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pSivida Corp and Hospital for Special Surgery Innovation Center Announce Opening of IND for Sustained-Release Implant for Severe Knee Osteoarthritis

WATERTOWN, Mass. and NEW YORK, Aug. 01, 2016 (GLOBE NEWSWIRE) -- pSivida Corp. (NASDAQ:PSDV) (ASX:PVA), a leader in the development of sustained release drug delivery products for eye diseases, and Hospital for Special Surgery (HSS), America's leading specialty hospital devoted to orthopedics and rheumatology, announce the opening of an investigational new drug application (IND) to begin an investigator-sponsored clinical study of a sustained-release implant to treat severe osteoarthritis (OA) of the knee. The implant is designed to provide long-term pain relief for severe knee OA, which is anticipated to delay the need for knee replacement surgery.

A photo accompanying this announcement is available at http://www.globenewswire.com/NewsRoom/AttachmentNg/b30de1ee-8226-49f1-b2ff-f4d7b3a0dc15

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This implant is designed to provide long-term pain relief for severe knee OA on a sustained release basis.

The implant is surgically implanted into the non-articulating area of the knee in an outpatient procedure. While the study is designed to evaluate the implant for six months, the duration of release following a single treatment is expected to extend to one year or more.

Dr. Mark P. Figgie, Chief of the Surgical Arthritis Service at HSS, filed the IND and will serve as the principal investigator for the investigator-sponsored study. Dr. Figgie is a leading expert in joint replacement for inflammatory arthritis and performs more than 500 joint replacement surgeries each year. With training in engineering and biomechanics, he has been instrumental in the design of implants for elbows, knees and hips.

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Knee OA is a degenerative joint disease that results from breakdown of joint cartilage and underlying bone, with joint pain and stiffness as the most common symptoms. More than 10 million people have knee OA. Nearly 50% of all people over 85 develop symptomatic knee OA, and two-thirds of obese people develop it in their lifetimes. No 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 700,000 of these surgeries were performed last year in the U.S. alone, and the number is expected to grow. Recent data from the Centers for Disease Control indicate that total knee replacements doubled between 2000 and 2010 for Americans over age 45, due in part to longer life expectancies and increases in obesity.

"We believe this product has the potential to provide long-term pain relief and to contribute to improved joint function for patients with severe osteoarthritis, which can delay knee replacement surgery. Implanting a small, secure reservoir that delivers a corticosteroid on a sustained basis directly to the knee could avoid the issues with systemic steroid delivery and repetitive knee injections. This implant, the result of the combined insights HSS and the expertise of pSivida, has the potential to create a paradigm shift in a variety of conditions," said Dr. Robert Hotchkiss, Medical Director of Clinical Research, HSS.

Dr. Paul Ashton, President and CEO of pSivida, said, "This IND is an important step in pSivida's goal of becoming the leader in sustained-release drug delivery products in ophthalmology and beyond. We hope to use our technologies to treat many chronic or debilitating conditions that require sustained, localized delivery of a drug."

The study is an open-label, single dose, safety and tolerability study of the screw implant to deliver dexamethasone, a corticosteroid previously proven to provide pain relief in knee osteoarthritis. Six patients will receive the implant in one knee. Although it is a safety and tolerability study, change from baseline in weekly mean of pain intensity scored at rest, during activity and at night will be assessed weekly through 24 weeks.

About HSS

HSS is the world's largest academic medical center focused on musculoskeletal health, and global leader in the field. HSS is nationally ranked No. 1 in orthopedics and No. 3 in rheumatology by U.S. News & World Report Best Hospitals 2015-16, 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. The HSS Research Institute is a cutting edge, internationally recognized leader in the scientific investigation of musculoskeletal and autoimmune diseases. The HSS Innovation Center supports our inventors and research pioneers in developing and commercializing devices, methods and drug discovery for the global healthcare community. HSS is an affiliate of Weill Cornell Medical College. HSS is located in New York City and online at www.hss.edu.

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 in 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: initiation of pivotal clinical trials for, obtaining FDA approval of, and commercialization of, a sustained release implant to treat OA of the knee; 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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