STA to License New Drug – ILUVIEN® – to Improve Vision in Patients with Diabetes-Induced Vision Loss

Melbourne, Australia and Atlanta, Georgia, 28 April 2014: Australian and New Zealand patients suffering from vision impairment due to a type of diabetes-induced eye disease will have access to a new treatment, following a license deal between Australian biopharmaceutical company Specialised Therapeutics Australia (STA) and Alimera Sciences. (NASDAQ: ALIM).

The exclusive agreement enables STA to distribute ILUVIEN® (190 micrograms fluocinolone acetonide intravitreal implant in applicator) – a sustained release intravitreal implant used to treat vision impairment associated with chronic diabetic macular oedema (DMO), when the condition is deemed insufficiently responsive to current available therapies.

Under the terms of the license arrangement, STA will be responsible for all regulatory and commercial activities for ILUVIEN in Australia and New Zealand. The agreement includes a milestone payment to Alimera Sciences on achievement of a Pharmaceutical Benefits Scheme (PBS) listing, as well as an increasing royalty payment based upon a specific sales target.

Australian Ophthalmologist Professor Mark Gillies from the Department of Clinical Ophthalmology and Eye Health, University of Sydney, said ILUVIEN was a welcome treatment option for patients with DMO who no longer respond to conventional therapies and who face progression to loss of vision.

“ILUVIEN provides a new treatment option for those patients for whom other current therapies are unsuitable,” Professor Gillies commented. “All people with diabetes, even those with well-managed conditions, face an increased risk of loss of vision from retinal disease.

“While there may be some side effects of ILUVIEN, these are treatable and a large clinical trial has demonstrated that many patients with advanced retinal

disease will experience sustained improvement in their vision after receiving the implant in their eye which may last for up to three years. Some drugs that are currently injected into the eye may only last four weeks."

Each ILUVIEN implant provides a therapeutic effect for up to 36 months by delivering sustained sub-microgram levels of the corticosteroid, fluocinolone acetonide (FAc).[1-3] ILUVIEN is injected into the back of the patient's eye to take advantage of the eye's natural fluid dynamics. The applicator employs a 25-gauge needle, which allows for a self-sealing wound.[1]

DMO is a primary cause of vision loss associated with diabetic retinopathy. The disease affects the macula, the part of the retina responsible for central vision. When the blood vessel leakage of diabetic retinopathy causes swelling in the macula, the condition has progressed to DMO. Onset of the condition is painless and may go undetected until it manifests as blurred central vision, or vision loss.

STA Chief Executive Officer, Mr Carlo Montagner, said as the population of people with diabetes increases, it is anticipated the annual incidence of diagnosed DMO will also rise.

He said ILUVIEN was not yet approved for sale in Australia and New Zealand but would be made available to patients via the Special Access Scheme until it is approved by the Therapeutic Goods Administration (TGA) and Medsafe.

"We look forward to ILUVIEN providing benefit to thousands of diabetic patients who suffer vision impairment as a result of type 1 or type 2 diabetes," Mr Montagner said.

"We will seek regulatory approval from the TGA and Medsafe as well as reimbursement through the PBS to enable wider availability of this important ophthalmic treatment."

The National Institute for Health and Care Excellence (NICE) in the United Kingdom (UK) has issued final guidance recommending ILUVIEN as an option for patients with chronic DMO.

President and Chief Executive Officer of Alimera Sciences, Mr Dan Myers, commented: "Not only does STA have a proven track record of successful product launches, STA has also consistently topped the IMS physicians surveys for having

the most highly qualified and experienced sales force. We look forward to ILUVIEN making a difference to patients in Australia and New Zealand."

About Specialised Therapeutics Australia

Specialised Therapeutics Australia Pty Ltd (STA) is a biopharmaceutical company dedicated to working with leading pharmaceutical and biotechnology companies worldwide to provide acute care therapies for high unmet medical needs to people living in Australia and New Zealand. The STA therapeutic portfolio and pipeline at present encompasses oncology, haematology, ophthalmology and infectious diseases. STA also has interests in the therapeutic areas of respiratory, dermatology, endocrinology and central nervous system (CNS). Additional information can be found at www.specialisedtherapeutics.com.au

About Alimera Sciences, Inc.

Alimera Sciences, Inc., based in Atlanta, Georgia, is a biopharmaceutical company that specialises in the research, development and commercialisation of prescription ophthalmic pharmaceuticals. Presently Alimera is focused on diseases affecting the back of the eye, or retina. Its primary product, ILUVIEN, is an intravitreal implant containing fluocinolone acetonide (FAc), a non-proprietary corticosteroid with demonstrated efficacy in the treatment of ocular disease.

About DMO

Diabetic macular oedema (DMO), the primary cause of vision loss associated with diabetic retinopathy, is a disease affecting the macula, the part of the retina responsible for central vision. When the blood vessel leakage of diabetic retinopathy causes swelling in the macula, the condition has progressed to DMO. The onset of DMO is painless and may go undetected by the patient until it manifests with the blurring of central vision or acute vision loss. The severity of

this blurring may range from mild to profound loss of vision. As the population of people with diabetes increases, it is anticipated the annual incidence of diagnosed DMO will increase.

About ILUVIEN®

ILUVIEN (190 micrograms of fluocinolone acetonide intravitreal implant in applicator) is a sustained release intravitreal implant used to treat vision impairment associated with chronic DMO considered insufficiently responsive to available therapies. Each ILUVIEN implant provides a therapeutic effect of up to 36 months by delivering sustained sub-microgram levels of fluocinolone acetonide (FAc).[1-3] ILUVIEN is injected into the back of the patient's eye to a position that takes advantage of the eye's natural fluid dynamics. The applicator employs a 25-gauge needle, which allows for a self-sealing wound.[1]

In July 2010, Alimera submitted a Marketing Authorization Application (MAA) to seven European countries via the Decentralised Procedure (DCP) with the Medicines and Healthcare products Regulatory Agency of the UK (MHRA) serving as the Reference Member State (RMS). The MAA included data from two Phase 3 pivotal clinical trials (collectively known as the FAME™ Study) for ILUVIEN conducted by Alimera.[4-5] The trials involved 956 patients in sites across the United States, Canada, Europe and India to assess the efficacy and safety of ILUVIEN for the treatment of DMO.[4-5] At the end of the DCP, a consensus was reached by the RMS and the other six countries that the MAA for ILUVIEN was approvable. To date, six of the seven countries, Austria, the UK, Portugal, France, Spain and Germany have granted national licenses for ILUVIEN. The national phase in Italy is ongoing. ILUVIEN has not been approved by the United States Food and Drug Administration.

Clinical trial data from the FAME Study showed that in patients with chronic DMO at month 30, after receiving the ILUVIEN implant, 38 percent experienced an improvement from baseline in their best corrected visual acuity on the Early Treatment of Diabetic Retinopathy Study (ETDRS) eye chart of 15 letters or more. At the completion of the 36-month study, 34 percent of patients had achieved the

same result. This effect was highly statistically significant ($p < 0.001$) as compared to the sham control group, which received laser and other intravitreally administered therapies.[5]

References

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