Date: May 1, 2012 For Immediate Release



Contact: Ashwin Pushpala

(408) 483-6518

## SinuSys Corporation Initiates First In Man (FIM) Study of Novel Osmotic Dilation System for the Treatment of Chronic Sinusitis

Company building on strong pre-clinical results

**Palo Alto, Calif.** — May 1, 2012 — SinuSys Corporation, the developer of a novel osmotic dilation device for chronic sinusitis, today announced initiation of a multicenter, two-arm study in Canada to evaluate the safety and efficacy of the company's investigational sinus dilation system for the treatment of chronic sinusitis.

Chronic sinusitis affects more than 31 million people in the United States. It is more prevalent than heart disease and asthma and has a greater impact on patients' quality of life than chronic back pain or congestive heart failure. The majority of patients with chronic sinusitis are treated with oral antibiotics and/or nasal steroids, which can increase the risk of antibiotic resistance and cause unwanted side effects such as epistaxis (nose bleeds), nasal ulcers, and nasal and oral infections. The most effective treatments are Functional Endoscopic Sinus Surgery (FESS) and balloon dilation at high pressures, which are known to cause significant patient discomfort and are predominately conducted in a surgical suite under general anesthesia or IV sedation. The United States healthcare system currently spends more than \$8 billion annually on improving the health of patients with sinus conditions.

"Current sinusitis treatments include extended and redundant use of oral steroids and antibiotics, which are often not effective in treating this patient population," said Dr. Amin Javer, Director of the University of British Columbia Sinus Centre and study Principal Investigator. "Some patients cannot use these medications because of health risks or side effects, and others do not achieve effective relief. There is a clear need for an atraumatic, office-based therapy that restores proper drainage and ventilation for the moderate to severe sinusitis patients who do not find relief from medications."

"In light of our therapy's promising pre-clinical results, SinuSys and our investigator team are excited to have commenced clinical work with sinusitis patients," said Tom Schreck, President and Chief Executive Officer of SinuSys Corporation. "We hope that our work may one day provide relief to tens of thousands of chronic sinusitis patients who are suffering."

## **About the Sinus Dilation System**

The company's initial focus is to provide an osmotically driven, self-expanding medical device, which remodels and opens the ostium of the maxillary sinus to restore natural sinus drainage and ventilation without causing patient discomfort. The insert does not require external hardware or physician training to support expansion, and can be placed in an office-based setting into maxillary sinus ostia, mitigating the need for general anesthesia and invasive sinus surgery and minimizing patient recovery time. The insert

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utilizes SinuSys' proprietary osmotic dilation technology to enable an effective outpatient procedure that can be performed by Ear, Nose and Throat (ENT) physicians with minimal additional training.

## **About SinuSys Corporation**

SinuSys Corporation is a Palo Alto, California based medical device company which is managed and backed by leading pharmaceutical and medical device professionals. For more information, visit www.sinusys.com.