

## **Intersect ENT Announces Publication of Randomized Pivotal Study of the SINUVA™ Sinus Implant, a New In-Office Treatment Option for Recurrent Nasal Polyps**

MENLO PARK, Calif.— January 22, 2018 — Intersect ENT, Inc. (NASDAQ: XENT) today announced publication of results from a randomized pivotal Phase III study of the company's SINUVA™ (mometasone furoate) Sinus Implant, a new targeted approach to treating recurrent nasal polyp disease in patients who have had previous ethmoid sinus surgery. Results were published in the [\*International Forum of Allergy & Rhinology\*](#).

Placed during a routine physician office visit, SINUVA expands in the sinus cavity and delivers an anti-inflammatory steroid directly to the site of polyp disease for up to 90 days. SINUVA was recently approved by the U.S. Food and Drug Administration (FDA), and will be commercially available to ear, nose and throat (ENT) physicians in the second quarter of 2018.

“The RESOLVE II study shows that SINUVA significantly reduces nasal obstruction and improves the sense of smell, while reducing the need for additional surgical procedures,” said Robert C. Kern, M.D., chairman of Otolaryngology – Head and Neck Surgery at Northwestern University Feinberg School of Medicine and national co-principal investigator of the study. “These results are particularly compelling, since the implant can be placed during a routine office procedure, typically requiring only topical anesthesia. I believe SINUVA will be an attractive option for patients with recurrent polyps.”

RESOLVE II was a randomized, blinded, sham-controlled Phase III clinical trial which assessed the safety and efficacy of the SINUVA implant. The RESOLVE II study evaluated 300 adult chronic sinusitis patients, all of whom were indicated for revision sinus surgery at study entry because of recurrent, medically refractory symptoms and bilateral nasal polyposis. Patients were randomized to either a treatment group, undergoing bilateral implant placement in the office setting, or a control group, undergoing a sham procedure. Both groups recorded symptoms using a daily diary and used mometasone furoate nasal spray once daily (200 mcg) through 90-day follow-up.

The study authors concluded that significant improvements over a range of subjective and objective endpoints, including a reduction in the need for sinus surgery by 61%, suggest that the SINUVA Sinus Implant may play an important role in management of recurrent nasal polyps.

The study authors note that “the observed magnitude of improvements with sinus implants is compelling,” especially because the study population comprised “patients with high prevalence of allergic rhinitis, asthma and aspirin exacerbated respiratory disease and those who failed several prior surgeries ... The treatment group demonstrated rapid superiority to controls in reducing Nasal Obstruction/Congestion scores by day 30 that was sustained throughout the duration of the study.”

“SINUVA, like our PROPEL family of products, is backed by robust clinical evidence, including four studies in over 400 patients,” said Lisa Earnhardt, president and CEO of Intersect ENT. “We are thrilled to offer this new targeted treatment for recurrent nasal polyp disease, giving patients a drastically different approach to the current regimen of repeat surgeries, high-dose oral steroids, and intranasal sprays and rinses, which rely heavily on patient compliance.”

As previously reported, the study met the co-primary efficacy endpoints and four pre-specified secondary efficacy endpoints. Patients treated with implants experienced significant reduction in both nasal obstruction/congestion score ( $p=0.0074$ ) and bilateral polyp grade ( $p=0.0073$ ) compared to control. At day 90, implants were also associated with significant reductions in four pre-specified secondary endpoints compared to control: proportion of patients still indicated for repeat sinus surgery

( $p=0.0004$ ), percent ethmoid sinus obstruction ( $p=0.0007$ ), nasal obstruction/congestion ( $p=0.0248$ ) and decreased sense of smell ( $p=0.0470$ ).

Safety was evaluated by endoscopic examination and evaluation of adverse events. The overall incidence of adverse events was similar in both groups, and the most common was acute sinusitis, which occurred less frequently in the treatment group.

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. Many people with chronic sinusitis and nasal polyps return to their ENT specialist within the first year following initial treatment. Approximately 635,000 Americans have had previous sinus surgery and continue to see their ENT physicians for treatment of recurring symptoms.

### **About SINUVA™ (mometasone furoate) Sinus Implant**

A new treatment option for patients with recurrent nasal polyps, SINUVA is placed during a routine physician office visit. The implant expands in the sinus cavity and delivers an anti-inflammatory steroid directly to the site of polyp disease for 90 days. Results from a randomized clinical trial demonstrated a 74% relative reduction in bilateral polyp grade (a measurement of the extent of ethmoid polyp disease) for patients treated with SINUVA, compared to control.

## **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  $\geq 18$  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](http://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](http://www.SINUVA.com).

### **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](http://www.IntersectENT.com). For more information about SINUVA, please visit [www.SINUVA.com](http://www.SINUVA.com).

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

### **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 successfully address FDA identified issues completely or on a timely basis, the adoption of SINUVA and the company's other therapies by physicians, 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, Form 10-Q available at the SEC's Internet site ([www.sec.gov](http://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.

# # #

XENT-G

**Media Contact:** Nicole Osmer  
650.454.0504  
[nicole@healthandcommerce.com](mailto:nicole@healthandcommerce.com)

**Investor Contact:** Jeri Hilleman  
650.641.2105  
[ir@intersectent.com](mailto:ir@intersectent.com)