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pSivida Corp. Announces Interim Data From Investigator-Sponsored Uveitis Study

WATERTOWN, Mass.--(BUSINESS WIRE)-- pSivida Corp. (NASDAQ:PSDV), a specialty pharmaceutical company that is a leader in developing sustained release drugs for the treatment of back-of-the-eye diseases, today announced interim data from an investigator-sponsored Phase I/II study of pSivida's injectable micro-insert in patients with posterior uveitis. The same micro-insert is being marketed in the EU as ILUVIEN® for the treatment of chronic Diabetic Macular Edema (DME) considered insufficiently responsive to available therapies by pSivida's collaborative partner, Alimera Sciences. The uveitis application is being independently developed by pSivida.

Through the first 12 months of enrollment in this study, none of the treated eyes had a recurrence of uveitis, and inflammation had been reduced in all treated eyes. By contrast, fellow (untreated) eyes showed either recurrence of uveitis or worsening or no improvement in inflammation. At the last follow-up visit, best corrected visual acuity (on the Early Treatment Diabetic Retinopathy Study eye chart) had improved by an average of more than nine letters in treated eyes and had declined by an average of one letter in fellow eyes.

The interim data showed that the micro-inserts were well-tolerated and the observed safety profile was consistent with the short-term safety profile reported in clinical studies of ILUVIEN in DME subjects. With one exception, intraocular pressure (IOP) measurements of treated eyes had all remained in the normal range. One treated eye, which at baseline had a history of elevated IOP, required surgery to control pressure.

"We are very happy with this early data," said Paul Ashton, Ph.D., President and CEO of pSivida Corp. "They are consistent with our hypothesis that our micro-insert will treat chronic non-infectious uveitis affecting the back of the eye with an efficacy profile that is comparable to Retisert, a current FDA- approved implant for uveitis developed by pSivida, and a side effect profile that is superior to Retisert and comparable to ILUVIEN in DME," said Dr. Ashton.

The three-year, investigator-sponsored Phase I/II study will evaluate the safety and efficacy of the micro-insert in up to 12 patients with uveitis affecting the posterior segment (intermediate, posterior and panuveitis). pSivida has recently initiated the first of two planned Phase III trials for the use of the micro-insert in the treatment of posterior uveitis, which are expected to enroll a total of approximately 300 patients. The primary end point in these trials will be the recurrence of uveitis within 12 months. pSivida will be permitted to reference much of the data, including the clinical safety data, from the clinical trials for ILUVIEN for DME conducted by Alimera.

Alimera has been granted marketing authorization for ILUVIEN for DME in six EU countries with a seventh pending. Alimera began the commercial launch of the product earlier last quarter in Germany, and, for private payers, in the UK. Uptake by the UK's National Health Service is expected later in the year following the positive appraisal consultation document issued from NICE in June. The U.S. Food & Drug Administration accepted Alimera's resubmission of the New Drug Application for ILUVIEN for DME with a PDUFA date of October 17, 2013. pSivida will be entitled to receive 20% of the net profits (as defined) on sales of ILUVIEN for DME by Alimera and a $25 million milestone payment from Alimera if the FDA approves.

"Both our micro-insert and Retisert deliver the same drug, which has been shown to be effective in treating uveitis. However, the micro-insert delivers a lower dosage, which we are optimistic will continue to show similar efficacy to Retisert in treating the disease," said Dr. Ashton. "We also expect that these micro-inserts in uveitis patients will have a comparable side effect profile to that seen with ILUVIEN in DME. Data from the approximately 1,000 patients who received these micro-inserts in the ILUVIEN DME Phase III studies showed an incidence of serious elevated IOP (above 30mmHg) that was three times lower than that shown in the Retisert Phase III trials and an incidence of required surgery to treat increased IOP that was lower by a factor of 7. As a result, we are optimistic that our micro-insert will be efficacious for treating posterior uveitis with a more favorable risk/benefit profile and fewer side effects than Retisert. Another advantage of these micro-inserts over Retisert is that the micro-inserts are injected into the eye in an office visit while Retisert must be surgically inserted."

Posterior uveitis is an inflammatory disease of one of the layers of the eye. In the U.S. posterior uveitis affects approximately 175,000 people and is responsible for approximately 30,000 cases of legal blindness, making it the third largest cause of blindness. Retisert is licensed to and marketed by Bausch & Lomb.

About pSivida Corp.

pSivida Corp., headquartered in Watertown, MA, develops tiny, sustained release, drugs designed to be released 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 has commenced the first of two 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 FDA-approved product, Retisert® for the treatment of posterior uveitis, is licensed to Bausch & Lomb. Other technologies under development by pSivida include protein and antibody delivery systems in early clinical stages.

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 actual results of the investigator-sponsored NDA for posterior uveitis including efficacy, visual acuity and side effects and the initiation, financing and success of Phase III posterior uveitis trials including efficacy, side effects and risk/benefit profile of the posterior uveitis micro-insert; 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; outcome of reimbursement for ILUVIEN in the U.K., 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.; 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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