Intersect ENT Announces Publication of a Pooled Analysis of the SINUVA Sinus Implant for Nasal Polyps

Pooled analysis of the RESOLVE and RESOLVE II Studies Provides Level 1a Clinical Evidence

MENLO PARK, Calif.— June 4, 2019 — Intersect ENT®, Inc. (NASDAQ: XENT), a company dedicated to transforming care for patients with ear, nose and throat conditions, today announced publication of a pooled analysis of the RESOLVE and RESOLVE II randomized controlled trials (RCT) in the *American Journal of Rhinology & Allergy*. The results provide level 1a clinical evidence supporting the use of the SINUVA® (mometasone furoate) Sinus Implant for management of patients with recurrent nasal polyps in adult patients who have had previous ethmoid sinus surgery.

The analysis included 375 patients with chronic sinusitis and nasal polyps who were candidates for revision endoscopic sinus surgery (RESS) because of persisting symptoms of nasal obstruction/congestion and recurrent bilateral nasal polyps (non-cancerous tissue growth) despite ongoing topical steroid therapy and a recent course of systemic steroids. Patients were randomized to undergo an in-office bilateral placement of SINUVA in the ethmoid sinuses under local anesthesia (treatment group) or an in-office bilateral sham procedure (control group). All patients were required to use mometasone furoate nasal spray (MFNS) once daily. All study patients were blinded during the baseline procedure and each follow-up endoscopic examination.

The pooled analysis met all four efficacy endpoints, demonstrating a decrease in nasal obstruction/congestion score ($p=0.0095$), bilateral polyp grade ($p=0.0008$) and ethmoid sinus obstruction ($p<0.0001$) at 90 days in SINUVA patients compared to the control group on MFNS alone. Additionally, results revealed a 59% reduction in the proportion of SINUVA patients who were still indicated for RESS at day 90 compared to a 31% reduction among patients in the control group ($p<0.0001$). Only one patient (0.4%) experienced an implant-related serious adverse event (epistaxis).

“The findings of this analysis reveal the favorable role SINUVA can play in the management of recurrent nasal polyps in patients who have had a previous sinus surgery,” said Pablo Stolovitzky, M.D., of ENT of Georgia in Atlanta, lead author of the study. “These data provide clinical evidence that SINUVA – administered through a quick and simple office procedure – offers significant benefits for patients, reducing polyp growth and nasal obstruction, and ultimately, reducing the need for repeat surgeries.”

Intersect ENT will sponsor several events at RhinoWorld Chicago from June 5 to 9. To learn more about SINUVA, visit Booth #18.

SINUVA was approved by the U.S. Food and Drug Administration (FDA) in December 2017. Placed during a routine 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.

“We are very pleased to see these strong study findings added to the foundational pool of data supporting the use of SINUVA,” said Lisa Earnhardt, president and CEO, Intersect ENT. “We are proud that this data provides further evidence for ENTs seeking improved outcomes for patients with nasal polyps and supports SINUVA as a favorable alternative to revision endoscopic sinus surgery.”

About the RESOLVE Study

RESOLVE was a double-blind RCT in 100 adult patients with chronic rhinosinusitis and nasal polyps, who had a previous sinus surgery and were indicated for revision endoscopic sinus surgery because they presented with recurrent nasal obstruction/congestion symptoms and recurrent bilateral sinus obstruction due to nasal polyps. The study evaluated the safety and efficacy of SINUVA to improve symptoms of nasal obstruction/congestion and reduce nasal polyps over three months. RESOLVE showed positive trends and an acceptable safety profile but did not meet its efficacy endpoints. The reduction in nasal obstruction/congestion score and bilateral polyp grade from baseline to day 90 reached statistical significance in a subset of patients with a higher polyp burden (grade 2 or higher on each side).

About the RESOLVE II Study

RESOLVE II was a double-blind RCT in 300 adult patients with chronic rhinosinusitis and nasal polyps who had a previous sinus surgery but were indicated for revision endoscopic sinus surgery because they presented with refractory symptoms of nasal obstruction/congestion and recurrent bilateral nasal polyps. The study evaluated the safety and efficacy of SINUVA over three months. Primary efficacy endpoints were a change in nasal obstruction/congestion score from baseline to 30 days and in bilateral polyp grade from baseline to 90 days. The SINUVA treatment group included 201 randomized patients who underwent bilateral placement of SINUVA in the ethmoid sinuses. Ninety-nine patients were randomized to the control group where they received a sham procedure. Patients receiving SINUVA demonstrated statistical improvements compared to the control group across multiple prespecified primary and secondary efficacy endpoints.

About Steroid Releasing Sinus Implants

Steroid releasing implants provide targeted delivery of an anti-inflammatory steroid directly to the site of disease. 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.

INDICATION AND IMPORTANT SAFETY INFORMATION FOR THE SINUVA® SINUS IMPLANT

INDICATION
SINUVA Sinus Implant is a prescription steroid-releasing (mometasone furoate) implant indicated for the treatment of nasal polyps in patients 18 years or older who have had ethmoid sinus surgery.

IMPORTANT SAFETY INFORMATION

Who should not use SINUVA?
Do not use SINUVA if you are allergic to mometasone furoate or any ingredients of the implant.
What should I tell my doctor before receiving SINUVA?
Before you receive SINUVA, tell your doctor about all medical conditions you have including nasal/sinus problems (such as nasal ulcers or trauma), eye problems (such as glaucoma or cataracts), or any untreated fungal, bacterial, or viral infections.

What are the possible side effects of SINUVA?
Serious side effects of SINUVA can include:
Local reactions including nosebleed and injury to nerves or blood vessels in the nose/sinus.
Serious allergic reactions have happened in patients using mometasone furoate including rash, itching or swelling of the lips, face, tongue, and throat, and breathing problems. Call your doctor right away if you have any of these reactions.
Weakened immune system that may increase your risk of infections. Avoid contact with people who have contagious diseases such as chickenpox or measles. Call your doctor right away if you have been near someone with chickenpox or measles.
Adrenal insufficiency is a condition in which the adrenal glands do not make enough steroid hormones and can cause tiredness, weakness, nausea and vomiting and low blood pressure. Talk to your doctor if steroid effects such as Cushing Syndrome and adrenal suppression appear.
The most common side effects of SINUVA (in more than 1% of subjects and that occurred more

frequently in the treatment group compared to control) in clinical studies were bronchitis, cold symptoms, middle ear infections, headache, lightheadedness or dizziness, asthma, and nosebleeds. Tell your doctor if you have any side effects that bother you or don't go away. Risks related with the insertion and removal of SINUVA are similar to other endoscopic sinus procedures.

SINUVA is made from materials designed to soften over time and may fall out of the nose on its own as polyps decrease or if you sneeze or blow your nose forcefully. The implant can be removed 90 days after placement or earlier at your doctor's discretion. Repeat use of SINUVA has not been studied.

Contact your doctor immediately if you have any changes in vision, 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.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

For important risk and use information, please see Full Prescribing Information for SINUVA at www.sinuva.com

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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