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pSivida Announces Submission of NDA to FDA for an Ophthalmic Product for Diabetic Macular Edema

WATERTOWN, Mass., Jun 29, 2010 (BUSINESS WIRE) --

pSivida Corp. (NASDAQ:PSDV) (ASX:PVA), a leader in the development of sustained release back of the eye drug delivery systems for difficult-to-treat conditions, today announced that its licensee, Alimera Sciences (NASDAQ:ALIM) has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration for Iluvien® for Diabetic Macular Edema. Iluvien, developed by pSivida and licensed to Alimera Sciences in 2005, is a sustained release drug delivery system releasing the steroid flucocinolone acetonide for the treatment of diabetic macular edema (DME). In the submission, Alimera requested priority review, which, if granted, could result in an action letter from the FDA in the fourth quarter of this year.

Dr. Paul Ashton, President and CEO of pSivida, said, "There are currently no drugs approved to treat DME, one of the leading causes of vision loss. Iluvien's clinical trials have demonstrated that Iluvien can significantly improve vision in DME patients." Dr. Ashton continued, "This is our third product for back-of-the-eye diseases to be submitted to the FDA for approval. The first two were approved, are currently on the market and are two of the only three sustained release drug delivery systems currently approved by the FDA to treat back-of-the-eye conditions."

Two pivotal phase three clinical trials (collectively known as the FAME Study) for Iluvien involving 956 patients in sites across the United States, Canada, Europe and India are being completed to assess the efficacy and safety of Iluvien for the treatment of DME. The primary efficacy endpoint for the FAME Study is the difference in the percentage of patients whose best corrected visual acuity (BCVA) improved by 15 or more letters from baseline on the ETDRS eye chart at month 24 between the treatment and control groups. The study will conclude later this year with the final patient visits at the three-year data point. The 24-month clinical read out from the study was announced in December 2009.

The NDA submission includes the 24-month low dose data from the FAME Study. Alimera has indicated that it plans to follow this NDA submission with registration filings in certain European countries and Canada in the near future. pSivida has joint ownership and reference rights to this NDA.

pSivida continues to work to develop new products for the sustained release of drugs and proteins based on its existing and new technologies. Additionally, Pfizer and pSivida are collaborating to develop ophthalmic products based on pSivida technology. While the Company remains primarily focused in ophthalmology, pSivida is exploring other therapeutic areas.

About pSivida Corp.

pSivida Corp is a world leader in the development of tiny, sustained release, drug delivery products and technologies that are administered by implantation, insertion or injection. The Company uses these systems to develop treatments for serious, unmet, medical needs. pSivida's intellectual property portfolio consists of 59 patent families, more than 100 granted patents, including patents accepted for issuance, and more than 150 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 anticipated results or other expectations expressed, anticipated or implied in our forward-looking statements: maintaining collaboration agreements with Alimera and Pfizer; modifications of existing terms of collaboration agreements with Alimera and Pfizer; achievement of milestones and other contingent contractual events; ability to prove safety and efficacy of, and achieve regulatory approvals for, and successfully commercialize Iluvien, BrachySil and other products;; ability to raise capital; ability to achieve profitability; ability to derive revenues from Retisert; ability to develop new products; impairment of intangibles; fluctuations in the fair values of certain outstanding warrants; fluctuations in operating results; termination of license agreements; ability to obtain partners to develop and market products; competition; extent of third-party reimbursement for products; product liability; ability to protect intellectual property or infringement of others' intellectual property; retention of

key personnel; consolidation in the pharmaceutical and biotechnology industries; compliance with laws; maintaining effective internal control over financial reporting; manufacturing risks; risks and costs of international business operations; 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; 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.

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