Proteon Therapeutics Announces Positive Long-Term Results From Phase 2 Study of Investigational New Drug Vonapanitase in Chronic Kidney Disease Patients Undergoing Surgical Creation of an Arteriovenous Fistula for Hemodialysis

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Data to be Presented at the National Kidney Foundation's 2015 Spring Clinical Meetings

DALLAS and WALTHAM, Mass., March 26, 2015 (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 positive results from a long-term analysis of more than three years of follow-up data from a Phase 2 study of its lead candidate, vonapanitase (formerly PRT-201). The study evaluated the safety and efficacy of vonapanitase, an investigational drug, in patients with chronic kidney disease (CKD) undergoing surgical creation of an arteriovenous fistula (AVF) for hemodialysis.

The Phase 2 multicenter, randomized, double-blind, placebo-controlled clinical study evaluated safety and efficacy of a single application of vonapanitase delivered immediately after surgical creation of an AVF. Data from the long-term analysis, to be presented at the National Kidney Foundation's (NKF) 2015 Spring Clinical Meetings in Dallas, demonstrated a trend of prolonged primary patency, the study's primary endpoint, and a statistically significant improvement in the rate of corrective procedures, a secondary endpoint, over more than three years of follow-up for the 30 mcg vonapanitase dose as compared to placebo. An analysis of the results in the subset of patients receiving a radiocephalic AVF, which was not pre-specified, showed statistically significant improvements in primary patency, secondary patency (AVF survival) and the rate of corrective procedures over more than three years of follow-up for the 30 mcg vonapanitase dose as compared to placebo. A radiocephalic AVF is the preferred form of hemodialysis vascular access and is currently being studied in a Phase 3 clinical trial of vonapanitase.

Patients that received vonapanitase reported adverse events related to the AVF comparable to placebo over more than three years. These events were consistent with the medical events experienced by chronic kidney disease patients undergoing surgical creation of an AVF.

Bradley Dixon, M.D., a nephrologist and Associate Professor of Medicine at the University of Iowa's Department of Internal Medicine, will present the results in a late-breaking clinical trial session on Saturday, March 28, 2015, at 9 a.m. CDT at the Spring Clinical Meetings. The data are also available as a poster presentation at the meetings and on Proteon's website here.

"These results suggest that a single treatment of vonapanitase immediately after radiocephalic AVF surgical creation may yield durable benefits for patients," said Dr. Dixon. "A radiocephalic AVF is the preferred form of vascular access for hemodialysis patients, and the benefits of vonapanitase, if observed in pivotal Phase 3 studies, would have great clinical importance to patients and their caregivers."

A functioning AVF, which is a surgically created connection between an artery and a vein, is a hemodialysis patient's lifeline, enabling the patient to undergo life-sustaining hemodialysis. AVFs are susceptible to patency loss, which occurs when an AVF has insufficient blood flow for hemodialysis, most often due to a blockage in the blood vessels of the AVF. Patency loss can result in additional surgical or other corrective procedures, such as balloon angioplasty, and reduced AVF survival.

"The results from more than three years of follow-up extend the positive findings we observed at one year in the non-pre-specified subset analysis of patients undergoing surgical creation of radiocephalic AVFs – the same patient population we are studying in our ongoing Phase 3 clinical trial," said Timothy Noyes, President and Chief Executive Officer of Proteon.

Proteon is currently enrolling patients in a Phase 3 multicenter, randomized, double-blind, placebo-controlled clinical study of vonapanitase in CKD patients undergoing surgical creation of a radiocephalic AVF for hemodialysis. The Company expects to complete enrollment by the end of 2015 and is anticipating initiating enrollment in a second Phase 3 clinical study in the second quarter of 2015. Proteon is also conducting an ongoing Phase 1 clinical study of vonapanitase in patients with symptomatic peripheral artery disease (PAD).

About Chronic Kidney Disease, Hemodialysis and Vascular Access

In the most severe stage of chronic kidney disease (CKD), also known as end stage renal disease (ESRD), the kidneys can no longer function to sustain life. The majority of ESRD patients require hemodialysis and need a high-flow vascular access to repeatedly connect the patient's bloodstream to a hemodialysis machine for this life-saving, chronic treatment: Three times per week for three to four hours each session, blood is pumped from the body and passed through a dialysis machine that removes waste and excess water normally excreted by the kidneys. The preferred form of vascular access, used by two-thirds of hemodialysis patients in the United States, is an arteriovenous fistula (AVF). An AVF is created when a surgeon connects a vein to an artery, typically at the wrist or elbow, resulting in a substantial increase in blood flow and vein dilation.

About Vonapanitase

Vonapanitase (formerly PRT-201) is an investigational drug designed to improve arteriovenous fistula (AVF) patency, the period of time during which an AVF remains open with adequate blood flow to enable hemodialysis. Vonapanitase is applied in a single administration and is currently being studied in a Phase 3 clinical trial in patients with chronic kidney disease (CKD) undergoing surgical creation of a radiocephalic arteriovenous fistula for hemodialysis. Vonapanitase has received fast track and orphan drug designations from the U.S. Food and Drug Administration (FDA), and orphan medicinal product designation from the European Commission, for hemodialysis vascular access indications. Vonapanitase may have multiple surgical and endovascular applications in which vessel injury leads to blockages in blood vessels and reduced blood flow, and is currently being evaluated in a Phase 1 clinical trial in patients with symptomatic 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, vonapanitase (formerly PRT-201), is designed to improve arteriovenous fistula (AVF) patency, the period of time during which an AVF remains open with adequate blood flow to enable hemodialysis. Proteon is currently evaluating vonapanitase in a Phase 3 clinical trial in patients with chronic kidney disease (CKD) undergoing surgical creation of a radiocephalic arteriovenous fistula for hemodialysis and a Phase 1 clinical trial in patients with symptomatic peripheral artery disease (PAD). For more information, please visit www.proteontherapeutics.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 "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should," "approximately," "potential," or, in each case, their negatives or other variations thereon or comparable terminology, although not all forward-looking statements contain these words. These statements, including those regarding the potential surgical and endovascular applications for vonapanitase, the timing of results of the Phase 1 study for patients with PAD, the potential treatment of renal and vascular diseases with vonapanitase, the effect of vonapanitase in patients with CKD and number of persons with CKD, timing of enrollment for Phase 3 trial, timing for initiation of enrollment for second Phase 3 trial, 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 clinical trials 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 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, 2014 as filed with the Securities and Exchange Commission on March 19, 2015, 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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