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Real World Data In Europe Show Majority Of Diabetic Macular Edema Patients Gain Or Maintain Vision With Iluvien® At 12 Months

Despite other prior treatments, improvements in visual acuity and retinal thickness were seen in the majority of patients

Efficacy and safety data are comparable with Phase III FAME clinical trials

ATLANTA, May 23, 2016 (GLOBE NEWSWIRE) -- Alimera Sciences Limited, the European subsidiary of Alimera Sciences, Inc. (NASDAQ:ALIM) (Alimera), a pharmaceutical company that specializes in the research, development and commercialization of prescription ophthalmic pharmaceuticals, announced the availability of real world data showing that the majority of diabetic macular edema (DME) patients who received ILUVIEN® (Fluocinolone Acetonide 190 micrograms intravitreal implant in applicator) in routine clinical practice gained or maintained vision at 12 months.

In contrast with the pivotal clinical trials known as the FAME studies, where all patients had prior laser therapy and few had received anti-vascular endothelial growth factor (anti-VEGF) therapies, in the ILUVIEN Registry Safety Study at least two thirds are known to have received prior anti-VEGF injections. Despite these prior treatments, patient vision outcomes, intraocular pressure (IOP) increases and other side effects were comparable to the FAME results.

"It is exciting to see that the ILUVIEN real world data in Europe in patients that are primarily refractory to anti-VEGF therapy mirror FAME results several years later after the emergence of changing treatment patterns with anti-VEGF therapy," said Dan Myers, Alimera's chief executive officer.

Professor Usha Chakravarthy from Queen's University Belfast, principal investigator of this post authorization study, said: "In these real world studies, patients were switched to ILUVIEN when clinicians had determined that despite other treatments there was vision decline and worsening appearance of the macula. Following the switch there were improvements in visual acuity and retinal morphology in the majority of patients showing that ILUVIEN is an important addition to our therapeutic armamentarium."

The data were revealed for the first time at the Royal College of Ophthalmologists (RCOpth) Annual Congress in Birmingham, England today. The two real world data sources consist of a European registry study and a patient review audit from the United Kingdom (U.K.).

- The ILUVIEN® Registry Safety Study is a post authorization safety study that Alimera is required to perform in Europe. Interim data presented at the RCOpth Congress is from 328 eyes (292 patients) from 25 centers in the U.K., 10 in Germany and one in Portugal. This study collects primary data on safety and some visual acuity, but no data from optical coherence tomography (OCT).
- The ongoing "Medisoft" audit is a post hoc chart review that has gathered data on 290 eyes (258 patients) from the Medisoft® EMR data systems used in 13 U.K. centers. Medisoft collects retrospective safety data and best collected vision and some data from OCT.

Vision improved in 58.0% of Registry Safety Study patients at 6 months and 61.0% at 12 months, which is comparable with the FAME trials. Mean visual acuity increased from 50.9 letters at baseline to 55.7 letters at six and twelve months, with 15.9% of patients gaining ≥15 letters at 6 months and 20.8% of patients gaining ≥15 letters at 12 months. 27.0% of patients at 6 months and 34.0% at 12 months regained vision that was better than 20/40, which is often a minimum requirement for driving.

In this study, unlike FAME, some patients were on IOP lowering medications prior to ILUVIEN use. Interim results from this European study show that 81.6% of patients required no new or additional IOP-lowering medication, 9.9% had an IOP increase of ≥10mm Hg and 8.2% had an IOP elevation of above 30mm Hg. Regarding cataract formation, among the 51 phakic (natural lens) eyes treated in the study, 14 (27.4%) underwent cataract surgery for an existing cataract concurrent with their ILUVIEN injection, 5 (9.8%) developed a cataract on ILUVIEN, and 10 (19.6%) underwent cataract surgery for existing or new cataracts.

In the interim Medisoft audit, visual acuity data was not captured because it was a post hoc audit and there was variability in the assessment procedures across clinical practices. The audit data show that 85.2% of patients required no new or additional IOP-lowering medication, which is similar to the registry study results. In the 14.8% of patients who did require new or additional IOP management, IOP changes were consistent with the FAME trials and well managed. In the small number of phakic patients included in the Medisoft audit, cataract progression was comparable to that seen in phakic patients in the FAME trials.

The mean change in foveal thickness (reduction in edema) at the last observation was -148.5 microns ($p < 0.001$).

Miss Clare Bailey from Bristol Eye Hospital, who leads the Medisoft audit, added, "Since the ILUVIEN Phase III registration clinical trials were conducted in 2005-2011, the management of patients with DME has changed significantly with the widespread use of anti-VEGF agents. These data demonstrate that in the real world, ILUVIEN can improve or preserve vision with a side effect profile similar to that seen in the Phase III FAME studies in the majority of patients with DME, even when previous anti-VEGF treatments have failed to deliver a sufficient response and we are very pleased to have it as a treatment option for our patients."

About ILUVIEN

www.ILUVIEN.com.

ILUVIEN'S U.S. Indication

ILUVIEN (fluocinolone acetonide intravitreal implant) 0.19 mg is a sustained release intravitreal implant approved in the U.S. to treat diabetic macular edema in patients who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure. Each ILUVIEN implant is designed to release submicrogram levels of fluocinolone acetonide, a corticosteroid, for 36 months.

ILUVIEN'S E.U. Indication

ILUVIEN is indicated for the treatment of vision impairment associated with chronic diabetic macular oedema, considered insufficiently responsive to available therapies.

The ILUVIEN® Registry Safety Study or IRISS is a requirement as part of the approval process in the EEA, where Alimera committed to conduct a five-year, post-authorization, open label registry study in 800 patients treated with ILUVIEN. Through March 31, 2016, Alimera has enrolled over 324 patients.

The "Medisoft" study is a 13 center, real world data UK study which gathers data from the Medisoft electronic medical records data systems used in the study centers. This was presented as a poster at the Royal College of Ophthalmologists' Annual Congress 2016 entitled "UK multi-centre, retrospective audit of electronic patient records to assess the real-world intraocular pressure events following treatment with ILUVIEN® 190 micrograms intravitreal implant for up to 24 months." This study is ongoing and latest interim data was extracted in February 2016.

About Diabetic Macular Edema (DME)

DME, 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 associated with diabetic retinopathy results in swelling of the macula, the condition is called DME. The onset of DME is painless and may go unreported 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. The Wisconsin Epidemiologic Study of Diabetic Retinopathy found that over a 10-year period approximately 19% of people with diabetes included in the study were diagnosed with DME. All people with type 1 or type 2 diabetes are at risk of developing DME.

About Alimera Sciences, Inc.

www.alimerasciences.com

Alimera Sciences (NASDAQ:ALIM), founded in June 2003, is a pharmaceutical company that specializes in the research, development and commercialization of prescription ophthalmic pharmaceuticals. Alimera is presently focused on diseases affecting the back of the eye, or retina, because these diseases are not well treated with current therapies and will affect millions of people in our aging populations. Alimera's commitment to retina specialists and their patients is manifest in Alimera's product and development portfolio designed to treat early- and late-stage diseases. For more information, please

visit www.alimerasciences.com.

For press inquiries:

Katie Brazel

for Alimera Sciences

404-317-8361

kbrazel@bellsouth.net

For investor inquiries:

CG Capital

for Alimera Sciences

877-889-1972

investorrelations@cg.capital

Primary Logo

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