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## **pSivida Submits New Drug Application (NDA) for Durasert™ Three-Year Treatment for Posterior Segment Uveitis to the U.S. FDA**

### **Proven Durasert Technology Has to Date Received FDA Approval for Three of the Four Sustained Release Drug Products Approved for Back-of-the-Eye Diseases**

WATERTOWN, Mass., Jan. 08, 2018 (GLOBE NEWSWIRE) -- pSivida Corp. (NASDAQ:PSDV) (ASX:PVA), a leader in the development of sustained release drug products and technologies, today announced it has submitted its New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for Durasert three-year treatment for posterior segment uveitis. The NDA includes data from two Phase 3 studies that each successfully achieved the primary efficacy endpoint at six months with a p value < 0.001. In addition, the safety profile of patients treated with Durasert three-year posterior segment uveitis treatment was consistent with the safety profile of steroid treatments that are currently considered standard of care for this disease.

"We have previously developed and out-licensed three sustained-release treatments for other back-of-the-eye diseases, all of which received FDA approval. This positive track record is an asset as we enter this next phase of development for our company's first commercial product," commented Nancy Lurker, President and CEO. "Durasert is our lead product candidate for the treatment for posterior segment uveitis, the third leading cause of blindness. Our goal with Durasert is to provide relief to the thousands of patients suffering from this debilitating disease for which today's standard of care is frequent injections of steroids or an implant that lasts up to three months with much higher costs. On behalf of everyone at pSivida, I want to thank the retinal specialists and patients for being involved in the studies as their commitment demonstrates the severity of uveitis as a condition with a significant unmet need. We look forward to the FDA's review process for our submission."

The FDA will next determine whether pSivida's NDA is complete and acceptable for review; this procedure is typically completed within 60 days from the original NDA submission date.

#### **About Posterior Segment Uveitis**

Posterior segment uveitis is a chronic, non-infectious inflammatory disease affecting the posterior segment of the eye, often involving the retina, which is believed to be a leading cause of blindness in the developed and developing countries. It affects 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 between 80,000 - 100,000 people. Today, 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.

#### **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 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<sup>®</sup>, a micro-insert for diabetic macular edema, licensed to Alimera Sciences, is currently sold directly in the U.S. 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, Durasert™ micro-insert for posterior segment uveitis, is being independently developed. Two pivotal Phase 3 studies with Durasert achieved their primary efficacy endpoint of prevention of recurrence of uveitis at six months of follow-up with statistical significance. pSivida's pre-clinical development program is focused on using its core platform technology Durasert to deliver drugs to treat wet 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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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 needed capital; fluctuations in our operating results; successful commercialization of, and receipt of revenues from, ILUVIEN® for diabetic macular edema ("DME"), which depends on Alimera's ability to continue as a going concern; Alimera's ability to obtain marketing approvals and the effect of pricing and reimbursement decisions on sales of ILUVIEN; the number of clinical trials and data required for the Durasert three-year uveitis marketing approval application in the U.S.; acceptance of the Durasert three-year uveitis NDA in the U.S.; our ability to use data in a U.S. NDA from clinical trials outside the U.S.; our ability to successfully commercialize Durasert three-year uveitis, if approved, in the U.S.; potential off-label sales of ILUVIEN for uveitis; consequences of fluocinolone acetonide side effects; the development of our next-generation Durasert shorter-duration treatment for posterior segment uveitis; potential declines in Retisert® royalties; efficacy and our future development of an implant to treat severe osteoarthritis; 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, including our agreement with Alimera; termination or breach of current license agreements, including our agreement with Alimera; our dependence on contract research organizations, vendors and investigators; 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; effects of the potential U.K. exit from the EU; legislative or regulatory changes; volatility of stock price; possible dilution; absence of dividends; and other factors described in our filings with the Securities and Exchange Commission. 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.

**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; 646-445-4800

Thomas Gibson - Media  
[tom@tomgibsoncommunications.com](mailto:tom@tomgibsoncommunications.com)  
201-476-0322

 [Primary Logo](#)

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