Medtronic News

HeartWare International Announces Appointment Of Katrin Leadley, M.D., As Chief Medical Officer

FRAMINGHAM, Mass., Aug. 4, 2014 /PRNewswire/ -- HeartWare International, Inc. (NASDAQ: HTWR), a leading innovator of less invasive, miniaturized circulatory support technologies that are revolutionizing the treatment of advanced heart failure, today announced the appointment of Katrin Leadley, M.D., as Chief Medical Officer of HeartWare, effective September 1, 2014. Leadley brings to HeartWare extensive strategic leadership, with more than 20 years of clinical and industry experience at life sciences firms, including Quintiles, Boston Scientific Corporation and JenaValve Technology in Munich, where she spent the last three years as CMO leading the company's clinical, regulatory, scientific and medical activities.

"Katrin has a wealth of clinical program management experience, and we are confident she will be a great addition to our team," said Doug Godshall, President and Chief Executive Officer. "Her knowledge of cardiovascular device trials and her relationships with many of our international key opinion leaders will enable her to begin making contributions immediately. Katrin has proven experience in identifying new market opportunities, ensuring patient safety and executing clinical development plans and regulatory strategies to achieve product approvals and market introductions of new medical therapies. Katrin will help lead HeartWare through our next stage of clinical and commercial growth, as we advance our ongoing trials, initiate new studies and move toward obtaining regulatory approval of devices in our pipeline."

During her time at JenaValve, Leadley oversaw the company's global clinical programs and worldwide regulatory strategy. She provided leadership and guidance as the company's safety officer for all JenaValve products throughout the product lifecycle, and she offered medical guidance to the organization's Research & Development, marketing and physician training programs. She was also responsible for the company's scientific communications and for collaborating with key opinion leaders in the field.

Previously, Leadley spent eight years at Boston Scientific – based in San Jose, California and Munich – where she most recently served as Global Senior Medical Director, Clinical Sciences. During her time at Boston Scientific, Leadley oversaw the implementation of worldwide policies and processes for the medical and clinical sciences function of the cardiovascular platforms. She also provided medical oversight and participated in preparing regulatory submissions and approvals in the U.S. and Europe.

In addition, Leadley has held managerial positions at several other life sciences companies based in California, including Advanced Stent Technologies in Pleasanton, Pulmonx in Palo Alto, and Quintiles/The Lewin Group in San Francisco.

Leadley earned her medical degree at Ludwig-Maximilian University Medical School in Munich. She has authored numerous scientific and medical publications and presented at industry conferences and events around the world. She also was awarded a National Institute of Health Postdoctoral Fellowship by the School of Public Health at the University of California at Berkeley.

Leadley will succeed David Hathaway, M.D., who has held the position of CMO at HeartWare since 2008 and has decided to retire.

"HeartWare would like to recognize and express our gratitude toward Dr. David Hathaway who has provided excellent stewardship during the past six years," said Godshall. "Dave has played an integral role in leading us through the clinical process to obtain regulatory approval of the HeartWare® Ventricular Assist System in Europe and as a bridge-to-transplantation therapy in the U.S. HeartWare values Dave's numerous, meaningful contributions and wishes him well in his retirement, as our organization continues to grow and build upon the foundation he helped us create."

About HeartWare International

HeartWare International develops and manufactures miniaturized implantable heart pumps, or ventricular assist devices, to treat Class IIIB / IV patients suffering from advanced heart failure. The HeartWare® Ventricular Assist System features the HVAD® pump, a small full-support circulatory assist device designed to be implanted next to the heart, avoiding the abdominal surgery generally required to implant competing devices. The HeartWare System is approved in the United States for the intended use as a bridge to cardiac transplantation in patients who are at risk of death from refractory end-stage left ventricular heart failure, has received CE Marking in the European Union and has been used to treat patients in 40 countries. The device is also currently the subject of a U.S. clinical trial for destination therapy. For additional information, please visit the Company's website at www.heartware.com.

HeartWare International, Inc. is a member of the Russell 2000® and its securities are publicly traded onThe NASDAQ Stock Market.

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Forward-Looking Statements

This announcement contains forward-looking statements that are based on management's beliefs, assumptions and expectations and on information currently available to management. All statements that address operating performance, events or developments that we expect or anticipate will occur in the future are forward-looking statements, including without limitation our expectations with respect to the commercialization of the HeartWare® Ventricular Assist System, continued support from international customers, progress of clinical trials and post-approval studies, regulatory status, research and development activities and our ability to take advantage of acquired and pipeline technology. Management believes that these forward-looking statements are reasonable as and when made. However, you should not place undue reliance on forward-looking statements because they speak only as of the date when made. HeartWare does not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required by federal securities laws and the rules and regulations of the Securities and Exchange Commission. HeartWare may not actually achieve the plans, projections or expectations disclosed in forward-looking statements, and actual results, developments or events could differ materially from those disclosed in the forward-looking statements. Forward-looking statements are subject to a number of risks and uncertainties, including without limitation those described in Part I, Item 1A. "Risk Factors" in HeartWare's Annual Report on Form 10-K filed with theSecurities and Exchange Commission. HeartWare may update risk factors from time to time in Part II, Item 1A "Risk Factors" in Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, or other filings with the Securities and Exchange Commission.

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