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pSivida Reports on Resubmission to FDA of NDA for ILUVIEN® for Chronic Diabetic Macular Edema

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 the submission of its response to the second Complete Response Letter from the U.S. Food and Drug Administration (FDA) with respect to ILUVIEN® for chronic diabetic macular edema (DME).

Alimera reported in its 10-K filing that it submitted the response, which includes additional analyses of the risks and benefits of ILUVIEN based on the clinical data available from the previously completed Phase III studies (FAME), following a meeting with the FDA in the second quarter 2012. Alimera said that the resubmission focuses on the safety aspects of ILUVIEN and the population of patients with chronic DME. This is the same group for which marketing approval of ILUVIEN has been granted in six EU countries thus far. Alimera reported that it will communicate the Prescription Drug User Fee Act (PDUFA) date once it is known from the FDA and that Alimera does not plan to conduct additional trials for ILUVIEN for DME at this time.

"We are pleased to see the resubmission of the NDA to the FDA," said Dr. Paul Ashton, president and CEO of pSivida Corp. "To date, we have received over $30m from Alimera from its license of ILUVIEN for DME, and if the FDA approves ILUVIEN, we would be entitled to an additional $25 million milestone payment as well as 20% of net profits, as defined, on any sales in the U.S. by Alimera."

pSivida is entitled to the same net profit share on sales of ILUVIEN for DME by Alimera in the EU. Alimera has announced its intent to commercially launch ILUVIEN in Germany and for private patients in the UK in the second quarter of 2013, upon approval of the commercial batch size.

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 FDA's acceptance of Alimera's resubmission of its NDA for ILUVIEN® for DME and 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 timing 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; 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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