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Intersect ENT Announces Positive Data from Pivotal Study of Propel Implant, Showing Significantly Improved Outcomes For Sinus Surgery

San Francisco and Palo Alto, Calif. – September 13, 2011 – Intersect ENT, Inc., an innovator in treatment solutions for ear, nose and throat clinicians and patients, today reported data from its pivotal clinical trial, ADVANCE II. ADVANCE II is a prospective, randomized, controlled, double-blind, multicenter trial showing that use of the Propel™ mometasone furoate implant significantly improves outcomes for patients undergoing endoscopic sinus surgery (ESS) for chronic sinusitis.

Propel is the first of a new category of products offering localized, controlled delivery of steroid directly to the sinus tissue. Inserted by the physician to maintain the surgical opening, the spring-like dissolvable implant expands to prop open the sinus, gradually delivering a corticosteroid with anti-inflammatory properties directly to the sinus lining.

The company also announced that following U.S. Food and Drug Administration (FDA) approval last month, Propel is now commercially available as part of a limited release in select regions with plans to introduce the product more broadly in the U.S. over the next year.

Pivotal Study Results Show Reduction in Postoperative Interventions, Need for Oral Steroids

The ADVANCE II trial studied 105 patients undergoing ESS for chronic sinusitis. Results were graded by an independent and blinded panel of ENT surgeons. In the study, Propel demonstrated 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 ($p=0.0881$). Reducing inflammation and scarring post-operatively is proven to improve long-term outcomes.¹

Findings were presented at the American Academy of Otolaryngology – Head & Neck Surgery (AAO-HNS) meeting in San Francisco by Bradley F. Marple, M.D., professor and vice chairman of the Department of Otolaryngology-Head and Neck Surgery at the University of Texas Southwestern Medical Center in Dallas.

“Three studies have now shown that the Propel implant maintains the results of sinus surgery. Data from this rigorously designed pivotal study confirm that the improvements we as clinicians see endoscopically translate into significant benefits for patients with chronic sinusitis, a condition that seriously impacts quality of life,” said Dr. Marple. “Intersect ENT’s commitment to clinical science is remarkable and much appreciated by the ENT community.”

Meta-Analysis Demonstrates First Level 1-A Evidence for Localized Steroid Delivery

Data from a meta-analysis of 143 patients enrolled in ADVANCE II and the initial Pilot study – clinical trials with similar demographics and endpoints – showed that, relative to controls, use of the Propel implant yielded a 35 percent reduction in postoperative medical and surgical intervention ($p=0.0008$), including a 40 percent reduction in the need for oral steroids ($p=0.0023$). It also demonstrated a 46 percent reduction in rate of frank polyposis ($p<0.0001$) relative to controls. Results were presented at the American Academy of Otolaryngic Allergy (AAOA) meeting in San Francisco by Joseph Han, M.D., director of Rhinology and Endoscopic Sinus Surgery and associate professor at the Eastern Virginia Medical Center.

This meta-analysis represents the first level 1a evidence demonstrating the benefit of localized steroid delivery in the post-ESS period.

“Patients and ENTs now have a meaningful option for keeping sinuses open and delivering drugs where they are needed most with Propel, the first and only product for chronic sinusitis patients that combines both a mechanical and medical benefit,” said Lisa Earnhardt, the company’s president and CEO. “We’re proud of the positive data we have amassed, which shows that Propel’s localized and controlled steroid delivery confers significant benefits to patients – reducing the need for post-operative medical and surgical therapies, which may mean shorter and less painful post-op visits and better long-term outcomes.”

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.,² 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.³ 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.⁴

About Propel™ Mometasone Furoate Implant

Propel is clinically proven to maintain sinus patency after surgery by propping open the sinuses in a spring-like fashion and by providing for 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.

Safety and efficacy of the Propel implant has been studied in three rigorous prospective clinical trials conducted in the United States enrolling a total of 205 patients, providing an unparalleled level of clinical evidence for an ENT product in challenging sinus patient populations: 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 assessing safety and 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 Palo Alto, Calif., is an innovator in local drug delivery focused on advancing clinically proven therapy solutions that improve quality of life for ear, nose and throat patients. The company’s initial focus is a dissolvable steroid-releasing implant to treat patients with 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 fifteen issued U.S. patents and more than 70 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.

¹Kennedy et al, *Laryngoscope*, 110 (Suppl. 94): 29 – 31, 2000

²Pleis et al, *National Health Interview Survey, 2006*. Vital Health Stat Series 10, Number 235

³Rosenfeld et al, *Otolaryngology–Head and Neck Surgery* (2007) 137, S1-S31

⁴Shaitkin et al, *Laryngoscope*, 113, Oct 2003

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