Adelaide, Australia, 18 July 2013 – Ellex Medical Lasers Limited (ASX:ELX), a pioneer in medical technologies for the diagnosis and treatment of eye disease, today announced that it has secured US FDA 510(k) approval for its proprietary Retinal Rejuvenation Therapy (2RT™) in the treatment of Clinically Significant Macular Edema (CSME), the most common form of diabetic eye disease which can result in legal blindness.

This follows the Company’s announcement in 2012 that it had received a CE Mark (European Conformity) for 2RT™ for the same indication.

Whilst treatment options already exist for CSME, including the Company’s Integre® photocoagulation laser portfolio, 2RT™ achieves similar clinical outcomes without the collateral damage to the retina associated with conventional thermal photocoagulation.

“Unlike photocoagulation, 2RT is a pain-free and damage-free treatment option for patients,” commented Ellex CEO, Tom Spurling.

Despite its important role in the treatment of CSME, which is a common occurrence in diabetic patients, it is the potential of 2RT™ to treat the early form of Age-Related Macular Degeneration (AMD) which is the principal focus of ongoing clinical and laboratory studies. These studies have shown promising results.

“The 510(k) approval will help us with our efforts to gain more clinical exposure for 2RT in the USA,” added Mr. Spurling.

AMD is the most common cause of blindness and severe vision loss in Australia, with one in seven Australians over the age of 50 affected by the disease.¹ The early form of the disease accounts for up to 80% of all cases of AMD. To date, no treatment exists to halt the progression of AMD to its advanced stage, which is associated with severe vision loss.

“Unlike other treatment options for AMD, which are invasive and target the late-stage complications associated with the disease, 2RT offers the potential to treat AMD in its early stages with a simple in-office treatment,” said Mr. Spurling.

“This means that, for the first time, AMD could be treated before legal blindness occurs or vision is lost.”

ABOUT ELLEX

Ellex Medical Lasers Limited (ASX:ELX) is a pioneer in the development of medical technologies for the diagnosis and treatment of eye disease. Since 1985, Ellex has evolved from a manufacturing company of primarily OEM products to direct marketing of its own branded products through subsidiaries in the United States, Japan, Germany and Australia, and a network of distribution partners in more than 100 countries. Today, more than 20,000 Ellex laser and imaging systems are used worldwide in the fight against blindness. In more recent times, Ellex has diversified its product range to include distribution of a number of complementary third-party ophthalmic products.

For additional information about Ellex and its products, please visit www.ellex.com

ABOUT 2RT

2RT™ is a non-damaging laser treatment that delivers nanosecond pulses of laser energy to stimulate a therapeutic response in the eye to rejuvenate retinal tissue that has been compromised by disease or age. This breakthrough therapy is aimed at treating a range of degenerative diseases that ultimately result in blindness, including Early AMD. Importantly, 2RT™ allows therapeutic benefit to be achieved without the collateral thermal damage and pain associated with conventional retinal laser treatment.

For additional information about 2RT™, please visit www.ellex.com/2RT.

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