



## FDA Performs Pre-Approval Inspection of Intersect ENT's Menlo Park Facility

November 6, 2017

MENLO PARK, Calif.--(BUSINESS WIRE)--Nov. 6, 2017-- Intersect ENT, Inc. (NASDAQ: XENT), a company dedicated to improving the quality of life for patients with ear, nose and throat conditions, today announced that the U.S. Food and Drug Administration (FDA) has performed a Pre-Approval Inspection (PAI) of the company's Menlo Park facility related to the company's New Drug Application (NDA) for the investigational SINUVA™ Steroid Releasing Sinus Implant. At the conclusion of the inspection, the FDA issued a Form 483 with four inspectional observations.

"We appreciate the FDA's close review and are committed to fully addressing the agency's observations within the 15-day response timeframe," said Lisa Earnhardt, president and CEO, Intersect ENT. "We are excited to have completed another important milestone as we continue to advance SINUVA through the NDA process."

The FDA has set a PDUFA target action date of January 7, 2018. The company does not expect these observations to impact the timeline for a decision from the FDA on approval of the SINUVA implant.

### 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 following 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 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. These forward-looking statements include, but are not limited to, statements about proceeding with the company's New Drug Application (NDA) for the investigational SINUVA Steroid Releasing Sinus Implant, fully addressing the FDA's observations within the 15-day response timeframe, expectations regarding the timing and approval of the NDA, and the expansion of adoption of our sinus implants by clinical practitioners. 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 the company's ability to successfully address FDA identified issues on a timely basis and the ability to receive FDA approval of the company's NDA for SINUVA on a timely basis 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.

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