

STAAR Surgical's VISIAN ICL(TM) Receives FDA Approval

Company Expects to Begin Product Shipments Within Six Weeks

MONROVIA, Calif., Dec. 23 /PRNewswire-FirstCall/ -- STAAR Surgical Company (Nasdaq: STAA) today reported that the U.S. Food and Drug Administration (FDA) has approved the Company's Myopic VISIAN ICL(TM) for use in the correction of myopia in adults.

Made of STAAR's proprietary, highly biocompatible Collamer(R) material, the ICL (an abbreviation for Implantable Collamer Lens) is the only minimally invasive foldable lens of its kind approved for the U.S. commercial market. As a result of the unique foldable design, the ICL procedure allows an incision up to 50% smaller than competing technology, and its placement in the eye behind the iris provides a more aesthetically pleasing outcome. In addition to the U.S., the ICL is also approved for sale in 41 countries, including the European Union and has successfully been implanted in more than 40,000 eyes worldwide.

The Company expects to begin shipping the VISIAN ICL to trained doctors in six to eight weeks. In addition, STAAR plans to showcase the new product through training courses and other educational sessions at key upcoming industry symposia including the Royal Hawaiian Eye Meeting and the American Society of Cataract and Refractive Surgery meeting.

"The ICL remains our most significant opportunity for profitable growth going forward and receipt of FDA approval represents a critical milestone," said David Bailey, President and CEO of STAAR Surgical. "Throughout the approval process, doctors' interest in our state-of-the-art lens has continued to build, driven by superior clinical outcomes, the stability and safety of the procedure and the high patient satisfaction rate. We believe the ICL offers patients and their doctors opportunities to achieve higher quality visual outcomes compared with competing technology and this characteristic will be an important growth driver of the refractive phakic implant market. Based upon these dynamics and the success of the ICL in the international markets, we believe that we are well positioned to begin building a strong franchise in the U.S.

"We continue to plan for a controlled commercial launch and believe that the investments we made in our marketing programs two years ago have allowed us to build the infrastructure necessary to be successful," continued Mr. Bailey. "As we have done internationally, we will guide doctors through our training and certification process, which includes proctoring the first five surgeries. Currently, we have more than 860 surgeons who have completed the first phase of training and are ready to be proctored by the five application specialists that we have on staff. Once the doctors have successfully completed the surgeries, they will become certified and will be eligible to order additional VISIAN ICL lenses without a proctor. We believe that this process, which focuses on correct technique, will support high quality clinical outcomes and better ensure proper use of the lens."

The VISIAN ICL is a refractive phakic implant intended for placement in the posterior chamber of the eye. The approved models are indicated for the correction of myopia in adults with myopia ranging from -3.0 to less than or equal to -15.0 diopters with astigmatism less than or equal to 2.5 diopters at the spectacle plane, and the reduction of myopia in adults with myopia ranging from greater than -15.0 to -20.0 diopters with astigmatism less than or equal to 2.5 diopters at the spectacle plane, in patients 21 to 45 years of age with anterior chamber depth (ACD) 3.00 mm or greater, and a stable refractive history within 0.5 diopters for one year prior to implantation.

About STAAR Surgical

STAAR Surgical is a leader in the development, manufacture and marketing of minimally invasive ophthalmic products employing proprietary technologies. STAAR's products are used by ophthalmic surgeons and include the revolutionary VISIAN ICL(TM) as well as innovative products designed to improve patient outcomes for cataracts and glaucoma. STAAR's ICL has received CE Marking, is approved for sale in 41 countries and has been implanted in more than 40,000 eyes worldwide.

Safe Harbor

All statements in this press release that are not statements of historical fact are forward-looking statements, including any statements regarding expectations for success of the ICL in U.S. or international markets, projections of sales, profitability or earnings, revenue, cash or other financial items, any statements of the plans, strategies, and objectives of management for future operations, statements of belief and any statements of assumptions underlying any of the foregoing. These statements are based on expectations and assumptions as of the date of this press release and are subject to numerous risks and uncertainties, which could cause actual results to differ materially from those described in the forward-looking statements. The risks and uncertainties include our limited capital resources and limited access to financing, our ability to overcome negative publicity resulting from warning letters and other correspondence from the FDA Office of Compliance, the willingness of surgeons and patients to adopt a new product and procedure, and our ability to successfully launch and market the ICL in the U.S. while overcoming the foregoing challenges. Our ability to capitalize on the opportunity presented by the ICL approval depends on our overall financial condition, which can be adversely affected by our ability to implement our cost savings strategies and realize our expected savings, our ability to reverse the decline in domestic sales of intraocular lenses ("IOLs"), our ability to maintain or enhance our existing product sales and gross profit margin and reduce compliance expenditures, the rapid pace of technological change in the ophthalmic industry, our ability to compete with much larger ophthalmic companies, general domestic and

international economic conditions, and other factors beyond our control, including those detailed from time to time in our reports filed with the Securities and Exchange Commission. STAAR assumes no obligation to update these forward-looking statements to reflect future events or actual outcomes and does not intend to do so.