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Primary Endpoint Met in pSivida's Utilization Study of New Medidur™ Inserter with Smaller Diameter Needle

Results to Form Part of Planned Applications for Marketing Approvals in EU and US

WATERTOWN, Mass., Aug. 09, 2016 (GLOBE NEWSWIRE) -- pSivida Corp. (NASDAQ:PSDV); (ASX:PVA), a leader in the development of sustained release drug delivery products primarily for eye diseases, announced that its utilization study of its new, proprietary 27-gauge inserter for Medidur for posterior uveitis has met its primary endpoint. In the study, 66 percent of injections using the new 27-gauge inserter achieved a satisfactory rating of "Routine," "Easy" or "Very Easy" while only 46 percent of injections utilizing the earlier, larger 25-gauge inserter used in the first Medidur Phase 3 trial met that standard. The results of this study will form part of pSivida's planned U.S. New Drug Application and application for EU marketing authorization for Medidur for posterior uveitis.

Paul Ashton, Ph.D., president and CEO of pSivida, said, "This is an excellent result for the new Medidur inserter. The design of the new inserter with its smaller diameter needle was shown in the study to facilitate the ease of administration of Medidur, and we expect it to be more popular with physicians than the earlier, larger needle model. By comparison, ILUVIEN® for diabetic macular edema uses a larger diameter 25-gauge inserter, and Ozurdex® for posterior uveitis, DME and retinal vein occlusion uses an even larger diameter 22-gauge inserter. We plan to use the smaller 27-gauge needle in the inserter in our TKI insert for wet age-related macular degeneration under development."

The multi-center, randomized, controlled, single masked utilization and safety study assessed the utilization and the safety of the 27-gauge inserter, and the safety of the Medidur insert, from the day of treatment through seven days following administration. In the study, 38 eyes were injected with Medidur, randomized approximately 2:1 to the new 27-gauge inserter or the earlier 25-gauge inserter. The primary endpoint of the study required the proportion of procedures with the new inserter scored as routine or easier to be at least as high as the corresponding proportion of procedures with the 25-gauge inserter. Patients will be followed for 12 months.

About Medidur. Medidur is an injectable micro-insert designed to treat posterior uveitis. Injected into the back of the eye in an office procedure, it provides sustained release of 0.18 mg of the corticosteroid fluocinolone acetonide at a controlled rate directly to the retina for three years.

About Posterior Uveitis. Posterior uveitis is a chronic, non-infectious inflammatory disease affecting the posterior segment of the eye, often involving the retina, which is a leading cause of blindness in the developed and developing countries. It afflicts people of all ages, producing swelling and destroying eye tissues, which can lead to severe vision loss and blindness. In the U.S., posterior uveitis affects approximately 175,000 people, resulting in approximately 30,000 cases of blindness and making it the third leading cause of blindness in the U.S.

Patients with posterior uveitis are typically treated with systemic steroids but over time frequently develop serious side effects that can limit effective dosing. Patients then often progress to steroid-sparing therapy with systemic immune suppressants or biologics, which themselves can have severe side effects including an increased risk of cancer. Medidur is designed to provide improved outcomes compared to standard of care but with a significant reduction in side effects.

About Medidur Phase 3 Trials. pSivida is conducting two Phase 3 trials to assess the safety and efficacy of Medidur for the treatment of posterior uveitis. These are randomized, sham-controlled, double-masked trials. The primary endpoint of both trials is recurrence of posterior uveitis at six months, with patients in both trials followed for three years. The first Phase 3 Medidur trial, which is fully enrolled with 129 patients in 16 centers in the U.S. and 17 centers outside the U.S., met its primary efficacy endpoint with high statistical significance. The second trial, which will include up to 150 patients in approximately 15 centers in India, is currently being enrolled.

About pSivida Corp. pSivida Corp. (www.psvida.com), headquartered in Watertown, MA, is a leader in the development of sustained release, drug delivery products for treating eye diseases. pSivida has developed three of only four FDA-approved sustained-release treatments for back-of-the-eye diseases. The most recent, ILUVIEN®, a micro-insert for diabetic

macular edema, licensed to Alimera Sciences, is currently sold in the U.S. and three EU countries. Retisert®, an implant for posterior uveitis, is licensed to and sold by Bausch & Lomb. pSivida's lead product candidate, Medidur™, a micro-insert for posterior uveitis being independently developed, is currently in pivotal Phase 3 clinical trials, with an NDA anticipated in 2017. pSivida's pre-clinical development program is focused on using its core platform technologies Durasert™ and Tethadur™ to deliver drugs and biologics to treat wet and dry age-related macular degeneration, glaucoma, osteoarthritis and other diseases. *To learn more about pSivida please visit www.psivida.com and connect on [Twitter](#), [LinkedIn](#), [Facebook](#) and [Google+](#).*

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. 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 include uncertainties with respect to: Designation of Medidur as an orphan medicinal product; our ability to achieve profitable operations and access to capital; fluctuations in our operating results; further impairment of our intangible assets; declines in Retisert royalties; successful commercialization of, and receipt of revenues from, ILUVIEN for DME; the effect of pricing and reimbursement decisions on sales of ILUVIEN for DME; consequences of fluocinolone acetonide side effects; safety and efficacy results of the second Medidur Phase 3 trial, number of trials and data required for, and timing of filing and acceptance of, the Medidur NDA and EU marketing approval applications, if at all; ability to use data in a U.S. NDA from trials outside the U.S.; any exercise by Pfizer of its option with respect to the latanoprost product; our ability to develop Tethadur to successfully deliver large biologic molecules and develop products using it; our ability to successfully develop product candidates, initiate and complete clinical trials and receive regulatory approvals; our ability to market and sell products; the success of current and future license agreements; termination or breach of current license agreements; effects of competition and other developments affecting sales of products; market acceptance of products; effects of guidelines, recommendations and studies; protection of intellectual property and avoiding intellectual property infringement; retention of key personnel; product liability; industry consolidation; compliance with environmental laws; manufacturing risks; risks and costs of international business operations; legislative or regulatory changes; volatility of stock price; possible dilution; absence of dividends; and other factors described in our filings with the SEC. You should read and interpret any forward-looking statements in light of these risks. 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. You should bear this in mind as you consider any 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.

Contact:

Beverly Jedynak

T: 312-943-1123

M: 773-350-5793

blj@bevlynconsulting.com

 Primary Logo

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