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Proteon Receives FDA Fast Track Designation For First Drug Candidate PRT-201

Waltham, Mass., September 10, 2008 — Proteon Therapeutics, Inc., announced today it has received Food and Drug Administration (FDA) fast track designation for the development program for PRT-201. PRT-201 is being investigated for its ability to improve vascular access in patients currently on or being prepared for hemodialysis. The fast track designation is intended to facilitate development and expedite review for drugs that treat serious diseases and fill unmet medical needs.

PRT-201 is a recombinant human elastase that is being studied for its ability to improve arteriovenous fistula (AVF) surgery outcomes in patients requiring chronic hemodialysis. PRT-201 acts by causing a rapid and persistent dilation of segments of arteries and veins following topical application during surgery. The dilation of vessels used to make an AVF and the resulting increased blood flow through the site may decrease AVF maturation failure rates, which may be as high as 60 percent. Improved AVF maturation rates will lead to fewer corrective surgical procedures, fewer hospitalizations, lower costs, and less suffering for hemodialysis patients. PRT-201 will also be studied for its ability to improve outcomes after arteriovenous graft (AVG) surgery by prolonging the time that AVGs can be used for chronic hemodialysis without the need for corrective procedures or replacement.

“This is a very important milestone for us as we prepare to initiate clinical trials with PRT-201 this year,” said Timothy P. Noyes, President and CEO of Proteon. “If successful, PRT-201 has the potential to make a very positive difference in the lives of patients who require chronic hemodialysis.”

About Proteon Therapeutics

Proteon Therapeutics, Inc., is a privately held biopharmaceutical company developing novel, first-in-class pharmaceuticals to address the critical medical needs of patients with kidney and vascular diseases. The company is leveraging a unique understanding of tissue remodeling to develop a pipeline of proprietary pharmaceuticals. The company is headquartered in Waltham, Mass., and has research facilities in Kansas City, Mo. For additional information, please visit www.proteontherapeutics.com.

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