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SinuSys Corp. to Support US Clinical Study of Next-Generation Steroid-Eluting Spacer Designed to Improve Outcomes for Functional Endoscopic Sinus Surgery (FESS)

PALO ALTO, Calif. – October 13, 2015 – SinuSys Corp., an innovative sinus health company, today announced initiation of a U.S. clinical trial studying the company's proprietary Restora™ technology platform incorporated in a steroid-eluting spacer designed to improve patient outcomes from functional endoscopic sinus surgery (FESS). The device is designed to improve upon currently available products by providing steady, predictable and localized drug delivery over a full seven-day period, as well as mechanical support, to prevent nasal tissue scarring and inflammation post-FESS.

This double-blind randomized trial will evaluate the investigational SinuSys technology in up to 50 patients with chronic rhinosinusitis. The study will compare the Restora device with the current standard of care. The trial is sponsored by Dr. Peter Catalano at St. Elizabeth's Medical Center in Boston and Dr. Mahmoud Ghaderi at Mercy Hospital in Philadelphia, with Dr. Catalano serving as principal investigator.

The primary endpoint of the trial is reduction in inflammation and scarring as measured by the Lund-Kennedy score at one month post-procedure. Secondary endpoints include the incidence of post-operative interventions and formation of synechiae (scarring of nasal tissue) at one month as well as and other outcomes measurements, including SNOT (Sino-Nasal Outcome Test) 22, evaluated at three months post-procedure.

"I look forward to evaluating this new, easy to use sinus spacer which promises to deliver a more predictable dose of a therapeutic agent during the time when its presence is most important to the healing process," said Dr. Catalano.

The Restora spacer is made of a non-resorbable rate-controlled membrane that delivers a steady dose of an anti-inflammatory agent (steroid) over a period of seven days. Because of its ability to locally and consistently deliver the drug, it has the potential to mitigate systemic use of steroids, which have been shown to be a health risk for patients. The device is designed to be easily removed during the first post-operative visit.

"We developed Restora at the request of leading physicians, who asked for a safe, mechanically robust and bio-inert spacer with longer and more stable drug delivery, with a view towards improving upon the current therapy today," said SinuSys Chief Executive Officer Thomas Schreck. "While this study is adjunctive to surgery, the SinuSys Restora technology platform also offers the potential to enable a stand-alone procedure

for virtually any patient requiring local drug delivery. This drug-infused device was developed based on the company's many years of institutional experience working with drug delivery technology."

FESS is the gold standard surgical intervention for chronic rhinosinusitis that is not adequately controlled with maximal medical therapy. In some patients, underlying inflammation (discharge, edema and polyposis), compounded by inflammation caused by surgical trauma, may lead to an uncontrolled healing response, which results in synechiae formation. While FESS is designed to open the nasal sinuses for ventilation and drainage, scarring can interfere with that process and often requires revision surgery. This scarring is the most common complication after sinus surgery, occurring in four to 35 percent of the more than 500,000 FESS cases performed annually in the U.S.

A U.S. pivotal trial is planned following the conclusion of the trial.

About SinuSys Corp.
SinuSys Corp. (www.sinusys.com) strives to improve the health of patients worldwide through the development and commercialization of the Restora™ drug delivery technology, the Vent-Os™ Sinus Dilation System and other osmotic and rate-controlled therapies for serious ear, nose and throat conditions. The company's proprietary technologies are designed to be atraumatic, tissue-sparing and easy to use, potentially enabling clinicians to intervene at earlier stages of sinus disease.

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