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pSivida Announces Completion of BrachySil(TM) Dose Ranging Study in Pancreatic Cancer

WATERTOWN, Mass., Oct 21, 2009 (BUSINESS WIRE) -- pSivida Corp. (NASDAQ:PSDV)(ASX:PVA)(FF:PV3), a leading drug delivery company today announced the completion of a second pancreatic clinical trial of BrachySil™ (P32 BioSilicon™), a potential new brachytherapy treatment for inoperable pancreatic cancer. Six patients were studied at two centers in the UK (Guy's and St Thomas' NHS Foundation Trust and University Hospital, Birmingham). The study was conducted to determine the safety of escalating radiation doses of the BrachySil™ device and to determine an optimum dosing level. Tumor response was also measured as a secondary end point.

The study escalated the absorbed targeted radiation dose by four-fold from the previous study to 400 Gy (Gy or Gray is a unit of absorbed radiation dose due to ionizing radiation). No device related serious adverse events were experienced at the elevated levels and independent dosimetry experts have concluded from the data that 400 Gy is the optimum dose.

The previous safety study presented last year at the American Society of Clinical Oncology-GI showed that BrachySil™ in combination with standard chemotherapy (gemcitabine), was well tolerated with no clinically significant adverse events related to the device. Data in the first study showed disease control in 82% of patients. BrachySil™ is implanted directly into the tumor and was found to be easily deliverable by endoscopic ultrasound.

"BrachySil™ has once again produced encouraging clinical results with 100% of patients experiencing stabilization in tumor growth," said Dr. Paul Ashton, President and CEO of pSivida Corp. "We are very encouraged by the results of both this dose ranging study and the prior safety study."

BrachySil™ is a novel oncology product which comprises a combination of BioSilicon™ (a proprietary porous silicon) and the isotope 32Phosphorus, a proven anti-cancer therapeutic. It is hoped this product will provide oncologists with an effective and user-friendly new treatment for this disease which has a high unmet clinical need.

Pancreatic cancer is the fourth most frequent cause of cancer death in the United States, and at least 80% of patients present with inoperable locally advanced or metastatic disease. The median survival for these patients following diagnosis is typically less than six months with standard chemotherapy. Accordingly, there is significant clinical and market demand for effective therapies.

About pSivida Corp.

pSivida is a world leader in the development of tiny, sustained release, drug delivery products that are administered by implantation, injection or insertion. pSivida's lead development product delivers fluocinolone acetonide (FA) for the treatment of diabetic macular edema (DME). This product candidate, formerly known as Medidur™ FA for DME, is licensed to Alimera, which is conducting fully recruited Phase III clinical trials and intends to commercialize the product under the name Iluvien®. pSivida also has two products approved by the Food and Drug Administration (FDA): Retisert® for the treatment of uveitis and Vitrasert® for the treatment of AIDS-related cytomegalovirus (CMV) retinitis. pSivida has licensed both of these products and the technologies underlying them to Bausch & Lomb Incorporated. pSivida has a worldwide collaborative research and license agreement with Pfizer Inc. under which Pfizer may develop additional ophthalmic products.

pSivida owns the rights to develop and commercialize a modified form of silicon known as BioSilicon™, which has potential therapeutic applications. The most advanced BioSilicon product candidate, BrachySil™, delivers a therapeutic P32, a radioactive form of phosphorus used to treat cancer, directly to solid tumors. pSivida has completed an initial safety clinical trial of BrachySil for the treatment of pancreatic cancer and is nearing completion of a follow-on dose-ranging clinical trial.

pSivida's intellectual property portfolio consists of 62 patent families, over 100 granted patents, including patents accepted for issuance, and over 200 patent applications. pSivida conducts its operations from Boston in the United States and Malvern in the United Kingdom.

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 forward-looking statements: continued losses and lack of profitability; inability to derive revenue from Retisert; impairment of intangibles; fluctuations in the fair values of certain outstanding warrants; fluctuations in operating results; inability to raise capital; termination of license agreements; inability to obtain regulatory approvals for products; inability to obtain partners to develop and market products; competition; insufficient third-party reimbursement for products; inability to protect intellectual property or infringement of others' intellectual property; failure to retain key personnel; consolidation in the pharmaceutical and biotechnology industries; failure to comply with laws and regulations; manufacturing problems; risks and costs of international business operations; volatility of stock price; possible dilution through exercise of outstanding warrants and stock options; possible influence by Pfizer; payment of registration penalties; nonpayment of dividends; and other factors that may be 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 make it clear that any projected results expressed or implied in such statements will not be realized.

SOURCE: pSivida Corp.

In US:
Beverly Jedynak
312-943-1123
bjedynak@janispr.com
or
In Australia:
Brian Leedman, Vice President for Australian Investor Relations
pSivida Corp.
+61 8 9227 8327
brianl@psivida.com