

Pervasis Receives FDA Fast Track Status for Vascugel® to Prevent Arteriovenous Access Failure in Patients Undergoing Hemodialysis

Novel Cell-Based Therapy Addresses Serious Unmet Medical Need, Aims to Reduce Need for Repeat Surgical Procedures and Improve Patient Outcomes

Cambridge, Mass., February 8, 2011 — Pervasis Therapeutics announced today that the U.S. Food and Drug Administration (FDA) has granted Fast Track review status for Vascugel® for the prevention of hemodialysis access failure in patients with end stage renal disease (ESRD).

Vascugel, a novel endothelial cell-based therapy and Pervasis' lead development program, aims to regulate the body's healing response following surgical interventions to create vascular access points which are necessary for ESRD patients undergoing hemodialysis, reducing the need for repeat surgical interventions and improving overall patient outcomes.

FDA established Fast Track to facilitate the development and accelerate the pre-market review of treatments for serious and life-threatening conditions, so that these products can reach approval more rapidly. To receive Fast Track designation, a product must address a serious unmet medical condition, and be supported by strong results from pre-clinical or clinical testing demonstrating the product potential.

Vascugel has demonstrated clinical proof of concept in two Phase 2 clinical trials involving patients with ESRD who require a permanent arteriovenous (AV) access for hemodialysis. In these trials, Vascugel exhibited an excellent safety profile and encouraging efficacy trends were observed, including improved duration of patency (or unimpeded blood flow) and a delay in time to first intervention as compared to placebo.

“The fact that these very sick patients must endure serious complications and repeat surgical procedures so that they can continue undergoing hemodialysis represents a significant unmet medical need—one that Vascugel is uniquely able to address,” stated Frederic Chereau, president and CEO of Pervasis. “Fast Track designation from the FDA further validates Vascugel's potential as a safe and effective therapy for patients with end stage renal disease, and will help accelerate the pace by which we can develop and deliver this potentially transformational cell-based therapy to improve patient outcomes.”

In May 2009, Pervasis received Orphan Drug Designation from the FDA for Vascugel in patients with ESRD. Last year, Pervasis announced that it had reached an agreement with the FDA for a Phase 3 clinical trial of Vascugel under the Agency'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. Pervasis is also awaiting official Orphan Drug Designation from the European Medicines Agency (EMA) after receiving a positive opinion on its application from The Committee for Orphan Medicinal Products (COMP) late last year.

Failure of Hemodialysis Access Points Leads to Poor Outcomes

ESRD is an advanced and irreversible condition treated mainly by hemodialysis or kidney transplantation. It is estimated more than 350,000 Americans with ESRD receive hemodialysis,

a blood purification therapy designed to replace critical kidney functions – such as filtering waste.

During hemodialysis, blood is removed from the body, filtered through a dialyzer, or artificial kidney, and then returned to the body. Patients must undergo a surgical intervention to create a vascular access point that enables blood to flow from the body to the dialyzer and back to the body. AV fistulae (created by directly joining an artery and vein) and AV grafts (created using a synthetic tube to join an artery and vein) are the two primary types of hemodialysis access points.

Due to an inflammatory cascade triggered by surgical intervention, these vascular access points often have difficulty healing, and quickly become unusable or clot rapidly, prompting the need for additional, recurring surgeries to create new access points and also leading to multiple complications. Up to 60 percent of all arteriovenous (AV) grafts require re-intervention after one year.^{1, 2} AV access failure is the most common reason for hospitalization among hemodialysis patients and can lead to anemia, infection, weight loss, jaundice, prolonged bleeding, and other serious complications.³

Vascugel – Combating Inflammation and Promoting Healing

Pervasis' novel approach to cell therapy uses adult-differentiated allogeneic endothelial cells (donor endothelial cells with a highly targeted biologic function) embedded in a patented polymer matrix to enhance the body's natural healing response. The endothelium is the thin layer of cells that lines the interior surface of blood vessels in the body. 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.

Vascugel, which utilizes Pervasis' patented endothelial cell-based platform, is placed on the outside of the blood vessel at the AV access site during the surgical intervention to create the AV access point. The endothelial formulations in Vascugel secrete several factors that combat inflammation and promote proper vascular healing, reducing thrombosis (or clotting) and the formation of intimal hyperplasia, or a thickening of the blood vessel wall in response to injury. After approximately four to eight weeks, Vascugel is safely resorbed by the body.

The company's other areas of clinical investigation include improving outcomes in patients with peripheral artery disease (PAD) following surgical procedures such as percutaneous transluminal angioplasties (PTAs) with stenting, the failures of which result in serious complications and a significant increase in medical costs. Last month, Pervasis announced it has also embarked on an oncology development program using its proprietary endothelial cell-based platform to prevent solid tumor growth, cancer recurrence and metastatic disease.

¹ Dixon et al. DAC Study Group. Effect of dipyridamole plus aspirin on hemodialysis graft patency. *N Engl J Med.* 2009; 360: 2191-2201.

² Hayashi et al. Vascular access for hemodialysis. *Nat Clin Pract Nephrol* 2006; 2: 504-513

³ Castner D. Recommendations for tracking arteriovenous access complications using a charting-by-exception model. *Anna Journal*, 1998; 25(4): 393-396.

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.

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.

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