Research Published in the New England Journal of Medicine Highlights Potential Benefits of Cameron Health's S-ICD System, the First Minimally Invasive Implantable Defibrillator for the Treatment of Sudden Cardiac Arrest

Subcutaneous Implantable Defibrillator Eliminates Need for Lead Placement in or on Heart and May Avoid Complications Associated with Transvenous ICDs

SAN CLEMENTE, Calif. – May 12, 2010 – Cameron Health, Inc. today announced the publication of study results online in the *New England Journal of Medicine* (NEJM) highlighting the development and potential benefits of the company's S-ICD® System, the first minimally invasive, subcutaneous implantable cardioverter defibrillator (ICD), for the treatment of sudden cardiac arrest (SCA). In the studies, the S-ICD detected 100 percent of induced and spontaneous episodes of irregular heart rhythms. This publication represents nine years of development and clinical work with 17 medical centers in seven countries, including the UK.

The S-ICD System is unique in that its implantation is entirely subcutaneous (under the skin), eliminating the need for lead placement in or on the heart and simplifying the surgery by eliminating the need for imaging equipment. Transvenous ICD's require placement of at least one lead in or on the heart. Most frequently, these leads are threaded through a vein and placed inside the heart, allowing for sensing of the heart's rhythm and delivery of a life-saving electric shock when a harmful arrhythmia is detected. The surgical placement and ongoing presence of these transvenous leads within the patient's heart are associated with a significant proportion of the complications related to this well established and highly effective therapy.

"Although implantable defibrillators are an effective treatment for those at risk of sudden cardiac arrest use has been limited to a proportion of patients that could benefit" said Andrew Grace, Consultant Cardiologist at Papworth Hospital and Cambridge University, UK, and senior author of the NEJM paper. "Our clinical studies reported in this paper suggest that the S-ICD System provides a viable alternative to conventional transvenous devices that may reduce barriers to treatment and lead to the wider adoption of lifesaving therapy."

The NEJM publication highlights four studies of the S-ICD System. Two short-term trials designed to identify a suitable device configuration and assess energy requirements were followed by two longer-term trials designed to assess the efficacy of the S-ICD System in detecting and treating ventricular fibrillation and ventricular tachyarrhythmias. The trials were conducted between September 2001 and November 2009. Results of the longer-term studies include 100 percent detection of induced arrhythmias and 98 percent conversion success for patients implanted with the S-ICD System. In addition, ventricular tachyarrhythmias were detected and treated in 100 percent of 12 spontaneous episodes.

"Cameron Health's goal in developing the S-ICD System was to significantly improve upon current ICD therapy by reducing the complications associated with transvenous leads, as well as to simplify implantation, programming and follow-up," said Kevin Hykes, President and Chief Executive Officer, Cameron Health, Inc. "The publication of these data is a clear acknowledgement of the important pioneering contributions made by the clinical investigators. We believe that the S-ICD System has the capability to significantly lower adoption barriers, increase patient acceptance and ultimately save more lives."

<u>Clinical Trial Design</u>

In the first of the short-term trials, four subcutaneous ICD configurations were evaluated in 78 patients who were candidates for ICD implantation. In the second of the short-term trials, the optimal configuration was then tested in 49 additional patients to determine the subcutaneous defibrillation threshold in comparison to the standard transvenous ICD. The optimal device configuration was as effective as a transvenous ICD but required a significantly higher energy requirement (36.6+/-19.8 joules vs. 11.1+/-8.5 joules). Long-term implants were evaluated in a six-patient pilot study followed by a 55-patient single-arm trial that included eight patients from the UK. In the pilot study, a total of 18 episodes of ventricular fibrillation were induced, all of which were appropriately detected, and all sustained episodes of ventricular fibrillation were successfully converted. In the 55-patient single-arm trial, all episodes of sustained ventricular fibrillation were appropriately detected, and 98% of patients satisfied implant testing criteria.

About the S-ICD® System
Components of the Cameron Health S-ICD System include the SQ-RX™ Pulse Generator, Q-TRAK™ Subcutaneous Electrode, Q-GUIDE™ Electrode Insertion Tool and the Q-TECH™ Programmer. The S-ICD System is implanted subcutaneously (just under the skin) with the electrode running parallel and slightly to the left of the sternum. The S-ICD System is capable of delivering 80 joules of energy. While most functions are automatic, adjustments and data retrieval can be easily achieved using the Q-TECH programmer, which is capable of wireless communication with the SQ-RX Pulse Generator. The S-ICD System received CE approval in 2009 and is commercially available in Europe. In the UK eligible patients may receive the S-ICD system as part of NHS treatment.

The first U.S. patient was enrolled on March 3, 2010, in Cameron Health's FDA pivotal trial (IDE number G090013). The trial, which is being conducted under an investigational device exemption (IDE), is a prospective, multicenter, single-arm design involving up to 330 subjects at up to 35 sites in the U.S., UK, Europe and New Zealand. More information about Cameron Health's IDE study can be found at http://www.clinicaltrials.gov (trial number NCT01064076), www.cameronhealth.com, or by contacting 1-800-877-3411 in the U.S. or +31 26 3550260 in Europe.

About Sudden Cardiac Arrest (SCA)
Sudden cardiac arrest is a sudden, abrupt loss of heart function caused by the rapid and/or chaotic activity of the heart known as Ventricular Tachycardia or Ventricular Fibrillation. SCA is an "electrical" malfunction of the heart that results in no blood flow to the body or the brain, and is fatal in 95% of the cases. SCA results in 70,000 deaths per year in the UK ICD's are proven to be 98% effective in stopping dangerous heart rhythms that can lead to SCA. Currently around 4000 people a year in the UK are given a device. SCA is not the same as a heart attack, which is a loss of heart muscle caused by blockage in a vessel that supplies blood to the heart that often scars part of the heart. Coronary Artery Disease and Cardiomyopathy are two of the most common conditions associated with an increased risk of SCA.

About Cameron Health, Inc.
Cameron Health, Inc. (www.cameronhealth.com), headquartered in San Clemente, California, is a pioneer in the development, manufacture and distribution of the next generation of implantable defibrillators.

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CAUTION: The products described are not approved for sale in the USA and can only be sold in those countries where appropriate regulatory agencies have approved products for commercial release. Use of these products is expressly limited to individuals skilled in cardiac rhythm management procedures. Cameron Health does not practice medicine or provide medical services. This material is intended for general educational purposes only.