CMS Consolidates SINUVA Sinus Implant Coverage Under a Distinct Code, J7402, and Publishes an ASP Clarifying Payment and Easing Payer Coverage Adjudication

March 8, 2021

Pass-Through Status Will Continue Under the New Code Through June 30, 2023

MENLO PARK, Calif.--(BUSINESS WIRE)--Mar. 8, 2021-- Intersect ENT®, Inc. (Nasdaq: XENT), a global ear, nose and throat ("ENT") medical technology leader dedicated to transforming patient care, today announced that the Centers for Medicare and Medicaid Services (CMS) published an average selling price (ASP) for the Company's SINUVA sinus implant, providing predictability, transparency, and confidence of reimbursement for providers and payers going forward. In January 2021, CMS created separate and distinct codes for Intersect ENT's two bioabsorbable implant product lines PROPEL (S1091) and SINUVA (J7402). CMS has now attached an ASP to J7402, "mometasone furoate sinus implant, (sinuva), 10 micrograms." Previously, a single code covered both products despite their substantial differences.

Additionally, CMS confirmed consolidation of all coding for SINUVA into the newly created Code, J7402. In so doing, CMS's action incorporates SINUVA "pass-through" status in ambulatory care settings with Medicare patients to the new J-Code, J7402, and eliminates the temporary sinus implant C-Code, C9122, issued in July 2020. These actions came as a result of the Company's application to CMS for clarification and simplification in coding of the products. The Company believes the separate and dedicated codes will have a positive impact on patient and physician access by improving accuracy in claims adjudication, supporting expanded use at multiple sites of service, and providing greater clarity of coverage for payers and providers.

"We are pleased that CMS consolidated SINUVA coverage to a single code and published a SINUVA ASP. These actions will help better inform ENT surgeons of the amount of implant reimbursement they can expect regardless of setting of care, thereby greatly reducing the uncertainty that can come with claims submissions," stated Thomas A. West, President and Chief Executive Officer of Intersect ENT. "CMS's recent decisions will also clearly differentiate coding for SINUVA and PROPEL, two very different products. This will serve to simplify and streamline coding and reimbursement across our portfolio and will support evidence-based and cost-effective care across the continuum of need in chronic rhinosinusitis."

SINUVA® Steroid Releasing Sinus Implant

SINUVA is a non-surgical, corticosteroid-eluting implant for the treatment of nasal polyps in adult patients who have had ethmoid sinus surgery. Its innovative 2-in-1 design incorporates a self-expanding, bioabsorbable implant structure along with the targeted delivery of an anti-inflammatory corticosteroid, mometasone furoate. It provides localized drug delivery for up to 90 days directly to the site of disease. By nature of its design as an office-administered implant with direct delivery of anti-inflammatory medication, SINUVA minimizes the reliance on patient compliance. SINUVA is clinically proven to reduce polyps and the need for revision nasal surgery, as well as improve the symptoms of nasal polyps, nasal obstruction, congestion and decreased sense of smell.

About Intersect ENT®

Intersect ENT is a global ear, nose and throat medical technology leader dedicated to transforming patient care. 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. In October 2020, Intersect ENT acquired Fiagon AG Medical Technologies, a global leader in electromagnetic surgical navigation solutions with an expansive portfolio of ENT product offerings, including the VENSURE sinus dilation balloon, that complement the Company's PROPEL ® and SINUVA® sinus implants and extend its geographic reach.

For additional information on the Company or the products including risks and benefits please visit www.IntersectENT.com. For more information about PROPEL® (mometasone furoate) sinus implants and SINUVA® (mometasone furoate) sinus implant, please visit www.PROPELOPENS.com and www.SINUVA.com.

SINUVA Indication & Important Safety Information

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 clinical studies were bronchitis, cold symptoms, middle ear infections, headache, lightheadedness or dizziness, asthma, and nosebleeds. The following adverse reactions have been identified during post-approval use of the SINUVA sinus implant. These events include implant migration, lack of efficacy, nasal pain, headache, 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 will be removed 90 days after placement or earlier at your doctor's discretion.

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 (www.SINUVA.com/PI).

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. We may, in some cases, use terms such as "look forward," confident," "promises," "predicts," "believe," "potential," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should," or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. 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 those related to the safety, efficacy and patient and physician adoption of the company's products and therapies, the ability to obtain and maintain reimbursement codes for its products, the company's ability to procure and maintain required regulatory approvals for our products, the company's ability to grow and expand its business, 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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IR Contact:
Randy Meier, 650-641-2105
Executive Vice-President & CFO
ir@intersectENT.com

Media Contact:
Erich Sandoval, 917-497-2867
Finn Partners for Intersect ENT
IntersectENT@finnpartners.com

Source: Intersect ENT, Inc.