July 5, 2016

pSivida Announces Successful Completion of Two Preclinical Studies of Durasert™ Sustained-Release Insert Delivering Repurposed Cancer Drug to Treat Wet AMD

Promising Results for Potential Sustained Treatment of Wet AMD Using a TKI

WATERTOWN, Mass., July 05, 2016 (GLOBE NEWSWIRE) -- pSivida Corp. (NASDAQ:PSDV) (ASX:PVA), a leader in the development of sustained release drug delivery products primarily for eye diseases, announced the completion of two animal studies of an injectable, sustained-release insert utilizing pSivida's proven Durasert™ technology to deliver a tyrosine kinase inhibitor (TKI) for treatment of wet age-related macular degeneration (AMD). The preclinical study data demonstrated that at the completion of the studies in well-established animal models, the TKI insert was comparably efficacious to an injection of an FDA-approved AMD biologic in both in preventing choroidal neovascularization and reducing vascular leakage. On the basis of these studies, pSivida plans to advance toward clinical trials of the Durasert TKI insert for wet AMD, including toxicology studies necessary for an investigational new drug application (IND).

Dr. Paul Ashton, president and CEO of pSivida said, "The successful completion of these studies is an exciting milestone in our development of a sustained-release treatment for wet AMD using our Durasert platform. The most commonly used therapies for the disease target only vascular endothelial growth factor (VEGF) and require injections as frequently as monthly. However, blocking VEGF alone does not result in long-term suppression of the disease, and studies suggest that platelet-derived growth factor (PDGF) as well as VEGF may play an important role in AMD. The TKI used in our insert is known to block both VEGF and PDGF. Our goal is to effectively treat AMD on a sustained basis for six months with a single injection, targeting both VEGF and PDGF while avoiding the toxic systemic side effects of TKIs and the frequent injections of current AMD anti-VEGF biologics."

AMD, the leading cause of vision loss in people over 65, is most commonly treated with intravitreal injections of biologics that block the VEGF molecules that are a factor in the abnormal sub-retinal blood vessel growth leading to the disease. FDA-approved Lucentis® and Eylea® and off-label use of the anti-cancer Avastin®, all anti-VEGF biologics that are multi-billion dollar products, are the leading treatments for wet AMD. These biologics must be injected into the eye as frequently as monthly and typically lose efficacy over time, resulting in vision loss and return of the disease. Although the exact cause of AMD is unknown, other growth factors such as PDGF are thought to be involved in AMD. Because they are not treated by anti-VEGF drugs, significant research in industry and academia is focused on combinations of drugs to target both VEGF and PDGF.

Approved for the treatment of cancer, some TKIs, including the one used by pSivida in this insert, are known to inhibit PDGF as well as VEGF. In cancer therapy, TKIs are taken orally, but their significant toxicity prevents their systemic use to treat AMD. By using Durasert sustained-delivery technology, pSivida plans to deliver a TKI dose directly to the retina that is approximately 1,000 times less drug than is used in a course of cancer therapy.

pSivida's preclinical studies of the TKI insert used both the laser injury model and the VEGF model. In the laser injury study, animals received an injected TKI insert, an injected placebo insert, an intravitreal injection of a TKI suspension or an intravitreal injection of an FDA-approved anti-VEGF AMD biologic followed in each case by retinal laser seven days later. At 14, 21 and 28 days post-laser, the areas of choroidal neovascularization were assessed by fluorescein imaging and at the end of 28 days post-laser by histopathology (flat mount analyses). In the VEGF model study, animals received an injected TKI insert, an injected sham insert or an intravitreal injection of an FDA-approved anti-VEGF AMD biologic followed by an intravitreal injection of a VEGF, which was repeated after weeks 2 and 4. Leakage was assessed by fluorescein angiography on days 3 and 5 following the initial and each subsequent VEGF injection.

About pSivida Corp. pSivida Corp. (www.psivida.com), 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 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. 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 around mid-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. *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: the safety and efficacy of the TKI insert for wet AMD, the initiation and completion of clinical trials and potential marketing approval of the insert; designation of Medidur as an orphan medicinal product; our ability to achieve profitable operations and access to capital; fluctuations in our operating results; further impairment of our intangible assets; declines in Retisert royalties; successful commercialization of, and receipt of revenues from, ILUVIEN for DME; the effect of pricing and reimbursement decisions on sales of ILUVIEN for DME; consequences of fluocinolone acetonide side effects; safety and efficacy results of the second Medidur Phase 3 trial, 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; ability to use data in a U.S. NDA from trials outside the U.S.; 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; 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; 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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Source: pSivida Corp