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pSivida Announces Submission of Marketing Authorization Application for an Ophthalmic Product for Diabetic Macular Edema In Certain European Union Countries

WATERTOWN, Mass., Jul 08, 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 Marketing Authorization Application (MAA) to the Medicines and Healthcare Products Regulatory Agency (MHRA) in the United Kingdom (UK) for Iluvien®. 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). The MAA is being submitted through the Decentralized Procedure with the UK MHRA as the Reference Member State (RMS). Applications have also been submitted to the following other Concerned Member States (CMS) in the European Union: Austria, France, Germany, Italy, Portugal and Spain.

This submission closely follows the submission last week of the NDA to the U.S. Food and Drug Administration for approval for Iluvien to treat DME. The MAA submission includes the 24 month low dose data from the FAME study. Alimera has indicated it plans to follow this MAA submission with a registration filing in Canada in the near future. pSivida has joint ownership and reference rights to the MAA and 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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