PROTEON THERAPEUTICS™

VONAPANITASE FOR RADIOCEPHALIC FISTULAS

In the Phase 3 PATENCY-2 clinical trial, Proteon is investigating a single administration of vonapanitase in patients with chronic kidney disease undergoing surgical creation of a radiocephalic arteriovenous fistula for hemodialysis.

Proteon Therapeutics is developing innovative therapies to address some of the most urgent needs of patients with chronic kidney disease (CKD).

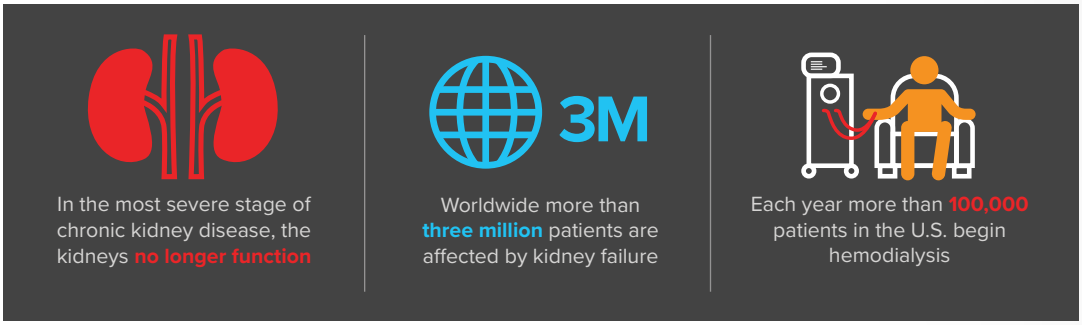
Proteon's lead drug candidate, vonapanitase, has the potential to redefine the care of patients with CKD who require a radiocephalic fistula for hemodialysis by reducing the rate of fistula abandonment and improving fistula use for hemodialysis. Improving radiocephalic fistula outcomes is an urgent priority for hemodialysis patients, surgeons, nephrologists and other caregivers. Vonapanitase has received breakthrough, 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 TECHNOLOGY OVERVIEW

Investigational vonapanitase is a recombinant human elastase intended to improve hemodialysis vascular outcomes by enhancing outward vascular remodeling and inhibiting neointimal hyperplasia.

For a fistula to become usable for hemodialysis, the outflow vein must increase in blood flow and diameter. In experimental models, elastin fragmentation is an early and essential event in outward fistula remodeling. Vessel injury resulting from surgical manipulation of the vein during fistula creation, turbulent blood flow or from corrective procedures to maintain or restore blood flow commonly results in neointimal hyperplasia, a form of vascular scaring that can reduce blood flow. Non-clinical studies have demonstrated that a single dose of vonapanitase, topically administered to the external surface of blood vessels, causes partial fragmentation of elastin fibers in the outer wall of blood vessels. We believe that elastin fragments generated by vonapanitase may accelerate the naturally occurring process of outward vascular remodeling and inhibit neointimal hyperplasia, focusing the healing response in the outer wall of blood vessels by attracting scar forming cells that might otherwise migrate to the inside wall. Vonapanitase has also been shown to lead to vessel dilation when administered at a sufficient concentration.

CHRONIC KIDNEY DISEASE AND HEMODIALYSIS VASCULAR ACCESS



For patients requiring hemodialysis, vascular access is their lifeline to care, enabling connection to a dialysis machine three times per week for life-saving blood cleansing. Approximately two-thirds of patients on hemodialysis gain vascular access through an arteriovenous fistula. Unfortunately, up to 40% of radiocephalic fistulas will be abandoned within the first year and more than 50% will fail to be used for hemodialysis because the fistula either has inadequate blood flow or cannot be successfully cannulated. The clinical consequences of fistula abandonment or non-use can be severe, including a reduction in dialysis adequacy and one or more additional surgical procedures to create a new vascular access and prolonged exposure to dialysis catheters, the worst form of vascular access due to the increased risk of infection, hospitalization, and death.

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