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pSivida Corp. Announces UK's NICE Says Yes to ILUVIEN® in Some Patients with Diabetic Macular Edema in New Draft Guidance

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diseases, today announced that the United Kingdom's National Institute for Health and Care Excellence (NICE) issued draft guidance recommending ILUVIEN® for the treatment of pseudophakic patients (those who have undergone prior cataract surgery) with chronic diabetic macular edema (DME) considered insufficiently responsive to available therapies. Following a rapid review by NICE, this recommendation proposes a change to the published guidance issued by NICE in January 2013 and takes into consideration a patient access scheme (PAS) submitted by Alimera.

"We are very pleased. If this recommendation becomes final, ILUVIEN will be available in the U.K. to pseudophakic as well as private pay and privately insured patients," said Dr. Paul Ashton, Chief Executive Officer of pSivida. "The pseudophakic DME population represents a large subgroup as patients with DME have a far higher incidence of cataract than the overall population. In the Phase III FAME™ trials of ILUVIEN, over 50% of control patients were pseudophakic at the end of the trial."

The NICE Appraisal Committee making the recommendation confirmed the conclusions that ILUVIEN is clinically effective in the treatment of vision impairment associated with chronic DME considered insufficiently responsive to available therapies as well as in the subgroup of pseudophakic chronic DME patients. Based on the PAS, the Committee concluded that the cost-effectiveness threshold had been met for the subgroup of chronic DME patients who are pseudophakic. NICE will issue final guidance after a comment period.

Professor Carole Longson, Health Technology Evaluation Center Director at NICE said, "Around 336,000 people with diabetes in the UK have diabetic macular edema... NICE is pleased to be able to recommend fluocinolone (ILUVIEN) for some people for the treatment of this condition in draft guidance." NICE will issue final guidance after a comment period.

"We are encouraged by Alimera's optimism that this recommendation will result in a change in the final published NICE guidance and by Alimera's plans to continue to work with NICE to seek to broaden access to ILUVIEN to include all chronic DME patients who could benefit from the treatment," added Dr. Ashton.

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 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 posterior uveitis.

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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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The President's Blog: http://www.thechairmansblog.com/paul-ashton

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