

ASX RELEASE

Ellex Medical Lasers Limited (ASX:ELX)

Adelaide, Australia

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Topic: **Ellex Secures China FDA Approval for Ophthalmic Treatment Lasers**



15 June 2016, Adelaide, Australia – Ellex Medical Lasers Limited (ASX:ELX), a global leader in medical devices for the diagnosis and treatment of eye disease, today announced that the China Food and Drug Administration (China FDA) has granted regulatory approval for the Company’s complete portfolio of glaucoma, vitreous floaters and secondary cataract treatment lasers (collectively referred to as the “YAG laser” portfolio) in the Chinese market. Previously, sales of the Company’s YAG lasers in China had been restricted to a specific limited market.

With the Company’s proprietary YAG laser portfolio now available to all ophthalmologists in China, the approval by China FDA is expected to lead directly to increased sales in China during the 2017 financial year.

“The approval process required a significant investment, with resources from our in-house regulatory team committed over a 12-month period. It marks an important milestone for our business as we expand our presence in the fast-growing market of Asia,” commented Ellex CEO, Tom Spurling.

The sales outlook in China is strong, with improved access to healthcare and new investments in ophthalmic infrastructure and technologies driving growing sales demand for ophthalmic products.

Ellex sales into Asia, of which China comprises approximately 80 percent, grew by 52 percent during the half year ended 31 December 2015, accounting for 10 percent of total group sales. The Company expects the growth in sales into Asia for the full year to 30 June 2016 to be materially higher.

“In view of the sales growth achieved to date in China with limited market access, we anticipate this approval will lead directly to higher sales in the 2017 financial year. The Company’s existing Chinese distributor will leverage its in-place sales force and infrastructure to drive this growth,” added Mr. Spurling.

Ellex will continue to invest in the Chinese market over the coming period to obtain regulatory approval of the Company’s proprietary Integre Pro Scan™ retinal treatment laser.

ABOUT GLAUCOMA TREATMENT LASERS

Glaucoma is one of the leading causes of blindness worldwide and is estimated to affect more than 82 million people. According to Market Scope, China has the highest reported incidence of glaucoma worldwide, with more than 20 million Chinese people currently suffering from the disease. Selective laser trabeculoplasty (SLT) is a restorative laser treatment for glaucoma that selectively targets pigmented cells within the eye’s drainage channel, known as the trabecular meshwork (TM), in order to create a more porous TM structure through which aqueous can flow, whilst preserving the surrounding tissue. Ellex is the world’s leading supplier of SLT lasers and manufactures and sells two SLT lasers for the treatment of glaucoma: the Tango™ SLT/YAG combination laser, and the Solo™ SLT laser. Current usage of SLT in China for the treatment of glaucoma is low, but is expected to grow as it has in other developed markets.

ABOUT SECONDARY CATARACT AND VITREOUS FLOATER TREATMENT LASERS

Market Scope currently estimates that more than 4 million cataract surgeries are performed each year in the USA, the world's largest ophthalmic market. In China, the number of cataract surgeries performed each year is growing rapidly, and is estimated at just over 1.6 million procedures, which places it as the world's third largest market for cataract procedures. The number of cataract procedures performed per capita in China is far lower than in the USA and other developed markets, however. The number of cataract surgeries performed is directly related to the number of secondary cataract procedures and the incidence of vitreous floaters. Ellex manufactures and sells two YAG lasers for the treatment of secondary cataracts: the Ultra Q™ microsurgical YAG laser, and the Ultra Q Reflex™ multi-modality YAG laser. The Ultra Q Reflex™ laser is also indicated for the treatment of vitreous strands and opacities (floaters).

ABOUT ELLEX

Ellex designs, develops, manufactures and sells innovative products that help eye surgeons around the world to effectively and efficiently treat eye disease. Ellex is a world leader in this field. Headquartered in Adelaide, Australia, Ellex has ophthalmic lasers and devices that treat glaucoma, retinal disease primarily caused by diabetes, secondary cataract and vitreous opacities, as well as age-related macular degeneration. Manufacturing is carried out in Adelaide, Australia and Fremont, California. Sales and service directly to eye surgeons is conducted via subsidiary offices in Minneapolis, Lyon, Berlin and Tokyo. A network of more than 50 distribution partners around the world services other markets.

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

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