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pSivida Corp. Reports FDA Approval of ILUVIEN® for Diabetic Macular Edema

pSivida earns $25 million milestone

WATERTOWN, Mass.--(BUSINESS WIRE)-- pSivida Corp. (NASDAQ: PSDV, ASX: PVA), a leader in the development of sustained release, drug delivery products for treating eye diseases, today announced that the U.S. Food and Drug Administration (FDA) has approved ILUVIEN® for the treatment of diabetic macular edema (DME). It is indicated for patients who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure (IOP). A single injection of the ILUVIEN micro-insert provides sustained treatment of DME for 36 months. Approximately 560,000 people in the U.S. are estimated to have clinically significant DME, the most frequent cause of vision loss in individuals with diabetes and the leading cause of blindness in young and middle-aged adults in developed countries. ILUVIEN is expected to be commercially available in the U.S. in early 2015.

FDA approval of ILUVIEN entitles pSivida to a $25 million milestone from its licensee Alimera Sciences. pSivida will also be entitled to 20% of the net profits from sales of ILUVIEN in the U.S.

"FDA approval of ILUVIEN, our third FDA-approved product for retinal disease, provides an important treatment option for DME patients in the U.S., the majority of whose DME, despite anti-VEGF intra-ocular injections as frequently as monthly, is not optimally managed. ILUVIEN's clinical trials showed that ILUVIEN can actually reverse vision loss in many DME patients. Another advantage of ILUVIEN over existing therapies is that a single injection provides sustained therapy for three years," said Paul Ashton, Ph.D., president and chief executive officer of pSivida.

"The $25 million milestone will help finance our ongoing product development program, including Medidur™ for posterior uvei and Tethadur™ for the sustained delivery of biologics," added Dr. Ashton. pSivida is independently developing Medidur, an injectable, sustained release micro-insert of the same design and delivering the same drug as ILUVIEN, for the treatment of chronic posterior uveitis, the third largest cause of blindness in the U.S. The Company plans to seek FDA approval of this product on the basis of its ongoing single Phase III clinical trial. Enrollment of this study is expected to be completed by the end of the first quarter of calendar 2015.

ILUVIEN is already commercially available in the U.K. and Germany, and has received or is pending marketing approval in seventeen other EU countries, for the treatment of patients with the chronic DME insufficiently responsive to available therapies. "We are very pleased that the FDA's approval of ILUVIEN is not limited, as in the EU, to the subset of patients with chronic DME, patients who have failed other therapies, or patients who have had cataract surgery," continued Dr. Ashton.

ILUVIEN is an injectable micro-insert that provides sustained treatment through continuous delivery of a submicrogram dose of the corticosteroid fluocinolone acetonide for 36 months. Current standard-of-care therapy requires anti-VEGF injections into the eye as frequently as monthly, and studies show that over 50 percent of patients are not optimally managed with this treatment. FDA approval was based on clinical trial data that showed that at month 24, 28.7 percent of patients receiving ILUVIEN experienced an improvement from baseline in their best corrected visual acuity on the Early Treatment Diabetic Retinopathy Study (ETDRS) eye chart of 15 letters or more. This improvement in vision was maintained through 36 months, the end of the trials.

About ILUVIEN®

ILUVIEN® (fluocinolone acetonide intravitreal implant) 0.19 mg is a sustained release intravitreal implant approved in the United States to treat DME in patients who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure. Each ILUVIEN implant is designed to release submicrogram levels of fluocinolone acetonide (FAc), a corticosteroid for 36 months.

Corticosteroids have a history of effective use in treating ocular disease inflammation. ILUVIEN is injected in the back of the patient's eye with an applicator that employs a 25-gauge needle, which allows for a self-sealing wound. In the FAME™ Study, phase 3 clinical study of ILUVIEN, the most frequently reported adverse drug reactions included cataract development and increased ocular pressure.

ILUVIEN Important Safety Information

ILUVIEN contains a corticosteroid and is indicated for the treatment of DME in patients who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure.

Intravitreal injections have been associated with endophthalmitis, eye inflammation, increased intraocular pressure, and retinal detachments. Patients should be monitored following the injection.

Use of corticosteroids may produce posterior subcapsular cataracts, increased intraocular pressure, glaucoma, and may enhance the establishment of secondary ocular infections due to bacteria, fungi, or viruses.

The implant may migrate into the anterior chamber if the posterior lens capsule is not intact. In controlled studies, the most common adverse reactions reported were cataract development and increases in intraocular pressure.

