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## **Phase 3 trial of Medidur™ in Posterior Segment Uveitis Meets Enrollment Target**

*Study is the Second of Two Ongoing Phase 3 Trials in Support Of Product Registration in the US*

*EU Filing Remains on Track for 1Q2017 Filing*

WATERTOWN, Mass., Oct. 04, 2016 (GLOBE NEWSWIRE) -- pSivida Corp. (NASDAQ:PSDV) (ASX:PVA), a leader in the development of sustained release drug technologies for eye diseases, announced that its second Phase 3 trial of Medidur in chronic, non-infectious posterior segment uveitis met its target enrollment of 150 patients. The trial is being conducted in clinical sites in India, with the same study design and endpoints as the first Phase 3 trial conducted in the US, EU and India. The results of both Phase 3 trials will support US product registration, with NDA submission planned for the second half of 2017. Filing for EU registration remains on track for the first calendar quarter of 2017.

"We are very pleased that the second Phase 3 trial of Medidur in posterior segment uveitis has met its patient enrollment goal on target and as expected," said Nancy Lurker, President and CEO of pSivida Corp. "Both Phase 3 trials are generating efficacy and safety data critical to regulatory filings in support of product registration. Reaching today's milestone brings us a step closer to making Medidur available to thousands of patients battling with recurrent episodes of ocular inflammation and the prospect of losing vision irreversibly."

This first Medidur trial met the primary efficacy endpoint of prevention of recurrence of posterior segment uveitis at six months in December 2015. Primary efficacy endpoint readout in the second study is expected in the second half of 2017.

**About Medidur.** Medidur is an injectable micro-insert designed to treat posterior segment uveitis and provide sustained release of a corticosteroid, fluocinolone acetonide, for three years. Injected into the back of the eye in an office procedure, it provides sustained release of 0.18 mg of fluocinolone acetonide at a controlled rate directly to the site of chronic inflammation.

**About Posterior Segment Uveitis.** Non-infectious posterior segment uveitis is a chronic inflammatory disease affecting the posterior segment of the eye, often involving the retina. This condition is a leading cause of blindness in developed countries. It afflicts people of all ages, producing swelling and destroying eye tissues critical for maintaining vision. In the US, posterior segment uveitis is estimated to affect approximately 175,000 people, resulting in approximately 30,000 cases of blindness, making it the third leading cause of blindness in the US.

Patients with posterior segment 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 can have severe side effects, including an increased risk of cancer. Medidur is designed to deliver small amounts of steroid locally over a sustained period in the eye resulting in potentially reduced systemic exposure compared to systemic medications.

**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 segment uveitis. These are randomized, sham injection-controlled, double-masked trials. The primary endpoint of both trials is recurrence of posterior segment 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 US and 17 centers outside the US, met its primary efficacy endpoint with high statistical significance. The second trial has met its target enrollment goal of 150 patients and is being conducted in 15 centers in India.

**About pSivida Corp.** pSivida Corp. ([www.psivida.com](http://www.psivida.com)), headquartered in Watertown, MA, is a leader in the development of sustained release drug technologies for eye diseases. pSivida has developed three of only four FDA-approved sustained-release treatments for back-of-the-eye diseases. The most recent, ILUVIEN<sup>®</sup>, a micro-insert for diabetic macular edema, licensed to Alimera Sciences, is currently sold in the US and three EU countries. Retisert<sup>®</sup>, an implant for posterior uveitis, is licensed to and sold by Bausch & Lomb. pSivida's lead product candidate, Medidur, a micro-insert for posterior segment uveitis being independently developed, is currently in pivotal Phase 3 clinical trials. 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.psvida.com](http://www.psvida.com) and connect on [Twitter](#), [LinkedIn](#), [Facebook](#) and [Google+](#).

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Contact:

EVC Group

Michael Polyviou/Doug Sherk - Investors

[mpolyviou@evcgroup.com](mailto:mpolyviou@evcgroup.com); [dsherk@evcgroup.com](mailto:dsherk@evcgroup.com)

212.850.6020; 415.652.9100

 Primary Logo

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