Intersect ENT Receives CE Mark Approval for PROPEL® Contour for Patients with Chronic Rhinosinusitis Following Frontal Sinus Surgery

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Localized steroid-releasing sinus implant designed to maintain sinus opening now available in select EU countries

MENLO PARK, Calif.--(BUSINESS WIRE)--May 20, 2021-- Intersect ENT®, Inc. (Nasdaq: XENT), a global ear, nose and throat ("ENT") medical technology leader dedicated to transforming patient care, today announced it has received CE Mark approval for the company's PROPEL ® Contour (mometasone furoate) sinus implant enabling sales and distribution in the European Union. The Contour CE approval expands the portfolio of PROPEL products available for commercialization inclusive of PROPEL and PROPEL Mini. PROPEL Contour is specifically designed to maintain patency and reduce inflammation, and conform to the sinus ostia (openings) by focusing mechanical support and steroid delivery where it is needed to optimize sinus surgery outcomes. It is the third localized drug delivery implant, completing the PROPEL family of drug-eluting, bioabsorable implants now available to ENT specialists in select EU countries.

PROPEL Contour features an innovative hourglass shape, specifically designed for placement in the frontal sinuses (between the eyebrows) following sinus surgery for chronic rhinosinusitis patients. The implant features a low-profile flexible delivery system to make it easier to access areas of the frontal sinus ostia.

"Having the ability to accommodate the size and variable shape of the frontal sinus openings with the PROPEL Contour sinus implant is a great advantage for ENT specialists who treat patients suffering from chronic rhinosinusitis," said Prof. Dr. Jan Gosepath, Chairman, Department of Otolaryngology, Head and Neck Surgery, Helios HSK Wiesbaden and Medical Director, Helios Private Clinic Wiesbaden. "Since this bioabsorbable implant is designed to be self-retaining against the tissue lining, the surgically enlarged sinus opening can be maintained and the steroid can be delivered directly to the site where it is needed most to improve post-operative outcomes."

Chronic rhinosinusitis is one of the most common chronic medical conditions worldwide, affecting all age groups, with an estimated incidence of nearly 11% in Europe.[i] Of those in the UK with chronic sinusitis, approximately 15 percent undergo sinus surgery yearly after failing medical treatment.[ii] Quality of life scores of patients with chronic sinusitis are significantly lower than in other common chronic diseases, such as congestive heart failure, angina, chronic obstructive pulmonary disease, and back pain.[iii] Chronic sinusitis symptoms may include drainage of excess mucus, nasal blockage or congestion, difficulty breathing, pain and tenderness around the eyes, cheeks, nose and forehead, a reduced sense of smell and taste, and fatigue and irritability.[iv]

"We are pleased that PROPEL Contour, the latest addition to the PROPEL family of steroid-releasing sinus implants, is now available in select EU countries to treat patients undergoing sinus surgeries, which represent the majority of procedures for the treatment of chronic rhinosinusitis," said Thomas A. West, President and Chief Executive Officer of Intersect ENT. "Our goal is to offer sinus physicians the broadest range of products so they can customize treatment for each patient with focused drug delivery and mechanical support where it is needed to optimize sinus surgery outcomes. The introduction of Contour is consistent with our strategic growth initiatives, where we expect to see more significant revenue contributions from PROPEL and our other technology platforms across Europe over the coming years."

The CE Mark approval was supported by positive data from the PROPEL Contour cohort of the US clinical study - PROGRESS, a prospective, randomized, blinded, multi-center trial of 80 patients designed to assess the safety and efficacy of the implant when placed in the frontal sinus ostia, following endoscopic sinus surgery (ESS) with traditional instrumentation, balloon dilation, or a combination of both. The study met its primary efficacy endpoint, demonstrating a statistically significant 65 percent relative reduction in the need for post-operative interventions, such as the need for additional surgical procedures or the need for oral steroid prescription, compared to surgery alone + standard of care. There were no implant related serious adverse events reported in the clinical studies. The most common adverse reactions observed in > 2% of subjects were acute sinusitis, asthma, headache, chronic sinusitis, upper respiratory tract infection, fungal sinusitis, nasopharyngitis, nausea, neck pain, sinus headache and streptococcal pharyngitis.

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, which is FDA-approved in the US 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.IntersectENT.de and www.SINUVA.com.

Intersect ENT, PROPEL®, and SINUVA® are registered trademarks of Intersect ENT, Inc. VenSure has pending trademark applications.

IMPORTANT SAFETY INFORMATION FOR PROPEL® SINUS IMPLANTS

The PROPEL Contour sinus implant is intended for use in patients ≥ 18 years of age with chronic rhinosinusitis following sinus surgery to maintain patency of the frontal sinus ostia and to locally deliver mometasone furoate to the sinus mucosa. The PROPEL Contour sinus implant

separates/dilates mucosal tissues, prevents obstruction by adhesions/scarring, and reduces edema. The implant reduces the need for post-operative intervention such as surgical adhesion lysis and/or use of oral steroids. For more information on the risks and benefits of PROPEL sinus implants, please visit www.intersectENT.com/products. For use by healthcare professionals 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. 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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[i] Albu S. (2020). Chronic Rhinosinusitis-An Update on Epidemiology, Pathogenesis and Management. Journal of clinical medicine, 9(7), 2285. https://doi.org/10.3390/jcm9072285.

[ii] Javanbakht, M., Saleh, H., Hemami, M.R. et al. A Corticosteroid-Eluting Sinus Implant Following Endoscopic Sinus Surgery for Chronic Rhinosinusitis: A UK-Based Cost-Effectiveness Analysis. PharmacoEconomics Open 4, 679–686 (2020). https://doi.org/10.1007/s41669-020-00198-8

[iii] Metson RB, Gliklich RE. Clinical outcomes in patients with chronic sinusitis. Laryngoscope. 2000;110(3 Pt 3):24–8.

[iv] Mayo Clinic. Chronic Sinusitis Symptoms and Causes https://www.mayoclinic.org/diseases-conditions/chronic-sinusitis/symptoms-causes/syc-20351661

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