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SinuSys Corp. to Support Clinical Study of New Steroid-Eluting Spacer Designed to Improve Sinus Surgery Outcomes

PALO ALTO, Calif. – February 3, 2015 – SinuSys Corp., an innovative sinus health company, today announced commencement of a new clinical trial studying its proprietary drug-eluting spacer infused with steroids for use following functional endoscopic sinus surgery (FESS). The device is designed to steadily and predictably deliver the drug over a seven-day period before removal.

The double-blind randomized trial will study the investigational SinuSys technology in 48 patients with chronic rhinosinusitis. The study will compare the SinuSys technology with the current standard of care (silastic spacers) and will be evaluated at 7, 35 and 90 days. The trial is sponsored by St. Paul's Sinus Center in British Columbia, with Amin Javer, MD FRCSC FARS, Director of the St. Paul's Sinus Centre and Assistant Clinical Professor at the University of British Columbia serving as principal investigator.

Primary endpoints of the trial are a reduction in post-operative interventions and use of steroids. Secondary endpoints include the incidence of scarring, inflammation and other outcomes measurements, including SNOT (Sino-Nasal Outcome Test) 22, and Philpott-Javer and Lund-Kennedy scores.

"There is a clinical need for a spacer that delivers a therapeutic agent predictably over a longer period of time than is currently available. This new technology shows promise in doing that, with the ultimate goal of improving patient outcomes after FESS," said Dr. Javer.

The SinuSys spacer is made of a rate-controlled membrane designed to protect the steroid within from fluids in the sinus environment, eliminating the bolus dose of steroid often seen with polymer or biofilm. The device has the potential to mitigate systemic use of steroids, which has been shown to be a health risk for patients.

"While this study is adjunctive to surgery, the technology offers the potential to serve as a stand-alone procedure for virtually any patient requiring steroids," said SinuSys Chief Executive Officer Thomas Schreck. "This drug-infused device is designed to amplify the benefits of FESS and was developed based on the company's many years of institutional experience working with drug delivery technology."

Scarring in the sinus – or synechiae formation - is the most common complication after surgery, occurring in four to 35 percent of the more than five million FESS cases

performed annually in the U.S. Traditional spacers are only partially successful in promoting healing and preventing scarring, while drug-eluting stents deliver steroids in a bolus dose that does not continue through the healing process. Scarring has been shown to impair ventilation and FESS outcomes.

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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