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pSivida Plans Medidur™ EU Marketing Approval Application Based on Single Phase 3 Clinical Trial

WATERTOWN, Mass., Dec. 28, 2015 (GLOBE NEWSWIRE) -- pSivida Corp.Â (NASDAQ:PSDV) (ASX:PVA), a leader in the development of sustained release drug delivery products for treating eye diseases, today announced that it plans to file for EU marketing approval of Medidur™ for chronic non-infectious uveitis of the posterior segment of the eye (posterior uveitis) based on data from a single pivotal trial as a result of the high statistical significance achieved in its first Phase 3 clinical trial. The U.K. Medicines and Healthcare Products Regulatory Agency (MHRA) advised pSivida that, consistent with the published Points to Consider (PtC) of the European Agency for Evaluation of Medicinal Products, an application for a product treating a condition like posterior uveitis could be based on statistically compelling and clinically relevant results from just one pivotal trial. The MHRA recently provided this specific advice in formal minutes of a meeting with pSivida held on October 29, 2015 (prior to the Company's receipt of topline results for its first Phase 3 clinical trial). With those results now available, pSivida plans to confirm with the MHRA the plan to file for EU marketing approval of Medidur based on one trial.Â

"We are delighted with this advice provided by the MHRA. We expect the high statistical significance of the efficacy data, clinical benefits and positive safety data in our first trial will meet the criteria used by MHRA and other EU regulatory authorities to approve a product on the basis of a single pivotal study," said Paul Ashton, president and CEO of pSivida Corp. "Using data from a single clinical trial would significantly accelerate our filing for EU marketing approval for Medidur. As posterior uveitis affects a similar number of people in the EU and the U.S., accelerated approval in the important EU market would be very beneficial to us." Â

pSivida's first Phase 3 clinical trial for Medidur for Posterior Uveitis met its primary endpoint of prevention of recurrence of disease at six months with exceptional statistical significance ($p < 0.00000001$, intent to treat). Exploratory analyses of Medidur-treated eyes compared to control at six months also showed statistical significance: improvement in visual acuity (gain of 15 or more letters on the Early Treatment Diabetic retinopathy Study (ETDRS) Eye Chart) ($p = 0.011$), reduction in treatment with systemic treatments (steroids, immunosuppressants and biologics) ($p < 0.01$), and prevention of loss of vision (loss of 15 or more letters) ($p <$ Â 0.0001). Safety data at six months comparing Medidur-treated eyes to control eyes were also positive, including the observation of modest relative increases in intraocular pressure (IOP) above 21mmHg and cataract surgeries.

Based on the PtC and MHRA minutes, and pending confirmation from the MHRA, pSivida plans to base its EU submission for Medidur for posterior uveitis on safety and efficacy data from the referenced single Phase 3 trial, available safety data from its second Phase 3 trial, data from a short-duration inserter study and data incorporated from ILUVIEN® from DME Phase 3 trials. pSivida expects to file for European approval in the second half of 2016. A U.S. New Drug Application is planned in the first half of 2017 based on results from both of pSivida's Phase 3 trials.

About Medidur Phase 3 Trials.Â pSivida is conducting two Phase 3 trials to assess the safety and efficacy of Medidur for the treatment of posterior uveitis. These are randomized, sham injection-controlled, double-masked trials. The primary endpoint of both trials is prevention of recurrence of posterior uveitis at six months, with patients in both trials followed for three years.Â The first Phase 3 Medidur trial, which enrolled 129 patients in 16 centers in the U.S. and 17 centers outside the U.S, achieved its primary efficacy endpoint with high statistical significance ($p < 0.00000001$; intent to treat analysis). The second trial, which is still enrolling patients, will enroll up to 150 patients in approximately 15 centers inÂ India. Assuming favorable results from the second Phase 3 trial, an NDA is anticipated in the first half of 2017.Â pSivida plans to seekÂ FDAÂ approval of Medidur based on six-month data from the two Phase 3 trials and a short-duration utilization study of pSivida's redesigned proprietary inserter, together with data referenced from the Phase 3 trials of ILUVIEN for DME.Â

About Medidur.Â Medidur is an injectable micro-insert designed to treat posterior uveitis.Â Injected into the back of the eye, it provides sustained release of 0.18 mg of the corticosteroid flucinolone acetonide at a controlled rate directly to the retina for three years. Medidur comprises the same micro-insert as ILUVIEN® for DME. ILUVIEN has been approved in the U.S. and 17 EU countries and is sold by pSivida's licensee in the U.S., U.K.,Â GermanyÂ andÂ Portugal.

About Posterior Uveitis.Â 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 affects 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 immunosuppressants 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.

AboutÂ pSivida Corp.Â pSivida Corp.Â (www.psivida.com), headquartered inÂ Watertown, MA, is a leader in the development of sustained release, drug delivery products for treating eye diseases. pSivida has developed three of only fourÂ 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 U.S. and three EU countries. Retisert®, an implant for posterior uveitis, is licensed to and sold by Bausch & Lomb.Â pSivida's lead product candidate, Medidur™, a micro-insert for posterior uveitis being independently developed, is currently in pivotal Phase 3 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 Tethadur™ to deliver drugs and biologics to treat wet and dry age-related macular degeneration, glaucoma, osteoarthritis and other diseases.Â *To learn more about pSivida, please visitÂ* www.psivida.comÂ *and connect on* Twitter*,Â* LinkedIn*,Â* Facebook *andÂ* Google+*.*

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