

## **PERVASIS THERAPEUTICS TO DEVELOP NOVEL CELL-BASED APPROACH TO TARGET TUMOR ENVIRONMENT, PREVENT CANCER RECURRENCE**

*Bolstered by Landmark Research and Multiple Preclinical Studies, Groundbreaking Therapy Holds Promise to Deliver Safe, Effective Cell Therapy Treatment for Solid Tumors*

**Cambridge, Mass. – January 19, 2011** – Pervasis Therapeutics, Inc. today announced that the company is pursuing a matrix-embedded endothelial cell-based therapy (PVS-30200) to target and regulate cell stroma (the tumor environment or “ecosystem” that is comprised of various supporting cell types distinct from cancer cells) in order to prevent key processes that play a role in advancing solid tumor growth and metastasis (the spread of cancer cells to secondary locations). A cornerstone of Pervasis’ oncology program, the company has entered into an exclusive patent license agreement with the Massachusetts Institute of Technology (MIT) for all discovery and development activities associated with cellular implants for cancer diagnosis, prognosis and treatment. In addition, supportive evidence from multiple preclinical studies demonstrates the powerful anti-angiogenic, anti-proliferative and anti-inflammatory properties of this endothelial cell-based approach in the presence of various solid tumor cancers, such as brain, lung, breast and prostate.

Pervasis, a clinical stage company based in Cambridge, Mass., is focused on developing breakthrough cell-based therapies that harness the healing power of the endothelium, the thin layer of cells that lines the interior surface of every blood vessel in the body. The company’s other areas of clinical investigation include improving outcomes following common vascular surgical and interventional procedures, such as hemodialysis access, angioplasties, stents and peripheral and coronary bypass grafts—the failures of which result in serious complications and a significant increase in medical costs.

“We are very excited to expand our focus to include the critical area of oncology,” stated Frederic Chereau, president and chief executive officer of Pervasis. “We already have amassed a significant amount of data demonstrating the safety and efficacy of utilizing our novel cell-based approach to improve outcomes associated with the treatment of other serious conditions. We look forward to leveraging this body of knowledge to develop a novel therapy that could lead to a safer, more effective treatment for solid tumors, preventing cancer recurrence and improving outcomes for cancer patients.”

### **The Role of Endothelial Cells in Regulating Cancer Cell Behavior**

Endothelial cells are critical to tissue repair and health, and have a well-understood role in regulating many of the body’s healing processes, including those associated with vascular repair. Endothelial cells work as the body’s “police force” – helping maintain homeostasis and control cells under a range of pathologic stresses. The research done at MIT upon which the licensed patent portfolio is based was led by Elazer Edelman, MD, PhD, Professor of Health Sciences and Technology at MIT and Professor of Medicine at Harvard Medical School, and Joseph Franses, a graduate student in the MIT Division of Health Sciences and Technology. They demonstrated that endothelial cells are a critical component of the tumor cell stroma and serve a similar role in cancer biology as they do in vascular biology, regulating cancer cell behavior, and suppressing proliferation, invasiveness and inflammation.

There is growing evidence that invasive tumor growth results from communication between cancer cells and the surrounding host cell stroma. To that end, the breakthrough MIT research, which was published today in *Science Translational Medicine*<sup>1</sup>, suggests that, in the tumor setting, quiescent endothelial cells are tumor-suppressive and slow the proliferation and invasiveness of cancer cells (as studied in culture and in animals), while disruption of the endothelial cells eliminates their ability to inhibit these actions that

---

<sup>1</sup> J. W. Franses, A. B. Baker, V. C. Chitalia, E. R. Edelman, Stromal Endothelial Cells Directly Influence Cancer Progression. *Sci. Transl. Med.* 3, 66ra5 (2011).

cause metastasis. Introducing exogenous functional, healthy endothelial cells to the stromal area can restore homeostasis.

“We are highly encouraged by our initial findings, as we believe they significantly advance our understanding of the critical role endothelial cells play in inhibiting many of the aggressive aspects of cancer,” stated Dr. Edelman, who is one of the original founders of Pervasis and a current member of the company’s Board of Directors. “We believe this research will open the door to vast horizons for future research and the development of novel therapies, and we look forward to the work Pervasis is undertaking to advance these concepts to the clinical stage.”

