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pSivida Announces Resubmission of New Drug Application for ILUVIEN(R)

WATERTOWN, Mass., May 13, 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, today announced that its licensee, Alimera Sciences, Inc., resubmitted a New Drug Application for the investigational drug ILUVIEN® for the treatment of diabetic macular edema (DME) to the U.S. Food and Drug Administration (FDA) on May 12, 2011 to address questions raised in the Complete Response Letter (CRL) Alimera received in December 2010.

Alimera reported that according to the FDA's classification scheme, this will be a Class 2 resubmission. Under the Prescription Drug User Fee Act (PDUFA), FDA review of a Class 2 resubmission is expected to be completed within a six-month period beginning on the date that the resubmission is received.

This resubmission is intended to address the FDA's request for additional analyses of safety and efficacy data though month 36 of the FAME Study. Alimera reported that data from the subgroup of patients with chronic DME presented at last week's Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting was also provided together with additional information regarding controls and specifications on the manufacturing, packaging and sterilization of ILUVIEN.

Upon approval of ILUVIEN, pSivida would be entitled to receive a $25 million milestone payment from Alimera and 20 percent of net profits, as defined, on sales of the drug by Alimera.

"We look forward to the FDA's response to Alimera's resubmission of the NDA for ILUVIEN for DME, which if approved, would be our third FDA-approved product," said Dr. Paul Ashton, President and Chief Executive Officer of pSivida. "We are also working on several earlier stage technologies including bioerodible systems to deliver proteins and small drug molecules for macular degeneration and glaucoma."

Alimera also reported that it believes the deficiencies in current good manufacturing practices (cGMP) observed during facility inspections at two of Alimera's third-party manufacturers of ILUVIEN noted by the FDA in the CRL had been resolved and that no further action is required because the FDA issued letters to both of these third-party manufacturers indicating that the inspections were now closed.

About the FAME Study

The FAME study, conducted by Alimera, consisted of two 36-month, Phase 3 pivotal clinical trials (collectively known as the FAME) study for ILUVIEN involving 956 patients in site across the United States, Canada, Europe and India to access the efficacy and safety of ILUVIEN with two doses of the corticosteroid fluocinolone acetonide (FAc), a high and low dose, for the treatment of DME. The primary efficacy endpoint for the FAME Study was the difference between the treatment and control groups. The study concluded in October 2010 with the final patient visit at the three-year data point.

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 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 investigational, extended release intravitreal insert 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 FAc. 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. pSivida uses these systems to develop treatments for serious, unmet, medical needs. In addition to ILUVIEN, pSivida's most advanced product candidate, pSivida has two products approved by the FDA for sustained release delivery of drug to treat chronic back-of-the-eye diseases: Retisert® for the treatment of posterior uveitis and Vitrasert® 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: 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; 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.

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