Perosphere Reports Complete and Sustained Reversal of Enoxaparin by the Investigational Broad Spectrum Reversal Agent Ciraparantag in Thrombosis Research

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DANBURY, Conn.-- Perosphere Inc. today announced publication of ciraparantag’s positive clinical results demonstrating broad spectrum reversal across two anticoagulant drug classes published in the international journal of Thrombosis Research (http://www.thrombosisresearch.com).

The article, titled “Ciraparantag safely and completely reverses the anticoagulant effects of low molecular weight heparin” describes a study demonstrating that ciraparantag reverses the whole blood clotting time induced by enoxaparin in a dose related manner and produces no procoagulant signal or deleterious adverse events in doses up to 300 mg.

The single-blind, placebo-controlled phase 1/2 study evaluated the safety, tolerability, pharmacokinetics and pharmacodynamic effects of varying doses of ciraparantag when administered four hours following a subcutaneous 1.5 mg/kg dose of the low molecular weight heparin, enoxaparin, in 40 healthy volunteers (ClinicalTrials.gov; #NCT02206100).

Complete and sustained reversal of enoxaparin anticoagulation, measured by a reduction of whole blood clotting time, was observed in all subjects who received a single ciraparantag dose ranging from 100 mg to 300 mg. The anticoagulation reversal occurred rapidly after bolus injection and persisted for the duration of the study. No procoagulant signals were detected as measured by D-dimer, F1.2, and tissue factor pathway inhibitor levels. Ciraparantag was well tolerated with only transient, minor side effects.

The journal also contains a letter to the editor titled “Ciraparantag for enoxaparin reversal: Adding to the evidence” in which key opinion leaders reference ciraparantag’s positive clinical results with heparin-class-anticoagulant enoxaparin as well as New Oral Anticoagulant or NOAC-class edoxaban and describe why “ciraparantag is a promising reversal agent.”

Dr. Jack Ansell, lead author of the article, former Chairman of the Department of Medicine at Lenox Hill Hospital in New York and a scientific advisor to Perosphere, stated “In clinical studies ciraparantag has now been shown to be safe, well tolerated, and effective in reversing edoxaban and enoxaparin thereby achieving an important milestone in the development of a truly broad-spectrum reversal agent.”

“Ciraparantag is the first and only anticoagulant reversal agent to clinically demonstrate efficacy across anticoagulant drug classes,” stated Dr. Solomon S. Steiner, CEO of Perosphere. “These
positive clinical results continue to replicate preclinical findings, so we look forward to repeated clinical success demonstrating ciraparantag’s effectiveness in the reversal of all NOACs.”

About Ciraparantag (PER977)

Perosphere's lead investigational drug product candidate, ciraparantag (PER977), is an intravenously administered small synthetic water soluble new molecular entity rationally designed and invented by Perosphere for use as a broad-spectrum reversal agent for anticoagulants including heparins and the new oral anticoagulants (NOACs) allowing rapid re-establishment of a normal blood coagulation state when clinically indicated. The NOACs include Daiichi Sankyo Co., Ltd.'s Savaysa™/Lixiana® (edoxaban), Boehringer Ingelheim GmbH's Pradaxa® (dabigatran), Johnson & Johnson's and Bayer HealthCare AG's Xarelto® (rivaroxaban), and Bristol-Myers Squibb Company's and Pfizer Inc.'s Eliquis® (apixaban). There is currently no approved broad-spectrum reversal agent for these NOACs. Ciraparantag is currently undergoing Phase 2 clinical trials in the United States.

About Perosphere

Perosphere is a private pharmaceutical company focused on developing unmet medical needs associated with anticoagulant therapies. For more information, please visit www.perosphere.com.

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