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## **pSivida Announces Opening of Investigator-Sponsored Trial for Injectable, Sustained Release FAc Insert for Posterior Uveitis**

WATERTOWN, Mass., Sep 12, 2011 (BUSINESS WIRE) --

Drug delivery company pSivida Corp. (NASDAQ:PSDV) (ASX:PVA) today announced the opening of an investigational new drug application (IND) for a Phase I/II clinical trial to study pSivida's injectable, sustained release insert delivering the corticosteroid fluocinolone acetonide (FAc) for the treatment of uveitis affecting the posterior segment of the eye (posterior uveitis). An insert of the same design is being developed for the treatment of diabetic macular edema (DME) by pSivida's licensee, Alimera Sciences, using Alimera's ILUVIEN® brand name.

Posterior uveitis is an inflammatory condition affecting the back of the eye which has been estimated to be responsible for up to 30,000 cases, or approximately 15%, of blindness in the U.S. and to be the third leading cause of blindness worldwide.

The insert is a third-generation insert based on pSivida's Durasert™ technology system. It is a tiny, cylindrical tube designed to provide a low, sustained dose of FAc for up to 36 months and is inserted by injection into the back of the eye in an office procedure.

pSivida licensed Alimera the insert for the treatment and prevention of eye diseases in humans other than uveitis. Alimera recently resubmitted a New Drug Application (NDA) for ILUVIEN for DME based on three-year results of Alimera's two Phase III trials involving 956 patients (FAME™ Study). Pursuant to its rights in the pSivida/Alimera agreement, pSivida plans to reference the NDA for ILUVIEN for DME (including the clinical data from the DME studies and the manufacturing and stability data) in support of any posterior uveitis regulatory filings.

The posterior uveitis study is an investigator-sponsored, dose-ranging study designed to assess safety and efficacy of inserts that deliver the high and low dose of FAc studied in the Phase III trials of ILUVIEN for DME. If successful, pSivida plans to advance the posterior uveitis product into pivotal multi-center Phase III trials. pSivida intends to use a new inserter, with a smaller gauge needle than that used in the DME studies, in any future posterior uveitis Phase III trials.

pSivida, together with partner Bausch & Lomb, previously developed the surgical implant Retisert®, which also provides sustained release of FAc to treat posterior uveitis. That product, a second generation Durasert implant, was the second back-of-the-eye implant approved by the FDA.

"We are extremely pleased to support this investigation of our FAc sustained-release insert to treat posterior uveitis," said Dr. Paul Ashton, President and CEO. "This insert, like our earlier Retisert implant for posterior uveitis, is designed to provide sustained delivery of FAc for up to approximately 36 months. But unlike Retisert, the posterior uveitis insert is injected in an office visit rather than surgically implanted. Further, because side effect data in Alimera's Phase III trials for ILUVIEN for DME showed far fewer side effects than Retisert showed in its clinical trials for either posterior uveitis or DME, we are looking forward to analyzing the results in this posterior uveitis trial. In addition, our ability to reference the NDA for ILUVIEN for DME has the potential to significantly abbreviate the clinical development and regulatory approval process for the insert for posterior uveitis."

### **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™. ILUVIEN® for the treatment of Diabetic Macular Edema, which is licensed to Alimera Sciences Inc., is pSivida's most advanced product candidate and is currently under review by the U.S. Food and Drug Administration. An investigator-sponsored Investigational New Drug application is open for an injectable insert to treat posterior uveitis of the same design as ILUVIEN for DME and an investigator-sponsored 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: ability to obtain additional capital when 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; Alimera's ability to successfully commercialize ILUVIEN if approved; risk/benefit profile of ILUVIEN; timeliness of approval, if any, of ILUVIEN 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.

**US Public Relations**

Martin E. Janis & Company, Inc  
Beverly Jedynek, +1 (312) 943 1123  
President

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

or

**pSivida Corp.**

Brian Leedman, +61 8 9443 4949  
Vice President, Investor Relations

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