



Intersect ENT Announces First Patient Enrolled in ASCEND Study of Investigational Drug-Coated Sinus Balloon

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Innovative Drug-Device Combination Will Leverage Company's Expertise in Localized Drug Delivery

MENLO PARK, Calif.--(BUSINESS WIRE)--Dec. 17, 2018-- Intersect ENT, Inc. (NASDAQ:XENT), a company dedicated to transforming care for patients with ear, nose and throat conditions, today announced the enrollment of the first patient in the company's study of its newest platform product, the ASCEND investigational drug-coated sinus balloon. This novel device is designed to deliver a corticosteroid (mometasone furoate) directly to the sinuses at the time of dilation.

"We are excited to begin enrollment in this study of our fifth product leveraging our expertise in localized drug delivery, and we believe that this product, if approved, would be complementary to our current product offerings," said Lisa Earnhardt, president and CEO of Intersect ENT. "This is an important milestone for Intersect ENT, and illustrates our continued commitment to developing innovative solutions for sinus patients."

The study will assess whether the ASCEND product can reduce inflammation by delivering a steroid directly to the dilated tissue while opening narrowed passageways in the sinuses. Balloons are currently used in approximately 200,000 sinus procedures annually in the United States. If successful, the product would be reviewed under the PMA pathway.

The ASCEND study is a prospective, randomized, blinded, multi-center trial of 70 patients that will assess the safety and efficacy of Intersect ENT's drug-coated sinus balloon. The ASCEND drug-coated sinus balloon will be randomized against an uncoated balloon. Similar to the clinical studies for the PROPEL[®] family of steroid releasing sinus implants, the primary endpoint will be evaluated at 30 days. The study will assess the device's ability to improve patency rates, as well as a number of other endoscopic parameters.

"The ASCEND study will aim to assess the potential benefits of directed drug delivery at the time of balloon dilation, a potential advance beyond the current treatment paradigm," said Boris Karanfilov, M.D., Director of the Ohio Sinus Institute, who serves as national Principal Investigator of the study.

Intersect ENT expects to report top line results by the end of 2019.

About PROPEL[®] Steroid Releasing Sinus Implants

Intersect ENT's PROPEL products are the first and only dissolvable steroid releasing sinus implants approved by the FDA. Clinically proven to improve outcomes for chronic sinusitis patients following sinus surgery, PROPEL sinus implants mechanically prop open the sinuses and release mometasone furoate, an advanced corticosteroid with anti-inflammatory properties, directly into the sinus lining then dissolve. PROPEL's safety and effectiveness for use in ethmoid sinuses is supported by Level 1-A clinical evidence from multiple clinical trials, which demonstrates that PROPEL implants reduce inflammation and scarring after ethmoid sinus surgery, thereby reducing the need for post-operative oral steroids and repeat surgical interventions. PROPEL is indicated for the ethmoid sinus; PROPEL Mini is indicated for the ethmoid and frontal sinuses; and PROPEL Contour is indicated for the frontal and maxillary sinuses.

About Intersect ENT[®]

Intersect ENT is dedicated to transforming ear, nose and throat care by providing innovative, clinically meaningful therapies to physicians and patients. The company's steroid releasing implants are designed to provide mechanical spacing and deliver targeted therapy to the site of disease. 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.

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.

ASCEND is an investigational drug-device combination and is not available for sale in the U.S.

IMPORTANT SAFETY INFORMATION FOR THE PROPEL FAMILY OF SINUS IMPLANTS

INDICATION

The PROPEL sinus implants are intended for use following sinus surgery to maintain the sinus openings and to locally deliver a drug to the sinuses: PROPEL for use in the ethmoid sinus, PROPEL Mini for use in the ethmoid sinus and frontal sinus opening and PROPEL Contour for use in the frontal and maxillary sinus openings. The products are intended for use in patients ≥ 18 years of age.

IMPORTANT SAFETY INFORMATION

These products are not intended for people who are allergic to the drug (mometasone furoate) or to certain polymers. Safety and effectiveness of the implant in pregnant or nursing females have not been studied. Risks may include, but are not limited to, pain/pressure, movement of the implant (within or out of the sinus), possible side effects of the drug, infection, and nose bleed. For more information on the risks and benefits of PROPEL sinus implants, please talk to your doctor. The FDA approved labeling can be found at www.IntersectENT.com. Rx only.

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, the results and outcomes of the ASCEND study, the safety, efficacy and patient and physician adoption of our products, including the ASCEND investigational drug-coated sinus balloon, and the company's ability to procure and maintain required regulatory approvals for our products, including the ASCEND investigational drug-coated sinus balloon. These risks and uncertainties, as well as others, are 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 and 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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