

# pSivida's Second Phase 3 Study for Durasert™ Three-year Treatment for Posterior Segment Uveitis Maintains Positive Efficacy and Safety Profile at 12 Months

Highly Significant Difference Between Durasert and Sham in Prevention of Uveitis Recurrence at 12 Months

Fiscal Q2 2018 Results Conference Call Scheduled for Today at 4:30 p.m.ET

WATERTOWN, Mass., Feb. 07, 2018 (GLOBE NEWSWIRE) -- pSivida Corp. (NASDAQ:PSDV) (ASX:PVA), a leader in the development of sustained release drug products and technologies, today announced that results from the Company's second Phase 3 trial for Durasert three-year treatment for posterior segment uveitis confirmed a significant reduction in uveitis recurrence rate at 12 months. The study involved 153 patients with posterior segment uveitis and the primary endpoint was prevention of recurrence of posterior uveitis at six months with patients continuing to be followed for 36 months. The key highlights from the trial at 12 months included:

- A significant reduction in the recurrence of posterior segment uveitis through 12 months; 36.6% of Durasert-treated patients had a recurrence compared to 71.2% of patients in the sham group (p < 0.001).
- A mean increase of intraocular pressure (IOP) of 2.0 and 0.0 mm Hg at 12 months over a baseline IOP of 13.3 and 13.1 mm Hg for Durasert and sham, respectively.
- Patients requiring IOP-lowering therapy at any time during the first 12 months of follow-up were 50.5% for Durasert and 51.9% for sham. Only one patient, assigned to Durasert, required IOP surgery during the first 12 months of follow-up.
- In patients with a natural (phakic) lens at baseline, 18.0% in the Durasert group required cataract surgery through 12 months compared to 8.6% in the sham group.

"The continued positive efficacy and safety data for Durasert, now confirmed in two separate Phase 3 studies at both six and 12 months, is encouraging for patients that are suffering from posterior segment uveitis," commented by Glenn J. Jaffe, M.D., Chief, Division of Retinal Ophthalmology, Duke University, and a primary clinical investigator in the phase 3 program. "While today's standard of care treatment options are mainly directed at controlling flares, Durasert is designed to help prevent flares for up to three years with a single injection administered in an office setting."

"As we await the US Food and Drug Administration's (FDA) decision on acceptance of our New Drug Application (NDA) submitted in January, we are solidifying our go-to-market plan," added Nancy Lurker, President and CEO of pSivida. "We continue to receive highly positive feedback from specialists regarding Durasert three year for posterior segment uveitis, which bolsters our team's confidence that there will be strong interest to treat patients dealing with this devastating disease, which is the third leading cause of blindness, pending a favorable regulatory review."

## **Conference Call**

pSivida Corp. will host its regularly scheduled live webcast and conference call today, February 7, 2018 at 4:30pm ET, to discuss its financial and operating results for the fiscal second quarter ended December 31, 2017. The conference call may be accessed by dialing (877) 312-7507 from the U.S. and Canada, or (631) 813-4828 from international locations. The conference ID is 8399835. A live webcast will be available on the Investor Relations section of the corporate website at <a href="http://www.psivida.com">http://www.psivida.com</a>.

A replay of the call will be available beginning February 7, 2018, at approximately 7:30 p.m. ET and ending on February 14, 2018, at 11:59 p.m. ET. The replay may be accessed by dialing (855) 859-2056 within the U.S. and Canada or (404) 537-3406 from international locations, Conference ID Number: 8399835. A replay of the webcast will also be available on the corporate website during that time.

### **About Durasert**

Durasert three-year uveitis, the Company's most advanced development product candidate, is designed to treat

chronic non-infectious uveitis affecting the posterior segment of the eye ("posterior segment uveitis") for three years from a single administration. Injected into the eye in an office visit, this product candidate is a miniaturized insert that delivers a micro-dose of a corticosteroid to the back of the eye on a sustained constant (zero order release) basis. The Company is developing Durasert three-year uveitis independently.

# About pSivida Corp.

pSivida Corp. (www.psivida.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 miniaturized 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. In January 2018, pSivida filed an NDA with the FDA for its lead product candidate, Durasert™ insert for posterior segment uveitis, which 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.psivida.com and connect on Twitter, LinkedIn, Facebook and Google+.

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: 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 shorterduration treatment for posterior segment uveitis; potential declines in Retisert® royalties; efficacy and the 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 <u>mpolyviou@evcgroup.com</u>; <u>dsherk@evcgroup.com</u> 212.850.6020; 646-445-4800

Thomas Gibson - Media tom@tomgibsoncommunications.com 201-476-0322



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