

Intersect ENT Initiates U.S. Clinical Study of a Novel In-Office Treatment for Chronic Sinusitis Patients

RESOLVE Study Will Evaluate Safety and Effectiveness of Steroid-Eluting Implant for Post-Sinus Surgery Patients with Recurrent Sinus Obstruction

Menlo Park, Calif. – January 31, 2013 – Intersect ENT, Inc., an innovator in treatment solutions for ear, nose and throat clinicians and their patients, today announced the start of RESOLVE, a prospective, randomized, blinded, multi-center clinical trial to study the use of the company's newest steroid delivery implant for patients with chronic sinusitis.

Intersect ENT's new product, which is placed during a routine physician office visit, is designed as a treatment alternative for patients with recurrent sinus obstruction. Like the company's PROPEL™ and PROPEL™ mini implants used in the operating room setting to improve surgical outcomes, the product being studied releases mometasone furoate, an advanced steroid with anti-inflammatory properties, directly into the sinus lining to resolve inflammation. The product has more radial strength than the PROPEL products in order to dilate the re-obstructed sinus, and releases the steroid over a longer period of time to keep inflammation at bay.

The RESOLVE Study will enroll 100 patients, at up to 20 U.S. sites, who suffer from chronic sinusitis due to recurrent sinus obstruction so severe that revision surgery is warranted.

"This novel in-office treatment promises to become an important treatment alternative to aggressive oral steroid therapy or revision sinus surgery for chronic sinusitis patients," said Steven K. Miller, M.D., of Intermountain, Ear, Nose and Throat Specialists in Salt Lake City, Utah, who treated the first patient enrolled in the trial. "This patient had a long history of chronic sinusitis, and continued to be extremely symptomatic despite prior sinus surgery and treatment with oral steroids. He was reluctant to have another sinus surgery and was pleased with the opportunity to enter the study."

Chronic sinusitis is a condition in which patients' sinuses become swollen and inflamed, leading to difficulty breathing, facial pain or headache, and reduced sense of smell and taste. The condition is common, affecting 31 million people in the U.S.,¹ and greatly impacts quality of life. Chronic sinusitis often requires a complex combination of surgical and medical treatments. Each year, 500,000 patients undergo sinus surgery to treat the condition.² Although sinus surgery is effective, majority of patients experience recurrent symptoms within the first year; as many as 25 percent then undergo revision surgery due to recurrent obstruction of the sinus cavity.³

The RESOLVE study is designed to evaluate Intersect ENT's implant in patients with polyps, which is the most challenging chronic sinusitis patient population. Polyps recur in up to 60 percent of patients following endoscopic sinus surgery (ESS) and are the leading cause for revision surgery.⁴

Co-Principal Investigators for the study are Keith D. Forwith, M.D., Ph.D. of Advanced ENT & Allergy in Louisville, KY, and Joseph Han, M.D., director of Rhinology and Endoscopic Sinus/Skull Base Surgery and professor at the Eastern Virginia Medical School.

"We are excited about the potential for this less invasive, more cost-effective treatment for chronic sinusitis patients, who suffer from debilitating symptoms," said Lisa Earnhardt, the company's president and CEO. "The reception from the physician community to localized steroid delivery and our PROPEL family of implants has been extraordinary, and we're proud to be partnering with leading clinicians on RESOLVE to further expand the treatment options for sinus sufferers."

About Intersect ENT

Intersect ENT Inc., located in Menlo Park, Calif., is an innovator in local drug delivery focused on advancing clinically proven therapy solutions that improve quality of life for patients with ear, nose and throat conditions. The company's initial products, the PROPEL and PROPEL mini dissolvable steroid-releasing implants, are the only products backed by Level 1-A clinical evidence to improve sinus surgery outcomes for patients suffering from chronic sinusitis. Chronic sinusitis is a common condition that affects one out of seven adults in the U.S.

and greatly impacts quality of life. The company holds twenty issued U.S. patents and more than 75 patents and pending applications worldwide. Intersect ENT is backed by Kleiner, Perkins, Caufield, & Byers; U.S. Venture Partners; PTV Sciences; and Medtronic. For more information please visit www.intersectENT.com.

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Patients with Chronic Sinusitis should consult their ENT surgeon for a full discussion of risks and benefits to determine whether this product is the right choice.

Media Contact:
Nicole Osmer
650.454.0504
nicole@nicoleosmer.com

¹ Pleis JR, Lethbridge-Çejku M. National Health Interview Survey, 2006. National Center for Health Statistics. Vital Health Stat 10(235). 2007.

² Rosenfeld et al. Clinical practice guideline: Adult sinusitis. Otolaryngology–Head and Neck Surgery. 137, S1-S31, 2007.

³ Shaitkin et al. Endoscopic Sinus Surgery. Laryngoscope, 103, Oct 1993.

⁴ Wynn et al, Recurrence Rates after Endoscopic Sinus Surgery for Massive Sinus Polyposis. Laryngoscope, 114, May 2004.