Peer-Reviewed Study Demonstrates the Use of DuraGraft May Reduce VGF-related Complications Post-CABG

Somahlution's peer-reviewed publication suggests CABG patients may benefit long-term clinical outcomes following surgery when treated with DuraGraft; First-in-class intraoperative vascular graft treatment shown to reduce the risk of graft failure.

JUPITER, FL – January 22, 2019 -- Somahlution, a global biotechnology company developing products to reduce the burden of ischemia-reperfusion injury in tissue grafting, organ transplant, and other surgical indications, announced today the publication of a clinical study that evaluated the Real World use of DuraGraft in a total of 2,436 consecutive patients who underwent coronary bypass grafting (CABG) surgery with at least one saphenous vein graft (SVG). The study was conducted by Miguel Haime, MD of VA, Roxbury, MA and Boston VA Research Institute, Boston, MA. Statistical analyses were conducted by MAVERIC (Massachusetts Veterans Epidemiology Research and Information Center) Boston, MA. The article was accepted by Expert Review of Cardiovascular Therapy, a peer-reviewed online journal in cardiovascular medicine and published October 14, 2018.

Results from the study demonstrated DuraGraft was associated with statistically significant lower risks for clinical complications following CABG; 45% in non-fatal myocardial infarction (MI) ($p < .0001$), 35% reduction in repeat revascularization ($p=0.037$), and 19% reduction of MACE (a composite of all major adverse cardiac events) ($p=0.005$), based on analysis of data from 1000 days to 15 years post-surgery.

"These positive results demonstrate that DuraGraft can lead to significantly improved long-term clinical outcomes in bypass surgery and significantly outperform saline by protecting the tissue from ischemia and ischemic reperfusion injury at the time of harvesting," said Satish Chandran, CEO of Somahlution.

The article titled "*Relationship between intra-operative vein graft treatment with DuraGraft® or saline and clinical outcomes after coronary artery bypass grafting*" presents the results from the investigator-initiated single-center, multi-surgeon, retrospective, comparative clinical trial, that focused on evaluating the impact of intraoperative preservation of SVGs in DuraGraft versus heparinized saline on saphenous vein graft failure (VGF)-related outcomes after CABG. Saphenous vein grafts remain the most often used conduits for CABG. Progressive intimal hyperplasia contributes to vein-graft disease and VGF. Outcomes were assessed using repeat revascularization (primary endpoint), and major adverse cardiac events (MACE) consisting of the composite of death, nonfatal myocardial infarction, or repeat revascularization.

Conclusions of the study suggest the use of DuraGraft, may lower the risk of long-term adverse events and reduce VGF-related complications post-CABG.

"These data are extremely encouraging as they suggest the importance of graft treatment at the time of surgery and its potentially significant role in reducing graft failure-related outcomes for thousands of CABG patients each year," said Miguel Haime, MD, the lead investigator of the study. "DuraGraft demonstrates an important step towards improving the intraoperative preservation of

SVGs, the most often used conduits in CABG, with new capabilities that can provide risk mitigation related to early contributors to vein graft disease and failure."

DuraGraft is Somahlution's first commercial product based on a proprietary technology platform that was licensed from the VA. The technology was invented and developed by Drs. Hemant Thatte, Ph.D. and Shukri Khuri, M.D. of VA at Roxbury, MA. DuraGraft is CE Marked in Europe and available in other global markets for CABG and peripheral bypass indications. DuraGraft is not yet available in the U.S.

About Somahlution

Somahlution is a global leader in the development of products to reduce the burden of ischemia-reperfusion injury in tissue grafting, organ transplant, and other surgical indications. The company's flagship product, DuraGraft, is a vascular graft treatment that improves clinical outcomes by reducing the incidence of complications associated with graft failure. DuraGraft enhances CABG surgical outcomes by significantly reducing major cardiac events such as repeat revascularization and myocardial infarction.

For more information about the company, please visit www.somahlution.com

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