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Topline Results from First Phase 3 Trial of pSivida's Medidur™ Presented at ASRS Annual Meeting

WATERTOWN, Mass., Aug. 15, 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 Dr. Glenn J. Jaffe, Robert Machemer Professor of Ophthalmology at Duke University School of Medicine in Durham, NC and the principal investigator on the first of pSivida's two Phase 3 trials of Medidur for recurrent non-infectious uveitis affecting the posterior segment of the eye, presented the topline results from the trial through its six-month primary endpoint and through 12 months of follow-up. Dr. Jaffe's presentation, "A Randomized, Masked, Controlled, Safety and Efficacy Study of an Injectable Fluocinolone Acetonide (FA) Intravitreal Insert in Non-Infectious Uveitis" took place at the Inflammatory and Infectious Disease session of the American Society of Retinal Specialists Annual Meeting, on Sunday, August 14, in San Francisco.

This was the first scientific presentation of the topline results from this Phase 3 trial, which met its primary end point, prevention of recurrence of disease at six months, with high statistical significance (p less than 0.00000001, intent to treat analysis) maintained through 12 months. In addition to data on prevention of recurrence of disease, Dr. Jaffe presented data on additional exploratory analyses on improvement of visual acuity, elimination of systemic treatments (which can cause serious side effects), and safety results including incidence of cataract and elevated intraocular pressure (which can be a result from the disease itself as well as from steroid treatment).

"Medidur's performance has continued to exceed our expectations in this phase 3 trial through the latest follow up," said Dr. Paul Ashton, president and chief executive officer of pSivida Corp. "This trial's results demonstrated that Medidur - administered by injection in an office setting - can prevent recurrence of disease on a long-term basis while maintaining a favorable safety profile. Medidur has the potential to be a promising new treatment for patients with posterior uveitis who have limited options to control their disease effectively."

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.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+](#).*

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.

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