



December 18, 2013

## **pSivida Corp. Reports FDA Labeling Discussions for ILUVIEN® for DME; Advisory Committee Meeting No Longer Necessary**

WATERTOWN, Mass.--(BUSINESS WIRE)-- pSivida Corp. (NASDAQ: PSDV) (ASX: PVA), a leader in the development of sustained release, drug delivery products for treating eye diseases, today announced that its licensee Alimera Sciences has entered into labeling discussions with the U.S. Food and Drug Administration (FDA) for ILUVIEN® for Diabetic Macular Edema (DME) and, as a result, reported its agreement with the FDA that the January 2014 Dermatologic and Ophthalmic Advisory Committee meeting to discuss ILUVIEN for DME was no longer necessary.

Alimera reported that it plans to respond to the FDA's October 2013 Complete Response Letter (CRL) in the first quarter of 2014 and intends to address the concerns raised regarding the facility at which ILUVIEN for DME is manufactured and to provide recent safety data from patients in the United Kingdom and Germany. Alimera reported that the FDA has indicated that new clinical trials will not be required in connection with the FDA's review of ILUVIEN for DME prior to approval.

"We are very pleased with Alimera's discussion with the FDA with respect to appropriate labeling for ILUVIEN for DME and next steps required to move it closer to an FDA approval," said Paul Ashton, Ph.D., President and CEO of pSivida. "We look forward to a first quarter resubmission and, hopefully, approval of this product. If approved, we will be entitled to a \$25 million milestone payment from Alimera and 20% of net profits (as defined) on sales of ILUVIEN for DME by Alimera in the U.S."

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 as the Reference Member State for ten additional European Union country approvals through the Mutual Recognition Procedure. pSivida will be entitled to 20% of net profits (as defined) on sales of ILUVIEN for DME by Alimera in the EU on a country-by-country basis.

### **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™. pSivida has insti the first of two planned pivotal Phase III clinical trials for its lead development product, Medidur™, an injectable, sustained release micro-insert for the treatment of posterior uveitis, a chronic back-of-the-eye disease. ILUVIEN® for the treatment of chronic DME considered insufficiently responsive to available therapies, which uses the same micro-insert as Medidur and is 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. Alimera has filed for ten additional EU country approvals through the Mutual Recognition Procedure. 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 finance, achieve additional marketing approvals, obtain adequate pricing and reimbursement for, successfully commercialize and achieve market acceptance of, and generate revenues to pSivida from, ILUVIEN for DME in the EU; 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.; 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 achieving acceptable risk-to-benefit and safety profiles in light of the CRL for ILUVIEN; initiation, financing and success of Latanoprost Product Phase II trials and any exercise by Pfizer of its option; ability of Tethadur to successfully deliver proteins, peptides and other large biologic molecules; ability 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. Should known or unknown risks materialize, or should underlying assumptions prove inaccurate, actual results could differ materially from past results and those anticipated, estimated or projected in the 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>

For more information on pSivida, visit [www.psivida.com](http://www.psivida.com).

In US:

Martin E. Janis & Company, Inc.

Beverly Jedynek, President

+1 312.943.1123; M: +1 773.350.5793

[bjedynak@janispr.com](mailto:bjedynak@janispr.com)

or

In Australia:

pSivida Corp.

Brian Leedman

Vice President, Investor Relations

+61 (0) 41 228 1780

[brianl@psivida.com](mailto:brianl@psivida.com)

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