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pSivida Corp. Announces Initiation of Phase III Clinical Trial in Posterior Uveitis

WATERTOWN, Mass.--(BUSINESS WIRE)-- pSivida Corp. (NASDAQ:PSDV), a specialty pharmaceutical company that is a leader in developing sustained release drugs for treatment of back-of-the-eye diseases, today announced that it has initiated the first of two planned pivotal Phase III trials of its micro-insert for the treatment of chronic, non-infectious uveitis affecting the posterior segment of the eye, a major cause of vision loss in the U.S.

"We are extremely pleased that our first three U.S. clinical sites have begun recruiting patients for this trial," said Paul Ashton, Ph.D., President and CEO of pSivida. "We are very optimistic that our micro-insert will be efficacious for the treatment of posterior uveitis with a more favorable risk/benefit profile, fewer side effects and greater ease of administration than Retisert®, our current FDA-approved product for the treatment of the same disease."

The micro-insert, a tiny tube about the size of an eyelash that releases the steroid fluocinolone acetonide on a sustained basis for up to 36 months, is the same micro-insert licensed by pSivida to Alimera Sciences, Inc. Alimera has received marketing approval for the micro-insert in six EU countries for the treatment of vision impairment associated with chronic diabetic macular edema (DME) considered insufficiently responsive to available therapies and has commenced the direct commercialization of the micro-insert in Germany and the United Kingdom under the name ILUVIEN®. The FDA has set a new Prescription Drug User Fee Act (PDUFA) goal date of October 17, 2013 for ILUVIEN. pSivida did not license the micro-insert to Alimera for the treatment of uveitis and is developing this product without a partner.

This is the first of two pivotal trials required by the FDA for approval of the micro-insert for the treatment of posterior uveitis. These trials are planned to involve approximately 15 U.S. clinical sites and additional sites world-wide. Both trials will have a primary end-point of recurrence of posterior uveitis at 12 months and are planned to involve approximately 300 patients in total. If the results of the trials are positive, the data will be used by pSivida to submit a New Drug Application to the FDA. The FDA has confirmed that pSivida will be able to reference much of the data, including the clinical safety data, from Alimera's Phase III clinical trials of ILUVIEN for chronic DME.

Posterior uveitis is an inflammatory disease of one of the layers of the eye. In the U.S., posterior uveitis affects approximately 175,000 people and can be difficult to treat effectively, resulting in an estimated 30,000 cases of blindness in the U.S.

"In our uveitis trials, we expect to maintain similar efficacy to that seen in the Retisert Phase III trials but with a similar side-effect profile to that seen in DME patients in the Phase III studies for ILUVIEN," said Dr. Ashton. "The Retisert implant is FDA approved for posterior uveitis and the micro-insert delivers the same drug as Retisert, so we expect the micro-insert to be efficacious. Based on the Phase III studies for ILUVIEN, we also expect the micro-insert to have a lower incidence of serious increased in intraocular pressure (IOP) than Retisert. The ILUVIEN studies showed an incidence of serious elevated IOP that was three times lower than that seen in the Retisert Phase III trials, and the incidence of patients requiring surgery for increased IOP in the ILUVIEN studies was seven times lower. The micro-insert releases drug at a slower rate and is also easier to administer than Retisert, because the micro-insert is injected in an office visit while Retisert must be implanted in a surgical procedure."

About pSivida

pSivida Corp., headquartered in Watertown, MA, develops tiny, sustained release, drug delivery products designed to deliver drugs at a controlled and steady rate for months or years. pSivida is currently focused on treatment of chronic diseases of the back of the eye utilizing its core technology systems, Durasert™ and BioSilicon™. The injectable, sustained release micro insert ILUVIEN® for the treatment of chronic DME considered insufficiently responsive to available therapies, licensed to Alimera Sciences, Inc., has received marketing authorization in Austria, France, Germany, Portugal, Spain and the U.K. and is awaiting authorization in Italy. Alimera has resubmitted the New Drug Application for ILUVIEN for DME to the U.S. Food and Drug Administration. pSivida plans to institute pivotal Phase III clinical trials for the treatment of posterior uveitis, a chronic back-of-the-eye disease, with the same micro-insert as ILUVIEN for DME. An investigator-sponsored clinical trial is ongoing for an injectable, bioerodible micro-insert to treat glaucoma and ocular hypertension. pSivida's FDA-approved Retisert® licensed to Bausch & Lomb Incorporated provides long-term, sustained drug delivery to treat posterior uveitis.

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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: the success of Phase III posterior uveitis trials including efficacy, side effects and risk/benefit profile of the posterior uveitis micro-insert and pSivida's ability to finance and complete the trials and receive marketing approvals; Alimera's ability to achieve a positive NICE recommendation for all ILUVIEN patients; Alimera's ability to obtain regulatory approval for, and if approved, to finance, successfully commercialize and achieve market acceptance of, and generate revenues to pSivida from, ILUVIEN for DME in the U.S.; Alimera's ability to finance, achieve additional marketing approvals, successfully commercialize and achieve market acceptance of, and generate revenues to pSivida from, ILUVIEN for DME in the EU; outcome of reimbursement for ILUVIEN in the U.K.; initiation, financing and success of Latanoprost Product Phase II trials and exercise by Pfizer of its option; development of products using Tethadur and BioSilicon; initiation and completion of clinical trials and obtaining regulatory approval of product candidates; adverse side effects; ability to attain profitability; ability to obtain additional capital; further impairment of intangible assets; fluctuations in operating results; decline in royalty revenues; ability to, and to find partners to, develop and market products; termination of license agreements; competition and other developments affecting sales of products; market acceptance; protection of intellectual property and avoiding intellectual property infringement; retention of key personnel; product liability; consolidation in the pharmaceutical and biotechnology industries; compliance with environmental laws; manufacturing risks; risks and costs of international business operations; credit and financial market conditions; legislative or regulatory changes; volatility of stock price; possible dilution; possible influence by Pfizer; absence of dividends; and other factors described in our filings with the SEC. Given these uncertainties, readers are cautioned not to place undue reliance on such 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.

IN US:
Martin E. Janis & Company, Inc.
Beverly Jedynak, 312-943-1123; 773-350-5793 (cell)
President
bjedynak@janispr.com
or
IN AUSTRALIA:
pSivida Corp.
Brian Leedman, +61 (0) 41 228 1780
Vice President, Investor Relations
brianl@psivida.com

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