First 510(k) Clearance for Company's Enhanced Commercial System Represents Key Step in Bringing Leading Next-Generation Laser Cataract Platform to Market

The Associated Press

ORLANDO, Fla.--(BUSINESS WIRE)--Jun 18, 2012-- LensAR Inc., developer of the LensAR Laser System(TM) for cataract surgery, announced today that it has received 510(k) clearance from the United States Food and Drug Administration (FDA) for the company's next-generation commercial system, for use in anterior capsulotomy, with and without laser phacofragmentation during cataract surgery. While LensAR's first-generation platform had received 510(k) clearances, this regulatory action covers the system that is now in final preparation for commercial launch in the U.S.

The LensAR Laser System combines the latest laser technology with unique product features specifically intended to improve both surgeon and patient interactions with the system. These enhancements include: -- Proprietary technology for 3D-imaging measurement and beam guided delivery that generates a personalized surgical treatment plan.

-- Precise measurement of lens tilt and decentration in 3D, which aligns the treatment plan with the patient's unique positioning, anatomy and visual axis.

-- Effective cataract fragmentation cutting algorithms capable of addressing all cataract grades, while significantly reducing, or eliminating entirely, the amount of ultrasound energy required to complete the surgery.

-- Laser head and patient docking system that easily moves to the patient while accommodating a standard patient gurney.

-- System footprint, mobility and ergonomics that have been designed specifically for compatibility with usual work-flows, as well as multiple operating room or treatment room layouts.

"The enhancements that LensAR has made to its technology have been quite impressive and have significantly increased the range of benefits the system can deliver to cataract surgeons," stated Dr.

Louis "Skip" Nichamin, member of LensAR's medical advisory board. "I'm particularly pleased with the company's dedication to creating a platform that not only delivers industry leading clinical outcomes but also considers and addresses the unique practice challenges facing today's cataract surgeons." "We couldn't be more pleased with the drive and determination of the LensAR team in receiving

their approval today. With the regulatory clearance, we eagerly anticipate the commercial launch of the system and meeting the needs of our customers and their patients," said Steve Elms, Managing Partner at Aisling Capital and Chairman of the Board of LensAR. "We are excited to support the company as they both gain market share and continue their leading edge innovation in order to continually provide our customers with best solutions for their patients and practices." The LensAR Laser System has been developed to meet the advancing needs of refractive cataract surgeons and their patients. The platform's proprietary 3D imaging measurement and beam guided delivery is designed to image and analyze the anatomy across all grades of cataract to improve proficiency. Unlike traditional imaging systems, LensAR's 3D technology provides clean, low noise images that are both high contrast and high-resolution from the anterior surface of the cornea to the posterior capsule. This precise technology allows for the creation of an exact capsulotomy incision size and placement based on IOL selection and fragments high grade cataracts for easier removal. Importantly, the system's sophisticated phacofragmentation techniques lead to a significant reduction in, and in some cases the complete elimination of, the use of ultrasound energy.

To date, commercial LensAR Laser Systems have been installed at the Instituto de Ojos Sacro Cuore in Lima, Peru and the Asian Eye Institute in the Philippines. Members of the Company's medical advisory board and nearly thirty select surgeons have conducted procedures on these systems. Their superior clinical results confirm that the LensAR Laser System is poised to compete well in the rapidly growing market for laser cataract surgery.

"Today's regulatory milestone validates all the work our team has put into enhancing our laser platform and moves us one critical step closer to the commercialization of the LensAR Laser System in the U.S.," said Nick Curtis, LensAR's Chief Executive Officer. "With final preparations for our U.S. commercial launch underway, we are excited to begin working with cataract surgeons across the country to integrate our leading laser technology into their practices." About LensAR, Inc.

LensAR, Inc. is a leader in the development and commercialization of a next generation laser and advanced 3D imaging technology for refractive cataract surgery. For more information please visit www.lensar.com Previous generations of the LensAR(TM) Laser System have been cleared by FDA for anterior capsulotomy and lens fragmentation. For other indications it is an investigational device limited by US law to investigational use only. The system has been used in more than 700 eyes outside the United States to date.

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