Boston Scientific

Landmark Defibrillator Study Shows Benefits of Dual-Chamber Pacing

NATICK, Mass., Jan. 2 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today announced that results of the largest implantable cardioverter defibrillator (ICD) study to date, known as INTRINSIC RV, were published in the January issue of the journal Circulation. INTRINSIC RV met its primary endpoint, showing that dual-chamber pacing in combination with Boston Scientific's AV Search Hysteresis (AVSH) programming -- a proprietary feature that proactively reduces right ventricular (RV) pacing when the heart's natural rhythm is present -- performs as well as single- chamber pacing in reducing heart failure hospitalization and all cause mortality ($p<0.001$, non inferiority).

"The results of this landmark study are important because dual-chamber ICD programming can provide benefits to patients that single-chamber programming may not, such as improved heart function and enhanced arrhythmia detection," said Brian Olshansky, M.D., Professor of Medicine, Director of Cardiac Electrophysiology, University of Iowa Hospitals and a lead investigator of the trial. "Prior studies have suggested that dual-chamber devices may lead to unnecessary RV pacing, which in some patients may pose safety concerns. This study showed that these perceived safety concerns were not present in the patient arm where dual-chamber pacing with AV Search Hysteresis was used."

INTRINSIC RV (Inhibition of Unnecessary RV Pacing with AV Search Hysteresis in ICDs) is a multi-center, randomized, prospective, non- inferiority trial that enrolled 1,530 patients with a current indication for an ICD at 108 centers in the United States, Germany, Italy and Australia. The primary endpoint was a composite of all-cause mortality and heart-failure hospitalization. Patients in the dual-chamber pacing with AVSH group experienced 33 percent fewer deaths and heart-failure hospitalizations compared to single chamber pacing ($p=0.072$, superiority).

"INTRINSIC RV represents Boston Scientific's ongoing commitment to clinical science, and is part of our larger program to demonstrate the distinctive value of these sophisticated, life-saving devices to patients and physicians," said Steven Zelenkofske, D.O., F.A.C.C., Vice President, Clinical Sciences and Chief Patient Safety Officer, Boston Scientific CRM.

Approximately 330,000 American adults experience sudden cardiac death (SCD) annually, and only 1 in 20 survives. SCD claims more lives each year than AIDS, breast cancer and lung cancer combined. SCD occurs six to nine times more often among heart-failure patients than in the general population. ICD's have been shown to prevent SCD and this technology continues to provide new opportunities for improved patient care.

Boston Scientific is a worldwide developer, manufacturer and marketer of medical devices whose products are used in a broad range of interventional medical specialties. For more information, please visit: http://www.bostonscientific.com/.

This press release contains forward-looking statements. Boston Scientific wishes to caution the reader of this press release that actual results may differ from those discussed in the forward-looking statements and may be adversely affected by, among other things, risks associated with new product development and commercialization, clinical trials, intellectual property, regulatory approvals, competitive offerings, integration of acquired companies, Boston Scientific's overall business strategy, and other factors described in Boston Scientific's filings with the Securities and Exchange Commission.

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