



July 7, 2015

## **pSivida Announces Top-Line Results from Investigator-Sponsored Phase II Study of Medidur™ for Uveitis to Be Reported Next Week**

*Dr. Glenn J. Jaffe to Present at 33<sup>rd</sup> Annual Scientific Meeting of American Society of Retina Specialists*

WATERTOWN, Mass.--(BUSINESS WIRE)-- pSivida Corp. (NASDAQ:PSDV) (ASX:PVA), a leader in the development of sustained release drug delivery products for treating eye diseases, announced that top line results from an investigator-sponsored, Phase II study of pSivida's Medidur for uveitis will be presented at the 33<sup>rd</sup> Annual Scientific Meeting of the American Society of Retina Specialists (ASRS) meeting to be held July 10-14 in Vienna, Austria. Dr. Glenn J. Jaffe, Robert Machemer Professor of Ophthalmology at Duke University School of Medicine in Durham, NC, who is conducting this study, will make the presentation. He also serves as principal investigator in pSivida's first pivotal Phase III trial for Medidur for posterior uveitis, which is currently underway.

The American Society of Retina Specialists, a non-profit corporation, provides a scientific forum to promote the advancement of vitreoretinal diseases and surgery to its more than 2,600 members in the United States, Puerto Rico and 59 countries.

**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 is estimated to affect 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's 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's 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.psvida.com](http://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 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 four 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-related macular degeneration (AMD), glaucoma, osteoarthritis and other diseases.

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: actual final IOP safety results for Medidur Phase III trials; ability to achieve profitable operations and access to capital; fluctuations in operating results; further impairment of intangible assets; decline in Retisert royalties; successful commercialization of, and receipt of revenues from, ILUVIEN for DME; effect of pricing and reimbursement decisions on sales of ILUVIEN for DME; consequences of fluocinolone acetonide side effects; number and cost of clinical trials and data necessary to support an NDA for, approval by Indian regulators of the trial design for, timing of filing the NDA for, and regulatory approval and successful commercialization of, Medidur; delays in completion of 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>

For more information on pSivida, visit [www.psivida.com](http://www.psivida.com)

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