Intersect ENT Announces FDA Approval of Additional Indication for PROPEL® Mini Sinus Implant

PROPEL Mini Now Indicated to Treat Patients With Frontal Sinus Disease

MENLO PARK, Calif.—March 23, 2016—Intersect ENT, Inc. (Nasdaq:XENT), a company dedicated to improving the quality of life for patients with ear, nose and throat conditions, today announced that the company has received approval from the U.S. Food and Drug Administration (FDA) for an expanded indication for the PROPEL® mini steroid releasing sinus implant to treat patients undergoing frontal sinus surgery.

This expanded indication allows Intersect ENT to market placement of PROPEL mini in the frontal sinuses, located behind the eyebrows. Previously, PROPEL mini was indicated solely for placement in the ethmoid sinuses, located just behind the bridge of the nose.

“This approval is significant for patients with frontal sinus disease, which has traditionally been difficult to treat and greatly impacts quality of life, with debilitating symptoms including severe headaches,” said Ameet Singh, M.D., of George Washington University School of Medicine & Health Sciences, who served as an investigator of the PROGRESS study. “We are grateful to the patients who participated in the PROGRESS trial. The clinical data from the study are compelling for a large majority of patients with chronic frontal sinusitis and clearly illustrate the improved clinical outcomes for frontal sinus surgery patients treated with PROPEL mini.”

“This expanded use of PROPEL mini is a significant step in furthering our mission to improve the quality of life for sinus sufferers and lower the overall cost of patient care,” said Lisa Earnhardt, president and CEO of Intersect ENT. “We are thrilled that patients with frontal sinusitis – which we estimate affects 25 to 30 percent of patients undergoing surgery for chronic sinusitis – can join the more than 100,000 patients to date who have received treatment with PROPEL.”

New Data from PROGRESS Shows Benefit of Treatment with PROPEL Mini

As previously reported, the PROGRESS study was a prospective, randomized, blinded, multi-center study designed to assess the safety and efficacy of PROPEL mini when used following frontal sinus surgery. This study demonstrated a statistically significant 38 percent relative reduction in the need for post-operative interventions compared to surgery alone. Additional statistically significant results included a 75 percent relative reduction in need for surgical intervention, a 56 percent relative reduction in need for oral steroids and a 54 percent relative reduction in frontal sinus restenosis. The device placement success rate was 100 percent and there were no device-related adverse events.

ABOUT PROPEL and PROPEL mini

Intersect ENT’s PROPEL and PROPEL mini are the first and only steroid releasing sinus implants approved by the FDA to maintain the open passages created in surgery. The bioabsorbable products release mometasone furoate, an advanced steroid with anti-inflammatory properties, over time directly into the sinus lining, then fully dissolve. PROPEL’s effectiveness is supported by the highest level of
clinical evidence, Level 1a, which demonstrates that PROPEL reduces inflammation and scarring after surgery, thereby lessening the need for post-operative surgical interventions and use of oral steroids. Both PROPEL and PROPEL mini are indicated for use following ethmoid sinus surgery. Additionally, PROPEL mini is indicated for use following frontal sinus surgery.

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.

INTERSECT ENT® and PROPEL® are registered trademarks of Intersect ENT, Inc.

Forward-Looking Statements
The statements in this press release regarding the potential expanded indication for PROPEL® mini and the ability of Intersect ENT to broaden access to its products by patients with chronic sinusitis are “forward-looking” statements. These forward-looking statements are based on Intersect ENT’s assessment of the market and its current expectations and as such these forward-looking statements inherently involve significant risks and uncertainties. These statements include those related to the number of patients with frontal sinusitis who undergo sinus surgery and the ability of PROPEL mini to lower the overall cost of patient care. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of risks and uncertainties, which include, without limitation, the performance of PROPEL and PROPEL mini, the development of competitive products, physician acceptance and use of our products, and Intersect ENT’s ability to market and sell PROPEL mini for a new indication. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in Intersect ENT’s filings on Form 10-K, Form 10-Q and the company’s other filings with the Securities and Exchange Commission (SEC) 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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