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pSivida Reports Receipt by Alimera Sciences of Complete Response Letter from FDA for ILUVIEN(R) for DME

WATERTOWN, Mass.--(BUSINESS WIRE)--Nov. 11, 2011-- 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. (Alimera) received a complete response letter (CRL) from the U.S. Food and Drug Administration (FDA) in response to the New Drug Application (NDA) for ILUVIEN® for the treatment of diabetic macular edema (DME) associated with diabetic retinopathy.

The FDA stated in the CRL that it was unable to approve the ILUVIEN NDA because the NDA 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 the FAME® Study were significant and were not offset by the benefits demonstrated by ILUVIEN in these clinical trials. The FDA stated that Alimera will need to conduct two additional clinical trials to demonstrate that the product is safe and effective for the proposed indication. Alimera reported that it will be requesting a meeting with the FDA to clarify next steps.

“We are obviously surprised and disappointed with the FDA’s decision,” said Paul Ashton, PhD, president and chief executive officer of pSivida.

Alimera reported that for Europe, Alimera expects to submit its formal response to the Preliminary Assessment Report to the Medicines and Healthcare products Regulatory Agency (MHRA) later this month. Alimera stated that based on this submission, the MHRA is expected to make a recommendation on the approvability of ILUVIEN for DME to Alimera and the Concerned Member States (Austria, France, Germany, Italy, Portugal and Spain) by the end of this year, with a decision regarding the approval of ILUVIEN for DME expected in the first half of 2012.

Conference Call to be Held Monday

pSivida Corp. will host a live webcast and conference call Monday, November 14, 2011, at 9:00 am ET to discuss the CRL. Access information will be announced later today.

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™.

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: ability to obtain additional capital if needed; future losses; impairment of intangibles; fluctuations in the fair values of certain outstanding warrants; fluctuations in operating results; decline of royalty income from Bausch & Lomb; Alimera's ability to obtain regulatory approval of ILUVIEN for DME; Alimera's ability to successfully commercialize ILUVIEN for DME if approved; risk/benefit profile of ILUVIEN for DME; timeliness of approval, if any, of ILUVIEN for DME and any limitations on uses thereof; ability to complete clinical trials, reference data and obtain regulatory approval of other product candidates; 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 publications; ability to protect intellectual property or 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 through exercise of outstanding warrants and stock options or future stock issuances; 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.

Source: pSivida Corp.

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