May 1, 2013

pSivida Corp. Announces New ILUVIEN® PDUFA Date of October 17, 2013

WATERTOWN, Mass.--(BUSINESS WIRE)-- pSivida Corp. (NASDAQ:PSDV - News), a leader in developing sustained release, drug delivery products for treatment of back-of-the-eye diseases, announced today that the U.S. Food and Drug Administration (FDA) acknowledged receipt of the resubmission of the New Drug Application (NDA) for ILUVIEN® for treatment of chronic diabetic macular edema (DME) and stated that the resubmission was considered a complete, class 2 response to the FDA's November 2011 complete response letter. The new Prescription Drug User Fee Act (PDUFA) goal date is October 17, 2013.

pSivida's licensee Alimera Sciences reported that in the resubmission it responded to the FDA's complete response letter and provided additional analyses as well as new information to support that ILUVIEN is safe and effective in the treatment of patients with chronic DME.

Using data from Alimera's two completed pivotal Phase 3 clinical trials (collectively the FAME™ Study), the resubmission focused on the safety aspects of ILUVIEN and the subgroup population of patients with chronic DME, the same subgroup for which marketing approval for ILUVIEN has been granted in six countries in the European Union. Additionally, Alimera reported that data was submitted from the completed physician utilization study for the ILUVIEN applicator and from a special reading center assessment of photographs of the fundus, or interior surface of the eye, which were collected during the FAME™ Stud

At month 36, the treatment effect for the chronic DME subgroup (i.e. the difference in the proportion of 15 Early Treatment Diabetic Retinopathy Study (ETDRS) eye chart letter responders between ILUVIEN and the sham control) was more than twice that seen for the overall population. Given that the risks associated with the chronic DME subgroup are similar to the risks in the overall population, Alimera reported its belief that the benefit to risk for this subgroup is optimized with ILUVIEN treatment.

Alimera further reported its belief that the FDA resubmission package includes important new information that demonstrates the safety and efficacy of ILUVIEN for patients suffering from chronic DME and that a clearer positioning now exists for ILUVIEN in the treatment of patients with chronic DME since a first-line pharmacotherapy for DME was approved by the FDA last year.

"We are very pleased with the FDA's acceptance of the resubmission of the NDA and the new PDUFA date for ILUVIEN," said Dr. Paul Ashton, President and CEO of pSivida Corp. "If the FDA approves ILUVIEN, we would be entitled to an additional $25 million milestone payment from Alimera as well as 20% of net profits, as defined, on any sales in the U.S. by Alimera. We are entitled to the same net profit share on sales of ILUVIEN for DME by Alimera in the EU, where Alimera has already launched in the UK and reported plans to launch in Germany in 2013."

About ILUVIEN

ILUVIEN (190 micrograms fluocinolone acetonide intravitreal implant in applicator) is a sustained release intravitreal micro-insert used to treat vision impairment associated with chronic DME considered insufficiently responsive to available therapies. Each ILUVIEN implant provides a therapeutic effect of up to 36 months by delivering sustained sub-microgram levels of fluocinolone acetonide (FAc). ILUVIEN is injected in the back of the patient's eye to a position that takes advantage of the eye's natural fluid dynamics. The applicator employs a 25-gauge needle, which allows for a self-sealing wound. In the FAME™ Stud the most frequently reported adverse drug reactions included cataract operation, cataract and increased ocular pressure.

In July 2010, Alimera submitted a Marketing Authorization Application (MAA) to seven European countries via the Decentralized Procedure (DCP) with the Medicines and Healthcare products Regulatory Agency of the U.K. serving as the Reference Member State (RMS). The MAA included data from the FAME Study, which involved 956 patients in sites across the United States, Canada, Europe and India to assess the efficacy and safety of ILUVIEN for the treatment of DME. At the end of the DCP, a consensus was reached by the RMS and the other six countries that the MAA for ILUVIEN was approvable. To date, six of the seven countries, Austria, the United Kingdom, Portugal, France, Germany and Spain have granted national licenses for ILUVIEN, which is now available in the United Kingdom for private pay and privately insured patients. ILUVIEN has not been approved by the FDA.

About pSivida Corp.

pSivida Corp., headquartered in Watertown, MA, develops tiny, sustained release, drug delivery products designed to deliver drugs at a controlled and steady rate for months or years. pSivida is currently focused on treatment of chronic diseases of the back of the eye utilizing its core technology systems, Durasert™ and BioSilicon™. The injectable, sustained release micro insert ILUVIEN® for the treatment of chronic DME, licensed to Alimera Sciences, Inc., has received marketing authorization in Austria, France, Germany, Portugal, Spain and the U.K. and is awaiting authorization in Italy. ILUVIEN for DME has not been approved in the U.S. pSivida plans to institute pivotal Phase III clinical trials for the treatment of posterior uveitis, a chronic back-of-the-eye disease, with the same micro-insert as ILUVIEN for DME. An investigator-sponsored clinical trial is ongoing for an injectable, bioerodible micro-insert to treat glaucoma and ocular hypertension. pSivida's FDA-approved Retisert® licensed to Bausch & Lomb Incorporated provides long-term, sustained drug delivery to posterior uveitis.

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: uncertainties with respect to: Alimera's ability to obtain regulatory approval for, and if approved, to finance, successfully commercialize and achieve market acceptance of, and generate revenues to pSivida from, ILUVIEN for DME in the U.S.; Alimera's ability to finance, achieve additional marketing approvals, successfully commercialize and achieve market acceptance of, and generate revenues to pSivida from, ILUVIEN for DME in the EU; outcome of reimbursement for ILUVIEN in the U.K.; financing and success of Phase III posterior uveitis trials including efficacy, side effects and risk/benefit profile of the posterior uveitis micro-insert; initiation, financing and success of Latanoprost Product Phase II trials and exercise by Pfizer of its option; development of products using Tethadur and BioSilicon; initiation and completion of clinical trials and obtaining regulatory approval of product candidates; adverse side effects; ability to attain profitability; ability to obtain additional capital; further impairment of intangible assets; fluctuations in operating results; decline in royalty revenues; ability to, and to find partners to, develop and market products; termination of license agreements; competition and other developments affecting sales of products; market acceptance; protection of intellectual property and avoiding intellectual property infringement; 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; possible influence by Pfizer; absence of dividends; and other factors described in our filings with the SEC. 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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