Intersect ENT Announces Positive Clinical Results of Pivotal Study of RESOLVE In-Office Steroid Releasing Implant

- *The RESOLVE II clinical study met both primary efficacy endpoints: reduction in nasal congestion and polyp burden*
- *Recurrent chronic sinusitis following sinus surgery affects 635,000 Americans, an underserved population, as current treatment relies on high-dose oral steroids and repeat surgery*
- *The RESOLVE II trial is a landmark study in rhinology: the largest multicenter, randomized, blinded, sham-controlled clinical trial enrolling patients with chronic sinusitis*
- *As part of its commitment to evidence based innovation, Intersect ENT plans to proceed with a U.S. regulatory submission for this product*

Menlo Park, Calif.– October 17 – Intersect ENT, Inc. (Nasdaq:XENT), a company dedicated to improving the quality of life for patients with ear, nose and throat conditions, today announced positive results from RESOLVE II, a randomized, blinded, multi-center clinical trial designed to assess the safety and efficacy 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 that might otherwise warrant a repeat surgical procedure.

The RESOLVE II pivotal phase III 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. Robert Kern, M.D., of Northwestern University and Pablo Stolovitzky, M.D., of ENT of Georgia served as national co-principal investigators of the study.

Both Primary Efficacy Endpoints Achieved

The study met both co-primary efficacy endpoints:

- **Reduction in Polyp Grade.** An independent panel of surgeons blinded to treatment assignment evaluated the change in mean bilateral polyp grade from baseline to day 90 based on video endoscopies. A statistically significant (p=0.007) difference in mean change from baseline favoring the treatment group was observed.
- **Reduction in Sense of Nasal Obstruction and Congestion.** The change in mean Nasal Obstruction/Congestion score was measured from baseline to day 30, as scored by patients using a daily diary. A statistically significant (p=0.007) difference in mean change from baseline favoring the treatment group was observed.

Secondary endpoints achieving statistical significance through day 90 include the proportion of patients still indicated for repeat sinus surgery and improvements in sense of smell, sense of nasal obstruction, and total symptom score. Safety was evaluated by endoscopic examination and evaluation of adverse events. One serious device-related adverse event, an intranasal bleed requiring intervention, was observed.

Approximately 635,000 patients suffer from recurrent chronic sinusitis following sinus surgery each year. Patients with recurrent disease currently have limited treatment options, which include high-dose oral steroids and repeat surgery.

“The RESOLVE II study outcomes are compelling, and the medical community is eager to embrace new treatment options such as this less invasive procedure that can easily be performed in a physician’s office,” said Robert Kern, M.D., Chair of Otolaryngology – Head and Neck Surgery at Northwestern Medical Center. “The study results suggest that RESOLVE has the potential to improve quality of life while allowing patients to avoid additional surgical procedures.”

“This is a significant milestone in our history and for our future as we look to dramatically expand the impact we have across the continuum of care for sinusitis sufferers,” said Lisa Earnhardt, president and CEO of Intersect ENT. “The RESOLVE product offers a less invasive and potentially more cost effective solution for this challenging patient population. As part of our commitment to evidence-based innovation, we look forward to taking the next step toward bringing RESOLVE to ENT physicians and their patients.”

Intersect ENT plans to submit a New Drug Application (NDA) in the first quarter of 2017 for regulatory approval from the U.S. Food and Drug Administration (FDA) to market the RESOLVE product.

Six-month results from the original RESOLVE study demonstrated that control patients were at 3.6 times higher risk of remaining indicated for revision sinus surgery compared to patients receiving the RESOLVE implant. This study was published in the *International Forum of Allergy and Rhinology* journal in June 2016.

About RESOLVE
The investigational RESOLVE steroid releasing implant is designed to be placed during a routine physician office visit to provide a less invasive treatment option for patients with recurrent ethmoid sinus obstruction that would otherwise warrant revision surgery. The RESOLVE implant releases mometasone furoate directly into the sinus lining to target inflammation. It was designed with greater radial strength than the PROPEL products in order to dilate an obstructed sinus and releases steroid over a longer period of time to reduce inflammation. The company estimates that there are approximately 635,000 potential candidates for the RESOLVE implant.

The RESOLVE implant is investigational and is not available for commercial use.

About the RESOLVE Study Program
Four clinical studies of the RESOLVE implant have been conducted over the past five years, including a pilot study of 12 patients to evaluate feasibility of placement, a pharmacokinetic study of five patients, the RESOLVE randomized controlled trial of 100 patients evaluating both safety and efficacy, and the recently completed RESOLVE II Phase III randomized controlled trial of 300 patients.

About Intersect ENT
Intersect ENT, Inc. is dedicated to improving the quality of life for patients with ear, nose and throat conditions. The company markets two steroid releasing implants, PROPEL and PROPEL mini, which have been clinically proven to improve surgical outcomes for chronic sinusitis patients undergoing sinus surgery. In addition, Intersect ENT is developing a pipeline of steroid releasing implants designed to provide ENT physicians with options to treat patients across the continuum of care for chronic sinusitis less invasively and more cost effectively. Chronic sinusitis is an inflammatory condition that can lead to debilitating symptoms and chronic infections, and is one of the most costly conditions to U.S. employers.

For additional information on the company or the products including risks and benefits please visit 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 timing of the submission, completion and success of FDA submissions, 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). 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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