

Kristen Spargo
Padilla Speer Beardsley Inc.
Office: 612-455-1741
Cell: 651-503-1231
kspargo@psbpr.com

Karen Grota
Acorn Cardiovascular
Office: 651-286-4892
karen.grota@acorncv.com

Advisory Panel Does Not Recommend Approval for New Heart Failure Therapy Researchers and Company Representatives Remain Optimistic

GAITHERSBURG, Md., June 22, 2005 – The Circulatory System Device panel of the U.S. Food and Drug Administration (FDA) recommended against approval of the CorCap Cardiac Support Device (CSD). This device was designed for patients with progressive heart failure, characterized by an enlarged heart and decreased pumping function. The FDA makes final decisions regarding approval, and is not bound to follow the recommendations of its panel advisors. Currently, Acorn Cardiovascular is in discussion with the FDA regarding next steps.

The panel, made up of physicians, scientists, researchers, and consumer and industry representatives, reviewed scientific results from the Acorn Clinical Trial. Trial results suggested that the device provides sustained improvements in heart size, heart shape and quality of life, with a decreased likelihood of additional cardiac procedures such as transplants or ventricular assist devices. However, panel members requested further statistical evidence. The CorCap CSD is the introductory product of Acorn Cardiovascular, a privately held medical device company located in St. Paul, Minn.

“We are pleased that the panel was able to review the clinical data of the CorCap CSD for heart failure patients and are optimistic that we will be able to address their questions promptly and conclusively,” said Rich Lunsford, Acorn Cardiovascular president and chief executive officer. “We will continue to work closely with the FDA to ensure that this innovative therapy can soon be made available to the many patients who could benefit from treatment.”

The CorCap CSD is the first heart failure therapy specifically designed to address the problem of cardiac enlargement, which is a hallmark of heart failure progression. An enlarged heart becomes increasingly less efficient at pumping blood, leaving patients feeling tired and short of breath, often compromising even basic daily activities. The CorCap CSD is a proprietary, compliant mesh wrap that is implanted around the heart to provide gentle support to the heart muscle. By relieving stress on the muscle wall, the CorCap CSD is intended to improve the heart's size and shape, correlating with improvements in the patient's quality of life.

The panel recommendation came following presentations by Dr. Douglas Mann of the Michael E. DeBakey VA Medical Center and Baylor College of Medicine, Dr. Michael Acker and Dr. Mariell Jessup of the University of Pennsylvania and Dr. Spencer Kubo of Acorn Cardiovascular. Their presentations included updated results from the Acorn Clinical Trial, a multi-center trial comparing treatment with the CorCap CSD to traditional therapies. Patients participating in the Acorn Clinical Trial had symptomatic heart failure with enlargement of the heart and were being treated with optimal drug therapy, including beta-blockers and ACE inhibitors.

The CorCap CSD received CE Marking in Europe in 2000. The panel recommendation does not impact existing regulatory approvals in other countries.

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About Heart Failure

Heart failure is a progressive and debilitating disease that stems from heart muscle damage, often caused by heart attacks, heart valve disorders or uncontrolled high blood pressure. As the heart attempts to supply the body with adequate blood, the stress on the heart builds in a degenerative cycle of muscle damage, often leading to an unhealthy dilation of the heart. An oversized heart cannot efficiently pump blood to meet the body's needs, leading patients to become fatigued and short of breath, even with activities such as climbing stairs or walking short distances.

Up to 50 percent of patients with advanced heart failure die within five years of diagnosis. Heart failure affects more than five million people in the United States and 25 million people worldwide. The alarming growth rate – an estimated 550,000 new cases are diagnosed each year in the United States alone – led the U.S. National Heart, Lung and Blood Institute to categorize heart failure as an epidemic.

About Acorn Cardiovascular

Acorn Cardiovascular is a privately held medical device company located in St. Paul, Minn. Incorporated in 1996, Acorn Cardiovascular develops innovative and effective treatments for patients with heart failure. The company's introductory product, the CorCap™ Cardiac Support Device (CSD), is intended to improve the heart's structure and function, leading to potential improvements in the quality and duration of a patient's life. For more information about Acorn Cardiovascular and the CorCap CSD, visit www.acorncv.com.

Editor's Note: Additional background information and images are available online at www.acorncv.com.

CAUTION: The CorCap CSD is an investigational device. Limited by USA law to investigational use.

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