



March 22, 2013

## **pSivida Reports Updates on ILUVIEN® for Planned Resubmission to FDA and European Launch**

WATERTOWN, Mass.--(BUSINESS WIRE)-- pSivida Corp. (NASDAQ:PSDV)(ASX:PVA), a specialty pharmaceutical company that is a leader in the development of sustained release ophthalmic drug treatments, today announced that its licensee Alimera Sciences, Inc. reported a number of updates with respect to ILUVIEN® for chronic diabetic macular edema (DME).

Alimera announced that it intends to resubmit its New Drug Application for ILUVIEN for DME to the U.S. Food and Drug Administration (FDA) by the end of March 2013. Using data from Alimera's two previously completed pivotal Phase III clinical trials (FAME™ Study), the resubmission will focus on the safety aspects of ILUVIEN and the population of patients with chronic DME considered insufficiently responsive to available therapies, the same group for which marketing approval for ILUVIEN has been granted in various EU countries, according to Alimera. Approval in the U.S. would entitle pSivida to a \$25 million milestone payment from Alimera and 20% of net profits, as defined, from U.S. sales of ILUVIEN by Alimera.

Alimera also announced that shipments of ILUVIEN to the German market are expected to begin in the second quarter of 2013 upon acceptance from the Medicine and Health products Regulatory Agency of the intended commercial batch size, a delay from Alimera's previous expectation that this would occur in the first quarter of 2013. Alimera further reported that it also expects to begin shipments to the U.K. in the second quarter of 2013 for treatment of privately insured patients.

Alimera reported the submission of a patient access scheme (PAS) for ILUVIEN for DME has been agreed to by the UK's Department of Health and is now under consideration by NICE for inclusion in its rapid review facility. NICE had previously issued final guidance that ILUVIEN is not a cost-effective treatment for chronic DME considered insufficiently responsive to available therapies. Alimera reported that under the review facility, NICE is expected to assess the impact of the PAS on ILUVIEN's cost effectiveness and determine whether an update to the final guidance is warranted.

### **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 Diabetic Macula Edema (DME), licensed to Alimera Sciences, Inc., has received marketing authorization in Austria, France, Germany, Portugal, the U.K. and Spain and is awaiting authorization in Italy. ILUVIEN® for DME has not been approved in the US. pSivida plans to institute pivotal Phase III clinical trials for the treatment of posterior uveitis 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 two FDA-approved products, Retisert® and Vitrasert®, are implants that provide long-term, sustained drug delivery to treat two other chronic diseases of the retina.

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: the timing of the resubmission of the NDA for ILUVIEN or of the commercial launch in Germany and the UK, any effect of the PAS on the NICE final guidance, 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; Alimera's resubmission of its NDA for ILUVIEN® for DME and its 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.; 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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