Pfizer Logo

pSivida Announces Phase I/II Clinical Study Evaluating Bioerodible, Sustained Release Latanoprost Device in Ocular Hypertension and Glaucoma

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WATERTOWN, Mass., Jun 14, 2011 (BUSINESS WIRE) --

Drug delivery company pSivida Corp. (NASDAQ: PSDV) (ASX: PVA) today announced the commencement of a Phase I/II clinical trial studying a new bioerodible drug delivery implant for the treatment of glaucoma and ocular hypertension. The implant is designed to provide long-term, sustained release of latanoprost, the most commonly prescribed agent for reduction of intraocular pressure in patients with ocular hypertension and glaucoma worldwide.

The product candidate is a new, compact drug-delivery implant based on the Company's DurasertTM technology system. The implant is designed to be administered by an eye care professional in a minimally invasive, outpatient procedure; it is also designed to be injected into the subconjunctival space of the eye and to be bioerodible.

The new study is a dose-escalating study designed to assess the safety and efficacy of the implant in patients with elevated intraocular pressure. If successful, pSivida plans to advance the product into a multi-center Phase II trial.

Dr Paul Ashton, President and CEO of pSivida Corp., said, "We are extremely pleased that this first application of our new bioerodible drug-delivery technology has entered clinical trials. We look forward to advancing this new delivery system both in glaucoma and potentially in other applications as well."

The insert is being developed under the recently amended Research and Collaboration Agreement with Pfizer Inc. Under the revised agreement, Pfizer will make an initial payment of $2.3 million. pSivida will, with technical assistance from Pfizer, have the right to develop this candidate for the reduction of intraocular pressure in patients with ocular hypertension or glaucoma through Phase II clinical trials. At that point, Pfizer has an option to take an exclusive, world-wide license to develop and commercialize the product candidate in return for a $20 million option exercise payment, double-digit royalty payments on sales of the product and additional development, regulatory and any sales performance milestone payments of up to $146.5 million. If Pfizer does not exercise its option, pSivida will retain the right to develop and commercialize the glaucoma product on its own or with a partner. As part of the amended agreement, pSivida regains all rights to its intellectual property in ophthalmic applications previously included in the original Research and Collaboration Agreement, other than those related to the latanoprost product.

About pSivida Corp.
pSivida is a world leader in the development of tiny drug delivery products that are administered by implantation, injection or insertion and provide sustained release of drugs on a controlled and level basis for months or years. The Company uses these systems to develop treatments for serious, unmet, medical needs. The Company's most advanced product candidate, ILUVIEN(R), delivers fluocinolone acetonide (FA) for the treatment of diabetic macular edema (DME). DME is a leading cause of vision loss, affecting more than a million people in the US alone, for which there is currently no FDA-approved drug therapy. ILUVIEN is licensed to Alimera Sciences, Inc., which has completed Phase III clinical trials and submitted a New Drug Application (NDA) with the Food and Drug Administration (FDA) in June 2010 based on 24-month data. In August 2010, the FDA granted Priority Review status for the NDA, and in December 2010, the FDA issued a Complete Response Letter. In February 2011, Alimera reported 36-month top-line results from the completed Phase III clinical trials and in May 2011, Alimera reported data which analyzed the subgroup of patients who had been diagnosed with DME for three or more years at entry of the study. Alimera resubmitted a New Drug Application for ILUVIEN to the FDA on May 12, 2011 to address questions raised in the Complete Response Letter (CRL) and reported that data from the subgroup of patients with chronic DME was also provided together with additional information regarding controls and specifications on the manufacturing, packaging and sterilization of ILUVIEN. pSivida has two products approved by the FDA for sustained release delivery of drug to treat chronic back-of-the-eye diseases: Retisert(R) for the treatment of posterior uveitis and Vitrasert(R) 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's intellectual property portfolio consists of over 50 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: ability of pSivida, with Pfizer, another partner or alone, to successfully develop, obtain regulatory approval for, finance, and commercialize a latanoprost implant; ability to obtain additional capital uncertain; future losses; impairment of intangibles; fluctuations in the fair values of certain outstanding warrants; fluctuations in operating results; decline of royalty income from Bausch & Lomb; Alimera's ability to obtain regulatory approval of ILUVIEN; Alimera's ability to successfully commercialize ILUVIEN if approved; risk/benefit profile of ILUVIEN; timeliness of approval, if any, of ILUVIEN and any limitations on uses thereof; ability to complete clinical trials and obtain regulatory approval of other product candidates; ability to find partners to develop and market products; termination of license agreements; competition; market acceptance of products and product candidates; reduction in use of products as a result of future publications; ability to protect intellectual property or infringement of others' intellectual property; retention of key personnel; product liability; consolidation in the pharmaceutical and biotechnology industries; compliance with environmental laws; manufacturing risks; risks and costs of international business operations; credit and financial market conditions; legislative or regulatory changes; 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; absence of dividends; 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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