Author's response to reviews

Title: A phase II, Randomized, Sham-Controlled, Double-Blinded Trial Testing the Safety and Efficacy of the Coronary Sinus Reducer in Patients with Refractory Angina: Rationale and Design.

Authors:

Marc E Jolicoeur (marc.jolicoeur@icm-mhi.org)
Shmuel Banai (banais@netvision.net.il)
Timothy D Henry (henry003@umn.edu)
Marc Schwartz (mschwartz@neovasc.com)
Serge Doucet (serge.doucet@icm-mhi.org)
Christopher J. White (drcjwhite@gmail.com)
Elazer Edelman (ere@mit.edu)
Stefan Verheye Verheye (stefan.verheye@telenet.be)

Version: 4 Date: 20 January 2013

Author's response to reviews:

Here is the revised version of the manuscript
Please be aware of the following change - in the Safety and efficacy monitoring section in page 14 - we have added one interim analysis for efficacy. In the previous version, it was said that no efficacy interim analysis was planned - which was not the case. The correction section now reads as follow:

An independent DSMB is chartered to monitor and evaluate patient safety to identify any clinically relevant trends, and to recommend whether the study should continue. The first DSMB review to assess safety will occur after approximately 30 randomized patients have 30-day data available. After approximately 50% of the cohort has completed their six-month visit, the DSMB will review safety and the results of an interim assessment of the primary outcome. The results of the interim efficacy assessment will be based on the Lan-DeMets method using an O'Brien – Fleming sending function, with one interim evaluation. At the time of the interim assessment of the primary outcome, the DSMB will also review the results from a conditional power analysis for futility.