



**FOR IMMEDIATE RELEASE**

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**ALIMERA ANNOUNCES POSITIVE RESULTS FROM THE TWO PHASE 3 FAME™ TRIALS OF ILUVIEN® IN PATIENTS WITH DIABETIC MACULAR EDEMA**

*For the patients treated with the low dose of Iluvien, 26.8% to 30.6% demonstrated improvement in best corrected visual acuity (BCVA) of 15 letters from baseline, and for patients receiving the high dose of Iluvien, 26.0% to 31.2% demonstrated improvement of 15 or more letters in BCVA from baseline, both at 2 years.*

*Company plans to file a New Drug Application (NDA) in the second quarter of 2010.*

*Alimera Sciences receives notices of exercise for an additional \$10 Million in extended Series C financing.*

ATLANTA, December 23, 2009 -- Alimera Sciences, Inc., a privately held biopharmaceutical company that specializes in the research, development and commercialization of prescription ophthalmic pharmaceuticals, today reported top-line results from the month 24 readout of the FAME Study.

The FAME Study consists of two Phase 3 pivotal clinical trials (Trial A and Trial B) for the use of Iluvien in the treatment of diabetic macular edema (DME). The primary efficacy endpoint for the FAME Study is the difference in the percentage of patients whose best corrected visual acuity (BCVA) improved by 15 or more letters from baseline on the ETDRS eye chart at month 24 between the treatment and control groups.

The month 24 analysis using the Full Analysis Set in Trial A demonstrated statistical significance with 26.8% (p value 0.029) of the low dose patients having an improvement in BCVA of 15 letters or greater over baseline and 26.0% (p value of 0.034) of the high dose patients having an improvement in BCVA of 15 letters or greater from baseline. In Trial B, the month 24 data demonstrated statistical significance with 30.6% (p value of 0.030) of the low dose patients having an improvement in BCVA of 15 letters or greater over baseline and 31.2% (p value of 0.027) of the high dose patients having an improvement in BCVA of 15 letters or greater from baseline.

The Full Analysis Set includes all 956 patients randomized into the FAME Study, with data imputation employed using last observation carried forward (LOCF) for data missing because of

patients who discontinued the trial or are unavailable for follow up. (This data set is commonly referred to as the "intent to treat" population.)

In addition, both the low and high dose Iluvien showed greater numerical efficacy at month 24 than at month 18, a requirement for submission with 24 month data in the United States.

Safety was assessed for all patients treated in the study. Intraocular pressure (IOP) increases of 30 millimeters of mercury (*mmHg*) or greater at any time point, a key adverse event studied in the trial, were seen in 16.3% of the low dose patients and 21.6% of the high dose patients. Over the 24 month period, 2.1% of patients receiving the low dose and 5.1% of the patients receiving the high dose had undergone a trabeculectomy (filtration procedure) to reduce their eye pressure.

Based on these and other data, Alimera plans to seek approval of the low dose of Iluvien for the treatment of DME in the second quarter of 2010, followed by registration filings in various European countries and Canada. Submission of the NDA will be based on the month 24 safety and efficacy data while the FAME Study will continue to month 36.

“I am very proud of the Alimera team for having completed trials which we believe demonstrate efficacy at the month 24 clinical readout and am confident that we will submit an NDA application for Iluvien in 2010 for the treatment of DME. If approved, we believe this would be the first drug approved for the treatment of this condition,” said Dan Myers, president and CEO of Alimera Sciences. “Additionally, we appreciate the efforts of our clinical sites around the world that have managed and continue to manage the patients in the FAME Study.”

In addition to the analysis described above, as prospectively planned in the protocol, Alimera also conducted several other analyses of the 24 month data. These included a) an All Randomized and Treated (ART) analysis of the 24 month data that includes data from all subjects randomized and treated with values imputed for all missing data using the LOCF method, and b) a Modified ART analysis that utilizes the ART population, but excludes data collected subsequent to the use of treatments prohibited by protocol (such as intravitreal injections of Avastin, Lucentis or triamcinolone acetonide) with the last observation prior to protocol violation imputed to month 24 using the LOCF method.

