



December 22, 2015

pSivida's Medidur™ Meets Primary Efficacy Endpoint in Phase 3 Trial: High Statistical Significance in Prevention of Recurrence of Posterior Uveitis (p Less Than 0.00000001)

Statistical Significance in Improvement in Visual Acuity and Reduction in Systemic Therapy

Positive Safety Data

WATERTOWN, Mass., Dec. 22, 2015 (GLOBE NEWSWIRE) -- pSivida Corp. (NASDAQ:PSDV) (ASX:PVA), a leader in the development of sustained release drug delivery products for treating eye diseases, today announced positive topline results from its first Phase 3 clinical trial evaluating the safety and efficacy of Medidur™ for the treatment of chronic noninfectious uveitis affecting the posterior of the eye (posterior uveitis). The 129 patient, multi-center, randomized and double-blinded trial was highly statistically significant in meeting its primary efficacy endpoint of prevention of recurrence of disease at six months (p less than 0.00000001; intent to treat analysis). Safety results were positive. Only 10.9% more Medidur-treated eyes than control eyes experienced an increase in intraocular pressure (IOP) above 21 mmHg through six months, which was reduced to 6.1% through the most recent follow-up visits (some as long as 24 months). In the Medidur trial, 87 eyes were treated with Medidur, and 42 eyes were randomized to control and received a sham injection.

A photo accompanying this announcement is available at <http://www.globenewswire.com/NewsRoom/AttachmentNg/b42de5fa-ff6b-480d-8cbb-e6ce8138d393>

At six-months of follow-up:

- | 18.4% of Medidur-treated eyes compared to 78.6% of control eyes had experienced recurrence of posterior uveitis (a statistically significant p less than 0.00000001).
- | 23.0% of Medidur-treated eyes compared to 4.9% 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 (a statistically significant p = 0.011).
- | 31.0% of control eyes compared to 4.6% of Medidur-treated eyes had lost 15 or more letters from baseline on the ETDRS Eye Chart for at least one observation (a statistically significant p less than 0.0001).
- | Of the 65 patients receiving systemic therapy (steroids, immuno-suppressants and biologics) at baseline, 52.4% of control patients compared to 18.2% of Medidur-treated patients were still being administered systemic treatment (a statistically significant p less than 0.01).
- | 27.6% of Medidur-treated eyes compared to 16.7% of control eyes had experienced an increase in intraocular pressure (IOP) above 21 mmHg for at least one observation.
- | Of the 64 study eyes with a natural lens at baseline, 9.5% of Medidur-treated eyes compared to 4.8% of control eyes had required cataract surgery.

"The results of this Phase 3 trial are extraordinary. With a single injection, Medidur showed the ability to control the recurrence of posterior uveitis, improve visual acuity and prevent vision loss," 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. "The high level of statistical significance achieved in this trial is dramatic and, along with the compelling benefit-risk ratio, suggests an important treatment option for patients who are typically treated with repeated systemic steroids, immuno-

 Medidur next to pencil tip

Medidur™, pictured below the pencil, is an injectable micro-insert designed to treat posterior uveitis. Injected into the back of the eye, it provides sustained release of 0.18 mg of a corticosteroid directly to the retina at a controlled rate for three years. This technology used in Medidur, developed by pSivida Corp., can deliver small molecule drugs at consistent release rates for pre-determined period of time - weeks, months or years - and underlies three of only four FDA-approved sustained release treatments for back-of-the-eye diseases. pSivida announced highly statistically-significant results of the first of two Phase 3 trials for Medidur for posterior uveitis.

suppressants or biologics, often facing recurring attacks of the disease as well as systemic side effects."A

The IOP elevation results for Medidur compare favorably to the Phase 3 trial results for ILUVIEN® for diabetic macular edema, which comprises the same micro-insert as Medidur. Other safety results were also positive. Through six months, 2.3% of Medidur-treated eyes and no control eyes required an incisional procedure to reduce IOP. Through the most recent follow-up, 3.4% of Medidur-treated eyes compared to 2.4% of control eyes required an incisional procedure to reduce IOP.

"The results from this Phase 3 trial indicate that Medidur has the opportunity to be an effective, safe and convenient treatment for this blinding eye disease, avoiding the potentially serious side-effects and administration compliance challenges of the cycles of systemic steroids, immuno-suppressants and biologics now used to treat the disease," said Dr. Charles Foster, Clinical Professor of Ophthalmology at Harvard Medical School and Founder and President of the Massachusetts Eye Research and Surgery Institution. "The ability to administer a three-year course of Medidur therapy for posterior uveitis in a single, in-office injection could allow many patients to significantly improve treatment outcomes and vision, reduce side effects and drastically simplify patient compliance as compared to current treatment alternatives."

The primary endpoint of pSivida's Phase 3 trial was prevention of recurrence of disease at six months. All other efficacy and safety data analyses were exploratory. Topline results and exploratory analyses were all based on intent to treat population.

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 injection-controlled, double-masked trials. The primary endpoint of both trials is prevention of recurrence of posterior uveitis at six months, with patients in both trials followed for three years. The first Phase 3 Medidur trial, which enrolled 129 patients in 16 centers in the U.S. and 17 centers outside the U.S, achieved its primary efficacy endpoint with high statistical significance (p less than 0.00000001; intent to treat analysis). The second trial, which is still enrolling patients, will enroll up to 150 patients in approximately 15 centers in India. Assuming favorable results from the second Phase 3 trial, an NDA is anticipated in the first half of 2017. pSivida plans to seek FDA approval of Medidur based on six-month data from the two Phase 3 trials and a short-duration utilization study of pSivida's redesigned proprietary inserter, together with data referenced from the Phase 3 trials of ILUVIEN for DME.

About Medidur. Medidur is an injectable micro-insert designed to treat posterior uveitis. Injected into the back of the eye, it provides sustained release of 0.18 mg of the corticosteroid flucinolone acetonide at a controlled rate directly to the retina for three years. Medidur comprises the same micro-insert as ILUVIEN® for DME. ILUVIEN has been approved in the U.S. and 17 EU countries and is sold by pSivida's licensee in the U.S., U.K., Germany and Portugal.

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 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 the first half of 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: our ability to achieve profitable operations and access to capital; further impairment of our intangible assets; fluctuations in our operating results; 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 flucinolone acetonide side effects; safety and efficacy results of the second Medidur Phase 3 trial, 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.

The photo is also available at Newscom, www.newscom.com, and via AP PhotoExpress.

Contact:

Beverly Jedynak

O: 312-943-1123

M: 773-350-5793

bjedynak@janispr.com

 Primary Logo

Source: pSivida Corp

News Provided by Acquire Media