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Psivida Corp. Announces Final Published Guidance from U.K.'s Nice and Pursuit of Patient Access Scheme for Iluvien® for DME

WATERTOWN, Mass.--(BUSINESS WIRE)-- pSivida Corp. (NASDAQ:[PSDV](#) - [News](#)), a leader in developing sustained release, drug delivery products for treatment of back-of-the-eye diseases, announced today that the United Kingdom's National Institute for Health and Clinical Excellence (NICE) has published final guidance indicating that ILUVIEN® is not cost effective for the treatment of chronic diabetic macular edema (DME) considered insufficiently responsive to available therapies. This final guidance is consistent with the final draft guidance issued on November 29, 2012.

pSivida's licensee for ILUVIEN for DME, Alimera Sciences, Inc., reported that it has chosen to pursue a Patient Access Scheme (PAS) for ILUVIEN for DME that is intended to allow treatment decisions to be based on patient need, rather than cost. Alimera further reported that the PAS is currently under review by the Patient Access Schemes Liaison Unit (PASLU) at NICE and that, if approved by the Department of Health, the PAS will be available to the Appraisal Committee for review and consideration. Alimera stated its belief that the PAS could be considered under NICE's rapid review facility should the PAS be accepted.

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™. The injectable, sustained release micro insert ILUVIEN® for the treatment of chronic DME, 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. ILUVIEN for DME has not been approved in the U.S. pSivida plans to institute pivotal Phase III clinical trials for the treatment of posterior uveitis 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 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: uncertainties with respect to: 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., Alimera's resubmission of its NDA for ILUVIEN for DME and its 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.; financing and success of Phase III posterior uveitis trials including efficacy, side effects and risk/benefit profile of the posterior uveitis micro-insert; 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.

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