



September 29, 2014

Alimera Sciences Provides Details On FDA Approval Of ILUVIEN® As The First Long-Term Treatment For Diabetic Macular Edema

A single ILUVIEN implant provides treatment for three years

Alimera will hold a conference call Wednesday, October 1, at 8:30 a.m. to discuss the approval

ATLANTA, Sept. 29, 2014 /PRNewswire/ -- Alimera Sciences, Inc. (NASDAQ: ALIM) ("Alimera"), a pharmaceutical company that specializes in the research, development and commercialization of prescription ophthalmic pharmaceuticals, today announced that it will hold a conference call to provide additional information regarding the recent approval by the U.S. Food and Drug Administration (FDA) of ILUVIEN® for the treatment of diabetic macular edema (DME) in patients who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure (IOP). ILUVIEN was approved without any restriction requiring patients to have undergone, or be scheduled for, cataract surgery.

"We are very excited with this news from the FDA and thank the many people who contributed to this outcome and believed in ILUVIEN, including the retinal specialists, clinical site personnel, reading centers, and the many patients and their caregivers for helping us bring this long-term treatment to people in the U.S. with DME," said Dan Myers, president and chief executive officer of Alimera. "The approval of ILUVIEN under this broader label brings a DME treatment to the U.S. that lasts years, not months, after a single injection and greatly expands the addressable market opportunity in the U.S."

The Company expects to begin selling ILUVIEN in the U.S. during the first quarter of 2015.

"The approval of ILUVIEN is wonderful news for the retinal community, as recent studies have indicated that as many as 50 percent of DME patients are not optimally managed with today's standard of care known as anti-VEGF therapies," said Pravin Dugel, M.D., Retinal Consultants of Arizona and clinical associate professor, Doheny Eye Institute, Keck School of Medicine, University of Southern California. "Having a multi-year delivery, low-dose corticosteroid drug will provide an additional treatment option for patients with this disease."

ILUVIEN® (flucinolone acetonide intravitreal implant) 0.19 mg is a sustained release intravitreal implant approved in the U.S. to treat diabetic macular edema (DME) 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 flucinolone acetonide (FAC), a corticosteroid, for 36 months. The ILUVIEN approval was based on clinical trial data that showed that at month 24 after receiving the ILUVIEN implant, 28.7 percent of patients (p value .002) experienced an improvement from baseline in their best corrected visual acuity on the Early Treatment Diabetic Retinopathy Study (ETDRS) eye chart of 15 letters or more. Patients treated with ILUVIEN experienced a statistically significant improvement in visual acuity compared to the control group by week three of follow up, and maintained a statistically significant advantage over the control through completion of the trial at month 36.

"As the role of inflammation in DME becomes more clearly understood, the use of a continuous, long-term, low-dose anti-inflammatory, such as ILUVIEN, is an important option for patients who have DME that persists," said Barry Kuppermann, M.D., Ph.D., professor and chief of the Retina Service at University of California, Irvine.

"As the glaucoma specialist on the FAME Study Data Safety Monitoring Board, I have extensive familiarity with the IOP data related to ILUVIEN," said Richard Parrish, M.D., Professor and Director of the Glaucoma Service at the University of Miami Miller School of Medicine, Bascom Palmer Eye Institute. "I am confident that the benefits of this important treatment for DME will outweigh concerns related to elevated IOP in the indicated patients."

Conference Call to be Held Wednesday, October 1

Alimera will hold a conference call on Wednesday, October 1, 2014 at 8:30 a.m. ET to discuss the ILUVIEN approval. The conference call will be hosted by Dan Myers, president and chief executive officer, and Rick Eiswirth, chief operating officer and chief financial officer.

To participate in the call, please dial (877) 369-6586 (U.S. and Canada) or (253) 237-1165 (international). A live webcast will be available on the Investor Relations section of the corporate website at <http://www.alimerasciences.com>.

A replay of the conference call will be available beginning October 1, 2014 at 11:30 a.m. ET and ending on October 8, 2014 at 11:59 p.m. ET by dialing (855) 859-2056 (U.S. and Canada) or (404) 537-3406 (international), Conference ID Number: 11897511. A replay of the webcast will also be available on the corporate website.

About ILUVIEN®

ILUVIEN® (fluocinolone acetonide intravitreal implant) 0.19 mg is a sustained release intravitreal implant approved in the U.S. to treat diabetic macular edema (DME) 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 (FAC), a corticosteroid, for 36 months.

