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., October 4, 2016 -- 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), 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®, a micro-insert for diabetic macular edema, licensed to Alimera Sciences, is currently sold in the US 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 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.psivida.com and connect on Twitter, LinkedIn, Facebook and Google+.

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commercialization of, and receipt of revenues from, ILUVIEN for DME; potential off-label sales of ILUVIEN for DME; Alimera's ability to continue as a going concern; the effect of pricing and reimbursement decisions on sales of ILUVIEN for DME; consequences of fluocinolone acetonide side effects; the outcome of a dispute with Alimera regarding commercialization expenses; safety and efficacy results of the second Medidur Phase 3 trial; the number of trials and data required for, and timing of filing and acceptance of, the Medidur NDA and EU marketing approval applications, if at all; maintenance of orphan designation for Medidur; performance by CROs, vendors and investigators; our ability to use data in a US NDA from trials outside the US; our ability to successfully commercialize Medidur, if approved; any exercise by Pfizer of its option with respect to the latanoprost product; our ability to develop Tethadur to successfully deliver large biologic molecules and develop products using it; efficacy and future development of a severe OA implant by us; 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; termination or breach of current 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; effects of the potential UK 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 SEC. 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.

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