Intersect ENT Announces FDA Submission of NOVA Bioabsorbable Steroid Releasing Implant for Patients with Chronic Sinus Disease

MENLO PARK, Calif.—Aug. 1, 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 submitted a supplemental premarket approval submission (PMA-s) to the U.S. Food and Drug Administration to seek approval for its new NOVA steroid releasing implant for patients with chronic sinus disease.

NOVA’s unique hourglass shape and lower profile is designed to allow for placement in smaller sinus openings, and may expand the applicable patient population for steroid releasing implants.

The NOVA cohort of the PROGRESS study was a prospective, randomized, blinded, multi-center trial of 80 patients designed to assess the safety and efficacy of the implant when placed in the frontal sinuses following surgery. As previously announced, the study met its primary efficacy endpoint, demonstrating a statistically significant 65% relative reduction in the need for post-operative interventions, such as the need for additional surgical procedures or need for oral steroid prescription, compared to surgery alone with standard post-operative care. The device placement success rate was 100% and there were no device-related adverse events through 90-day follow-up.

“This submission is another important milestone in our efforts to address unmet needs for chronic sinusitis patients across the continuum of care,” said Lisa Earnhardt, president and CEO, Intersect ENT. “NOVA’s design, which allows for placement in smaller sinus openings, has the potential to be an important option for physicians treating and managing chronic sinus disease.”

ABOUT NOVA
The investigational NOVA steroid releasing implant is designed to prop sinuses open mechanically while delivering anti-inflammatory medication following surgical interventions, such as sinus surgery in the operating room or sinus dilation in the physician’s office. NOVA’s unique hourglass shape and lower profile is designed for placement in the smaller sinus openings, which may expand the applicable patient population for steroid releasing implants. NOVA has not been approved by the FDA and is available for investigational use only.

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 adoption of the NOVA device and the potential expansion of the applicable patient population for steroid releasing implants 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 risks and uncertainties, which include, without limitation, the performance of the Company's steroid releasing implants, FDA approval of the NOVA steroid releasing implant, physician acceptance of the Company's products and the development of competitive products. 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 on 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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