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pSivida Reports Safety and Efficacy Results from 18-Month Interim Readout of Human PK Iluvien(R) Study

WATERTOWN, Mass., Sep 29, 2009 (BUSINESS WIRE) -- pSivida Corp (NASDAQ: PSDV)(ASX: PVA), a leading drug delivery company that has developed two of the only three products approved by the FDA for the long-term, sustained release delivery of drug to treat chronic back of the eye disease, today reported the interim 18-month safety and efficacy results from the first human pharmacokinetic study (PK Study) of Iluvien®. The PK trial is being conducted by Alimera Sciences, the licensee for Iluvien.

Dr. Paul Ashton, CEO of pSivida, said: "We are encouraged with the results we see from this small, 37-patient PK study, particularly as it relates to the safety profile. The lower incidence of elevated IOP with Iluvien in the PK study compared to the higher incidence shown in the data for studies of Retisert® (one of our FDA-approved, surgically inserted products which uses the same steroid), is very promising. In this PK study, we see an increase in efficacy in the high dose group and a decrease in efficacy in the low dose group in the results at 18 months as compared to 12 months. While the efficacy data is encouraging, these are very small patient numbers. Data from the almost 1000 patient Phase III FAME™ trial is due at the end of the year, which will give us a clearer picture of the relative efficacy of Iluvien dosages."

This present 36-month, open-label, Phase II study is designed primarily to assess systemic exposure of the corticosteroid, fluocinolone acetonide (FA), after administration of Iluvien in patients with DME. Secondarily, the PK Study is designed to provide information on the safety and efficacy of Iluvien in a DME patient population. A total of 37 subjects were enrolled in the PK Study, 20 patients on the low dose of Iluvien (an approximate 0.23 micrograms (ug) per day dose), and 17 patients on the high dose of Iluvien (an approximate 0.45ug per day dose).

In the 18-month interim readout, data again demonstrated no adverse events related to intraocular pressure (IOP) in low dose patients, and a similar level of increased IOP in the high dose patients as reported at 12 months. No patients receiving the low dose of Iluvien experienced IOP increases of 30 millimeters of mercury (*mmHg*) or greater at any time point, while 29 percent of the patients receiving the high dose of Iluvien experienced IOP increases of 30*mmHg* or greater at some time point.

In this trial, a subset of 11 patients in the high dose group and 13 patients in the low dose group met the visual acuity inclusion criteria of the nearly 1000 patient Phase III FAME trial. Of the 11 patients in the high dose group, six patients or 55 percent had an improvement in best corrected visual acuity (BCVA) of 10 letters or greater from baseline and four patients or 36 percent of the high dose patients had an improvement in BCVA of 15 letters or greater over baseline.

Of the 13 patients in the low dose group meeting the visual acuity criteria of the FAME trial, three patients or 23% percent had an improvement in BCVA of 10 letters or greater from baseline, while no patients showed an improvement in BCVA of 15 letters or greater from baseline at this time point. Iluvien is an investigative, extended release intravitreal insert currently under development for the treatment of Diabetic Macular Edema (DME). Each Iluvien insert is designed to provide a sustained therapeutic effect of up to 36 months, for the low dose Iluvien, and up to 24 months, for the high dose of Iluvien. Iluvien is inserted into the patient's eye with a 25-gauge needle, which allows for a self-sealing wound. This insertion is very similar to an intravitreal injection, a procedure commonly employed by retinal specialists. An NDA for Iluvien is expected to be filed with the FDA early in 2010 by Alimera.

About pSivida Corp.

pSivida is a world leader in the development of miniaturized, injectable, drug delivery systems for the eye. pSivida's lead development product, Iluvien®, delivers fluocinolone acetonide (FA) for the treatment of diabetic macular edema (DME). Formerly known as Medidur™ FA for DME, Iluvien is in fully recruited Phase III clinical trials. pSivida has licensed certain drug delivery technology to Alimera Sciences, Inc. for the development of Iluvien and certain other ophthalmic products. pSivida also has two products approved by the Food and Drug Administration (FDA): Retisert® for the treatment of 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 has completed an initial safety clinical trial of BrachySil for the treatment of pancreatic cancer and is conducting a follow-on dose-ranging clinical trial.

pSivida's intellectual property portfolio consists of 45 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.

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