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pSivida Corp. Receives FDA Clearance for Pivotal Trials for Injectable Sustained-Release Micro-Insert to Treat Uveitis

WATERTOWN, Mass.--(BUSINESS WIRE)-- pSivida Corp. (NASDAQ: PSDV)(ASX: PVA), a leader in developing sustained release, drug delivery products for treatment of back-of-the-eye diseases, today announced that the U.S. Food and Drug Administration (FDA) has cleared its Investigational New Drug (IND) application to treat posterior uveitis with pSivida's injectable sustained-release micro-insert. pSivida is now permitted to move directly to two Phase III trials to treat patients with posterior uveitis. These trials, which pSivida expects would enroll a total of 300 patients, would be in addition to the investigator-sponsored trial studying the same device for posterior uveitis announced last month.

"We are very pleased to be cleared to commence phase III clinical trials for the treatment of this blinding disease without the necessity of Phase I or Phase II trials," said Dr. Paul Ashton, President and CEO of pSivida Corp. "Importantly, the FDA has agreed that the primary end point in these trials will be recurrence of uveitis within 12 months and that we can reference much of the data, including the clinical safety data, from the clinical trials for ILUVIEN® for Diabetic Macular Edema (DME) conducted by our collaborative partner Alimera Sciences, Inc. (Alimera). We appreciate the input provided by the FDA about the design of these trials and believe these design features will be advantageous in terms of cost and time.

"Because the micro-insert delivers the same drug as our approved Retisert® product for posterior uveitis, we expect to these trials will show efficacy. Further, as the same micro-insert was used in the ILUVIEN trials, we expect to observe a comparable side-effect profile in uveitis patients as was seen in DME patients. As a result, we are optimistic that our micro-insert will be efficacious for posterior uveitis with a favorable risk/benefit profile and fewer side effects than Retisert."

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 is responsible for approximately 30,000 cases of blindness, making it the third largest cause of blindness.

pSivida's injectable micro-insert to treat posterior uveitis is a tiny tube about the size of an eyelash. It releases the off-patent steroid flucinolone acetonide at a consistent rate over a period of approximately 36 months. The micro-insert is injected into the back of the eye during an office visit through the use of a fine gauge needle. The same micro-insert has recently received marketing authorization for chronic DME considered insufficiently responsive to available therapies in the UK, Austria, France and Portugal following a positive review under the Decentralized Procedure. Marketing authorization in the remaining countries is anticipated in the coming months. Alimera has reported that it expects the insert, to be marketed under the name ILUVIEN, to be the first sustained-release pharmaceutical in the EU to treat DME.

About pSivida Corp.

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™. ILUVIEN® for the treatment of Diabetic Macular Edema (DME), which is licensed to Alimera Sciences, Inc., is pSivida's most advanced product candidate. It has received marketing authorization for chronic DME considered insufficiently responsive to available therapies in the UK, France, Austria and Portugal following a positive review by Austria, France, Germany, Italy, Portugal, Spain and the UK under the Decentralized Procedure. Marketing authorization in the remaining countries is anticipated in the coming months. An investigator-sponsored clinical trial is ongoing for an injectable, bioerodible insert to treat glaucoma and ocular hypertension. pSivida's two FDA-approved products, Retisert® and Vitrasert®, are implants that provide long-term, sustained drug delivery to treat two other chronic diseases of the retina.

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: necessity to raise additional capital to finance Phase III uveitis trials as well as other working capital needs; ability to obtain additional capital; ability to initiate and complete clinical trials and obtain regulatory approval of product candidates; adverse side effects;

Alimera's ability to successfully obtain regulatory approval of and commercialize ILUVIEN for DME in the EU; actions with respect to regulatory approval of ILUVIEN for DME in the U.S.; ability to attain profitability; exercise by Pfizer of the Latanoprost Product option; further impairment of intangible assets; fluctuations in operating results; decline in royalty revenues; ability to find partners to develop and market products; termination of license agreements; competition; market acceptance of products and product candidates; reduction in use of products as a result of future guidelines, recommendations or studies; ability to protect intellectual property and avoid infringement of others' intellectual property; 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; ability to pay any registration penalties; absence of dividends; and other factors described in our filings with the Securities and Exchange Commission. 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.

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