

## **Groundbreaking Clinical Evidence Demonstrates Benefit of PROPEL Implant for Chronic Sinusitis Patients**

*Results Published in Two Peer-Reviewed Journals Show Significant Reduction in Need for Additional Surgical Interventions and Oral Steroids*

**Menlo Park, Calif.** – June 6, 2012 – Intersect ENT, Inc., an innovator in treatment solutions for ear, nose and throat clinicians and their patients, today announced two key clinical publications demonstrating the benefit of the PROPEL™ steroid-releasing implant for chronic sinusitis patients.

A meta-analysis of two separate, randomized, controlled, multicenter clinical studies was published in the June issue of *International Forum of Allergy & Rhinology*. Results of the meta-analysis demonstrate that, compared to controls, use of PROPEL reduced postoperative interventions by 35 percent ( $p=0.0008$ ) following endoscopic sinus surgery (ESS). PROPEL also decreased adhesion lysis by 51 percent ( $p=0.0016$ ), the need for oral steroids to treat inflammation by 40 percent ( $p=0.0023$ ), and frank polyposis by 46 percent ( $p<0.0001$ ). Early postoperative healing, including reduced inflammation, is a predictor of longer-term success after sinus surgery.<sup>1</sup>

“The level of clinical evidence in these two publications is unparalleled in the management of chronic sinusitis,” said Joseph Han, M.D., director of Rhinology and Endoscopic Sinus Surgery and associate professor at the Eastern Virginia Medical Center, the lead author of the meta-analysis publication. “The results clearly demonstrate that the PROPEL implant offers significant advantages for patients undergoing endoscopic sinus surgery.”

“We are proud to have collaborated with clinicians across the country to develop a product that delivers meaningful clinical benefits to chronic sinusitis sufferers. PROPEL is the first and only product for patients undergoing sinus surgery to be backed by Level 1-A clinical evidence,” said Lisa Earnhardt, the company’s president and CEO. “We are very pleased with the success of our launch in select U.S. markets to date, and look forward to bringing PROPEL to additional U.S. regions later this year.”

The meta-analysis included results from 105 patients at 11 centers enrolled in the ADVANCE II pivotal trial of the PROPEL implant and from 38 patients undergoing ESS for chronic sinusitis at four centers in a pilot study of the device.

### ***Second Publication Shows Reduction in Postoperative Interventions, Need for Oral Steroids***

In addition, results of the prospective, randomized, controlled, double-blind, multicenter ADVANCE II pivotal trial of the PROPEL implant were published in the June issue of *Otolaryngology – Head and Neck Surgery*.

Results of the study demonstrate that use of the PROPEL mometasone furoate implant significantly improves outcomes for patients undergoing ESS for chronic sinusitis. In the study, PROPEL provided a 29 percent reduction in the need for postoperative interventions ( $p=0.0280$ ) relative to controls, including a 52 percent reduction in surgical lysis of adhesions or scar formation ( $p=0.0053$ ) and a 29 percent reduction in the need for oral steroids to resolve recurrent inflammation ( $p=0.0881$ ). These results, which were graded by an independent and blinded panel of ENT surgeons, show that the improvements clinicians see endoscopically translate into significant patient benefits.

## **About Chronic Sinusitis**

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.,<sup>2</sup> 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.<sup>3</sup> 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.<sup>4</sup>

## **About the PROPEL™ Mometasone Furoate Implant**

PROPEL is clinically proven to improve outcomes of sinus surgery, reducing the need for oral steroids and surgical interventions. PROPEL props open the sinuses in a spring-like fashion and provides safe, effective and localized delivery of steroid directly to the sinus lining. The self-expanding implant conforms to the highly variable sinus anatomy, and effectively delivers anti-inflammatory medication where it's needed most as the implant dissolves.

The only product used in sinus surgery to be supported by Level 1-A clinical evidence, PROPEL has been studied in three rigorous prospective clinical trials conducted in the United States enrolling a total of 205 patients: a randomized, double-blind pilot study, recognized with the 2010 Maurice Cottle Research Award honoring best clinical or basic science by American Rhinologic Society; the ADVANCE single-cohort study which showed significant improvement in patient symptoms to six months; and the ADVANCE II randomized, controlled, double-blind clinical trial, which included review by an independent panel of surgeons.

## **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 product, the PROPEL™ dissolvable steroid-releasing implant, is clinically proven to improve sinus surgery outcomes for patients suffering from Chronic Sinusitis, a common condition that affects one out of seven adults in the U.S. and greatly impacts quality of life. The company holds seventeen 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](http://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.

- <sup>1</sup> Kennedy DW, Wright ED, Goldberg AN. Laryngoscope. 2000;110:29–31.
- <sup>2</sup> Pleis JR, Lethbridge-Çejku M. National Health Interview Survey, 2006. National Center for Health Statistics. Vital Health Stat 10(235). 2007
- <sup>3</sup> Rosenfeld et al. Clinical practice guideline: Adult sinusitis. Otolaryngology–Head and Neck Surgery. 137, S1-S31, 2007.
- <sup>4</sup> Shaitkin et al. Endoscopic Sinus Surgery. Laryngoscope, 103, Oct 1993.

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