

## NEWS RELEASE



### **Pervasis Therapeutics Presents Promising Preclinical Data for its Minimally Invasive Cell Therapy at the European Association of Percutaneous Cardiovascular Interventions Annual Congress (EuroPCR)**

*Study Findings Show Treatment with PVS-10200 Following Angioplasty and Stent Placement for Peripheral Artery Disease in a Porcine Model Reduces Intimal Area and Enhances Vascular Repair*

**CAMBRIDGE, Mass. – May 19, 2009** – Pervasis Therapeutics, Inc., a biotechnology company pioneering biologically active cellular therapies to treat vascular and other serious diseases, today announced new preclinical data for the Company's minimally invasive cell therapy, PVS-10200. Results from the preclinical study found that treatment with PVS-10200 (tissue engineered allogeneic endothelial cells) following an intervention for peripheral arterial disease (PAD) resulted in a statistically significant increased lumen area, reduced intimal area, and decreased occlusion compared to control. These data were presented in an oral presentation today at EuroPCR, the official congress of the European Association of Percutaneous Cardiovascular Interventions in Barcelona, Spain.

In this preclinical study, researchers evaluated treatment with ultrasound-guided percutaneous (needle delivered) administration of PVS-10200 to the outside of porcine (pig) femoral arteries immediately following angioplasty and stent placement. Animals in the control group received angioplasty and stents with no further treatment (sham standard of care control). A third group was treated with injection of matrix alone. A total of 36 femoral arteries were evaluated in the study and evaluations were conducted at 30 and 90 days following treatment. At 90 days, PVS-10200 treated arteries had significantly decreased intimal area ( $3.3 \pm 0.4 \text{ mm}^2$ ) compared to control ( $6.2 \pm 0.5 \text{ mm}^2$ ,  $P < 0.05$ ) and increased lumen area ( $20.4 \pm 0.7 \text{ mm}^2$ ) compared to control ( $16.1 \pm 0.9 \text{ mm}^2$ ,  $P < 0.05$ ). After 90 days, PVS-10200 treated arteries had a 50 percent decrease in percent occlusion compared to sham control ( $P < 0.05$ ). Treatment with the gelatin matrix alone did not differ significantly from the sham control.

"Restenosis, or narrowing of the arteries, following procedural treatment for PAD occurs frequently and is associated with a number of vascular complications and re-interventions," added Helen M. Nugent, Ph.D., co-founder and vice president, research and development at Pervasis and co-author of the study. "PVS-10200 provides endothelial-based factors to the injured artery, which regulates the inflammatory response within the blood vessel and promotes natural healing. Results from this study indicate that PVS-10200 may offer a novel therapeutic option that can effectively reduce the intimal area and reduce occlusion, and therefore limit restenosis following treatment for PAD."

"We are pleased to present this compelling preclinical data for PVS-10200," stated Frederic Chereau, president and chief executive officer of Pervasis Therapeutics. "Treatment with drug-eluting stents has shown no benefit within the peripheral vasculature. There continues to be a significant unmet medical need and a large market potential for new therapies to effectively address common complications related to vascular intervention. Based on the encouraging results seen in this study, we are initiating a Phase 2 trial to further evaluate the safety and efficacy of PVS-10200 in treating interventions for PAD."

Pervasis has demonstrated proof-of-concept for this novel cellular approach in two Phase 2 trials with Vascugel<sup>®</sup>, the Company's first cellular treatment developed using its proprietary technology

platform, in patients with end-stage renal disease receiving arteriovenous (AV) access for hemodialysis. The two studies, known as V-HEALTH, showed that perivascular placement of Vascugel<sup>®</sup> at the time of AV access creation resulted in higher patency rates, extended time to first intervention and greater lumen diameter at six months. Results also showed that treatment with Vascugel<sup>®</sup> was safe with fewer thrombotic events, early complications and interventions than compared to placebo. Additionally, positive efficacy trends were shown in various other secondary endpoints.

### **About Peripheral Artery Disease**

Peripheral arterial disease (PAD) affects approximately 8 million Americans according to the American Heart Association and is characterized by the build up of fatty deposits on the inner lining of the artery walls. Over time, the build up of fatty deposits restricts blood flow primarily in the arteries leading to the kidneys, arms, legs, stomach and feet. PAD becomes more common as a person ages and by age 65, about 12 to 20 percent of the population has the disease. People with PAD have a four to five times higher risk of heart attack and stroke compared to those who do not have the disease. Treatment often begins with lifestyle changes, including smoking cessation, diet and exercise. Medication is often used along with lifestyle changes to treat PAD. Some patients require additional intervention to help manage the disease and these patients may undergo angioplasty, stent placement or have surgery to help treat the narrowed artery. Restenosis is a large problem for patients following treatment for PAD and to date, drugs have had limited success in treating restenosis.

### **About PVS-10200**

PVS-10200 is a minimally invasive cell therapy currently being developed by Pervasis to treat interventions for PAD and other vascular applications. The Company's proprietary technology platform harnesses the power of the endothelium to promote natural healing to repair and restore vascular function following an intervention, such as angioplasty, stent placement, peripheral and coronary bypass, and AV access placement for patients with end-stage renal disease. By supplementing the existing endothelium, PVS-10200, an allogeneic endothelial cell treatment, may regulate the inflammatory response and promote natural healing in the vasculature. PVS-10200 may represent a therapeutic advance in treating any vascular intervention and has the potential to become an off-the-shelf, standard-of-care treatment.

### **About Pervasis Therapeutics, Inc.**

Pervasis Therapeutics, Inc. is a clinical-stage cell-based biotechnology company pioneering biologically active products to treat vascular and other serious diseases. The Company has developed a novel, allogeneic endothelial cell therapy that repairs and restores vascular function after injury by mimicking the body's natural healing process. Pervasis believes its proprietary cell therapy may become the standard of care to promote natural healing following any vascular intervention. Pervasis is also exploring broader indications for its groundbreaking technology in non-vascular applications, such as bone and joint repair, wound healing and inflammation. Pervasis is a privately held company with funding from Flagship Ventures, Polaris Venture Partners, and Highland Capital Partners. For more information, please visit [www.pervasistx.com](http://www.pervasistx.com).

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