Medtronic News

HeartWare International Comments On FDA Warning Letter

FRAMINGHAM, Mass., June 4, 2014 /PRNewswire/ -- HeartWare International, Inc. (Nasdaq: HTWR) announced that on June 3, 2014 it received a warning letter from the U.S. Food and Drug Administration (FDA) resulting from an inspection of the company's operations, development and manufacturing facility in Miami Lakes, Florida, conducted in January 2014.

The FDA letter cites four categories for the company to address: procedures for validating device design, including device labeling; procedures for implementing corrective and preventive action (CAPA); maintaining records related to investigations; and validation of computer software used as part of production or quality systems.

The letter issued by FDA does not require any action by physicians or patients and does not restrict use of HeartWare's devices.

HeartWare takes this matter seriously and will respond to the letter within the required 15 days. The company expects to implement new and enhanced systems and procedures, and will perform additional actions as may be required to resolve the issues raised in the FDA communication.

"HeartWare is committed to providing the highest quality products in compliance with FDA regulations to ensure the safety and welfare of patients who rely on our devices, and we are dedicating the resources necessary to address the items discussed in the letter," said Doug Godshall, President and Chief Executive Officer.

About HeartWare International

HeartWare International develops and manufactures miniaturized implantable heart pumps, or ventricular assist devices, to treat 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. 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. For additional information, please visit the company's website at www.heartware.com.

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 our ability to timely and effectively respond to the FDA warning letter and the amount and nature of resources required to address the issues raised in the warning letter. 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 the Securities 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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