Corticosteroids have a history of effective use in treating ocular disease inflammation. ILUVIEN is injected in the back of the patient's eye with an applicator that employs a 25-gauge needle, which allows for a self-sealing wound. In the FAME™ Study, phase 3 clinical study of ILUVIEN, the most frequently reported adverse drug reactions included cataract development and increased ocular pressure.

Please see www.ILUVIEN.com for additional information.

ILUVIEN Important Safety Information

Intravitreal injections have been associated with endophthalmitis, eye inflammation, increased intraocular pressure, and retinal detachments. Patients should be monitored following the injection.

Use of corticosteroids may produce posterior subcapsular cataracts, increased intraocular pressure, glaucoma, and may enhance the establishment of secondary ocular infections due to bacteria, fungi, or viruses.

The implant may migrate into the anterior chamber if the posterior lens capsule is not intact.

In controlled studies, the most common adverse reactions reported were cataract development and increases in intraocular pressure.

Patients are advised to have follow-up eye examinations at appropriate intervals following treatment with ILUVIEN. For full prescribing information, log onto www.alimerasciences.com.

About 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 of diabetic retinopathy causes swelling in the macula, the condition has progressed to DME. The onset of DME 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. The Wisconsin Epidemiologic Study of Diabetic Retinopathy found that over a 10-year period approximately 19 percent of people with diabetes studied were diagnosed with DME. All people with type 1 or type 2 diabetes are at risk of developing DME. As the population of people with diabetes increases, Alimera expects the annual incidence of diagnosed DME to increase, as well.

Duration of diabetes is the greatest risk factor for increased retinopathy and is associated with an increased prevalence of DME. The appearance of retinopathy is associated with an upregulation of vascular endothelial growth factor (VEGF) causing an increase in permeability of vessels leading to leakage of fluid. As retinopathy worsens, an up-regulation of multiple cytokines (inflammatory factors) takes place. Corticosteroids offer a broad effect on down regulation of multiple cytokines associated with DME that persists.

About Alimera Sciences, Inc.

Alimera Sciences, Inc., headquartered in Alpharetta, Georgia, is a pharmaceutical company that specializes in the research, development and commercialization of prescription ophthalmic pharmaceuticals. Alimera's European operations are conducted from London by its subsidiary, Alimera Sciences Limited. For more information, please visit www.alimerasciences.com.

Forward Looking Statements

This press release contains "forward-looking statements," within the meaning of the Private Securities Litigation Reform Act of 1995, regarding, among other things, the availability of ILUVIEN in the U.S. and expectations regarding the annual incidence of diagnosed DME. Such forward-looking statements are based on current expectations and involve inherent risks and

uncertainties, including factors that could delay, divert or change any of them, and could cause actual results to differ materially from those projected in its forward-looking statements. Meaningful factors which could cause actual results to differ include, but are not limited to, uncertainty as to Alimera's ability to commercialize, and market acceptance of, ILUVIEN in the United States, as well as other factors discussed in the "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of Alimera's Annual Report on Form 10-K for the year ended December 31, 2013 and Quarterly Report on Form 10-Q for the quarter ended June 30, 2014, which are on file with the Securities and Exchange Commission (SEC) and available on the SEC's website at www.sec.gov. In addition to the risks described above and in Alimera's Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other filings with the SEC, other unknown or unpredictable factors also could affect Alimera's results. There can be no assurance that the actual results or developments anticipated by Alimera will be realized or, even if substantially realized, that they will have the expected consequences to, or effects on, Alimera. Therefore, no assurance can be given that the outcomes stated in such forward-looking statements and estimates will be achieved.

All forward-looking statements contained in this press release are expressly qualified by the cautionary statements contained or referred to herein. Alimera cautions investors not to rely too heavily on the forward-looking statements Alimera makes or that are made on its behalf. These forward-looking statements speak only as of the date of this press release (unless another date is indicated). Alimera undertakes no obligation, and specifically declines any obligation, to publicly update or revise any such forward-looking statements, whether as a result of new information, future events or otherwise.

For press inquiries:

Katie Brazel, FleishmanHillard
for Alimera Sciences
404-739-0150
Katie.Brazel@fleishman.com

For investor inquiries:

John Mills, ICR
for Alimera Sciences
310-954-1105
John.Mills@ICRINC.com

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