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## **FDA Issues Complete Response Letter Regarding New Drug Application for ILUVIEN(R)**

WATERTOWN, Mass., Dec 23, 2010 (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<sup>®</sup> for the treatment of Diabetic Macular Edema (DME), today announced that Alimera Sciences, Inc, pSivida's collaborative partner, received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding its New Drug Application (NDA) for ILUVIEN. The FDA issued the CRL to communicate its decision that the NDA cannot be approved in its present form.

The NDA seeks approval to market ILUVIEN (fluocinolone acetonide intravitreal insert), an investigational, sustained drug delivery system that releases sub-microgram levels of fluocinolone acetonide for the treatment of DME. The ILUVIEN NDA was submitted to the FDA on June 29, 2010 with safety and efficacy data through month 24 of the FAME Study. The FDA granted the NDA Priority Review status on August 30, 2010.

In the CRL, the FDA asked for analyses of safety and efficacy data through month 36 of the FAME Study, including exploratory analyses in addition to those previously submitted in the NDA, to further assess the relative benefits and risks of ILUVIEN. Alimera has completed month 36 of the FAME Study and has reported that it is preparing the analyses that the FDA has requested. Alimera further reported that it has requested a meeting with the FDA to clarify the path to regulatory approval. The FDA did not ask for any new clinical studies in the CRL.

In the CRL, the FDA is also seeking additional information regarding controls and specifications concerning the manufacturing, packaging and sterilization of ILUVIEN, which Alimera reports it is in the process of compiling. Additionally, FDA indicated in the CRL that it had observed deficiencies in current good manufacturing practices (cGMP) during facility inspections of two of Alimera's third-party manufacturers, which were completed in August and September of 2010, and that all facilities and controls will need to comply with cGMP. Alimera reports that its third-party manufacturers are in the process of resolving these deficiencies.

### **About the FAME Study**

Alimera conducted two 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, a high and low dose, for the treatment of DME. The primary efficacy endpoint for the FAME Study is 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.

### **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 (DME). DME is a leading cause of vision loss, affecting more than a million people in the US alone, for which there is currently no FDA-approved drug therapy. Iluvien is licensed to Alimera Sciences, Inc. pSivida has two products approved by the FDA for sustained release delivery of drug to treat chronic back-of-the-eye diseases: Retisert<sup>®</sup> for the treatment of posterior uveitis and Vitrasert<sup>®</sup> for the treatment of AIDS-related cytomegalovirus (CMV) retinitis. pSivida has licensed both of these products and the technologies underlying them to Bausch & Lomb Incorporated. pSivida also has a worldwide collaborative research and license agreement with Pfizer Inc. under which Pfizer may develop additional ophthalmic products using certain of the Company's technologies. pSivida's intellectual property portfolio consists of over 50 patent families, more than 100 granted patents, including patents accepted for issuance, and more than 150 patent applications. pSivida conducts its operations from Boston in the United States and Malvern in the United Kingdom.

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: 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 raise capital; ability to achieve profitability; impairment of intangibles; fluctuations in the fair values of certain outstanding warrants; fluctuations in operating results; ability to derive revenues from Retisert; ability to obtain 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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