Gore REDUCE Clinical Study Principal Investigators Respond to Recent RESPECT Clinical Trial and PC Trial Results

The Associated Press

FLAGSTAFF, Ariz.--(BUSINESS WIRE)--Nov 15, 2012--W. L. Gore & Associates (Gore) today released the following statement from the Gore REDUCE Clinical Study Principal Investigators on behalf of the Gore REDUCE Clinical Study Steering Committee in response to the recent RESPECT Clinical Trial and PC Clinical Trial results presentation. The Gore REDUCE Clinical Study is a prospective, randomized, multi-center, multi-national trial designed to demonstrate safety and effectiveness of the GORE® HELEX® Septal Occluder and GORE® Septal Occluder for PFO closure in patients with history of cryptogenic stroke or imaging-confirmed Transient Ischemic Attack (TIA). The unique study includes up to eighty investigational sites in the US, Canada, and Europe. More information can be found at www.clinical.goremedical.com/REDUCE.

The Steering Committee message is as follows: “On October 25, 2012 at the Transcatheter Cardiovascular Therapeutics (TCT) annual meeting in Miami, Dr. John Carroll (Aurora, CO) presented the results of the RESPECT Clinical Trial, a prospective, multicenter, randomized controlled trial of patent foramen ovale (PFO) closure with the AMPLATZER® PFO Occluder device (St. Jude Medical, Inc) versus best medical therapy for the prevention of recurrent stroke in patients with cryptogenic stroke and PFO. In a subsequent presentation, Dr. Stephen Windecker (Bern, Switzerland) presented the results of the PC Trial, a separate prospective, multicenter, randomized controlled trial of percutaneous PFO closure with the AMPLATZER PFO Occluder device (St. Jude Medical, Inc) versus best medical therapy in patients with cryptogenic embolism and PFO.

As presented, the primary results of the RESPECT Clinical Trial and PC Trial both showed non-statistically significant reductions of 50.8% (HR=0.49; 95% CI: 0.22-1.11) and 37% (HR=0.63; 95% CI: 0.24-1.62), respectively, in the primary endpoint for patients receiving device closure as compared to best medical therapy alone.

The response to these findings has, thus far, been mixed. Those in favor of PFO closure have emphasized that these findings, together with the secondary endpoint analyses, reaffirm that carefully selected patients with a history of cryptogenic stroke and PFO may, indeed, benefit in stroke risk reduction from device closure over medical management alone. Others, however, are quick to point out that this evidence is inconclusive given the lack of statistically significant primary endpoint results demonstrating superiority of one therapy over another.

The RESPECT Study reinforces our position, as noted in our previous critique of the CLOSURE I study, stating well defined and adhered to inclusion / exclusion criteria

for these studies are imperative to their success. In reviewing the information presented on the RESPECT Study, it appears that the target patient population was well defined. In fact, the Gore REDUCE Clinical Study shares notable similarities to the RESPECT Study which we feel will help lead to a beneficial study outcome. These include: All qualifying events must be confirmed by neuroimaging studies, which will prevent the inclusion of spurious neurological events that are not vascular in origin. Eligibility criteria are extremely stringent and are well suited to exclude patients with non-cryptogenic strokes, such as the exclusion of lacunar strokes and exclusion of patients with a substantial burden of vascular risk factors. The primary endpoint requires imaging evidence of a subsequent neurological event, thus excluding clinical TIA events. We, the Gore REDUCE Clinical Study Principal Investigators, conclude that continued stringent patient selection focused on truly cryptogenic strokes and the use of a device with a low complication rate will help determine whether PFO closure is superior to medical therapy alone. In addition to these features, the Gore REDUCE Clinical Study may additionally benefit from notable differences in its design as compared to other studies that have been presented to date: Both test and control arms for the study are prescribed the same medical therapy (antiplatelets). Sites are directed to apply a uniform medical therapy regimen for both test and control subjects throughout the study duration, thereby avoiding a confounding effect on the study endpoints. As designed, subjects are followed for a minimum of two years and up to five years after randomization. Strokes occurring between two and five years after randomization will be included in the primary endpoint analysis and should assist with the statistical power of this assessment. Neuroimaging is conducted on every subject at two years following treatment. Clinically silent infarcts are noted at a greater frequency than clinical events, and thus an assessment of these silent infarcts across treatment arms may further support the proof of concept of device closure as a superior treatment option for patients with PFO and cryptogenic stroke. Much remains to be determined regarding the best course of therapy for cryptogenic stroke patients with PFO. We will continue to follow the latest data, and, in partnership with our investigators and the FDA, will evaluate the implications of these findings on the design assumptions and path forward for the Gore REDUCE Clinical Study.

In light of the totality of evidence presented to date, the need for further investigation of device closure as a superior treatment to medical therapy alone in patients with PFO and cryptogenic stroke is warranted. Furthermore, until new evidence is presented, these data reaffirm the need for the diligent continuation of the Gore REDUCE Clinical Study. We implore our investigators to aggressively continue to refer and enroll all qualifying patients, without echocardiographic, neuroradiological, or clinical bias, to the Gore REDUCE Clinical Study according to its stringent inclusion / exclusion criteria.

Thank you for your continued commitment to this important study.” Scott Kasner, MD, Neurology Principal Investigator John Rhodes, MD, Cardiology Principal Investigator Lars Søndergaard, MD, Cardiology Principal Investigator Lars Thomassen, MD, PhD, Neurology Principal Investigator ABOUT W. L. GORE & ASSOCIATES The Gore Medical Products Division has provided creative therapeutic solutions to complex medical problems for more than 35 years. During that time,

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