Intersect ENT Announces Positive Data from Clinical Trial of New In-Office Implant for Recurrent Chronic Sinusitis

Results Presented at the Annual American Rhinologic Society Meeting 2014; Recognized with Cottle Award for Best Clinical Science

Menlo Park, Calif. and Orlando, Fla. – Sept. 22, 2014 – Intersect ENT, Inc. (Nasdaq:XENT), a company dedicated to improving the quality of life for patients with ear, nose and throat conditions, today announced initial results from RESOLVE, a clinical study of the company's investigational steroid eluting implant designed to treat patients with recurrent sinus obstruction in the office setting. Results were presented at the annual American Rhinologic Society meeting in Orlando, Fla., and were recognized by the society with the Cottle Award for Best Clinical Science Research, Intersect ENT's third Cottle Award for the clinical evidence supporting its products.

RESOLVE is a prospective, randomized, blinded, multi-center clinical trial to study the use of the company's RESOLVE steroid eluting implant when placed in the office setting. The study enrolled 100 patients who suffer from chronic sinusitis due to recurrent ethmoid sinus obstruction so severe that revision surgery is indicated. Joseph Han, M.D., director of Rhinology and Endoscopic Sinus/Skull Base Surgery and professor at the Eastern Virginia Medical School in Norfolk, Va., and Keith Forwith, M.D., of Advanced ENT & Allergy in Louisville, Ky., served as co-principal investigators of the study.

The study met its primary safety endpoints, with 100% implant placement success and no serious adverse events. In addition, initial data compiled through the first 90 days of the six-month study demonstrated:

- Statistically significant reductions in clinicians' endoscopic scoring of bilateral nasal polyp burden and ethmoid sinus obstruction in the treatment group, as compared to the control group through 90 days.
- Clinically meaningful, two-fold greater improvement in patient symptoms measured by nasal obstruction/congestion score for the treatment group, as compared to controls at 90 days. This difference was statistically significant for patients who had a higher polyp burden at baseline.
- At 90 days, 52% of patients in the treatment arm were no longer indicated for sinus surgery, compared with 22% of the patients in the control arm, demonstrating a clinically meaningful reduction in the need for revision surgery.

"These results represent a significant improvement in the management of chronic sinusitis patients who have recurrent nasal polyps and symptoms despite surgery and ongoing medical treatment, who normally require systemic steroid therapy or additional sinus surgeries to alleviate symptoms," said Dr. Han, who presented the data at the conference. "It is remarkable that the nasal polyps responded so quickly to the steroid implant – within seven days – and that at 90 days, more than half of patients treated with this implant were no longer indicated for surgery – especially considering the fact that all the patients were candidates for revision surgery at the time of enrollment. I believe this novel in-office treatment has the potential to make a significant positive impact on patients' quality of life and cost of care."

Intersect ENT's new investigational product is placed during a routine physician office visit and is designed as an alternative to current treatment options for patients who have previously had sinus surgery yet return to the ENT physician with symptoms of recurrent sinus obstruction. Like the company's commercially available PROPEL® and PROPEL® mini implants used to improve surgical outcomes following sinus surgery, the RESOLVE product releases mometasone furoate, an advanced steroid with anti-inflammatory properties, directly into the sinus lining to reduce inflammation. The RESOLVE product has more radial strength than the PROPEL products in order to dilate the obstructed sinus, and releases the steroid over a longer period of time.

"We are pleased with the positive clinical results from the RESOLVE study," said Lisa Earnhardt, president and CEO, Intersect ENT. "We are continuing development toward the goal of providing a non-surgical treatment alternative for sufferers of severe chronic sinusitis with the next step of using this data to finalize the trial design for our subsequent pivotal study to support FDA approval."

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 drug-eluting implants, PROPEL and PROPEL mini, clinically proven to improve surgical outcomes for patients with chronic sinusitis undergoing ethmoid sinus surgery. In addition, Intersect ENT is developing new drug-eluting implants designed to provide ENT physicians with even more customized options to treat patients with chronic sinusitis less invasively and more cost effectively. Chronic sinusitis is an inflammatory condition leading to debilitating symptoms and chronic infections, and is one of the most costly conditions to U.S. employers.

Forward-Looking Statements

The statements in this press release that the in-office steroid delivery implant may used to treat recurrent sinusitis and that the implant may be further developed and approved by the FDA are "forward-looking" statements. 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, 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 completion of and the success of clinical trials, market competition, as well as other risks detailed from time to time in Intersect ENT's filings with the Securities and Exchange Commission, including its prospectus filed with the SEC on July 24, 2014 and the 10-Q filed on September 4, 2014. 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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