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**FDA APPROVES RXSIGHT'S LIGHT ADJUSTABLE LENS,
FIRST IOL TO ENABLE REFRACTIVE CORRECTION AFTER
CATARACT SURGERY**

Company also announces CE Mark certification

ALISO VIEJO, Calif., November 22, 2017 – RxSight, Inc. announced today that the U.S. Food and Drug Administration (FDA) has approved the RxSight™ Light Adjustable Lens and the Light Delivery Device (LDD) for patients with pre-existing astigmatism of ≥ 0.75 diopters undergoing cataract surgery. This action ushers in a new era in the treatment of cataracts, as RxSight's Light Adjustable Lens is the first and only FDA approved intraocular lens (IOL) that can be adjusted post-operatively to improve uncorrected visual acuity.

"Predictable and accurate refractive outcomes are essential to ensure patients are happy with their vision following cataract surgery," said Vance Thompson, M.D. of Vance Thompson Vision in Sioux Falls, SD. "Until my work as an investigator in the Phase III study of the Light Adjustable Lens, I had never encountered an IOL that consistently delivered the refractive accuracy that my premium cataract patients demand."

Dr. Thompson continued, "Unfortunately, no matter what we do preoperatively with our measurements and mathematical calculations, the implant power is rarely perfect because of the variables of incision healing and the final effective lens position. With the Light Adjustable Lens, we can address these limitations for the first time ever and more predictably deliver the results patients desire. Light adjustable implants will change the way we do cataract surgery forever, and I am thrilled that I will be able to finally deliver this level of care to my patients."

FDA approval was based on results of a U.S. randomized, pivotal study comparing the Light Adjustable Lens to a commercially available monofocal lens in 600 patients with pre-existing astigmatism at 17 investigational sites. Patients receiving the Light Adjustable Lens, followed by light treatment with the LDD, achieved UCVA of 20/20 or better at six months postoperatively at approximately twice the rate of patients receiving a monofocal lens.



91.8% of Light Adjustable Lens patients also achieved a result that was within 0.50 D of target manifest refraction spherical equivalent, which is similar to the refractive accuracy seen in recent LASIK studies. Study safety parameters were based on a comparison to the safety and performance endpoints for intraocular lenses (ISO 11979-7), and results showed that 100% of study eyes had a best corrected visual acuity of 20/40 or better at the six month post-operative visit. The approved device allows correction of up to 2 diopters of post-operative sphere and/or -0.75 to -2 diopters of residual postoperative refractive cylinder.

“We are extremely pleased to have successfully reached this milestone with the world’s first post-operative adjustable IOL,” said Eric Weinberg, Chief Commercial Officer. “This is an exciting opportunity for patients, surgeons and referring optometrists who have been awaiting a true breakthrough in refractive IOL technology. We are very grateful to all of those who have been involved in this effort, including the outstanding clinical coordinators, study investigators and their staff who facilitated the study, as well as the RxSight and FDA personnel who prepared and reviewed the regulatory submission.”

RxSight has also received its CE mark for an expanded cylinder range (-0.5 to -3.00 diopters).

Mr. Weinberg added, “In the near term, RxSight will focus on its post market study, additional indications, platform improvements and building scalable infrastructure.”

About Cataracts

Cataracts, which occur when the eye’s natural lens becomes clouded, are the most common age-related eye condition and leading cause of preventable blindness. In cataract surgery, the clouded natural lens is removed and replaced with an artificial intraocular lens (IOL). According to Market Scope, approximately 27 million cataract surgeries were performed worldwide in 2017, with 4.2 Million in the U.S., making it one of the world’s most prevalent surgical procedures.

Residual refractive error, even with the most modern cataract surgery technologies, is still common due to unpredictable wound healing and variations in post-operative lens position. RxSight’s Light Adjustable Lens addresses this by enabling physicians to make office-based refractive adjustments to the implanted lens after the cataract is removed and the eye is stable.

About RxSight

RxSight is the global leader in adjustable IOL technology. Using a proprietary light treatment to produce precise modifications in lens curvature, RxSight’s Light Adjustable Lens enables doctors and patients to predictably optimize vision after cataract surgery through an office based IOL enhancement. Additional information about RxSight can be found at www.rxsight.com.