Proteon Therapeutics Announces Increase to Enrollment of Ongoing Phase 3 PATENCY-2 Clinical Trial

May 2, 2017

WALTHAM, Mass., May 02, 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 that it will increase the planned enrollment of its ongoing Phase 3 PATENCY-2 trial to 600 patients. The increased sample size follows a review of the statistical plan, which revealed a calculation error that overstated the trial's power for secondary patency, one of the co-primary endpoints. The increased sample size provides 88% power to detect the differences observed in the PATENCY-1 trial with a p-value ≤0.05 for secondary patency, and 98% power with a p-value ≤0.05 for fistula use for hemodialysis, the other co-primary endpoint.

The increase in sample size does not alter the study endpoints, which use the same definitions as in the PATENCY-1 trial.

- **Secondary patency** is defined as the length of time from surgical creation until fistula abandonment (final failure). In PATENCY-1, vonapanitase-treated patients experienced a 34% reduction in the risk of secondary patency loss over one year, compared to placebo (p=0.048). At the end of one year, 74% of vonapanitase-treated patients maintained secondary patency, compared to 61% of placebo-treated patients.

- **Use for hemodialysis** is defined as use of the fistula for hemodialysis for at least 90 days or, if hemodialysis was not initiated at least 90 days prior to the patient's last visit, for at least 30 days prior to the patient's last visit and in use at the patient's last visit. In PATENCY-1, 64% of vonapanitase-treated patients used their fistula for hemodialysis, compared to 44% of placebo-treated patients (p=0.006), a 45% relative increase.

With this change in sample size, Proteon expects to complete enrollment in the first quarter of 2018 and to report top-line data in the first quarter of 2019. Proteon still expects to submit a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) in 2019.

Proteon received written confirmation from the FDA that, if the PATENCY-2 trial is successful in showing statistical significance (p≤0.05) on each of the 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 study.

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 program 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 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 currently enrolling patients in PATENCY-2, a Phase 3 clinical trial evaluating vonapanitase in patients with chronic kidney disease (CKD) undergoing surgical creation of a radiocephalic arteriovenous fistula for hemodialysis. 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 the number of patients to be enrolled in and the timing of enrollment in the PATENCY-2 trial, when the Company expects to report top-line data from the PATENCY-2 trial, whether and when we may submit a BLA in the United States, whether additional studies will be necessary to support a BLA submission as a single pivotal trial, the potential treatment of renal and vascular diseases with vonapanitase, the effect or benefit of vonapanitase in patients with CKD, whether vonapanitase improves fistula patency or use for hemodialysis, 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, 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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