

Regado Biosciences Reports Clinical Results For REG1 Anticoagulation System At European Society Of Cardiology Congress 2008

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Regado Biosciences, Inc. announced the presentation of comprehensive results from Phase Ia, Ib and Ic studies of the Company's REG1 Anticoagulation System at the European Society of Cardiology's Congress 2008, currently being held in Munich, Germany. REG1 is a two-component system composed of an aptamer-based anticoagulant, RB006, and its matched, active reversal agent, RB007, which binds to and neutralizes RB006.

Results from the three Phase I studies showed RB006 inhibited the activity of factor IXa, a protein essential to blood clotting, and RB007 rapidly, safely and specifically reversed the activity of RB006. Results from the Phase Ic study further support the potential for RB007 to reverse the anticoagulant effect of RB006 in a graded fashion either completely or partially, depending on the dose of RB007. Detailed findings included:

-- Escalating doses of RB006 achieved a dose-dependent increase in pharmacodynamic activity in healthy subjects, prolonging the activated partial thromboplastin time (aPTT), a measure of the blood's ability to clot.

-- This response also was seen in patients with stable coronary artery disease, thereby confirming pharmacodynamic reproducibility in the target patient population.

-- Escalating doses of RB007 rapidly achieved a dose-dependent decrease in aPTT in patients previously dosed with RB006. Complete inhibition of RB006 was shown within 1-5 minutes of administration of sufficient doses of RB007.

-- No major bleeding, allergic or thrombotic events occurred in any of the studies. The majority of events were minor bleeds at the venous access site. The incidence of additional minor events, including headache, dizziness, nausea, fatigue and hypotension, was similar to placebo.

"Our studies consistently have confirmed the two major attributes of the REG1 system, rapid anticoagulant activity and rapid and predictable reversal of this effect," stated David J. Mazzo, Ph.D., President and Chief Executive Officer of Regado Biosciences. "Based on the encouraging Phase I study data, we anticipate results from our ongoing Phase IIa studies evaluating REG1 in

patients undergoing elective PCI will further confirm that REG1 has the potential to replace standard heparin therapy."

"In striving to meet the needs of individual patients in varied and oftentimes complex settings, it is essential for physicians to quickly, safely and effectively achieve the

desired anticoagulation effect and, when required for specific clinical indications, to attenuate or fully reverse this effect," stated Richard C. Becker, M.D., Professor of Medicine, Duke University Medical Center, and Director, Duke Cardiovascular Thrombosis Center, Duke Clinical Research Institute. "As we enter a new era of anticoagulant pharmacotherapy, a therapeutic system offering these attributes would be of great benefit and may have a profound impact on patient care."

Clinician-scientists from the Duke Clinical Research Institute (DCRI) and Regado evaluated REG1 in three Phase I studies: Phase Ia, a healthy volunteer drug dose-escalating pharmacokinetic-pharmacodynamic (PK-PD) study; Phase Ib, a drug dose-escalating study in subjects with stable coronary artery disease who were receiving aspirin with or without clopidogrel; and Phase Ic, a multiple exposure, dose-ranging study in 39 healthy volunteers. Top-line results from these three studies were presented last year at the American Heart Association's 2007 Scientific Sessions and subsequently published in top-tier scientific journals -- Circulation and the Journal of Thrombosis and Haemostasis.

Regado is currently evaluating REG1 in 26 patients undergoing elective percutaneous coronary intervention (PCI). The multi-center, open-label, randomized Phase IIa study designated REVERSAL-PCI will assess whether REG1 can replace standard heparin therapy during the performance of PCI with stenting.

REG1 is the first specific, direct-acting anticoagulant controllable by its matched reversal agent. Regado is developing REG1 for use in patients suffering from acute coronary syndrome who undergo coronary revascularization procedures. These procedures, which include percutaneous coronary intervention (PCI) and coronary artery bypass grafting (CABG), put patients at a high risk for therapy-related bleeding complications. REG1 is being developed initially to increase therapeutic flexibility and improve patient outcomes in coronary revascularization procedures. Intellectual property covering this technology derives from work originating in Duke University Medical Center's Division of Surgical Sciences, which was not involved in the subsequent clinical studies. Duke exclusively licensed the technology to Regado and will receive certain payments from Regado under this license.

REG1 is a two-component system, consisting of an aptamer-based anticoagulant and its matched reversal agent. The REG1 anticoagulant component, RB006, is a single-stranded, nucleic acid aptamer. RB006 selectively and potently binds to and inhibits factor IXa, a protein that is critical to blood coagulation. The reversal agent, RB007, is a complementary nucleic acid that binds to and neutralizes RB006. The amount of RB007 administered allows physicians to fine tune the pharmacodynamic effect of RB006, from slight reduction in anticoagulation all the way to complete reversal.

About Regado Biosciences

Regado Biosciences is pioneering a new therapeutic field with the discovery and development of two-component drug systems, comprising an aptamer therapeutic that

can be controlled directly by a specific and matched reversal agent. Regado's technology is designed to give physicians the ability to directly control and fine tune each product's therapeutic effect. This control and flexibility allows physicians to meet the individual needs of each patient independent of the setting. Regado initially is focusing its discovery and development efforts on acute care injectable antithrombotics, a multi-billion dollar market in need of therapeutics with improved safety profiles.

Current investors in Regado include Domain (Princeton, NJ), Quaker BioVentures (Philadelphia, PA), Aurora Funds (Durham, NC) and Caxton Advantage Life Sciences Fund (New York, NY), as well as individual investors, including Robert Kierlin.

Regado Biosciences, Inc.

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