October 18, 2013

pSivida Reports Complete Response Letter From FDA for ILUVIEN®

WATERTOWN, Mass.--(BUSINESS WIRE)-- pSivida Corp. (NASDAQ: PSDV) (ASX: PVA), a specialty pharmaceutical company that is a leader in developing sustained release drugs for treatment of back-of-the-eye diseases, today announced that its licensee Alimera Sciences, Inc. has received a Complete Response Letter (CRL) for the New Drug Application (NDA) for ILUVIEN® from the U.S. Food and Drug Administration (FDA).

Identifying concerns regarding the benefit to risk and safety profiles of ILUVIEN, the FDA stated that the NDA could not be approved in its present form. To address the clinical and statistical deficiencies identified, the FDA indicated that results from a new clinical trial would need to be submitted, together with at least 12 months of follow-up for all enrolled patients. The FDA suggested that a meeting with the Dermatologic and Ophthalmic Drugs Advisory Committee may be of assistance in addressing the deficiencies identified above and providing advice whether a patient population can be identified in which the benefits of the drug product might outweigh the risks. Alimera reported that in a separate written communication from the staff of the FDA, it was notified that an Advisory Committee meeting would be convened on January 27, 2014. In the CRL, the FDA also referenced deficiencies at the facility where ILUVIEN is manufactured.

"We are extremely disappointed by the FDA's decision not to approve ILUVIEN at this time," said Paul Ashton, PhD, president and chief executive officer of pSivida. "However, we are pleased that Alimera plans to continue to work with the FDA, through the advisory committee, to determine whether there is a path forward in the U.S. for ILUVIEN, and that Alimera believes it is well positioned for growth in Europe, irrespective of the U.S. outcome, based on current traction in the countries in which ILUVIEN has already been approved, coupled with the continued pursuit of further country approvals."

Alimera reported that its commercial focus is on Europe, where the ILUVIEN is approved and commercially available in the United Kingdom and Germany and slated to launch in France early next year. ILUVIEN is also approved in Austria, Portugal and Spain and pending approval in Italy. In addition, Alimera has filed with the Medicines and Healthcare Products Regulatory Agency in the United Kingdom (U.K.) as the Reference Member State for 10 additional European Union country approvals through the Mutual Recognition Procedure.

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™, including Tethadur™. The injectable, sustained release micro-insert ILUVIEN® for the treatment of chronic Diabetic Macula Edema (DME) considered insufficiently responsive to available therapies, licensed to Alimera Sciences, Inc., is marketed in the U.K. and Germany and has also received marketing authorization in Austria, France, Portugal, and Spain and is awaiting authorization in Italy. pSivida has instituted the first of two planned pivotal Phase III clinical trials for Medidur™ for the treatment of posterior uveitis, a chronic back-of-the-eye disease. An investigator-sponsored clinical trial is ongoing for an injectable, bioerodible micro-insert to treat glaucoma and ocular hypertension, a product candidate on which Pfizer Inc. has an option. pSivida's FDA-approved Retisert®, licensed to Bausch & Lomb Incorporated, provides long-term, sustained drug delivery to treat 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 ILUVIEN for DME in the U.S. through the advisory committee or otherwise, 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 complete pricing and reimbursement discussions for, commercialize and achieve market acceptance of, and generate revenues to pSivida from, ILUVIEN for DME in the EU;; the ability to finance, complete and achieve a successful outcome for Phase III trials for, and file and achieve marketing approvals for, Medidur for posterior uveitis, including efficacy, side effects and risk/benefit profile, as well as uncertainty as to the ultimate results of the investigator-sponsored trial for Medidur for posterior uveitis; initiation, financing and success of Latanoprost Product Phase II trials and exercise by Pfizer of its

option; ability to utilize Tethadur and BioSilicon to develop product candidates and products and potential related collaborations; initiation and completion of clinical trials and obtaining regulatory approval of product candidates; continued sales of Retisert; adverse side effects; ability to attain profitability; ability to obtain additional capital; further impairment of intangible assets; fluctuations in operating results; decline in royalty income; 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; 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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The President's Blog: http://www.thechairmansblog.com/paul-ashton

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