Data from FAME II Trial Concludes FFR-Guided PCI is Cost Effective and Improves Patient Outcomes

The Associated Press

ST. PAUL, Minn.--(BUSINESS WIRE)--Oct 24, 2012--St. Jude Medical, Inc. (NYSE:STJ), a global medical device company, today announced that Fractional Flow Reserve (FFR)-guided treatment using PressureWire ™ was cost effective for coronary interventions when compared to the best available medical therapy. Cost utility analysis data from the FAME II trial was presented as a late-breaking clinical trial at the 24 th annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium, sponsored by the Cardiovascular Research Foundation.

Three-year projected results derived from FAME II trial data revealed that FFR-guided percutaneous coronary intervention (PCI) plus medical therapy had an incremental cost-effectiveness ratio (ICER) of $32,000 per quality-adjusted life year (QALY) compared to medical therapy alone in treating patients with stable coronary artery disease. For comparison, a common threshold of $50,000 per QALY is often cited when evaluating the cost effectiveness of therapies. Interventions with ICERs from $50,000 to $150,000 per QALY are thought to be cost-effective and those below $50,000 per QALY are considered highly cost effective per thresholds established by the World Health Organization. Results reported in FAME II cost-effectiveness data are well below that threshold.

While FFR-guided PCI had a higher initial cost than patients treated by medical therapy alone, after one year the cost gap narrowed by more than 50 percent due to a higher number of hospital re-admissions for patients treated only with medical therapy.

Clinical results from the FAME II trial previously established that FFR-guided PCI plus medication improves patient outcomes. Cost-effectiveness analysis also found that the use of St. Jude Medical PressureWire ™ FFR measurement technology (which measures blood flow restriction in the coronary arteries) for patients treated with FFR-guided PCI plus medical therapy also significantly improves quality of life indicators, such as freedom from angina and chest pain.

“The FAME II cost-effectiveness analysis offers evidence that FFR-guided treatment is an economically attractive option that provides improved patient outcomes,” said Dr. William F. Fearon, associate professor, Stanford University Medical Center, who presented the data. “The results are quite different from what was seen in the COURAGE trial, and I believe further demonstrate that FFR is a critical contributing factor to successful PCIs.” To determine costs, the analysis measured both direct medical costs of the procedure as well as those for follow-up events. Quality of life was assessed using the EQ-5D (a standardized instrument for measuring health outcomes). Data for this analysis of the FAME II trial was collected and analyzed up until trial enrollment was stopped earlier in the year when the FAME II independent

Data Safety Monitoring Board (DSMB) recommended investigators stop patient enrollment due to a highly statistically significant reduction in the need for hospital readmission and urgent revascularization. Since the trial was stopped early, the incremental cost-effectiveness ratio was estimated based on in-trial results and extrapolated to estimate three years of patient follow-up.

These results add to the economic analysis of PressureWire-guided PCI using data from the original FAME trial, which compared coronary stenting guided by FFR to standard angiography in more than 1,000 patients with multivessel coronary artery disease. The analysis found that in addition to superior clinical outcomes (which include a 34 percent reduction in death or heart attack), the FFR-guided intervention strategy reduced health care costs per patient by more than $2,000, or 14 percent in the U.S.

“In today’s health care environment, medical technology needs to demonstrate clinical and economic benefits for patients, physicians and hospitals,” said Frank J. Callaghan, president of the Cardiovascular and Ablation Technologies Division at St. Jude Medical. “Today’s cost-effectiveness analysis adds to the body of evidence in support of PressureWire technology to improve patient outcomes while delivering value.” FFR is a physiological index used to determine the hemodynamic severity of narrowings (or lesions) in the coronary arteries, and is measured using St. Jude Medical PressureWire ™ Aeris and PressureWire ™ Certus. FFR specifically identifies which coronary narrowings are responsible for obstructing the flow of blood to a patient’s heart muscle (called ischemia), and helps guide the interventional cardiologist in determining which lesions warrant stenting, resulting in improved patient outcomes and reduced health care costs.

About The FAME Trials The original FAME (Fractional Flow Reserve (FFR) vs. Angiography in Multivessel Evaluation) trial compared outcomes for patients whose treatment was guided by FFR to those whose treatment was guided only by angiography using St. Jude Medical PressureWire Certus technology. Results demonstrated improved clinical outcomes in patients with stable coronary artery disease and two or three vessel disease.

The St. Jude Medical-sponsored FAME II trial is a randomized, international multicenter trial that compares the clinical outcomes of FFR-guided contemporary percutaneous coronary intervention (PCI) plus the best available medical therapy to medical therapy alone in 1,220 patients with stable coronary artery disease.

The FAME II trial determined that PCI plus medical therapy was found to improve outcomes compared to medical therapy alone for patients with significant blood flow blockages as determined by FFR. There was an 86 percent relative risk reduction for instances of unplanned hospital re-admission due to urgent revascularization, with fewer occurrences in patients in the FFR-guided PCI arm of the trial.

Results of both the FAME and FAME II trials were published in the New England Journal of Medicine.

FAME vs. COURAGE The FAME II trial provides insights about the benefits of coronary intervention and answers questions raised by the COURAGE (Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation) trial. The COURAGE trial demonstrated no difference in outcomes between patients treated with PCI plus medical therapy compared to medical therapy alone, but did not require use of FFR measurement technology. FAME II FFR-guided PCI appears to be more cost effective than angiography-guided PCI as used in the COURAGE cost-effectiveness analysis. The COURAGE study showed angiography-guided PCI cost-effectiveness ratios of $168,000 or higher per QALY under various scenarios.

About St. Jude Medical St. Jude Medical develops medical technology and services that focus on putting more control into the hands of those who treat cardiac, neurological and chronic pain patients worldwide. The company is dedicated to advancing the practice of medicine by reducing risk wherever possible and contributing to successful outcomes for every patient. St. Jude Medical is headquartered in St. Paul, Minn. and has four major focus areas that include: cardiac rhythm management, atrial fibrillation, cardiovascular and neuromodulation. For more information, please visit sjm.com.

Forward-Looking Statements This news release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that involve risks and uncertainties. Such forward-looking statements include the expectations, plans and prospects for the Company, including potential clinical successes, anticipated regulatory approvals and future product launches, and projected revenues, margins, earnings and market shares. The statements made by the Company are based upon management’s current expectations and are subject to certain risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. These risks and uncertainties include market conditions and other factors beyond the Company’s control and the risk factors and other cautionary statements described in the Company’s filings with the SEC, including those described in the Risk Factors and Cautionary Statements sections of the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2011 and Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2012. The Company does not intend to update these statements and undertakes no duty to any person to provide any such update under any circumstance.

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