May 19, 2015

pSivida Reports Positive IOP Safety Data in Phase III Trial of Medidur™ for Posterior Uveiti

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 positive safety data from its ongoing assessment of masked safety data from its first Phase III clinical trial of Medidur™ for posterior uveitis, a blinding eye disease. At three months, only 4% more study eyes (2/3 of which received Medidur) experienced elevated intraocular pressure (IOP) than the fellow non-study eyes (none of which received Medidur). Initial IOP elevation is an indication of the likelihood of subsequent clinically significant IOP increases. The minimal difference observed in elevated IOP in the assessment suggests highly favorable results for a key safety measure of the trial, the number of eyes that develop clinically significant increases in IOP within 12 months of receiving Medidur relative to control eyes.

"These data are very encouraging for the safety profile of Medidur," said Dr. Paul Ashton president and CEO of pSivida Corp. "A significant treatment challenge with posterior uveitis patients is managing the serious side effects of prolonged steroid use, the current first-line treatment. A therapy that can provide the benefits of steroids on a sustained basis for three years with a single injection with a lower incidence of side effects would be a very significant advance in treatment of this disease."

The assessment of masked data compared the elevation of IOP over 21mmHg at three months study eyes and fellow eyes for the 105 out of 129 enrolled subjects with at least three month follow-up data.

"We are very optimistic for the final IOP safety results in this trial," said Dr. Ashton. "We originally expected that the final IOP safety profile for Medidur would be at least as good as the IOP safety profile of the FDA-approved ILUVIEN® for diabetic macular edema (DME) (which uses the same micro-insert as Medidur and delivers the same dose of the same drug), and much better than the IOP safety profile of the FDA-approved Retisert® (which delivers a higher dose of the same drug in Medidur). On the basis of this ongoing assessment of masked study safety data, we now believe the final IOP results in the Medidur trial could be even better than those shown in the ILUVIEN and Retisert Phase III trials. At 36 months, 24% more patients treated with ILUVIEN and 45% more patients treated with Retisert required medication for elevated IOP than controls in their Phase III trials. We expect top line results from this first Phase III trial of Medidur to be available in Q2 2016, and with favorable results from this and our second trial, which has just been initiated, we intend to file for U.S. approval in the first half of 2017."

About Medidur. Medidur is an injectable micro-insert designed to treat posterior uveitis that provides sustained release of flucinolone acetonide (a corticosteroid) for three years. Medidur comprises the same micro-insert (same design, same polymers, same drug, same dose) as ILUVIEN for DME. ILUVIEN has been approved in the U.S. and 17 EU countries and is sold the U.S., the U.K., Germany and Portugal.

About Posterior Uveitis. Posterior uveitis is a chronic, non-infectious inflammatory disease affecting the posterior segment of the eye, often involving the retina, which is a leading cause of blindness in the developed and developing countries. It afflicts people of all ages, producing swelling and destroying eye tissues, which can lead to severe vision loss and blindness. In the U.S., posterior uveitis affects approximately 175,000 people, resulting in approximately 30,000 cases of blindness and making it the third leading cause of blindness in the U.S.

Patients with posterior uveitis are typically treated with systemic steroids but over time frequently develop serious side effects that can limit effective dosing. Patients then often progress to steroid-sparing therapy with systemic immune suppressants or biologics, which themselves can have severe side effects including an increased risk of cancer. Medidur is designed to provide improved outcomes compared to standard of care but with a significant reduction in side effects.

About the Phase III Trials. The two Phase III clinical trials are double-blind studies comparing injections of Medidur to sham injections on a two-to-one basis. The first trial is fully enrolled with 129 patients in 16 centers in the U.S. and 17 centers outside the U.S. The primary end point of the trial is recurrence of posterior uveitis within one year. The last scheduled visit for the last patient will be in March 2016, and top-line data is expected in the second quarter of 2016. The second trial will enroll up to150 patients in approximately 15 centers in India. The primary endpoint will be recurrence of posterior uveitis within six months. Patients in both trials will be followed for three years. pSivida plans to seek approval for Medidur for posterior uveitis based on 12-month data from the first Phase III trial, six-month data from the second phase III trial and data from a utilization study of pSivida's redesigned proprietary inserter together with data referenced from the Phase III trials of ILUVIEN for DME. With favorable results, pSivida expects to file an NDA in the first half of 2017.

About pSivida Corp.

pSivida Corp. (www.psivida.com), headquartered in Watertown, MA, is a leader in the development of sustained release, drug delivery products for treating eye diseases. pSivida has developed three of only four FDA-approved treatments for back-of-the-eye diseases. The most recent, ILUVIEN®, a micro-insert for diabetic macular edema, is licensed to Alimera Sciences and sold in the U.S. and four EU countries. Retisert®, an implant for posterior uveitis, is licensed to and sold by Bausch & Lomb. pSivida's lead product candidate, Medidur™, a micro-insert for posterior uveitis, is currently in pivotal phase III clinical trials with an NDA anticipated in the first half of 2017. pSivida's preclinical development program is focused on using its core platform technologies, Durasert™ and/or Tethadur™, to deliver drugs and biologics to treat wet and dry age-related macular degeneration (AMD), glaucoma, osteoarthritis and other diseases.

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 statement 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 include uncertainties with respect to: actual final IOP safety results for Medidur Phase III trials; ability to achieve profitable operations and access to capital; fluctuations in operating results; further impairment of intangible assets; decline in Retisert royalties; successful commercialization of, and receipt of revenues from, ILUVIEN for DME; effect of pricing and reimbursement decisions on sales of ILUVIEN for DME; consequences of fluocinolone acetonide side effects; number and cost of clinical trials and data necessary to support an NDA for, approval by Indian regulators of the trial design for, timing of filing the NDA for, and regulatory approval and successful commercialization of, Medidur; delays in completion of clinical trials; increases in cost of clinical trials; changes in, or misunderstandings with respect to, FDA guidance on required clinical trials; development of the Latanoprost Product and any exercise by Pfizer of its option; ability of Tethadur to successfully deliver large biologic molecules and to develop products using it; ability to successfully develop product candidates, complete clinical trials and receive regulatory approvals; ability to market and sell products; success of current and future license agreements; termination of license agreements; effects of competition and other developments affecting sales of products; market acceptance of products; effects of guidelines, recommendations and studies; protection of intellectual property and avoiding intellectual property infringement; retention of key personnel; product liability; industry consolidation; compliance with environmental laws; manufacturing risks; risks and costs of international business operations; legislative or regulatory changes; volatility of stock price; possible dilution; absence of dividends; and other factors described in our filings with the SEC. You should read and interpret any forward-looking statements together with these risks. 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. You should bear this in mind as you consider any 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.

Follow pSivida on social media:

Twitter: https://twitter.com/pSividaCorp

Facebook: https://www.facebook.com/pages/PSivida-Corp/544893792199562

LinkedIn: http://www.linkedin.com/company/psivida

Google+: https://plus.google.com/u/0/b/113754643626984244726/113754643626984244726/posts

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

For more information on pSivida, visit www.psivida.com.

View source version on businesswire.com: http://www.businesswire.com/news/home/20150519005734/en/

Martin E. Janis & Company, Inc.
Beverly Jedynak, 312-943-1123
President
M: 773-350-5793
bjedynak@janispr.com

Source: pSivida Corp.