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pSivida Reports Presentation of Additional Positive 24-Month Data from Iluvien(R) Phase 3 FAME(TM) Study for Diabetic Macular Edema at Angiogenesis 2010

WATERTOWN, Mass., Mar 03, 2010 (BUSINESS WIRE) -- pSivida Corp. (NASDAQ:PSDV) (ASX:PVA) (FF:PV3), a leader in the development of ophthalmic sustained release drug delivery products, with two of the only three such products approved by the FDA for treatment of back of the eye diseases, today said that 24-month data from the FAME Phase 3 study for Iluvien presented at Angiogenesis 2010 included additional efficacy and safety data that reinforced the positive top-line results reported in December 2009 by pSivida and its licensee, Alimera Sciences, Inc.

Peter A. Campochiaro, MD, of The Johns Hopkins University School of Medicine, presented the 24-month results from the FAME study at the Angiogenesis 2010 meeting in Miami based on analysis of the Full Analysis Set representing all randomized patients. As previously reported, the difference in the percentage of patients in this dataset whose best corrected visual acuity (BCVA) improved by 15 or more letters from baseline on the Early Treatment Diabetic Retinopathy Study (ETDRS) eye chart at month 24 was statistically significant for both doses of Iluvien in each of the two trials composing the FAME Study as well as on a combined basis. For the combined analysis, 28.7% of patients treated with low dose Iluvien, and 28.6% of patients treated with high dose gained at least 15 letters, compared with 16.2% of control patients, p = 0.002 for high and low dose. Based on the 24-month data, Alimera previously announced that it intends to file a New Drug Application (NDA) for regulatory approval of the Iluvien low-dose in Q2 calendar 2010.

Among the new efficacy data reported by Dr. Campochiaro, over 50% of Iluvien low dose patients gained at least 5 letters at 24 months. Further, over 75% of the Iluvien low dose patients received only a single administration of Iluvien. Over one-third of the one-administration patients with 24 month data gained more than 15 letters at 24 months.

Patients receiving low dose Iluvien were also less likely to receive additional treatments for their DME. During the 24-month period, almost twice as many patients in the control group received laser treatment compared to the low dose Iluvien patients (58.9% of control versus 36.7% of low dose Iluvien), and more than twice as many patients in the control group received an off-protocol treatment (intravitreal injection of Kenalog® or LUCENTIS® or Avastin® or vitrectomy) compared to patients in the low dose Iluvien group (28.6% of control versus 12.5% of low dose Iluvien).

Also reported was additional safety data. As previously reported patients receiving low dose Iluvien were more likely to have increased intraocular pressure. The new data showed that patients receiving low dose Iluvien were also slightly more likely to develop glaucoma (deemed serious by the reporting physician) than control patients (2.7% of low dose Iluvien versus 1.1% of control). Low dose Iluvien patients also experienced slightly lower rates of retinal detachment (0.5% of low dose Iluvien versus 1.6% of control) and vitreous hemorrhage (2.1% of low dose Iluvien versus 2.7% of control) deemed serious by the reporting physician.

Cataracts, which can generally be corrected with standard cataract surgery, occur more commonly in patients with DME and in patients receiving steroids. In the FAME study approximately one third of patients had cataract surgery before they entered the trial. Of the remaining patients, those randomized to Iluvien low dose were approximately twice as likely to develop cataract as those randomized to control (over 80% of low dose Iluvien versus approximately 45% of control) and approximately three times more likely to have cataract surgery than control patients (75% of low dose Iluvien versus 23% of control).

"We are very encouraged by the additional data presented at the Angiogenesis 2010 meeting and look forward to the upcoming NDA filing for potentially the first ophthalmic drug therapy approved for DME," said Dr. Paul Ashton, President and CEO of pSivida.

The FAME study, conducted at 101 sites in North America, Europe and India, enrolled 956 patients in two randomized, double-masked, parallel groups to study Iluvien for treatment of diabetic macular edema. The enrollees were randomized in a 2:2:1 (two received the high dose Iluvien; two received the low dose Iluvien; and one received a sham procedure). The primary efficacy endpoint for the FAME Study is the difference in the percentage of patients whose BCVA improved by 15 or more letters from baseline on the ETDRS eye chart at month 24 between the treatment and control groups. In the trials, at the physicians' discretion, patients were allowed to receive additional administrations of Iluvien after 12 months of follow-up, and additional laser treatments 6 weeks after randomization.

In the Full Analysis Set of all randomized patients used to analyze the overall efficacy data for the Angiogenesis presentation, if 24 month data was missing it was imputed from the last available observation. At 24 months, 22.7% of patients in the control group had discontinued the trial or were unavailable for follow up compared to 19.9% of the low dose Iluvien patients. As a result, the amount of imputed data are approximately the same in the treatment and control groups (approximately 20% in each group) utilizing the Full Analysis Set.

