

Intersect ENT Announces FDA Approval of New Steroid-Releasing Implant, Allowing More Chronic Sinusitis Patients to Benefit from Localized Drug Delivery

PROPEL™ mini Offers Same Clinical Benefits and Dose of Mometasone Furoate Provided by PROPEL

Menlo Park, Calif. – November 6, 2012 – Intersect ENT, Inc., an innovator in treatment solutions for ear, nose and throat clinicians and their patients, today announced U.S. Food and Drug Administration (FDA) approval of the company's second steroid-releasing product, PROPEL™ mini, allowing more patients suffering from chronic sinusitis to benefit from localized drug delivery.

The PROPEL™ mometasone furoate implant, approved last year by the FDA, is a spring-like implant that is inserted by a physician following endoscopic sinus surgery. The implant expands to prop open the sinus, gradually delivers an advanced steroid with anti-inflammatory properties directly to the sinus lining, then dissolves into the body. The result is improved surgical outcomes, reducing the need for additional surgical procedures and for systemic steroids, which can have serious side effects.

PROPEL mini, the second in a pipeline of localized drug delivery products in development by Intersect ENT, is a smaller version of PROPEL. PROPEL mini offers the same clinical benefits and dose of mometasone furoate provided by PROPEL, allowing patients with less extensive surgery and smaller anatomy to benefit from improved surgical outcomes.

"PROPEL has been recognized as a revolutionary advancement in the treatment of chronic sinusitis from both a technological and a clinical perspective," said Dr. Joseph Jacobs, Professor and Director of Rhinology at NYU Langone Medical Center NY, NY. "Clinical studies have clearly demonstrated that localized drug delivery offers significant advantages for patients undergoing endoscopic sinus surgery. My surgical patients have benefited from the addition of PROPEL to their care, and I am pleased that I will soon be able to offer this innovative treatment to a broader range of my patients."

"We are excited that the significant clinical benefits of PROPEL will now be available to more patients suffering from chronic sinusitis, a condition that has a severe impact on quality of life," said Lisa Earnhardt, the company's president and CEO. "PROPEL mini and PROPEL, clinically proven to maintain sinus patency after surgery, are the first and only products for patients undergoing sinus surgery to be backed by Level 1-A clinical evidence. Bringing two combination products to market in just over a year illustrates Intersect ENT's commitment to delivering meaningful products to our ENT customers and their patients."

Intersect ENT initiated sales of PROPEL in limited regions of the country over the past year. PROPEL mini will be offered in select hospitals starting this month and will be launched nationwide in conjunction with a planned sales force expansion in 2013.

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., 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, 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.³

About the PROPEL™ and PROPEL mini Mometasone Furoate Implants

The only products 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. A meta-analysis of two separate, randomized, controlled, multicenter clinical studies demonstrated 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.⁴

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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 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 nineteen 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.

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 ³ Shaitkin et al. Endoscopic Sinus Surgery. Laryngoscope, 103, Oct 1993.
⁴ Kennedy DW, Wright ED, Goldberg AN. Laryngoscope. 2000;110:29–31.