



June 30, 2014

## **pSivida Corp. Reports Positive Regulatory Outcome for ILUVIEN®; Moves to National Phase for Marketing Authorizations in 10 More EU Countries**

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 that the regulatory process for marketing authorizations in Belgium, the Czech Republic, Denmark, Finland, Ireland, Luxembourg, the Netherlands, Norway, Poland and Sweden has entered the national phase following the successful completion of the Mutual Recognition Procedure (MRP) for subsequent authorizations. In the national phase, each of these countries will grant a marketing authorization for ILUVIEN for the treatment of vision impairment associated with chronic DME considered insufficiently responsive to available therapies. ILUVIEN initially received marketing authorizations in Austria, France, Italy, Portugal, Spain as well as the United Kingdom and Germany where it is now commercially available.

The application was submitted through the Mutual Recognition Procedure (MRP). After a medicine is first authorized in one EU member state in accordance with its national procedures, the same authorization can be subsequently used to obtain marketing authorization in other member states not involved in the original, authorization. These member states agree to recognize the validity of the original national marketing authorization.

"Continuing to expand the countries where ILUVIEN can reach patients with this devastating disease is important, and we look forward to the addition of these ten countries," said Dr. Paul Ashton, president and chief executive officer of pSivida.

Alimera also resubmitted the New Drug Application for ILUVIEN for chronic DME in March 2014, and the U.S. Food and Drug Administration (FDA) has set a PDUFA goal date of September 26, 2014. If ILUVIEN is approved by the FDA, we are entitled to a \$25 million milestone payment from our licensee Alimera Sciences. We are also entitled to share in the net profits from Alimera's sales of ILUVIEN on a country-by-country basis.

### **About pSivida Corp.**

pSivida Corp., headquartered in Watertown, MA, is a leader in the development of sustained release, drug delivery products for treating eye diseases. pSivida is currently focused on treatment of chronic diseases of the back of the eye utilizing its core technology systems, Durasert™ and BioSilicon™, including Tethadur™. The injectable, sustained release ~~insert~~ ILUVIEN® for the treatment of chronic DME considered insufficiently responsive to available therapies, licensed to Alimera Sciences, Inc., is marketed in the U.K. and Germany and has also received marketing authorization in Austria, France, Italy, Portugal and Spain. Alimera has filed for ten additional EU country approvals through the Mutual Recognition Procedure. Alimera resubmitted its NDA for ILUVIEN in March 2014 and the FDA has set a PDUFA goal date of September 26, 2014. pSivida has instituted a Phase III clinical trials of Medidur™ for the treatment of posterior uveitis, a chronic ~~back~~-the-eye disease, which uses the same micro-insert as ILUVIEN. An investigator-sponsored clinical trial is ongoing for an injectable, bioerodible micro-insert to treat glaucoma and ocular hypertension, a product candidate on which Pfizer Inc. has an option. pSivida's FDA-approved Retisert®, licensed to Bausch & Lomb Incorporated, provides long-term, sustained drug delivery to treat posterior uveitis.

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: the number of clinical trials necessary to support an NDA for Medidur; Alimera's ability to finance, achieve additional marketing approvals, obtain adequate pricing and reimbursement for, successfully commercialize and achieve market acceptance of, and generate revenues to pSivida from, ILUVIEN for DME in the EU; 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.; the ability to finance, complete and achieve a successful outcome for Phase III trials for, and file and achieve marketing approvals for, Medidur for posterior uveitis, including achieving acceptable risk-to-benefit and safety profiles in light of the CRL for ILUVIEN; initiation, financing and success of Latanoprost Product Phase II trials and any exercise by Pfizer of its option; ability of Tethadur to successfully deliver proteins, peptides and other large biologic molecules; ability to develop product candidates and products and potential related collaborations; initiation

and completion of clinical trials and obtaining regulatory approval of product candidates; continued sales of Retisert; adverse side effects; ability to attain profitability; ability to obtain additional capital; further impairment of intangible assets; fluctuations in operating results; decline in royalty income; 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; 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. 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. 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>

For more information on pSivida, visit [www.psivida.com](http://www.psivida.com).

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