

Regado Biosciences Announces First Patient Enrolled in RADAR (Phase 2b) Study of REG1 Anticoagulation System

BASKING RIDGE, N.J., Sept. 9 /PRNewswire/ -- Regado Biosciences, a privately held company leading the development of antithrombotic therapeutic aptamers with active control agents, announced that on September 8, 2009 enrollment of the first patient in a Phase 2b, randomized, partially-blinded, multi-center, active-controlled, dose-ranging study of its lead product candidate, the REG1 anticoagulation system (REG1) was achieved. REG1 comprises the selective factor IXa inhibitor, RB006, and its specific active control agent, RB007. The trial, called RADAR, will assess the safety, efficacy, and pharmacodynamics of REG1 compared to unfractionated heparin or low molecular weight heparin in subjects with acute coronary syndromes (ACS). Regado recently successfully completed a phase 2a study of REG1 in stable coronary artery disease patients undergoing elective PCI.

The primary objectives of RADAR will be to determine the clinically acceptable dose range of the specific active control agent, RB007, which can be used to reliably partially or totally reverse the anticoagulant effect of RB006 while reducing bleeding in comparison to heparin, and to determine the pharmacodynamics of the REG1 anticoagulation system in subjects intended for cardiac catheterization within 24 hours who are admitted for ACS-unstable angina and myocardial infarction without ST-segment elevation (UA/NSTEMI).

RADAR, led by principal investigator John H. Alexander, MD, MHS, FACC of Duke University, will enroll 800 subjects at approximately 75 centers around the world. Participating countries include USA, Canada, Poland, France, Germany, Netherlands and Belgium. More information about RADAR can be found at www.clinicaltrials.gov. The identifier for this trial is NCT00932100.

"We are very excited to report the first patient being enrolled in the RADAR study," stated Steven L. Zelenkofske, DO, FACC, Chief Medical Officer of Regado Biosciences. "This event marks a key milestone in the development of this innovative anticoagulation system with its simple yet elegant approach to balancing concomitantly risk reduction of ischemia and bleeding." David J. Mazzo, Ph.D., President and CEO of Regado Biosciences, added, "Successful development of REG1 promises to bring an unprecedented level of control to the physician, ultimately leading to improved outcomes and better safety for patients in the multi-billion dollar worldwide market of antithrombotic therapies."

ABOUT REGADO BIOSCIENCES

Regado Biosciences is pioneering a new therapeutic technology with the creation and development of two-component drug systems. Each system comprises a nuclease-stabilized RNA aptamer that can be controlled directly by its specific and complementary oligonucleotide active control agent. This technology is being applied to injectable antithrombotics, including anticoagulants and antiplatelet agents, a multi-billion dollar market in need of therapeutics with improved safety profiles and a greater degree of therapeutic control. Regado's technology is designed to give physicians the ability to actively and directly control each system's therapeutic effect providing a safe and unique approach to personalized medicine.

ABOUT REG1 and REG2

Regado's lead program, the anticoagulant system REG1, consists of two parenteral agents both administered by IV bolus, the first being a potent highly selective Factor IXa inhibitor (RB006) and the second being its complementary active control agent (RB007). RB007 can be used to selectively completely or partially reverse the anticoagulant effect of RB006. REG1 is intended for application in arterial thrombosis applications, initially in Acute Coronary Syndrome patients undergoing Percutaneous Coronary Intervention. REG2, Regado's second product candidate, consists of a subcutaneously administered formulation of RB006 paired with the IV bolus formulation of RB007. REG2 is intended for use in venous thrombosis indications

ABOUT APTAMERS

RB006 is a member of a class of compounds called aptamers. Aptamers are single stranded oligonucleotides that adopt a specific conformation enabling direct, specific inhibition of the targeted protein. A key unique feature of aptamers derives from the fact that they are formed from nucleic acids. As such, their pharmacologic activity can be controlled by a matched, complementary oligonucleotide active control agent (the Watson-Crick base pair complement of a fraction of the agent to be controlled), which can bind to the aptamer, removing it from its target and reversing its biologic effects.

More information can be found at <http://www.regadobio.com>.

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