



Proteon Therapeutics Completes Enrollment in PATENCY-2, Phase 3 Clinical Trial of Investigational Vonapanitase

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- Top-line data from PATENCY-2 expected in March of 2019 -

WALTHAM, Mass., March 05, 2018 (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 that it has completed enrollment in PATENCY-2, the second Phase 3 clinical trial of investigational [vonapanitase](#), Proteon's lead development candidate. Top-line data from this trial is expected in March of 2019.

PATENCY-2 is a multicenter, randomized, double-blind, placebo-controlled Phase 3 clinical trial in patients with chronic kidney disease (CKD) receiving or expecting to receive hemodialysis and undergoing surgical creation of a radiocephalic arteriovenous fistula. The trial is designed to evaluate, over one year, whether a single administration of 30 micrograms of vonapanitase can improve radiocephalic fistula use for hemodialysis and secondary patency, the trial's co-primary endpoints. Secondary patency is defined as the length of time from surgical creation until fistula abandonment (final failure).

"We are excited to have completed enrollment in the second Phase 3 trial of vonapanitase, a significant achievement for Proteon and for the dialysis community," said Timothy Noyes, President and Chief Executive Officer of Proteon Therapeutics. "We look forward to continuing to work closely with the FDA under our Breakthrough Therapy designation to complete this important development effort."

The trial treated 603 patients at 39 centers across the United States and Canada. If the PATENCY-2 trial is successful, Proteon expects to submit a Biologics License Application (BLA) for vonapanitase to the U.S. Food and Drug Administration (FDA) in 2019. Proteon received written confirmation from the FDA that if the PATENCY-2 trial demonstrates statistical significance ($p < 0.05$) on each of its co-primary endpoints, the PATENCY-2 trial together with data from previously completed studies would provide the basis for a BLA submission as a single pivotal trial.

PATENCY-2 is the fourth multicenter, randomized, double-blind, placebo-controlled clinical trial evaluating vonapanitase in patients with CKD receiving or expecting to receive hemodialysis and undergoing surgical creation of an arteriovenous fistula. Combined, these studies have enrolled more than 1,100 CKD patients at 62 centers in the United States and Canada.

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 lower arm, 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 clinical trial in patients with CKD undergoing surgical creation of a radiocephalic arteriovenous fistula for hemodialysis. Vonapanitase has received Breakthrough Therapy, 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 currently conducting a Phase 1 clinical trial of vonapanitase 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 evaluating vonapanitase in patients with CKD undergoing surgical creation of a radiocephalic arteriovenous fistula. Proteon is also evaluating vonapanitase in a Phase 1 clinical trial in patients with 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 when the Company expects to report top-line data from the PATENCY-2 trial, whether the PATENCY-2 trial will serve as a single pivotal trial or additional studies will be necessary to support a BLA submission, whether and when we may submit a BLA in the United States, the potential treatment of renal and vascular diseases with vonapanitase, the effect or benefit of vonapanitase in patients with CKD, whether vonapanitase improves fistula use for hemodialysis or secondary patency, 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 studies; whether vonapanitase will advance through the clinical study 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, 2016, as filed with the Securities and Exchange Commission ("SEC") on March 16, 2017, 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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