# Perosphere Receives FDA Fast Track Designation for Investigational Anticoagulant Reversal Agent PER977

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DANBURY, Conn.--(BUSINESS WIRE)--Perosphere Inc. today announced that the U.S. Food and Drug Administration (FDA) granted Fast Track designation for PER977, an investigational anticoagulant reversal agent.

The FDA established the Fast Track designation process to facilitate the development and expedite the review of drugs intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs. An important feature of Fast Track is that the FDA may grant frequent and expedited interactions to discuss study design, extent of safety data required to support approval, dose-response concerns, and use of biomarkers. Fast Track also offers the opportunity for the FDA to consider a "rolling review" of completed sections of the New Drug Application (NDA) before the complete application is submitted.

Perosphere's CEO, Dr. Solomon Steiner stated: "We are pleased that the FDA has granted Fast Track status for PER977 at this opportune time. We are currently preparing for Phase 3 trials and expedited FDA guidance will facilitate optimal design and execution of our pivotal trials."

**About PER977**

PER977 is a small synthetic water-soluble new molecular entity that directly combines with the NOACs (i.e., direct Xa- and IIa- inhibitors), fondaparinux, low molecular weight heparins and unfractionated heparins allowing rapid re-establishment of a normal blood coagulation state. This reversal effect is due to direct binding to the anticoagulant molecule with no binding to blood coagulation factors or to other proteins in the blood. PER977 is undergoing clinical development as a sterile, intravenous injection.

**About Perosphere**

Perosphere is a private specialty pharmaceutical company focused on developing rescue medications. For more information, please visit www.perosphere.com.

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