Patients are advised to have follow-up eye examinations at appropriate intervals following treatment with ILUVIEN. Full prescribing information will be available at http://www.accessdata.fda.gov/scripts/cder/drugsatfda/.

About DME

Diabetic Macular Edema, the primary cause of vision loss associated with diabetic retinopathy, is a disease affecting the macula, the part of the retina responsible for central vision. When the blood vessel leakage of diabetic retinopathy causes swelling in the macula, the condition has progressed to DME. The onset of DME is painless and may go undetected by the patient until it manifests with the blurring of central vision or acute vision loss. The severity of this blurring may range from mild to profound loss of vision. The Wisconsin Epidemiologic Study of Diabetic Retinopathy found that over a 10-year period approximately 19 percent of people with diabetes studied were diagnosed with DME. All people with type 1 or type 2 diabetes are at risk of developing DME. As the population of people with diabetes increases, the annual incidence of diagnosed DME is expected to increase, as well.

Duration of diabetes is the greatest risk factor for increased retinopathy and is associated with an increased prevalence of DME. The appearance of retinopathy is associated with an up-regulation of vascular endothelial growth factor (VEGF) causing an increase in permeability of vessels leading to leakage of fluid. As retinopathy worsens, an up-regulation of multiple cytokines (inflammatory factors) takes place. Corticosteroids offer a broad effect on down regulation of multiple cytokines associated with DME that persists.

About pSivida Corp.

pSivida Corp., headquartered in Watertown, MA, is a leader in the development of sustained release, drug delivery products for treating eye diseases. pSivida is currently focused on treatment of chronic diseases of the back of the eye utilizing its core technology systems, Durasert™ and BioSilicon™, including Tethadur™. pSivida has instituted a pivotal Phase III clinical tr its lead product candidate, Medidur™ for treatment of the chronic, back-of-the-eye disease posterior uveitis. Medidur uses the same injectable, sustained release micro-insert as pSivida's lead licensed product, ILUVIEN® for the treatment of DME, licensed to Alimera Sciences, Inc. In the EU, ILUVIEN is marketed in the U.K. and Germany and has received or is pending marketing authorization in seventeen EU for the treatment of chronic DME considered insufficiently responsive to available therapies. In the U.S., ILUVIEN has been approved for the treatment of DME in patients who have previously completed a course of therapy with a steroid without experiencing a clinically significant increase in IOP. pSivida's FDA-approved Retisert®, an implant which provides long-term, sustained drug delivery to treat posterior uveitis, is licensed to and sold by Bausch & Lomb Incorporated. pSivida's preclinical research is focused on ocular and systemic delivery of biologics and treatment of wet and dry age-related macular degeneration, osteoarthritis and glaucoma.

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: ; Alimera's ability to fund the $25 million milestone and to finance, successfully commercialize and achieve market acceptance of, and generate revenues to pSivida from, ILUVIEN for DME in the U.S.; timing of commencement of sales of ILUVIEN in the U.S.; Alimera's ability to finance, achieve additional marketing approvals, obtain adequate pricing and reimbursement for, successfully commercialize and achieve market acceptance of, and generate revenues to pSivida from, ILUVIEN for DME in the EU; pSivida's ability to finance, complete and achieve a successful clinical outcome for its clinical trials of, and file and achieve marketing approvals for, Medidur for posterior uveitis, including achieving acceptable risk-to-benefit and safety profiles in light of the CRL for ILUVIEN; initiation, financing and success of Latanoprost Product Phase II trials and any exercise by Pfizer of its option; ability of Tethadur to successfully deliver proteins, peptides and other large biologic molecules; ability to develop product candidates and products and potential related collaborations; initiation and completion of clinical trials and obtaining

regulatory approval of product candidates; continued sales of Retisert; adverse side effects; ability to attain profitability; ability to obtain additional capital; further impairment of intangible assets; fluctuations in operating results; decline in royalty income; ability to, and to find partners to, develop and market products; termination of license agreements; competition and other developments affecting sales of products; market acceptance; protection of intellectual property and avoiding intellectual property infringement; 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; absence of dividends; and other factors described in our filings with the SEC. Given these uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements. Should known or unknown risks materialize, or should underlying assumptions prove inaccurate, actual results could differ materially from past results and those anticipated, estimated or projected in the 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.

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The President's Blog: http://www.thechairmansblog.com/paul-ashton

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