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## **pSivida Corp. Reports Alimera's Intention to Resubmit Application to FDA for ILUVIEN® in DME Using Data from Completed Trials**

WATERTOWN, Mass.--(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 reported that its licensee Alimera Sciences, Inc. has indicated its intention to resubmit its application for ILUVIEN® for diabetic macular edema (DME) to the U.S. Food and Drug Administration (FDA). Based on a recent meeting with the FDA, Alimera intends to use data from Alimera's two previously completed pivotal Phase III clinical trials (FAME® Study). pSivida expects the resubmission to address the issues raised by the FDA in its November 2011 Complete Response Letter (CRL) and in its recent meeting with Alimera.

pSivida anticipates the resubmission will focus on the population of patients with chronic DME considered insufficiently responsive to available therapies, the same indication for which regulatory approval for ILUVIEN has been granted in various EU countries. Alimera has not reported an expected time for resubmission.

"We are very pleased at this development in the U.S. in addition to the recent marketing authorizations in Austria, France, Germany, Portugal and the U.K.," said Dr. Paul Ashton, President and CEO of pSivida.

Under a collaboration agreement with Alimera, pSivida granted Alimera an exclusive worldwide license to manufacture and sell ILUVIEN for the treatment and prevention of eye diseases in humans other than uveitis. Alimera agreed to fund all development costs, pay pSivida a \$25.0 million milestone payment upon FDA approval of ILUVIEN and 20% of any net profits, as defined, on sales of ILUVIEN by Alimera.

In November 2011, the FDA stated in the CRL that it was unable to approve the ILUVIEN new drug application because it did not provide sufficient data to support that ILUVIEN is safe and effective in the treatment of patients with DME. The FDA stated that the risks of adverse reactions shown for ILUVIEN in Alimera's clinical trials were significant and were not offset by the benefits demonstrated by ILUVIEN in these clinical trials and indicated that Alimera would need conduct two additional clinical trials.

pSivida is a US listed company with a primary listing on NASDAQ. It is also listed on the ASX and subject to the ASX's continuous disclosure rules

### **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 and the U.K. and is awaiting authorization in Italy and Spain. The FDA has cleared pSivida's Investigational New Drug application (IND) to treat posterior uveitis with the same micro-insert. An investigator-sponsored clinical trial is ongoing for an injectable, bioerodible 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: no assurance that Alimera will resubmit its application or be able to demonstrate to the FDA that the benefits outweigh the risks of ILUVIEN for DME using data from the FAME Study, that additional clinical trials will not be required, that the population of chronic DME patients will be acceptable to the FDA or that Alimera will be able to obtain regulatory approval for ILUVIEN for DME in the U.S.; ability of Alimera to consummate its pending financing; the timing and conditions for additional regulatory approvals are subject to decisions by regulators; necessity to raise additional capital to finance Phase III uveitis trials as well as

other working capital needs; ability to obtain additional capital; ability to initiate and complete clinical trials and obtain regulatory approval of product candidates; adverse side effects; Alimera's ability to successfully obtain regulatory approval of and commercialize ILUVIEN for DME in the EU; actions with respect to regulatory approval of ILUVIEN for DME in the U.S.; ability to attain profitability; exercise by Pfizer of the Latanoprost Product option; further impairment of intangible assets; fluctuations in operating results; decline in royalty revenues; 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 guidelines, recommendations or studies; ability to protect intellectual property and avoid 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; 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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