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pSivida Corp. Completes Targeted Enrollment of Phase III Trial of Medidur™ for Posterior Uveitis

WATERTOWN, Mass.--(BUSINESS WIRE)-- pSivida Corp. (NASDAQ:PSDV; ASX:PVA), a leader in the development of sustained release drug delivery products for treating eye diseases, today announced the completion of the originally targeted enrollment of 120 patients in its pivotal Phase III clinical trial of Medidur™ for the treatment of posterior uveitis, a blinding eye disease. pSivida will permit 10 additional patients seeking entry into the trial who met the entry criteria to enroll. pSivida expects to report top line data from the trial in the second half of 2016, and based on the results, to file for regulatory approval in late 2016 or early 2017.

"This is a major advance in the treatment of uveitis, in my opinion, with the delivery of medication into the vitreous cavity without the need for travel to an operating room and with effective provision of corticosteroid for a sustained three years," said Dr. C. Stephen Foster, president and CEO of Massachusetts Eye Research & Surgical Institute; founder and president of Ocular Immunology and Uveitis Foundation and a clinical professor of ophthalmology at Harvard Medical School. Dr. Foster's site enrolled the most patients in the study.

Medidur is an injectable micro-insert delivering the steroid flucinolone acetonide (FA) on a sustained basis for 36 months. Medidur uses the same micro-insert (same design, same polymers, same drug, same dose) as ILUVIEN® for diabetic macular edema (DME) developed by pSivida, which has been approved in the U.S. and in 15 EU countries to date. Medidur is inserted via a redesigned applicator that utilizes a needle of the same gauge as that typically used for intra-ocular injections.

Posterior uveitis is a chronic, non-infectious inflammatory disease affecting the posterior segment of the eye, often involving the retina. 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 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 progress to steroid-sparing therapy with systemic immune suppressants or biologics, which themselves can have severe side effects including an increased risk of cancer.

"Based on results of a Phase II study and prior experience with this implant, we believe that Medidur will provide improved outcomes compared to standard of care but with a significant reduction in side effects. Medidur should also lower treatment costs and offer the reduced invasiveness of an injection every three years compared with the frequent administration of existing therapies," said Dr. Paul Ashton, President and CEO of pSivida Corp. "We are focused on providing solutions for retinal diseases and believe that this study will demonstrate the safety and effectiveness of Medidur."

The Medidur Phase III trial is a double-blind study comparing injections of Medidur to sham injections on a two-to-one basis. Patients are enrolled in 16 centers in the U.S. and 17 centers in the EU and India. The primary end point of the trial is recurrence of posterior uveitis within one year. pSivida plans to seek approval based on the safety and efficacy data from this single Phase III trial together with short term data from a utilization study of pSivida's proprietary inserter. The FDA has confirmed that pSivida can reference much of the data, including the clinical safety data, from the Phase III clinical trials of ILUVIEN for DME.

About pSivida Corp.

pSivida Corp., (www.psivida.com), headquartered in Watertown, MA, develops tiny, sustained-release products designed to deliver drugs and biologics at a controlled and steady rate for weeks, months or years. Using its core technology platforms, Durasert™ and Tethadur™, the Company is focused on treatment of chronic diseases of the back of the eye and is also exploring applications outside ophthalmology. The Company's lead product candidate, Medidur™, uses the same injectable, sustained release micro-insert as pSivida's lead licensed product, ILUVIEN® for the treatment of DME. ILUVIEN has been approved in the U.S., is marketed in the U.K., Germany and Portugal and has or is pending marketing authorization in 14 other EU countries. pSivida's other licensed product, Retisert®, an implant that treats posterior uveitis, is sold in the U.S. pSivida's pre-clinical research is focused on ocular and systemic delivery of biologics and drugs to treat wet and dry age-related macular

degeneration, glaucoma, osteoarthritis and other diseases.

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. The following are 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: uncertainties with respect to: ability to achieve profitable operations and access to capital; fluctuations in operating results; further impairment of intangible assets; decline in Retisert royalties; successful commercialization of, and receipt of revenues from, ILUVIEN for DME; effect of pricing and reimbursement decisions on sales of ILUVIEN for DME; consequences of flucinolone acetonide side effects; number of clinical trials necessary to support an NDA for, and regulatory approval and successful commercialization, of Medidur; development of the Latanoprost Product and any exercise by Pfizer of its option; ability of Tethadur to successfully deliver large biologic molecules and development of products using Tethadur; ability to successfully develop product candidates, complete clinical trials and receive regulatory approvals; ability to market and sell products; success of current and future license agreements; termination of 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 together with 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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For more information on pSivida, visit www.psivida.com.

Martin E. Janis & Company, Inc.
Beverly Jedynak
President
T: 312-943-1123
M: 773-350-5793
bjedynak@janispr.com

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