

## **Intersect ENT Submits New Drug Application to FDA for Office-Based RESOLVE Steroid Releasing Implant for Recurrent Chronic Sinus Disease**

*Submission Supported by Four Clinical Studies Evaluating Safety and Effectiveness*

Menlo Park, Calif. – March 8, 2017 – Intersect ENT, Inc. (Nasdaq: XENT), a company dedicated to improving the quality of life for patients with ear, nose and throat conditions, today announced submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for review and approval of the company’s investigational RESOLVE steroid releasing implant.

Placed during a routine physician office visit, the RESOLVE steroid releasing implant is designed to provide a less invasive treatment option for patients with recurrent ethmoid sinus obstruction, including polyps, who might otherwise warrant a repeat surgical procedure.

More than 635,000 Americans are potential candidates for the RESOLVE implant – an underserved population, as current treatment relies on high-dose oral steroids and repeat surgery.

“This FDA submission for our fourth steroid releasing implant is a significant milestone for Intersect ENT as we look to provide innovative solutions for patients with this persistent form of chronic sinusitis,” said Lisa Earnhardt, president and CEO of Intersect ENT. “The RESOLVE implant offers the potential for a less invasive and potentially more cost effective solution that can be easily performed in the physician’s office.”

A total of four clinical studies have been conducted to assess the safety and effectiveness of the product. The pivotal study, RESOLVE II, was a randomized, blinded, multi-center pivotal phase III clinical trial designed to assess the safety and efficacy of the product. The study evaluated the implant in 300 adult chronic sinusitis patients, all of whom were indicated for revision sinus surgery at study entry due to recurrent symptoms and obstructive inflammation. Patients were randomized to one of two groups: a treatment group consisting of bilateral RESOLVE implant placement in the office, or a control group consisting of a sham procedure; both groups continued to receive standard treatments such as topical nasal steroid sprays.

The trial met both co-primary efficacy endpoints, demonstrating a statistically significant reduction in nasal congestion and polyp burden. Secondary endpoints achieving statistical significance through day 90 included a reduction in the proportion of patients still indicated for repeat sinus surgery, reduction in ethmoid sinus obstruction, and improvements in both nasal obstruction symptoms and sense of smell.

### **About RESOLVE Steroid Releasing Sinus Implant**

The investigational steroid releasing implant currently called RESOLVE is designed to be placed during a routine physician office visit to provide a less invasive treatment option for chronic sinusitis patients with recurrent sinus obstruction that would otherwise warrant revision surgery. The implant releases mometasone furoate directly into the ethmoid sinus lining to target inflammation directly. It was designed with greater radial strength than Intersect ENT’s PROPEL products in order to dilate obstructed sinuses and releases steroid over a longer period of time to reduce inflammation. RESOLVE has not been approved by the FDA and is available for investigational use only.

## **About Intersect ENT®**

Intersect ENT is dedicated to transforming the landscape of care for patients with ear, nose and throat conditions. The company's PROPEL® family of dissolvable steroid releasing sinus implants are clinically proven to improve outcomes for chronic sinusitis patients undergoing sinus surgery. In addition, Intersect ENT is continuing to expand its portfolio of products based on the company's unique localized steroid releasing technology and is committed to broadening patient access to less invasive and more cost effective care.

Intersect ENT: Delivering Innovation. Where It's Needed.

For additional information on the company or the products including risks and benefits please visit [www.IntersectENT.com](http://www.IntersectENT.com).

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## **Forward-Looking Statements**

This release contains forward-looking statements within the meaning of Sections 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Forward-looking statements should not be read as a guarantee of future performance or results, and may not necessarily be accurate indications of the times at, or by, which such performance or results will be achieved. These forward-looking statements are based on Intersect ENT's current expectations and inherently involve significant risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, that the short-term and long-term effects of the investigational product relative to alternative treatments may not be as Intersect ENT expects, the development of competitive products, the uncertain response of FDA to the NDA submission, physician acceptance of our products and therapies, reimbursement coverage and cost effectiveness of our products, as well as other risks detailed from time to time in Intersect ENT's filings with the Securities and Exchange Commission (SEC), including Intersect ENT's filings on Form 10-K, Form 10-Q available at the SEC's Internet site ([www.sec.gov](http://www.sec.gov)). Intersect ENT does not undertake any obligation to update forward-looking statements and expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein.

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