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pSivida Announces New Iluvien(R) Pilot Study in Patients with Macular Edema Secondary to Retinal Vein Occlusion

WATERTOWN, Mass.--(BUSINESS WIRE)--Sep. 23, 2009-- pSivida Corp. (NASDAQ:PSDV)(ASX:PVA)(FWB:PV3), 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 announced that enrollment has begun for a pilot study to assess the safety and efficacy of Iluvien® in patients with macular edema secondary to retinal vein occlusion. The trial is being sponsored by pSivida's licensee, Alimera Sciences of Alpharetta, Georgia.

The randomized, double-masked pilot study, named FAVOR (Fluocinolone Acetonide for Vein Occlusion in Retina) compares two doses of Iluvien (0.23 and 0.45 micrograms per day).

"Retinal vein occlusion (RVO), a common disorder of the retina, is one of the leading causes of blindness after diabetic eye disease and age-related macular degeneration (AMD). Iluvien is already in phase III clinical trials for DME and is in pilot studies for wet and dry AMD," said Dr. Paul Ashton, CEO of pSivida.

Dr. P.A. Pearson, Professor and Chairman of Ophthalmology at the University of Kentucky, an investigator in this trial added: "RVO occurs when the circulation of a retinal vein (central or branch) becomes obstructed. This occlusion can ultimately cause capillary leakage leading to macular edema, which is the leading cause of visual loss in RVP."

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. Iluvien is in pivotal Phase III clinical trials for the treatment DME. The 24-month top-line data from these Phase III trials are expected to be reported in December of this year, with an NDA expected to be filed with the FDA for approval early in 2010.

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.

SAFE HARBOR STATEMENTS UNDER THE PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995: Various statements made in this release are forward-looking and involve a number of risks and uncertainties. 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: failure of FA or the Iluvien device to act as a VEGF inhibitor or neuroprotectant; inability to expand the treatment indications for Iluvien;

maintaining key collaboration agreements with Alimera and Pfizer; modification of existing terms of key collaboration agreements with Alimera and Pfizer; uncertainties regarding the achievement of milestones and other contingent contractual payment events; failure to prove safety and efficacy of Iluvien or BrachySil; inability to raise capital; continued losses and lack of profitability; inability to derive revenue from Retisert; termination of license agreements; inability to pay any registration penalties; inability to develop or obtain regulatory approval for new products; inability to protect intellectual property or infringement of others' intellectual property; inability to obtain partners to develop and market products; competition; risks and costs of international business operations; manufacturing problems; insufficient third-party reimbursement for products; failure to retain key personnel; product liability; failure to comply with laws; failure to achieve and maintain effective internal control over financial reporting; impairment of intangibles; volatility of stock price; possible dilution through exercise of outstanding warrants and stock options or future stock issuances; possible influence by Pfizer; 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. We do not undertake to publicly update or revise our forward-looking statements even if experience or future changes make it clear that any projected results expressed or implied in such statements will not be realized.

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