Menlo Park, Calif. – May 22, 2017 – Intersect ENT, Inc. (NASDAQ: XENT), a company seeking to improve the quality of life for patients with ear, nose and throat conditions, today announced that the U.S. Food and Drug Administration (FDA) has accepted the New Drug Application (NDA) for the company’s investigational SINUVA™ Steroid Releasing Sinus Implant and set a PDUFA target action date of January 7, 2018.

The SINUVA implant, previously known as the RESOLVE product, is placed during a routine physician office visit. The implant is designed to provide a less invasive treatment option for patients with recurrent ethmoid sinus obstruction, including polyps, that might otherwise warrant a repeat surgical procedure. More than 635,000 Americans are potential candidates for the SINUVA implant – an underserved population, as current treatment relies on high-dose oral steroids and repeat surgery.

“The SINUVA implant offers the potential to provide a less invasive and more cost-effective solution, performed easily in the doctor’s office, for patients suffering from persistent chronic sinusitis,” said Lisa Earnhardt, president and CEO of Intersect ENT. “We are excited that FDA’s filing of this NDA advances us a step closer to bringing this important innovation to ENT physicians and their patients.”

SINUVA, Intersect ENT’s fourth steroid releasing implant, was evaluated in four clinical studies to assess the safety and effectiveness of the product. The randomized, blinded, multi-center phase III RESOLVE II pivotal trial evaluated 300 adult chronic sinusitis patients, all of whom were indicated for revision sinus surgery at study entry due to recurrent symptoms and obstructive inflammation. Patients were randomized to one of two groups: a treatment group consisting of bilateral SINUVA implant placement in the office, or a control group consisting of a sham procedure; both groups continued to receive standard treatments such as topical nasal steroid sprays.

The trial met both co-primary efficacy endpoints, demonstrating a statistically significant reduction in nasal congestion and polyp burden. Secondary endpoints achieving statistical significance through day 90 included a reduction in the proportion of patients still indicated for repeat sinus surgery, reduction in ethmoid sinus obstruction, and improvements in both nasal obstruction symptoms and sense of smell.

About SINUVA Steroid Releasing Sinus Implant
The investigational SINUVA Steroid Releasing Sinus Implant is designed to be placed during a routine physician office visit to provide a less invasive treatment option for chronic sinusitis patients with recurrent sinus obstruction that would otherwise warrant revision surgery. The implant releases mometasone furoate to the ethmoid sinus lining to target inflammation directly. It was designed with...
greater radial strength than Intersect ENT’s PROPEL products in order to dilate obstructed sinuses and releases steroid over a longer period of time to reduce inflammation. SINUVA has not been approved by the FDA and is available for investigational use only.

**About Intersect ENT**
Intersect ENT is dedicated to transforming the landscape of care for patients with ear, nose and throat conditions. The company’s PROPEL family of dissolvable steroid releasing implants are clinically proven to improve outcomes for chronic sinusitis patients undergoing sinus surgery. 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).

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

**Forward-Looking Statements**
The statements in this press release regarding Intersect ENT’s continued growth, product development and product adoption are "forward-looking" statements. These forward-looking statements are based on Intersect ENT’s current expectations and inherently involve significant risks and uncertainties. These statements and risks include Intersect ENT's ability to provide solutions to improve surgical outcomes, Intersect ENT’s ability to expand the use and adoption of its current products and advance its pipeline, Intersect ENT’s ability to obtain and maintain FDA or other regulatory approvals for our products, including SINUVA, and the ability to procure and maintain adequate coverage and reimbursement for our products and/or the procedures in which they are used. 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 are described in the company's filings on Form 10-K, Form 10-Q and the company’s other filings with the Securities and Exchange Commission (SEC) 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
Inquiries:

Media: Nicole Osmer  
       650.454.0504  
       nicole@healthandcommerce.com

Investors: Jeri Hilleman  
           650.641.2105  
           ir@intersectENT.com