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## **pSivida Announces NDA for Medidur™ Now Planned Using Six Month Efficacy Data from Both Phase III Trials; FDA Concur**

### ***Top-Line Data from First Trial Expected December 2015***

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 the Company now plans to file a New Drug Application (NDA) for Medidur for posterior uveitis based on six-month efficacy data for both Phase III trials. The U.S. Food & Drug Administration (FDA) has advised pSivida that this data will be acceptable for review by the agency. pSivida previously planned to utilize 12-month efficacy data from the first trial and six-month efficacy data from the second trial. As six-month visits in the first trial will be completed this month, top-line results from the first Phase III trial are now anticipated to be reported in December 2015. Enrollment in the second Phase III trial continues and is expected to be completed during the first half of 2016, with an NDA anticipated in the first half of 2017.

"We are very pleased that the FDA has agreed to review an NDA for posterior uveitis based on six-month efficacy data," said Dr. Paul Ashton, president and CEO of pSivida. "The primary end-point of the Phase III trials is recurrence of disease, which in the majority of patients occurs typically within six months. Our analysis of the masked data from our first trial is consistent with this. We believe therefore that six-month data from our two trials will show safety and efficacy. We look forward to being able to announce the top-line results from the first trial at the end of this year."

**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-masked studies comparing injections of Medidur to sham injections on a two-to-one basis. The primary end point of both trials is recurrence of uveitis within six months. The first trial is fully enrolled with 129 patients in 16 centers in the U.S. and 17 centers outside the U.S. The last scheduled visit for the last patient in this trial is in September 2015, and top-line data is expected in December 2015. The second trial will enroll up to 150 patients in approximately 15 centers in India. Patients in both trials will be followed for three years. pSivida plans to seek approval for Medidur for posterior uveitis based on six-month data from the two trials 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., 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 pre-clinical 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. *To learn more about pSivida please visit [www.psivida.com](http://www.psivida.com) and connect on [Twitter](#), [LinkedIn](#), [Facebook](#) and [Google+](#).*

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