



[SinuSys Corp. Receives Health Canada and Australian TGA Approvals for AerOs™ Sinus Dilation System](#)

Company Completes Patient Enrollment in Canadian Clinical Study

PALO ALTO, Calif. – January 7, 2013 – [SinuSys Corporation](#), an innovative sinus health company, today announced that the Company has received a Health Canada license and an Australian Therapeutic Goods Administration (TGA) Certificate for its [AerOs™ Sinus Dilation System](#). The AerOs System is designed to treat chronic sinusitis by gently opening the sinus ostia, thereby restoring natural sinus drainage and ventilation using a simple, two-step interventional approach. The Company has also completed patient enrollment in its initial Canadian clinical study and will continue patient follow-up as it awaits a response to its FDA 510(k) submission.

Unlike balloon dilation devices that use rapid, high-pressure inflation, the AerOs Sinus Dilation System is a low pressure, self-expanding insert designed to gently and gradually open the maxillary ostia (openings that connect a sinus to the nasal cavity.) The AerOs device 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.

"All patients followed to-date in the clinical study have experienced patency of their maxillary ostia," said Dr. Amin Javer, Director of the University of British Columbia Sinus Centre. "While the clinical study procedures were conducted in an operating room setting, the simplicity and low-pressure expansion of the AerOs System should translate well to an office setting."

The Company previously announced that it had received CE Mark for the AerOs Sinus Dilation System in September of 2012 and is currently commercializing in Europe.

"Obtaining regulatory approvals in Canada, Australia and Europe, and completing enrollment in our clinical study, demonstrate that we are moving forward aggressively in achieving key milestones as we prepare for a U.S. launch, pending our FDA 510(k) clearance," said SinuSys Chief Executive Officer Thomas Schreck. "Most importantly, we are bringing a simpler and gentler procedure to otolaryngologists to enable them to intervene earlier in the disease continuum, which has the potential to dramatically improve patients' quality of life around the world."

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 the 20 percent of sinusitis patients whose disease is not resolved with drug therapy.

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