The results of these separate analyses were as follows: by the ART analysis, in Trial A, 26.8% of low dose patients and 26.2% of high dose patients gained 15 or more letters at 24 months compared with 14.7% of control patients ( $p = 0.029$  and  $0.032$ , respectively). In Trial B of the ART analysis, 31.3% of high dose and 30.8% of low dose patients gained 15 or more letters compared with 17.8% of control patients ( $p = 0.028$  and  $0.026$  respectively). The results for both doses in both trials were statistically significant. By the Modified ART method, in Trial A 22.6% of patients in the low dose and 24.1% of patients in the high dose gained 15 or more letters compared with 12.6% of control patients ( $p = 0.057$  and  $0.026$ , respectively). Trial A was not statistically significant for either dose. In Trial B by Modified ART, 29.7% of patients in the low dose and 29.3% of patients in the high dose gained 15 or more letters compared with 13.3% of control patients ( $p = 0.004$  and  $0.005$ , respectively). The results for both doses were statistically significant.

The FAME study protocol provides that the primary assessment of efficacy will be based on the Modified ART dataset and that the other datasets will be considered secondary; the protocol did

not specify the Full Analysis Set as a dataset for analyzing the study. However, consistent with the FDA-adopted International Conference on Harmonization guidance, it is anticipated that the FDA will consider the Full Analysis Set to be the most relevant population for determining safety and efficacy in Trials A and B.

A more detailed analysis will be presented in February 2010 at the Angiogenesis, Exudation and Degeneration 2010 Meeting in Miami, Florida.

## **ALIMERA SCIENCES RECEIVES NOTICES OF EXERCISE FOR AN ADDITIONAL \$10 MILLION IN EXTENDED SERIES C FINANCING**

On August 24, 2009, Alimera announced that it had closed an extension of its Series C financing in which it issued shares of its Series C preferred stock and warrants to purchase shares of its Series C preferred stock. By their terms, the warrants were to be exercised in full within 30 days of the delivery of top line data from the Company's Phase III trials for Iluvien. Today, Alimera announced that it had received written notice from its principal warrant holders of their election to exercise the warrants. This warrant exercise, which will result in \$10 million in proceeds to Alimera, will close in January 2010.

### **About the FAME Study**

The Phase 3 FAME Study consists of two multi-center, randomized, double-masked trials for Iluvien in sites across the United States, Canada, Europe and India. The two trials have identical protocols and enrolled 953 patients across 101 academic and private practice centers. Patients in each trial were randomly assigned to one of three groups in a 2:2:1 randomization, respectively. One group received a high dose of Iluvien (an approximate initial 0.45 micrograms ( $\mu\text{g}$ ) per day dose), a second received a low dose of Iluvien (an approximate initial 0.23 micrograms ( $\mu\text{g}$ ) per day dose) and the third group (control) received sham. The sham included all the steps involved in the insertion procedure with the exception that patients in this group had a blunt inserter without a needle to apply pressure to the anesthetized eye in order to simulate an insertion. This procedure mimics an intravitreal insertion and helps to maintain proper patient masking.

### **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 is called 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% of diabetics studied were diagnosed with DME. Based on this study and the current U.S. diabetic population, Alimera estimates that there will be an incidence of approximately 340,000 cases of DME annually in the United States. As the population of people with diabetes increases, Alimera expects the annual incidence of diagnosed DME to increase as well.

## **About Iluvien®**

Iluvien is an investigative, extended release intravitreal insert that Alimera is developing for the treatment of DME. Each Iluvien insert is designed to provide a therapeutic effect of up to 36 months by delivering sustained sub-microgram levels of fluocinolone acetonide (FA). Iluvien is inserted in the back of the patient's eye to a position that takes advantage of the eye's natural fluid dynamics. Iluvien is inserted with a device that employs a 25-gauge needle, which allows for a self-sealing wound.

## **About Alimera Sciences, Inc.**

Alimera Sciences is a biopharmaceutical company that specializes in the research, development and commercialization of prescription ophthalmic pharmaceuticals. Presently the company is focused on diseases affecting the back of the eye, or retina. Its most advanced product candidate is Iluvien®, which is being developed for the treatment of diabetic macular edema, or DME.

Alimera is also pursuing the development, license and acquisition of rights to compounds and technologies with the potential to treat diseases of the eye that Alimera believes are not well treated by current therapies. Alimera has entered into agreements with Emory University, where by it acquired exclusive, worldwide rights under patent applications covering two classes of nicotinamide adenine dinucleotide phosphate reduced form (NADPH) oxidase inhibitors. Alimera's initial focus is on the use of NADPH oxidase inhibitors in the treatment of the dry form of age-related macular degeneration (AMD), particularly the late stage of this condition known as geographic atrophy. Alimera plans to evaluate the use of NADPH oxidase inhibitors in the treatment of other diseases of the eye, including the wet form of AMD and diabetic retinopathy.

For more information on Alimera Sciences, visit [www.alimerasciences.com](http://www.alimerasciences.com).

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