



February 3, 2011

## **pSivida Announces Positive Results from the 36 Month Readout of Completed Phase 3 FAME(TM) Study of ILUVIEN(R) in Patients with Diabetic Macular Edema**

WATERTOWN, Mass., Feb 03, 2011 (BUSINESS WIRE) --

pSivida Corp. (NASDAQ:PSDV) (ASX:PVA), a leader in developing sustained release, drug delivery products for treatment of back-of-the-eye diseases, including the investigational drug ILUVIEN® for the treatment of Diabetic Macular Edema (DME), today announced month 36, top-line readout results for the FAME™ Study prepared by its licensee, Alimera Sciences, Inc. (Alimera).

Alimera previously presented the month 24, top-line results from the now completed FAME Study. The FAME Study consisted of two 3-year, Phase 3 pivotal clinical trials (Trial A and Trial B) to assess the safety and efficacy of ILUVIEN in the treatment of DME. Patients in the trials were randomized to receive either high dose ILUVIEN, low dose ILUVIEN or control treatment. The primary endpoint for efficacy in the trials was the difference in the percentage of patients whose best corrected visual acuity (BCVA) improved by 15 or more letters from baseline on the Early Treatment Diabetic Retinopathy Study (ETDRS) eye chart at month 24 between the treatment and control groups. Alimera presented data for both the low and high dose patient results at 24 months. Based on these data, Alimera submitted a New Drug Application (NDA) on June 29, 2010 for approval of only the low dose. Therefore, only the low dose data from the 36 month readout is being released by Alimera and is discussed in this release.

Alimera reported that data through month 36 for the Full Analysis Set in Trial A demonstrated statistically significant therapeutic effects of 28.9% at month 30 ( $p=0.011$ ) and 28.4% at month 33 ( $p=0.042$ ) of ILUVIEN patients gaining 15 or more letters compared to the control group, in which fewer than 17% of patients gained 15 or more letters. The therapeutic effect was maintained at month 36 (with 28.4% of patients gaining 15 or more letters); however, as 18.9% of the control group gained 15 or more letters, the  $p$  value increased to  $p=0.106$ .

Results from Trial B reported by Alimera were similar. Statistically significant therapeutic effects of 33.9% at month 30 ( $p=0.002$ ) and 29.6% at month 33 ( $p=0.046$ ) of ILUVIEN patients gaining 15 or more letters over baseline were reported compared to the control group, which had fewer than 18% of patients making such gains. At month 36, 29.0% of ILUVIEN patients gained 15 or more letters compared with 18.9% of control patients ( $p=0.086$ ).

By comparison, in the month 24 data earlier reported by Alimera, 26.8% of ILUVIEN patients and 14.7% of control patients had gained 15 or more letters ( $p=0.029$ ) at month 24 in Trial A. In Trial B at month 24, 30.6% of ILUVIEN patients and 17.8% of control patients ( $p=0.030$ ) had gained 15 letters or greater over baseline.

As reported by Alimera, Trial A and B data combined demonstrated a statistically significant effect at week three, and this effect was maintained throughout the 36 months. On a combined basis, 28.7% of ILUVIEN patients and 16.2% of control patients ( $p=0.002$ ) had an improvement in BCVA of 15 letters or greater over baseline at month 24, 31.4% versus 15.1% at month 30 ( $p<0.001$ ), 29.0% versus 17.3% at month 33 ( $p=0.004$ ) and 28.7% versus 18.9% at month 36 ( $p=0.018$ ).

"We believe this data is very promising, and look forward to the response from the FDA. If approved, pSivida will be entitled to a \$25.0 million milestone payment from Alimera and 20% of profits (as defined) on sales of ILUVIEN by Alimera," said Paul Ashton, president and CEO of pSivida.

The Full Analysis Set includes 376 patients in the ILUVIEN arm and 185 patients in the control arm with data imputation employed using last observation carried forward (LOCF) only for missing data. Data for the Full Analysis Set includes 190 patients in Trial A and 186 patients in Trial B randomized to the ILUVIEN arm.

Alimera reported safety data for all patients treated with ILUVIEN low dose and control group in the study. Increases in intraocular pressure (IOP) to 30 millimeters of mercury (*mmHg*) or greater at any time point were reported in 18.4% of the patients by month 36 compared to 16.3% by the month 24 readout. By month 36, 4.8% of patients had undergone an incisional surgical procedure to reduce elevated pressure versus 3.7% of patients by month 24. The incidence of cataract among patients with a natural lens in their eye at the start of the trial was 81.7% at month 36, with 80% undergoing a cataract

operation, compared to 80% and 74.9%, respectively, by the time of the month 24 readout.

