PSIVIDA ANNOUNCES POSITIVE TOP LINE RESULTS FROM INVESTIGATOR-SPONSORED PHASE II STUDY OF MEDIDUR™ FOR UVEITIS

Statistically Significant Reduction in Recurrence of Disease and Statistically Significant Improvement in Visual Acuity

Watertown, MA (July 13, 2015) -- (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 positive top line results from a Phase II investigator-sponsored study of pSivida's Medidur for uveitis affecting the posterior of the eye (posterior, intermediate and pan-uveitis). Dr. Glenn J. Jaffe, Robert Machemer Professor of Ophthalmology at Duke University School of Medicine in Durham, NC, presented the top line results during an oral abstract session at the American Society of Retina Specialists in Vienna, Austria, reporting a statistically significant reduction in recurrence of uveitis and a statistically significant improvement in visual acuity in eyes treated with Medidur.

In the three–year, ongoing study, 11 participants with recurrent non-infectious intermediate, posterior or pan uveitis were randomized to receive a masked low or a high dose of Medidur. (pSivida is studying only the low dose of Medidur in its Phase III clinical trials.) Fellow eyes with uveitis were treated with standard of care, which included steroid eye drops. At the most recent follow-up visit reported, participants have been followed for between 12 and 24 months.

Through the last follow-up visit reported, none of the eyes treated with Medidur had any recurrence of uveitis, while fellow eyes treated with standard of care averaged 2.33 recurrences. The difference between treatment with Medidur and standard of care was statistically significant (p=0.014).

Eyes treated with Medidur experienced a significant improvement in visual acuity, gaining an average of 17 letters from baseline letters at 12 months on the Snellen eye chart (p=0.014 at 12 months). At the last follow up visit reported, the average gain from baseline in Medidur-treated eyes was over 20 letters, while eyes treated with standard of care declined an average of 10 letters.

The most common adverse event in study eyes was elevated intraocular pressure (IOP). Through the last follow-up visit reported, three study eyes developed elevated IOP and were treated with eye drops, with filtering procedures subsequently performed in two of these eyes. However, those two eyes still gained an average of over 25 letters from baseline at the last observation. The study remains masked as to the dosage so results cannot yet be separated for the low and high doses of Medidur.

pSivida recently announced that at three months in its first Phase III trial, which is testing only the low dose of Medidur, only 4% more study eyes (2/3 of which received Medidur) experienced elevated IOP than the fellow non-study eyes (none of which received Medidur). Initial IOP elevation is an indication of the likelihood of subsequent clinically significant IOP increases. The minimal difference observed in elevated IOP in the assessment suggests highly favorable results for a key safety measure of the trial, the number of eyes that develop clinically significant increases in IOP within 12 months of receiving Medidur relative to control eyes.

“The results in Dr. Jaffe’s study are very dramatic. The efficacy of Medidur in controlling uveitis and restoring visual acuity was spectacular. At the extreme, in addition to completely arresting any recurrence of uveitis, Medidur restored vision to two eyes that were legally blind at baseline, improving from 20:400 to 20:25 and from 20:500 to 20:40 at the last follow-up visit. We look forward to the unmasking of the data to view the results for the low dose of Medidur we are studying,” said Dr. Paul Ashton, President and Chief Executive Officer of pSivida Corp.

About the Phase II Trial. The investigator-sponsored Phase II study is evaluating the tolerability, safety and benefits of high and low dose Medidur in recurrent non-infectious posterior, intermediate or pan-uveitis. Eleven enrolled participants were randomized to receive a masked low or a high dose of Medidur in the worse eye. (Only the low dose is being studied in pSivida’s Phase III trials.) Fellow eyes with uveitis are treated with standard of care. Eyes are observed on the day of injection, on days 1, 7, 14, 28, then monthly for up to six months, then every three months for 18 additional months. For purposes of these results, all participants were followed for a minimum of one year, with a mean follow-up duration of 20.5 months. Because the study is ongoing, the dose remained masked, and the results present aggregate data for the low and high dose. Full top-line results of this Phase II study have been submitted for publication.

About Medidur. Medidur is an injectable micro-insert designed to treat posterior uveitis that provides sustained release of flucinolone acetonide (a corticosteroid) for three years. Medidur comprises the same micro-insert (same design, same polymers, same drug, same dose) as ILUVIEN® for DME. ILUVIEN has been approved in the U.S. and 17 EU countries and is sold in the U.S., the 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 the Phase III Trials. pSivida's two Phase III trials for Medidur are double-blind studies comparing injections of Medidur to sham injections on a two-to-one basis. The first trial is fully enrolled with 129 patients in 16 centers in the U.S. and 17 centers outside the U.S. The primary end point of the first trial is recurrence of posterior uveitis within one year. The last scheduled visit for the last patient in this trial is in March 2016, and top-line data is expected in the second quarter of 2016. The second trial will enroll up to 150 patients in approximately 15 centers in India. The primary endpoint of the second trial is recurrence of posterior uveitis within six months. Patients in both trials will be followed for three years. pSivida plans to seek approval for Medidur for posterior uveitis based on 12-month data from the first Phase III trial, six-month data from the second Phase III trial and data from a utilization study of pSivida's redesigned proprietary inserter together with data referenced from the Phase III trials of ILUVIEN for DME. With favorable results, pSivida expects to file a New Drug Application in the first half of 2017.

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 treatments for back-of-the-eye diseases. The most recent, ILUVIEN®, a micro-insert for diabetic macular edema, is licensed to Alimera Sciences and 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, is currently in pivotal phase III clinical trials with an NDA anticipated in the first half of 2017. pSivida's preclinical development program is focused on using its core platform technologies, Durasert™ and/or Tethadur™, to deliver drugs and biologics to treat wet and dry age-related macular degeneration (AMD), glaucoma, osteoarthritis and other diseases.

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clinical trials; increases in cost of clinical trials; changes in, or misunderstandings with respect to, FDA guidance on required clinical trials; development of the Latanoprost Product and any exercise by Pfizer of its option; ability of Tethadur to successfully deliver large biologic molecules and to develop products using it; ability to successfully develop product candidates, complete clinical trials and receive regulatory approvals; ability to market and sell products; success of current and future license agreements; termination of 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 together with 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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The President's Blog: http://www.thechairmansblog.com/paul-ashton

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