Medtronic News

European Economic Analysis Shows Cost Benefit of Cardiac Resynchronization Therapy in Mild Heart Failure Patients

New Findings from Sub-Analysis of REVERSE Trial Published in the European Heart Journal

MINNEAPOLIS, Dec 02, 2010 (BUSINESS WIRE) --

Medtronic, Inc. (NYSE: MDT) announced findings from an economic sub-study of the REVERSE (Resynchronization Reverses Remodeling in Systolic Left Ventricular Dysfunction) trial published in the *European Heart Journal* demonstrating for the first time that cardiac resynchronization therapy (CRT) is cost-effective in mildly symptomatic heart failure (HF) patients.

The results of this analysis showed a EUR 14 278 per Quality Adjusted Life Years (QALY) gained for CRT, compared to the commonly used European willingness to pay (WTP) threshold of EUR 33 000 (£ 30 000) per QALY gained. Additionally, the analysis showed patients receiving CRT are estimated to gain almost one full life year (0.94) or 0.80 QALYs compared to the group not receiving CRT, at an additional cost of EUR 11 455, over a ten year time horizon.

"While prior studies have proven the numerous benefits and cost-effectiveness of CRT in treating symptomatic heart failure patients, now for the first time, these data show that CRT not only helps keep less sick heart failure patients out of the hospital more, but it is also a more cost-effective treatment approach than many other therapeutic options currently available," said Cecilia Linde, MD, PhD, Karolinska University, Stockholm, Sweden. "We look forward to conducting additional analyses demonstrating the economic value of this treatment approach in a mildly symptomatic patient population."

In this economic analysis of a subset of patients in the REVERSE trial, 262 European patients were randomized to receive CRT therapy or to have CRT therapy switched off for 24 months. An economic model was developed to predict the effect of CRT on life years, quality-adjusted life years (QALYs) and costs over time periods up to 10 years. The economic analysis was based on clinical data that showed at 24 months a worsening of heart failure in 34 percent of patients who did not have CRT therapy, compared with 19 percent of patients who did receive CRT therapy. Additionally, the time to first heart failure hospitalization was significantly longer in the CRT-on than the CRT-off group (hazard ratio = 0.39, $p < 0.01$). *[Caution: The CRT devices used in the REVERSE trial are investigational for the patient population studied; their use is limited by United States law to investigational use for this indication.]*

The REVERSE trial, sponsored by Medtronic, is a large-scale, global, randomized, double-blind trial that demonstrated the benefits of CRT in improving the function of the heart, including reduction in heart size and improvements in pumping efficiency, in certain asymptomatic or mild heart failure patients. CRT uses a stop-watch sized implantable device to resynchronize the contractions of the ventricles by sending tiny electrical impulses to the heart muscle. Resynchronizing the contractions of the ventricles may help the heart pump blood throughout the body more efficiently and reduce symptoms.

Twelve and 24-month REVERSE data have been published in peer reviewed journals. As previously reported, the trial did not meet statistical significance for its primary endpoint (percent of patients worsened at 12 months using a heart failure Clinical Composite Score). However, patients experienced a significant improvement in cardiac function and reduction in HF hospitalizations. Furthermore, the European sub-group, which was followed through 24 months, demonstrated statistical significance for the same endpoint (19% versus 34% worsened in the CRT ON and OFF groups, $p = 0.01$).

"Given its economic and clinical burden, heart failure is one of the most challenging problems currently plaguing the global healthcare system," said Pat Mackin, president of the Cardiac Rhythm Disease Management business and senior vice president at Medtronic. "At Medtronic, we are dedicated to providing innovative and cost-effective solutions to meet these

challenges. The valuable data uncovered by the REVERSE trial should move us closer to expanding the use of CRT, and our hope is that earlier intervention with this treatment will allow physicians to provide better and more cost-effective patient care to combat this serious and often debilitating condition."

About Medtronic

Medtronic, Inc. (www.medtronic.com), headquartered in Minneapolis, is the global leader in medical technology - alleviating pain, restoring health, and extending life for millions of people around the world.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

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