estimated that more than 500,000 severe cartilage lesions are treated each year in the US.

NeoCart® is an autologous engineered neocartilage implant created outside the body using the patient's own cartilage cells (chondrocytes) that are integrated into a three-dimensional collagen matrix. It has the biological characteristics of native articular cartilage.

About Histogenics

Histogenics develops and manufactures products that improve the body's ability to regenerate healthy cartilage, improve joint function and prevent degenerative disease. Formed in 2000, the company takes an interdisciplinary approach to engineering neocartilage that looks, acts, and lasts like hyaline cartilage. It is developing new treatments for sports injuries and other orthopedic conditions, where demand is growing for long-term alternatives to joint replacement. Histogenics has successfully completed Phase I and Phase II clinical trials in which the NeoCart autologous tissue implant's effectiveness is compared to that of standard microfracture surgery. Based in Waltham, Massachusetts, the company is privately held. Major investors include Boston Millennia Partners, Foundation Medical Partners, Altima Partners, Stryker Corporation, Inflection Point Partners, Takagi Sangyo and a private investor. For more information, visit <http://www.histogenics.com>.

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