

# **Perosphere and Daiichi Sankyo Enter into a Clinical Trial Collaboration Agreement for Phase 3 Studies of PER977 to Investigate Reversal of the Anticoagulant Activity of the Investigational Factor Xa-Inhibitor Edoxaban**

## *Daiichi Sankyo to Support and Co-sponsor Phase 3 Clinical Studies*

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DANBURY, Conn.--(BUSINESS WIRE)--Perosphere Inc. announced today that it has entered into a third clinical trial collaboration agreement with Daiichi Sankyo, Inc. to study PER977, Perosphere's investigational anticoagulant reversal agent, in phase 3 registration studies with edoxaban, Daiichi Sankyo's investigational oral, once-daily, direct factor Xa-inhibitor. PER977 is a synthetic, small new molecular entity being developed by Perosphere that has been shown in preclinical and phase 1 and phase 2 clinical studies to directly bind to heparins as well as circulating direct factor Xa- and IIa-inhibitors reversing their anticoagulant effect. PER977 does not bind to blood coagulation factors or other blood proteins. In healthy volunteers, PER977 reverses anticoagulant activity after a single intravenous administration of 100 mg to 300 mg and does not require an extended infusion in order to maintain the reversal.

Under the terms of the agreement, Perosphere will seek FDA and EMA regulatory approval of PER977 to reverse the anticoagulant activity of edoxaban and commercialize PER977 in the U.S. and EU. Perosphere retains full worldwide commercial rights to PER977. Perosphere will receive an upfront payment from Daiichi Sankyo and is eligible to receive additional clinical development milestone payments.

"Some potential anticoagulation reversal agents under evaluation are recombinant proteins or fully humanized monoclonal antibody fragments that are limited in the types of anticoagulants they can reverse," stated Dr. Solomon S. Steiner, CEO of Perosphere. "PER977 is a novel synthetic agent that is being investigated as a specific antidote for both direct factor Xa- and IIa-inhibitors as well as low molecular weight heparin, unfractionated heparin, and fondaparinux. We believe that a reversal agent that works against a broader range of anticoagulants would have a place in hospital formularies. We also expect that as a small molecule, PER977 would be an affordable anticoagulant reversal agent option."

Perosphere intends to pursue an Accelerated Approval pathway with the FDA and file an NDA in June 2015 for PER977. Initially, Perosphere will seek regulatory approval in the U.S. and EU for the reversal of the low molecular weight heparin, enoxaparin; unfractionated heparin, and if approved, edoxaban. Subsequently, Perosphere will seek regulatory approval for reversal of the other factor Xa- and IIa-inhibitors: Johnson & Johnson's and Bayer HealthCare AG's Xarelto® (rivaroxaban); Bristol-Myers Squibb Company's and Pfizer Inc.'s Eliquis® (apixaban); and Boehringer Ingelheim GmbH's Pradaxa® (dabigatran). Perosphere will also pursue approval of PER977 in Japan and elsewhere in the world.

Perosphere is targeting three medical applications for PER977:

- Emergency reversal of new oral anticoagulants, low molecular weight heparins, and fondaparinux; usage in traumas, emergency surgeries, overdoses, and uncontrolled bleeding due to anticoagulant treatment. There are currently no approved reversal agents for these anticoagulants.
- A reversal agent for unfractionated heparin;
- For patients who undergo elective surgery (e.g., endoscopies with biopsies) and who are being treated with an anticoagulant; usage to limit the time a patient is off therapeutic anticoagulation.

Based on the clinical observation that some standard laboratory tests for coagulation may not reflect the bleeding that a patient may be experiencing or the ability of a bleeding patient to clot, Perosphere has developed an approach to directly measure the degree of anticoagulation in patients. Perosphere believes that its direct test of coagulation may enable better outcomes with patients than reliance only on standard laboratory tests for coagulation.

Perosphere is currently in discussions with potential commercialization partners for PER977.

### **About Perosphere**

Perosphere is a private specialty pharmaceutical company focused on developing rescue medications. For more information, please visit [www.perosphere.com](http://www.perosphere.com).

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