Intersect ENT Announces Positive Results from Pilot Study of Novel In-Office Implant for Chronic Sinusitis Patients

Recognized by American Rhinologic Society for Best Clinical Research

Menlo Park, Calif. and Vancouver – Sept. 30 2013 – Intersect ENT, Inc., an innovator in treatment solutions for ear, nose and throat clinicians and their patients, today reported findings from a prospective U.S. multi-center pilot study to evaluate the feasibility, safety and efficacy of the company's newest steroid delivery implant for patients suffering from the debilitating symptoms of chronic sinusitis. Results were presented at the Annual American Rhinologic Society Meeting in Vancouver, Canada and were recognized by the society with the Cottle Award for Best Clinical Science Research.

Intersect ENT's new drug eluting implant, 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 conjunction with sinus surgery to improve surgical outcomes, the product releases mometasone furoate, an advanced steroid with anti-inflammatory properties, directly into the sinus lining, then dissolves. The implant has more radial strength than the PROPEL products in order to dilate the obstructed sinus, and releases the steroid over a longer period of time.

"The results from the pilot study are highly promising, demonstrating feasibility of this novel in-office solution for patients suffering from chronic sinusitis," said Francois Lavigne, MD, FRCSC, adjunct professor of the University of Montreal and director of Institut ORL in Montréal, Quebec, Canada. "Patients experienced dramatic improvement in symptoms through the six-month follow-up period, and the vast majority of patients were able to avoid the need for costly revision surgery or oral steroids, which can have serious side effects."

Patients who had prior sinus surgery but experienced recurrent disease refractory to medical therapy were treated and then followed for six months. At three months, the mean ethmoid sinus obstruction was significantly reduced by 43%, from 66% obstruction at baseline to 21% obstruction ($p=0.0002$). The reduction was sustained through six months ($p=<0.0001$). Statistically significant reductions in polyp grades and patient symptom scores were also observed, and the results were sustained through six months. Use of the implant eliminated the need for revision surgery in 64% of patients.

"The results of the pilot study confirm the potential of our office-based product, which is designed to be a less-invasive, more cost-effective treatment alternative for chronic sinusitis patients facing another surgery," said Lisa Earnhardt, the company's president and CEO. "The larger randomized RESOLVE study, which is currently enrolling patients, will provide additional evidence regarding the clinical and economic benefits of the technology."

The RESOLVE Study (www.ResolveSinusStudy.com) is a prospective, randomized, blinded, multi-center clinical trial enrolling 100 patients at up to 20 U.S. sites. The trial is designed to evaluate the safety and efficacy of Intersect ENT's implant in patients with inflammatory masses called polyps, which is the most challenging chronic sinusitis patient population. Polyps recur in up to 60 percent of patients following endoscopic sinus surgery and are the leading cause for revision surgery.

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., 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. Although sinus surgery is effective, the 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.

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-one issued U.S. patents and more than 80 patents and pending applications worldwide. Intersect ENT is backed by Kleiner Perkins Caufield & Byers; U.S. Venture Partners; PTV Sciences; Norwest Venture Partners, 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.

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