Other analyses of the data performed by protocol, which were previously reported, included a Modified ART analysis of all patients randomized and treated, which was specified as the primary method for assessing efficacy in the protocol. In the Modified ART analysis, in addition to imputing 24-month data that was missing, 24 month data was also imputed if a patient had an off-protocol treatment. In the Modified ART analysis therefore approximately 50% of the control data and approximately 30% of the Iluvien low dose data was imputed. The Modified ART analysis was the only dataset of the three analyses performed that did not achieve statistical significance for low dose Iluvien.

Following the recent release of the top-line two year data from the FAME Study, Alimera raised $10 million from its investors via the exercise of warrants. Alimera is due to begin monthly principal payments of $500,000 to pSivida plus quarterly interest payments at 20% annually based on a $15 million contingent note in April 2010.

About DME

DME, the primary cause of vision loss associated with diabetic retinopathy, is a disease affecting the macula, the part of the retina responsible for central vision. When the blood vessel leakage of diabetic retinopathy causes swelling in the macula, the condition is called DME. The onset of DME is painless and may go undetected by the patient until it manifests with the blurring of central vision or acute vision loss. The severity of this blurring may range from mild to profound loss of vision. The Wisconsin Epidemiologic Study of Diabetic Retinopathy found that over a ten-year period approximately 19% of diabetics studied were diagnosed with DME. Based on this study and the current U.S. diabetic population, Alimera estimates that there will be an incidence of approximately 340,000 cases of DME annually in the United States. As the population of diabetics increases, Alimera expects the annual incidence of diagnosed DME to increase.

About Iluvien®

Iluvien is an investigative, extended release intravitreal insert that Alimera is developing for the treatment of DME. Each Iluvien insert is designed to provide a therapeutic effect for up to 36 months by delivering sustained sub-microgram levels of fluocinolone acetonide (FA). Iluvien is inserted in the back of the patient's eye to a position that takes advantage of the eye's natural fluid dynamics. Iluvien is inserted with a device that employs a 25-gauge needle, which allows for a self-sealing wound.

About pSivida Corp.

pSivida is a world leader in the development of tiny, sustained release, drug delivery products that are administered by implantation, injection or insertion. pSivida's lead development product delivers fluocinolone acetonide (FA) for the treatment of diabetic macular edema (DME). This product candidate, formerly known as Medidur™ FA for DME, is licensed to Alimera, which is conducting fully-recruited Phase III clinical trials and intends to commercialize the product under the name Iluvien®. pSivida also has two products approved by the Food and Drug Administration (FDA): Retisert® for the treatment of posterior uveitis and Vitrasert® for the treatment of AIDS-related cytomegalovirus (CMV) retinitis. pSivida has licensed both of these products and the technologies underlying them to Bausch & Lomb Incorporated. pSivida has a worldwide collaborative research and license agreement with Pfizer Inc. under which Pfizer may develop additional ophthalmic products.

pSivida owns the rights to develop and commercialize a modified form of silicon known as BioSilicon™, which has potential therapeutic applications. The most advanced BioSilicon product candidate, BrachySil™, delivers a therapeutic P32, a radioactive form of phosphorus used to treat cancer, directly to solid tumors. pSivida conducted an initial safety clinical trial of BrachySil for the treatment of pancreatic cancer and in October 2009 completed of a follow-on dose-ranging clinical trial.

pSivida's intellectual property portfolio consists of 62 patent families, over 100 granted patents, including patents accepted for issuance, and over 200 patent applications. pSivida conducts its operations from Boston in the United States and Malvern in the United Kingdom.

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 forward-looking statements: inability to commercialize Iluvien or significant delays in the commercialization of Iluvien; inability to obtain regulatory approvals of Iluvien; failure to achieve an appropriate relationship between the benefits of Iluvien's efficacy and the risks of its side effect profile; regulatory agency imposition of limitations on the uses for which Iluvien may be

marketed, subsequent withdrawal of approval or other actions adverse to our business; failure of Iluvien to be granted priority review or receive approval within the six month priority review/approval cycle; continued losses and lack of profitability; inability to derive revenue from Retisert; impairment of intangibles; fluctuations in the fair values of certain outstanding warrants; fluctuations in operating results; inability to raise capital; termination of license agreements; inability to obtain regulatory approvals for products; inability to obtain partners to develop and market products; competition; insufficient third-party reimbursement for products; inability to protect intellectual property or infringement of others' intellectual property; failure to retain key personnel; consolidation in the pharmaceutical and biotechnology industries; failure to comply with laws and regulations; manufacturing problems; risks and costs of international business operations; volatility of stock price; possible dilution through exercise of outstanding warrants and stock options; possible influence by Pfizer; payment of registration penalties; nonpayment of dividends; and other factors that may be 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.

For more information on pSivida, visit www.psivida.com.

SOURCE: pSivida Corp.

US Contact:
Beverly Jedynak, President,
Martin E. Janis & Company, Inc.,
312-943-1123, bjedynak@janispr.com
or
Australia Contact:
Brian Leedman, Vice President, Investor Relations,
pSivida Corp.,
+61 8 9227 8327, brianl@psivida.com