

Intersect ENT Announces U.S. Food and Drug Administration Approval for First Drug Releasing Implant for Chronic Sinusitis Patients

Breakthrough Treatment Improves Outcomes for Sinus Surgery

Palo Alto, Calif. – August 15, 2011 – Intersect ENT, Inc., an innovator in treatment alternatives for ear, nose and throat clinicians and patients, today announced that the U.S. Food and Drug Administration (FDA) has approved the company's Pre-market Approval (PMA) application for the Propel™ mometasone furoate implant offering localized, controlled drug delivery for chronic sinusitis patients.

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 one in seven adults 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, 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

Propel is the first of a new category of products offering localized, controlled delivery of steroid directly to the sinus tissue. Inserted by a physician following endoscopic sinus surgery, the spring-like implant expands to prop open the sinus and gradually delivers an advanced corticosteroid with anti-inflammatory properties directly to the sinus lining to maintain sinus patency.

The Propel system has been clinically proven to prevent obstruction of the ethmoid sinus following surgery. The result is improved post-operative outcomes, reducing the need for additional surgical procedures and systemic steroids that can have serious side effects.

"The FDA approval of this innovative new product is great news for ENT clinicians and patients," said David W. Kennedy, M.D., F.A.C.S., professor of Otorhinolaryngology at the University of Pennsylvania Health System in Philadelphia, PA, a widely recognized pioneer in functional endoscopic sinus surgery. "Propel reduces the occurrence of inflammation and scarring in the post-operative period. As a result, it promises to substantially improve long-term outcomes for sinus surgery and, as my research has demonstrated, reduced scarring and inflammation correlates with absence of the need for further surgery. I believe the combination of minimally invasive techniques and local drug delivery will be the wave of the future in sinus treatment."

"The FDA approval of Propel marks an exciting milestone for Intersect ENT as well as sinus sufferers and their physicians who will now have an important new treatment option, clinically proven to maintain the benefits of sinus surgery," said Lisa Earnhardt, the company's president and CEO. "We look forward to launching our product to clinicians and their patients in select US locations this fall."



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 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 then 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 prospective clinical trials conducted in the United States enrolling a total of 205 patients. These trials include a randomized double-blind Pilot Study, the ADVANCE safety study, and the ADVANCE II randomized, double-blind clinical trial. Results from the ADVANCE II study, which will be presented at the annual American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) conference in San Francisco, and findings from a meta-analysis of data from the pilot study and from ADVANCE II will be announced in September.

About Intersect ENT

Intersect ENT Inc., located in Palo Alto, Calif., is an innovator in local drug delivery focused on advancing clinically proven therapy alternatives 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.

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¹ Pleis et al. National Health Interview Survey, 2006. Vital Health Stat Series 10, Number 235

² Rosenfeld et al. Otolaryngology-Head and Neck Surgery (2007) 137, S1-S31

³ Shaitkin et al. Laryngoscope 103 Oct 2003