Intersect ENT Announces Launch of SINUVA™ Sinus Implant, a New In-Office Treatment Option for Recurrent Nasal Polyps

New Treatment Is Clinically Proven to Reduce Polyps and Symptoms of Nasal Congestion

MENLO PARK, Calif. — April 2, 2018 — Intersect ENT, Inc. (NASDAQ: XENT), a company dedicated to transforming care for patients with ear, nose and throat conditions, today announced U.S. commercial availability of the SINUVA™ (mometasone furoate) Sinus Implant, a new approach to treating nasal polyp disease in adult patients who have had previous sinus surgery.

Placed during a routine doctor’s office visit under local or topical anesthesia, SINUVA is designed to deliver an anti-inflammatory steroid directly to the site of disease for an extended period of time (up to 90 days) following placement into the sinus cavity. SINUVA is clinically proven to reduce polyps and symptoms of nasal congestion. In addition, in a study of patients indicated for repeat sinus surgery, less than half of patients still needed surgery following placement of the SINUVA implant.

“Recurrent nasal polyposis is one of the most challenging conditions for ENT physicians. Many sufferers return to their ENT physician despite sinus surgery due to recurrence of symptoms,” said Satish Govindaraj, M.D., associate professor and vice chairman of Clinical Affairs in the Department of Otolaryngology of Mount Sinai Medical Center, one of the clinical trial sites involved in the pivotal study of SINUVA. “The clinical data supporting the use of the SINUVA implant is compelling. I believe this innovative treatment option will be attractive for many of my patients.”

Nasal polyps are inflammatory growths along the lining of nasal passages or sinuses that can cause nasal congestion, infections and loss of sense of smell. Approximately 635,000 Americans have had previous sinus surgery and continue to see their ENT physicians for treatment of recurring symptoms.

“After years of development and multiple clinical studies, we are thrilled to provide physicians with SINUVA to treat patients with nasal polyps. SINUVA offers an alternative to patients who have exhausted routine medical management who don’t want to return to the operating room for a repeat surgery,” said Lisa Earnhardt, president and CEO of Intersect ENT. “We are introducing SINUVA through a targeted launch, working to build success through positive initial adoption and positioning SINUVA for the long-term growth we believe is achievable.”

“Steroid releasing implants have been a mainstay of my treatment for patients following sinus surgery. SINUVA represents a related technology uniquely designed for patients who continue to struggle with nasal polyps,” said Greg Davis, M.D., M.P.H., associate professor of otolaryngology-head and neck surgery at the University of Washington School of Medicine in Seattle. He was among the first in the United States to utilize the SINUVA product. “The SINUVA implant delivers steroids in a time-released fashion right to the source where we need it, in a simple office procedure.”

The efficacy of the SINUVA Sinus Implant was demonstrated in the landmark RESOLVE II pivotal study in 300 patients who were indicated for repeat sinus surgery. RESOLVE II met both co-primary efficacy endpoints as patients receiving SINUVA experienced (1) a statistically significant reduction from baseline to 90 days in bilateral polyp grade (p=0.007), which corresponded to 74% relative reduction in the extent of ethmoid polyp disease; and (2) a significant reduction from baseline to 30 days in nasal obstruction/congestion score (p=0.007), which corresponded to 30% relative improvement, compared to controls. Four of the five pre-specified secondary endpoints achieved statistical significance through day 90 favoring the SINUVA group, including reduction in percent
ethmoid sinus obstruction, reduction of nasal obstruction/congestion symptoms, improvement in sense of smell, and reduction in the proportion of patients still indicated for repeat sinus surgery.

**About Steroid Releasing Sinus Implants**
Steroid releasing implants provide targeted delivery of an anti-inflammatory steroid directly to the site of disease. The use of PROPEL® steroid releasing sinus implants, which are utilized following a surgical procedure to maintain the opening of the sinus passages, has been proven to reduce the likelihood that patients will need additional surgical interventions or require high-dose oral steroids. Placed during a routine doctor’s office visit with local or topical anesthesia, the SINUVA™ (mometasone furoate) Sinus Implant is designed to deliver a treatment for nasal polyp disease for adults who have had prior ethmoid sinus surgery.

The American Rhinologic Society (ARS) endorsed the utilization of drug eluting sinus implants in 2016, citing the number of well-controlled studies on drug-eluting implants in the paranasal 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. For more information about SINUVA, please visit www.SINUVA.com.

Intersect ENT and PROPEL are registered trademarks and SINUVA is a trademark of Intersect ENT, Inc.

**IMPORTANT SAFETY INFORMATION FOR SINUVA™ (MOMETASONE FUROATE) SINUS IMPLANT**

**INDICATION**

The SINUVA Sinus Implant is a corticosteroid-eluting (mometasone furoate) implant indicated for the treatment of nasal polyps, in patients ≥ 18 years of age who have had ethmoid sinus surgery.

**IMPORTANT SAFETY INFORMATION**

Patients with a known hypersensitivity to the mometasone furoate drug, or any of the ingredients in SINUVA, should not use SINUVA. Hypersensitivity reactions, including rash, pruritus, and angioedema have been reported with the use of corticosteroids. If corticosteroid effects such as hypercorticism and adrenal suppression appear in patients, consider sinus implant removal.

SINUVA is made from bioabsorbable polymers designed to soften over time. As the implant softens and polyps decrease, the implant may be expelled out of the nose on its own or with actions such as sneezing or forceful nose blowing. The implant can be removed 90 days after placement or earlier at the physician’s discretion. Repeat administration of SINUVA has not been studied.

As with other endoscopic sinus procedures, there are risks associated with the insertion or removal of SINUVA. SINUVA should be inserted by physicians trained in otolaryngology.
The nasal mucosa adjacent to the SINUVA Sinus Implant should be monitored for any signs of bleeding (epistaxis), irritation, infection, or perforation. Avoid the use of SINUVA in patients with nasal ulcers or trauma.

The most common adverse reactions observed in clinical studies were bronchitis, nasopharyngitis, otitis media, headache, presyncope, asthma, and epistaxis.

Patients experiencing excessive nasal bleeding, symptoms of infection or symptoms suggesting that the implant has moved, such as irritation or a choking sensation in the back of the throat, should immediately contact a healthcare professional.

Close monitoring is recommended if patients have a change of vision or a history of increased intraocular pressure, glaucoma and/or cataracts.

You may report side effects to your physician or to the FDA at 1-800-FDA-1088 or www.fda.gov.medwatch. You may also report side effects to Intersect ENT at 1-866-531-6004.

RX Only. For important risk and use information about SINUVA, please see Full Prescribing Information at www.SINUVA.com.

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 statements include those related to the safety, efficacy and patient and physician adoption of SINUVA. 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 company’s ability to procure and maintain required regulatory approvals for our products and the adoption of SINUVA and the company’s other therapies by physicians and patients, 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 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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