First Clinical Study Demonstrates Vent-Os Sinus Dilation System Effectively Establishes and Maintains Patency of Maxillary Sinus Ostia

The Associated Press

PALO ALTO, Calif.--(BUSINESS WIRE)--Apr 11, 2013--SinuSys Corporation, an innovative sinus health company, today announced that the Vent-Os™ Sinus Dilation System met its primary safety and effectiveness endpoints in its initial clinical study. The Vent-Os System is designed to gently open the sinus ostia, thereby restoring natural sinus drainage and ventilation using a simple, two-step interventional approach.

Twelve chronic rhinosinusitis (CRS) patients with maxillary sinus disease requiring functional endoscopic sinus surgery (FESS) were enrolled in the study, which was conducted at the University of British Columbia in Vancouver, Canada. The Vent-Os device was inserted into the maxillary sinus opening (MSO) at the start of surgery and removed after 60 minutes. No adverse events occurred during insertion or removal of the device. Ten patients completed three-month follow-up. In these patients, fourteen MSOs were evaluated for patency, of which thirteen (93 percent) were confirmed patent via endoscopy. The remaining opening was confirmed patent via subsequent CT scan.

The study results are featured as a poster presentation at the 2013 Combined Otolaryngology Spring Meetings (COSM) being held April 10-14 in Orlando, FL.

“Our initial clinical study of the Vent-Os System in FESS patients demonstrated the ability of the device to establish and maintain patency of the maxillary sinus ostia, as well as its potential as an option to treat earlier-stage CRS patients under local anesthesia,” said Amin Javer, MD FRCSC FARS, Director of the St. Paul's Sinus Centre and Assistant Clinical Professor at the University of British Columbia.

Additional results from the study will be presented by Dr. Javer at the 2nd Meeting of European Academy of ORL and Head and Neck Surgery to be held on April 27-30 in Nice, France.

“We are enthusiastic about the positive clinical results for the Vent-Os System, and are encouraged about the opportunity to provide a simple, highly tolerable treatment option for early-stage sinusitis patients in an office setting,” said SinuSys Chief Executive Officer Thomas Schreck.

Unlike balloon dilation devices that use rapid, high-pressure inflation, the Vent-Os (formerly AerOs) Sinus Dilation System is a low pressure, self-expanding insert designed to gently and gradually open the maxillary ostia (openings that connect the maxillary sinus to the nasal cavity.) The Vent-Os System incorporates the Company’s proprietary osmotic technology, which utilizes the body’s natural fluids

to expand the insert. After the ostia are opened, the insert is removed. The low-pressure, gradual expansion and simplicity of the device are designed to make it compatible for use in office-based procedures under local anesthesia.

The Vent-Os System has received the CE Mark, Health Canada license and Australian Therapeutic Goods Administration (TGA) Certificate, and is currently being commercialized in those regions. Availability in the US is pending a 510(k) currently under review by FDA.

About 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 U.S. healthcare system currently spends more than $8 billion annually on improving the health of patients with sinus conditions. However, approximately 20 percent of sinusitis patients do not experience adequate relief from current pharmaceutical treatments, which can have unpleasant side effects even when effective. For these patients, the most effective treatments to-date have been Functional Endoscopic Sinus Surgery (FESS) and high-pressure balloon dilation, which can cause significant patient discomfort and are conducted in a surgical suite under general anesthesia or IV sedation.

About SinuSys Corp.
SinuSys Corp. (www.sinusys.com) develops medical device therapies to improve the health of millions of patients suffering from chronic sinusitis worldwide. The company's proprietary self-expanding, osmotic technology is designed to be atraumatic, tissue-sparing and easy to use, potentially enabling clinicians to intervene at earlier stages of sinus disease. The company seeks to provide improved options for sinusitis patients whose disease is not resolved with drug therapy.