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pSivida's Medidur™ Maintains Same High Statistical Significance in Primary Endpoint through 12 Months in First Phase 3 Trial (p Less Than 0.00000001)

Incremental Risk of Elevated IOP Relative to Control Decreases Through Last Follow-up Visit

WATERTOWN, Mass., July 27, 2016 (GLOBE NEWSWIRE) -- pSivida Corp. (NASDAQ:PSDV) (ASX:PVA), a leader in the development of sustained release drug delivery products primarily for eye diseases, today announced its first Phase 3 trial of Medidur for the treatment of posterior uveitis continued to meet its primary endpoint (prevention of recurrence of disease) with high statistical significance through 12 months follow-up (p less than 0.00000001; intent to treat analysis). Posterior uveitis was much less likely to recur in eyes treated with a Medidur injection than those receiving a sham injection through 12 months (26.4% compared to 85.7%). The average increase in intraocular pressure (IOP) at 12 months was only 0.6mmHg more in Medidur-treated eyes than control eyes (1.3mmHg versus 0.7mmHg).

"The continued high efficacy and favorable safety results of Medidur in the treatment of posterior uveitis are impressive. Particularly encouraging is the effectiveness of Medidur in controlling recurrence of disease over the longer 12-month period. Medidur-treated eyes were over 5.2 times more likely to be free of recurrence through 12 months than control eyes," said Dr. Glenn Jaffe, Duke University Robert Machemer Professor of Ophthalmology and Chief of the Division of Retinal Ophthalmology and principal investigator for this trial.

Medidur was generally well tolerated through the last follow-up visit (minimum 12 months, maximum 30 months, average 18 months). The incremental risk of elevation of IOP for Medidur-treated eyes compared to control eyes was lower than it was through six months for over 21mmHg (8.3% versus 10.9%) as well as for the more serious elevation over 25mmHg (5.1% versus 11.3%). Elevated IOP was generally well treated with eye drops, and the percentage of eyes requiring incisional surgery to reduce IOP was essentially the same in Medidur-treated and control eyes through the last follow-up (4.6% versus 4.8%).

Dr. Paul Ashton, president and CEO of pSivida, said, "These results are demonstrating the potential for treating posterior uveitis by delivering a very small amount of drug directly to the back of the eye over an extended period with a single injection. We were pleased to see that over 80% of the Medidur-treated patients who were on systemic meds at baseline were able to come off of them entirely through 12 months."

pSivida has completed initial exploratory analyses and safety evaluations through 12 months of follow up and through the last follow-up visit including the following:

- 22.9% of Medidur-treated eyes and 11.9% of control eyes showed improvement in visual acuity, gaining 15 or more letters from baseline on the Early Treatment Diabetic Retinopathy Study (ETDRS) Eye Chart through 12 months. The improvement in visual acuity in Medidur-treated eyes seen at six months was maintained at 12 months. This percentage improvement was twice that of control eyes through 12 months, despite the improvement in visual acuity for control eyes.
- Of the 65 patients receiving systemic therapy (steroids, immune suppressants and biologics) at baseline, 52.4% of control patients compared to 18.2% of Medidur treated patients were still being administered systemic treatment at 12 months. These percentages are unchanged from six months.
- Of the study eyes with a natural lens at baseline, 45.2% of Medidur-treated eyes compared to 9.5% of control eyes required cataract surgery through the last follow-up visit. Cataracts are both a side effect of treatment with steroids and a natural consequence of posterior uveitis. 51.7% of Medidur-treated eyes and 50.0% of control eyes had already received cataract surgery before enrolling in the study.

In the first Phase 3 trial, a 129-patient, multi-center, randomized and double-blinded trial evaluating the safety and efficacy of Medidur for the treatment of chronic noninfectious uveitis affecting the posterior of the eye (posterior uveitis), 87 eyes were injected with Medidur, and 42 eyes were randomized to control and received a sham injection. The primary endpoint of the trial was prevention of recurrence of disease at six months, which the study achieved with high statistical significance (p

less than 0.00000001; intent to treat analysis). All other efficacy and safety data analyses are exploratory. Topline results and exploratory analyses are all based on intent to treat population. Patients will be followed for three years from injection at six-month intervals.

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 enrolling patients.

About pSivida Corp. pSivida Corp. (www.psivida.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+*.*

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Contact:

Beverly Jedynak

T: 312-943-1123

M: 773-350-5793

blj@bevlynconsulting.com

Primary Logo

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