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HSS and pSivida Report Positive Phase 1 Knee Osteoarthritis Pain Study Data

Sustained Release Technology Well Tolerated and Provides Pain Reduction

WATERTOWN, Mass. and NEW YORK, Dec. 14, 2017 (GLOBE NEWSWIRE) -- pSivida Corp. (NASDAQ:PSDV) (ASX:PVA), a leader in the development of sustained release drug delivery products, and Hospital for Special Surgery (HSS), the national leader for orthopedics, today announced the results of a Phase I safety and exploratory efficacy pilot study for a sustained release implant integrating pSivida's Durasert™ delivery technology and an HSS-designed implantable device.

The implant was designed to deliver a continuous-low dose of dexamethasone into the knee joint for several months. Six subjects, screened for radiologically-confirmed and symptomatic osteoarthritis (OA) of the knee, were enrolled for a study duration of six months. Average weekly pain scores were compared against baseline values using a survey of pain at rest, at night, and during activity on a 0-10 scale taken biweekly. Safety monitoring included serial radiographs and plasma dexamethasone concentrations.

Subjects experienced an average 3.8 point reduction in average weekly pain by week 4 that did not diminish over the 24 week period (4.7 and 5.0 point reductions at weeks 12 and 24, respectively). Based on OMERACT-OARSI strict responder criteria using the average weekly pain score, four subjects were considered strict responders by week 4, while all six subjects were strict responders on weeks 12 and 24. Plasma dexamethasone concentrations were found to be lower than those reported by other standard-of-care treatments and no adverse events were reported.

Based on the study findings, the implant was well tolerated and showed potential analgesic effects through the six-month study period.

"This system has the potential to fill a much-needed therapeutic gap for knee OA patients," commented Dr. Mark P. Figgie, principal investigator, study sponsor and Chief of the Surgical Arthritis Service at HSS.

"This is a very promising start of a collaboration, combining the know-how, experience and technology of the pSivida team with the clinical expertise and insight of HSS. With the ageing and more active population, we are in need of novel and perhaps superior treatment alternatives for pain relief in arthritis," commented Dr. Robert N. Hotchkiss, co-inventor of the implant and Medical Director of Innovation at HSS.

"The positive Phase I data demonstrates that Durasert™ technology has applications beyond our core back-of-the-eye disease markets," commented Nancy Lurker, pSivida's President and CEO. "We believe patients suffering from severe knee OA deserve better non-narcotic, non-opioid options to help manage their pain, and our collaboration with HSS to apply our technology to these patients has the potential to provide longer-term relief of their pain."

Knee OA is a degenerative joint disease that results from the breakdown of joint cartilage and underlying bone, with joint pain and stiffness the most common symptoms. More than 10 million people have knee OA and there is a high unmet need for a non-narcotic treatment option given the potential risk of addiction with opioids. No current cure exists, but pain and movement restriction associated with the disease are currently treated with oral analgesics, non-steroidal anti-inflammatory drugs, corticosteroids taken orally or injected into the knee, or hyaluronic acid injected into the knee. With degeneration, damage and pain from knee OA can become severe, making it the leading cause of total knee replacement surgery.

More than 600,000 of these surgeries were performed last year in the U.S. and the number is expected to grow. Given this anticipated increase a longer-term option is desirable. The Durasert™ product together with the HSS-designed implantable devices offers a potential new approach for the longer-term management of knee pain associated with OA. In addition, the implant has the potential to treat patients who are unable to undergo total knee replacement surgery for medical reasons or those who need more time to improve their health prior to knee replacement.

About the Hospital for Special Surgery

Hospital for Special Surgery (HSS) is the world's leading academic medical center focused on musculoskeletal health. HSS

is nationally ranked No. 1 in orthopedics and No. 3 in rheumatology by U.S. News & World Report (2017-2018), and is the first hospital in New York State to receive Magnet Recognition for Excellence in Nursing Service from the American Nurses Credentialing Center four consecutive times. HSS has one of the lowest infection rates in the country. HSS is an affiliate of Weill Cornell Medical College and as such all Hospital for Special Surgery medical staff are faculty of Weill Cornell. The hospital's research division is internationally recognized as a leader in the investigation of musculoskeletal and autoimmune diseases. HSS has locations in New York, New Jersey and Connecticut. www.hss.edu

About pSivida Corp.

pSivida Corp. (www.pshivida.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, 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. pSivida's lead product candidate, Durasert™ micro-insert for posterior segment uveitis, 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, and the Company plans to file an NDA by late December 2017/early January 2018. 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.pshivida.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.; our ability to file and the timing of filing and 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 shorter-duration treatment for posterior segment uveitis; 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 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.

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