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pSivida Out-licenses EMEA Rights for Durasert™ Three-year Treatment for Posterior Segment Uveitis While Retaining U.S. Commercial Rights; Amended Global Collaboration Agreement with Alimera for ILUVIEN® Improves pSivida's Revenue Generation

WATERTOWN, Mass., July 10, 2017 (GLOBE NEWSWIRE) -- pSivida Corp. (NASDAQ:PSDV) (ASX:PVA), a leader in the development of sustained release drug products and technologies, today announced an amendment of its exclusive license and collaboration agreement with Alimera Sciences, Inc. (NASDAQ:ALIM) that grants Alimera rights to pSivida's Durasert™ three-year treatment for posterior segment uveitis (Durasert) in Europe, the Middle East and Africa (EMEA). With this license, Alimera plans to pursue a secondary indication for ILUVIEN for posterior segment uveitis in EMEA, which could accelerate the uveitis indication approval as well as commercialization. pSivida retains commercialization rights for posterior segment uveitis in all other countries, including the United States. The amended agreement also modifies the companies' existing global licensing agreement for ILUVIEN for the treatment of diabetic macular edema (DME).

Key terms of the restructured global licensing agreement for ILUVIEN include:

- pSivida grants Alimera the rights to Durasert in EMEA under the ILUVIEN trademark in exchange for tiered sales-based royalty payments.
- Converts the existing profit share arrangement for the global ILUVIEN DME indication to the same tiered sales-based royalty payments as the uveitis indication effective July 1, 2017, and improves pSivida's revenue generation from DME indication sales.
- Sales-based royalty payments to pSivida start at 2% and increases to 6% upon the earliest of (i) Alimera's receipt of the first EU country marketing approval for ILUVIEN for the treatment of posterior segment uveitis; (ii) January 1, 2019 and (iii) one year from Alimera's filing of a marketing authorization application in the EU for posterior segment uveitis. The sales-based royalty payment will rise to 8% based on total ILUVIEN revenues in excess of $75 million in any calendar year.
- Under the previous agreement, pSivida's net profits were to be partially offset by accumulated net ILUVIEN commercialization losses. The balance of accumulated losses has now been capped at $25 million, of which $10 million is cancelled in exchange for granting Alimera license rights for posterior uveitis in EMEA. An additional $5 million will be cancelled based on certain milestones achieved by Alimera. The remaining $10 million of accumulated ILUVIEN commercialization losses is subject to a partial offset against sales-based royalty payments over time.
- pSivida will withdraw its EU marketing approval application (MAA) and orphan drug designation for posterior segment uveitis and Alimera will be responsible for filing a Type II variation for ILUVIEN for the treatment of posterior segment uveitis in the 17 countries in the EU where ILUVIEN is currently approved for the treatment of DME.

Benefits of the EMEA out-license and revised ILUVIEN agreement for pSivida include:

- Standardizes and improves revenue generation from the ILUVIEN global collaboration agreement and is expected to provide a more predictable and steady flow of revenue for pSivida.
- Management of EMEA regulatory filings and manufacturing is transferred to Alimera, thereby potentially accelerating the uveitis indication approval and commercialization timing.
- Leverages Alimera's established EMEA ILUVIEN field force with retinal specialists.
- Reduces pSivida's financial outlays for European regulatory and manufacturing matters, allowing pSivida to focus resources on the New Drug Application (NDA) with the US Food and Drug Administration (FDA) and commercialization readiness efforts for Durasert for posterior segment uveitis in the US.

"Today's announcement fulfills a core pSivida objective to out-license Durasert EMEA rights as a means to optimize product value," said Nancy Lurker, President and CEO of pSivida. "We believe the EMEA out-license to Alimera, a company that is familiar with the complexity of the EU reimbursement environment and is currently marketing to target specialty physicians, could accelerate commercialization uptake and revenue realization for pSivida. The EMEA revenue opportunity for Durasert is estimated to be $30 to $50 million, and in the US it is estimated to be $80 to $120 million. We remain on track to file an NDA with the FDA by the end of this year. In parallel, the restructured global collaboration agreement benefits our shareholders as we immediately begin to recognize royalty income from sales of ILUVIEN as well as increase its long-term revenue opportunity."

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. and EU, posterior uveitis affects approximately 200,000 people, annually. 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.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®, a micro-insert for diabetic macular edema, licensed to Alimera Sciences, Inc. is currently sold directly in the U.S. and three EU countries. Retisert®, an implant for posterior uveitis, is licensed to and sold by Bausch & Lomb Inc. pSivida's lead product candidate, Durasert™ micro-insert for posterior segment uveitis is being independently developed. Two pivotal Phase 3 clinical trials achieved their primary efficacy endpoint 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; further impairment of our intangible assets; successful commercialization of, and receipt of revenues from, ILUVIEN® for diabetic macular edema ("ILUVIEN"), which depends on Alimera's ability to continue as a going concern 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 applications in the U.S. and EU; our ability to file and the timing of filing and acceptance of the Durasert three-year uveitis marketing approval applications in the U.S.; our ability to use data in a U.S. NDA from clinical trials outside the U.S.; ours and Alimera's ability to successfully commercialize Durasert three-year uveitis, if approved; consequences of fluocinolone acetonide side effects; 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 agreements with Alimera; termination or breach of current license agreements, including our agreements 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.

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