### **PVS-30200 – Advantages over Current Cancer Therapies**

Many current approaches to treating cancer are plagued by significant limitations such as high toxicity and serious side effects, and are systemic in nature, unable to locally target tumors. In addition, despite addressing the primary tumor, metastasis remains one of the most challenging aspects of treating cancer, and is a process that is often unpreventable and uncontrollable.

PVS-30200 utilizes Pervasis’ proprietary implantable material comprised of healthy allogeneic endothelial cells embedded in a polymer matrix that is delivered locally at the time of tumor excision to prevent cell-proliferation, inflammation and angiogenesis, key processes that lead to tumor growth and survival. The well-studied patented technology on which PVS-30200 is founded has a proven safety profile, as demonstrated by data from six clinical studies, and can be administered and targeted locally at the site of the tumor. A novel cell therapy approach, PVS-30200’s use of allogeneic cells, as opposed to autologous cells, enables “off the shelf” administration, eliminating the challenging logistical processes that are involved with the use of autologous cells.

“We plan to present our preclinical findings as well as the PVS-30200 technology to the oncology community as soon as possible; we believe this therapy has the potential to dramatically advance the promise of cell therapy as an innovative and viable treatment paradigm for cancer,” said Mr. Chereau.

### **Pervasis’ Current Clinical Programs**

Pervasis is currently conducting a Phase 1/2 clinical study of PVS-10200, an investigational new drug under development to prevent restenosis in patients with peripheral arterial disease who undergo angioplasty and stent placement in the superficial femoral artery. The company’s most advanced program, Vascugel®, has demonstrated proof of concept and safety in two Phase 2 trials in patients undergoing arteriovenous access procedures for hemodialysis. In 2010, Pervasis announced that it had reached an agreement with the U.S. Food and Drug Administration (FDA) for its Phase 3 clinical trial of Vascugel under the FDA’s Special Protocol Assessment (SPA) procedure. Through the SPA procedure, FDA formalized its agreement that the design of the Phase 3 trial was acceptable to support a regulatory submission seeking new drug approval.

### **About Pervasis**

Pervasis Therapeutics, Inc. is a clinical stage company developing a broad portfolio of biologically active therapeutics. Building on its deep understanding of the specialized role that the endothelium plays in regulating natural healing and repair processes associated with disease, Pervasis is advancing groundbreaking new therapies to dramatically improve the outcomes of common vascular interventions, such as arteriovenous access, angioplasties, stents, and peripheral and coronary bypass grafts – the failure of which result in serious complications and a significant increase in medical costs. The company’s most advanced program, Vascugel®, has demonstrated proof of concept and safety in two Phase 2 trials in patients undergoing vascular access for hemodialysis. In addition, Pervasis is pursuing a cell-based oncology program focused on targeting and regulating cell stroma in order to prevent key processes that play a role in advancing solid tumor growth and survival. Pervasis is also applying its platform technology to develop products in other key therapeutic areas including inflammatory disease and orthopedic injury.

Pervasis is a privately held company with funding from Flagship Ventures, Polaris Venture Partners, Highland Capital Partners and the Richter Family Fund. For more information, please visit [www.pervasistx.com](http://www.pervasistx.com).

---

*This news release contains certain forward-looking statements that involve risks and uncertainties. Such statements are only predictions and the company's actual results may differ materially from those anticipated in these forward-looking statements. Factors that may cause such differences include the timing of clinical trials, the risk that products that appeared promising in early research and clinical trials do not demonstrate safety or efficacy in clinical trials and the risk that the company will not obtain approval to market its products.*

**Company Contact:**

Margaret O'Toole  
Pervasis Therapeutics, Inc.  
617-871-1201  
[motoole@pervasistx.com](mailto:motoole@pervasistx.com)

**Media Contact:**

Liz Falcone  
Feinstein Kean Healthcare  
617-256-6622  
[liz.falcone@fkhealth.com](mailto:liz.falcone@fkhealth.com)