Proteon Therapeutics Announces Two Presentations at the American Society of Diagnostic and Interventional Nephrology Meeting

February 6, 2017

Review results of PATENCY-1, the Phase 3 trial of investigational vonapanitase

Data on impact of fistula outcomes on Medicare costs

WALTHAM, Mass., Feb. 06, 2017 (GLOBE NEWSWIRE) -- Proteon Therapeutics, Inc. (Nasdaq:PRTO), a company developing novel, first-in-class therapeutics to address the medical needs of patients with kidney and vascular diseases, today announced the upcoming presentation of results from Proteon's previously reported PATENCY-1 Phase 3 clinical trial and a new ground-breaking study on the costs to Medicare of fistula management at the American Society of Diagnostic and Interventional Nephrology (ASDIN) 13th Annual Scientific Meeting in New Orleans, Louisiana.

The presentation of Phase 3 results titled, "PATENCY-1: Phase 3 Outcomes of Vonapanitase on Radiocephalic AVF Outcomes," will be given by Timmy Lee, M.D., Associate Professor of Medicine in the Division of Nephrology at the University of Alabama at Birmingham and an investigator in PATENCY-1. The oral presentation, which will detail the previously announced study results, will be given on Saturday, February 11, 2017, during a session beginning at 11:00 a.m. CST.

Proteon previously announced results from the PATENCY-1 clinical trial with investigational vonapanitase. Vonapanitase-treated patients had a 17% reduction in the risk of primary unassisted patency loss over one year compared to placebo, although the difference was not statistically significant (p=0.254), and a 34% reduction in the risk of secondary patency loss (fistula abandonment) compared to placebo (p=0.048). Unassisted use of the fistula for hemodialysis, a tertiary endpoint in PATENCY-1, was higher in vonapanitase-treated patients compared to placebo (p=0.035). PATENCY-1 evaluated a single administration of investigational vonapanitase in patients with chronic kidney disease receiving or expecting to receive hemodialysis who underwent surgical creation of a radiocephalic arteriovenous fistula.

Additionally at ASDIN, new data on the impact of fistula outcomes on Medicare costs will be presented by Timothy Pflederer, M.D., past President of the ASDIN, during a presentation entitled, "Cost of Access Care," on Sunday, February 12, 2017, during a session beginning at 10:30 a.m. CST.

This presentation will include an analysis of Medicare claims related to the management of hemodialysis vascular access, which totaled $2.8 billion in 2013, accounting for 12% of all end-stage renal disease costs. Data will also be reported on the multi-year costs associated with fistula management based on fistula outcomes in the first year following surgical creation. The retrospective analysis utilized information from the United States Renal Data System (USRDS) for all elderly Medicare patients initiating hemodialysis during 2010-2011.

"Vascular access failures lead to increased morbidity and mortality, and this ground-breaking analysis of fistula-related costs clearly demonstrates the burden that access failures place on the healthcare system," stated Steven Burke, M.D., Senior Vice President and Chief Medical Officer of Proteon Therapeutics. "We believe the data presented at ASDIN are important contributions to the understanding of fistula outcomes."

About Chronic Kidney Disease, Hemodialysis and Vascular Access

In the most severe stage of chronic kidney disease (CKD), also known as kidney failure, the kidneys can no longer function to sustain life. The majority of patients with kidney failure undergo chronic hemodialysis, which requires a high-flow vascular access to repeatedly connect the patient's bloodstream to a hemodialysis machine for this life-saving treatment. The preferred form of vascular access for hemodialysis is a radiocephalic arteriovenous fistula, created when a surgeon connects a vein to an artery in the forearm, resulting in a substantial increase in blood flow and vein dilation.

About Vonapanitase

Vonapanitase is an investigational drug intended to improve hemodialysis vascular access outcomes. Vonapanitase is applied in a single administration and is currently being studied in a Phase 3 trial in patients with CKD undergoing surgical creation of a radiocephalic arteriovenous fistula for hemodialysis. Vonapanitase has received fast track and orphan drug designations from the FDA, and orphan medicinal product designation from the European Commission, for hemodialysis vascular access indications. In addition, vonapanitase may have other surgical and endovascular applications in diseases or conditions in which vessel injury leads to blockages in blood vessels and reduced blood flow. Proteon is also evaluating vonapanitase in Phase 1 clinical trials in patients with peripheral artery disease (PAD).

About Proteon Therapeutics

Proteon Therapeutics is committed to improving the health of patients with kidney and vascular diseases through the development of novel, first-in-class therapeutics. Proteon's lead product candidate, vonapanitase, is an investigational drug intended to improve hemodialysis vascular access outcomes. Proteon is currently enrolling patients in a Phase 3 clinical trial, PATENCY-2. Proteon is also evaluating vonapanitase in Phase 1 clinical trials in patients with peripheral artery disease (PAD). For more information, please visit www.proteontx.com.

Cautionary Note Regarding Forward-Looking Statements

This press release contains statements that are, or may be deemed to be, "forward-looking statements." In some cases these forward-looking statements can be identified by the use of forward-looking terminology, including the terms "estimates," "anticipates," "expects," "plans," "intends," "may," or "will," in each case, their negatives or other variations thereon or comparable terminology, although not all forward-looking statements contain these words. These statements, including the cost impact of fistula failures, the effect or benefit of vonapanitase in patients with CKD, whether vonapanitase improves fistula patency or fistula use for hemodialysis, the potential surgical and endovascular applications for vonapanitase, and those relating to future events or our future financial performance or condition, involve substantial known and unknown risks, uncertainties and other

important factors that may cause our actual results, levels of activity, performance or achievements to differ materially from those expressed or implied by these forward-looking statements. These risks, uncertainties and other factors, including whether our cash resources will be sufficient to fund our operating expenses and capital expenditure requirements for the period anticipated; whether data from early nonclinical or clinical studies will be indicative of the data that will be obtained from future clinical trials; whether vonapanitase will advance through the clinical trial process on the anticipated timeline and warrant submission for regulatory approval; whether such a submission would receive approval from the U.S. Food and Drug Administration or equivalent foreign regulatory agencies on a timely basis or at all; and whether we can successfully commercialize and market our product candidates, are described more fully in our Annual Report on Form 10-K for the year ended December 31, 2015, as filed with the Securities and Exchange Commission ("SEC") on March 14, 2016, and our subsequent Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, as filed with the SEC, particularly in the sections titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations." In light of the significant uncertainties in our forward-looking statements, you should not place undue reliance on these statements or regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. The forward-looking statements contained in this press release represent our estimates and assumptions only as of the date of this press release and, except as required by law, we undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise after the date of this press release.

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