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FOR IMMEDIATE RELEASE

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**ACORN CARDIOVASCULAR, INC.™ COMPLETES ENROLLMENT IN
MOST EXTENSIVE SURGICAL HEART FAILURE
STUDY EVER UNDERTAKEN**

Acorn Pivotal Randomized Clinical Trial Enrolls 300 Participants

ST. PAUL, Minn. [Oct 20, 2003] – Acorn Cardiovascular, Inc.™ (Acorn), a leading innovator of solutions to improve quality of life and survival for patients with heart failure (HF), announced completed enrollment in the Acorn Pivotal Randomized Clinical Trial of the CorCap™ Cardiac Support Device (CSD). The trial has enrolled 300 patients in 29 centers across North America, making it the most extensive controlled evaluation of a surgical treatment for HF ever undertaken.

The CorCap CSD is a proprietary fabric mesh implant that is surgically positioned around the ventricles of the heart to provide passive support. Pre-clinical studies have shown that supporting the heart in this manner reduces wall stress, thereby stopping deterioration of the heart muscle. These studies have also demonstrated a reduction in heart size and improvement in heart function. It is therefore anticipated that the CorCap CSD could provide relief of heart failure symptoms, improve quality of life and ultimately, extend survival for those who suffer from HF.

“The CorCap CSD represents a potential breakthrough in the treatment of patients with HF, being uniquely designed to address a critical clinical pathway associated with HF progression.” said Richard Lunsford, president and chief executive officer of Acorn Cardiovascular. “Because of the limited options available to patients with HF, and the expense associated with other device therapies, it is our hope that the CorCap CSD will become a widespread surgical alternative for people who suffer from HF.”

The primary criteria for participation in the Acorn Pivotal Trial were patients diagnosed with an enlarged heart in Class III or early Class IV heart failure (as defined by the New York Heart Association), age 18-80, in stable condition and currently under medical management with beta-blockers and ACE inhibitors.

“The research completed in pre-clinical studies and follow-up data from Acorn’s safety studies of the CorCap CSD have been very encouraging,” said Dr. Michael Acker, principal investigator at the University of Pennsylvania and the first surgeon to perform a CorCap CSD

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implant in North America in June 2000. "Although we are still in the process of collecting data for the Acorn Pivotal Trial, it is the impression of the cardiologists at our institution that their patients have done well following treatment with the CorCap CSD, in several cases demonstrating dramatic improvement in exercise capacity."

Acorn is currently in the process of completing the required minimum one-year follow up for all patients enrolled in the Acorn Pivotal Trial. During this time, the company and investigators are maintaining objectivity by being blinded to the aggregate data. Results are closely monitored by an independent data and safety monitoring board to ensure that patient safety is not compromised. Consolidated results will be available when the follow-up period and the final data analysis are completed, anticipated in the fall of 2004. Acorn anticipates submitting clinical trial data to the FDA in early 2005 with the opportunity for FDA approval in mid-2005.

About Acorn Cardiovascular, Inc.™

Acorn Cardiovascular, Inc.™ (Acorn) is a privately held medical device company located in St. Paul, Minn., USA. Incorporated in 1996, Acorn develops innovative therapies for the treatment of heart failure, with the mission to improve the quality and extend the life of heart failure (HF) patients. The company's commitment to research and development, medical device innovation and extensive experience in pre-clinical studies and human safety studies have solidified the company's leadership position in the arena of device therapies for treating heart failure. The first human implant of the CorCap™ Cardiac Support Device (CSD) was in April 1999, by Prof. Wolfgang F. Konertz in Berlin, Germany. The first implant of the CorCap CSD in North America was in June 2000, by Dr. Michael Acker at the University of Pennsylvania. Since then, 496 patients have enrolled in CorCap CSD clinical studies worldwide and 272 implantations have been performed. For more information about the company and its product, the CorCap CSD, visit www.acorncv.com.

About Heart Failure

Heart Failure (HF) is a condition that results from damage to the heart muscle, resulting in the inability of the heart to pump enough blood to meet the needs of the body. HF is a highly debilitating and progressive disorder that affects more than five million people in the United States and 25 million people worldwide. According to the American Heart Association, 550,000 new cases are diagnosed in the U.S. every year. In recent years, the incidence of heart failure rose to levels so alarming that the US National Heart, Lung and Blood Institute categorized it as a new epidemic.^{1,2} The economic burden imposed by this disease has reached more than \$33 billion annually.³

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¹ *National Heart, Lung and Blood Institute data fact sheet, Congestive heart failure in the United States: a new epidemic. NHLBI*

² *American Heart Association. Heart disease and stroke statistics – 2003 update*

³ *O'Connell JB, Bristow MR. Economic impact of heart failure in the United States: time for a different approach. J Heart Lung Transplant. 1994; 13:S107-S112*