Alimera reported that the statistical significance observed in both trials at month 33 met the criteria for replication of two studies and that Alimera will provide the 36 month safety and efficacy data to the FDA in connection with the pending NDA for ILUVIEN.

Webcast slides prepared by Alimera containing more detailed information with respect to the 36 month data are being filed by pSivida with the Securities & Exchange Commission on Form 8-K. The information in this press release is qualified in its entirety by the more detailed information contained in those slides.

Additional data and analysis of the FAME Study will be presented by Peter Campochiaro, M.D., on February 12, 2011, at 1:40 p.m. at the Angiogenesis, Exudation and Degeneration 2011 Meeting in the Mandarin Oriental Hotel, Miami, FL. Dr. Campochiaro is a professor in the Department of Ophthalmology at The Wilmer Eye Institute, Retina Division at Johns Hopkins.

### **About the FAME Study**

Alimera conducted two 36-month, Phase 3 pivotal clinical trials (collectively known as the FAME Study) for ILUVIEN involving 956 patients in sites across the United States, Canada, Europe and India to assess the efficacy and safety of ILUVIEN with two doses of the corticosteroid fluocinolone acetonide (FA), a high and low dose, for the treatment of DME. The primary efficacy endpoint for the FAME Study was the difference in the percentage of patients whose best corrected visual acuity improved by 15 or more letters from baseline on the ETDRS eye chart at month 24 between the treatment and control groups. The study concluded in October 2010 with the final patient visit at the three-year data point. Alimera prepared the analyses of the data from the FAME Study.

Following its NDA submission to the FDA, Alimera submitted a Marketing Authorization Application to the Medicines and Healthcare products Regulatory Agency in the United Kingdom. Applications have also been submitted to regulatory agencies in Austria, France, Germany, Italy, Portugal and Spain. Based upon the analysis of the FAME Study, all filings included the 24-month data. The FDA, in a December 2010 Complete Response Letter, requested further information, including the month 36 data from the FAME Study.

### **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 percent of people with diabetes studied were diagnosed with DME. 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 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. The insertion device employs a 25-gauge needle, which allows for a self-sealing wound.

### **About pSivida Corp.**

pSivida is a world leader in the development of tiny drug delivery products that are administered by implantation, injection or insertion and provide sustained release of drugs on a controlled and level basis for months or years. The Company uses these systems to develop treatments for serious, unmet, medical needs. The Company's most advanced product candidate, Iluvien<sup>®</sup>, delivers fluocinolone acetonide (FA) for the treatment of diabetic macular edema.

SAFE HARBOR STATEMENTS UNDER THE PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995: Various statements made in this release are forward-looking, and are inherently subject to risks, uncertainties and potentially inaccurate assumptions. All statements that address activities, events or developments that we intend, expect or believe may occur in the future are forward-looking statements. The following are some of the factors that could cause actual results to differ materially from the anticipated results or other expectations expressed, anticipated or implied in our forward-looking statements: ability to obtain additional capital uncertain; future losses; impairment of intangibles; fluctuations in the fair values of certain outstanding warrants; fluctuations in operating results; decline of royalty income from Bausch & Lomb; Alimera's ability to obtain regulatory approval of Iluvien including analysis of results through month 36 of the FAME Study, safety and efficacy of Iluvien, controls and specifications concerning the manufacturing, packaging and sterilization of Iluvien and cGMP at manufacturers of Iluvien; Alimera's ability to successfully commercialize Iluvien if approved; risk/benefit profile of Iluvien; timeliness of approval, if any, of

Iluvien and any limitations on uses thereof; ability to complete clinical trials and obtain regulatory approval of other product candidates; ability to find partners to develop and market products; termination of license agreements; competition; market acceptance of products and product candidates; reduction in use of products as a result of future publications; ability to protect intellectual property or infringement of others' intellectual property; retention of key personnel; product liability; consolidation in the pharmaceutical and biotechnology industries; compliance with environmental laws; manufacturing risks; risks and costs of international business operations; credit and financial market conditions; legislative or regulatory changes; volatility of stock price; possible dilution through exercise of outstanding warrants and stock options or future stock issuances; possible influence by Pfizer; ability to pay any registration penalties; absence of dividends; and other factors described in our filings with the Securities and Exchange Commission. Given these uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements. Our forward-looking statements speak only as of the dates on which they are made. We do not undertake any obligation to publicly update or revise our forward-looking statements even if experience or future changes makes it clear that any projected results expressed or implied in such statements will not be realized.

SOURCE: pSivida Corp.

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