Current Agreements

Dealdoc

Collaboration agreement for ECLIPSE clinical trial

Cardiovascular Systems
Cardiovascular Research Foundation

Nov 02 2016

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Companies:	Cardiovascular Systems Cardiovascular Research Foundation
Announcement date:	Nov 02 2016
Deal value, US$m:	n/d

Details

Announcement date:	Nov 02 2016
Industry sectors:	Academic Research tools Services
Asset type:	Technology
Therapy areas:	Cardiovascular
Technology types:	Clinical testing
Deal components:	Collaborative R&D

Financials

Deal value, US$m:	n/d

Termsheet

Cardiovascular Systems debuted the design of its new ECLIPSE clinical trial in a presentation at the Transcatheter Cardiovascular Therapeutics (TCT) conference.

The trial will compare CSI’s Diamondback 360 Coronary Orbital Atherectomy System (OAS) versus conventional angioplasty, including specialty balloons, for vessel preparation prior to drug-eluting stent (DES) implantation.

Press Release

Cardiovascular Systems In Collaboration With Cardiovascular Research Foundation Debuts Largest Randomized Trial To Study Coronary Atherectomy For Calcified Coronary Lesions At Transcatheter Cardiovascular Therapeutics Conference

ST. PAUL, Minn. & WASHINGTON--(BUSINESS WIRE)--Cardiovascular Systems, Inc. (CSI) (NASDAQ: CSII), today debuted the design of its new ECLIPSE clinical trial in a presentation at the Transcatheter Cardiovascular Therapeutics (TCT) conference in Washington, D.C. The trial will compare CSI’s Diamondback 360® Coronary Orbital Atherectomy System (OAS) versus conventional angioplasty, including specialty balloons, for vessel preparation prior to drug-eluting stent (DES) implantation.

“The ECLIPSE trial reflects the growing complexity of coronary artery disease (CAD) seen in the modern-day cardiac catheterization laboratory, and will be the largest randomized clinical trial to date to assess the use of adjunctive coronary atherectomy for calcific coronary artery disease”

“The ECLIPSE trial reflects the growing complexity of coronary artery disease (CAD) seen in the modern-day cardiac catheterization laboratory, and will be the largest randomized clinical trial to date to assess the use of adjunctive coronary atherectomy for calcific coronary artery disease,” said Dr. Ajay Kirtane, director of the Cardiac Catheterization Laboratories at NewYork-Presbyterian/Columbia University Irving Medical Center, and co-principal investigator of the trial.

ECLIPSE will be a prospective, multi-center, randomized clinical trial of up to 2,000 subjects performed in up to 60 sites in the United States. Half the participants will receive orbital atherectomy prior to DES implantation, while the other half will receive conventional angioplasty, including specialty balloons, followed by DES implantation. The trial will be powered to demonstrate differences in the primary endpoints of post-procedural minimal cross-sectional area (assessed by intravascular imaging in a subset of up to 400 patients) as well as in the clinical outcome of target vessel failure at one year. The trial is expected to begin recruiting in spring 2017.

ECLIPSE co-principal investigator Dr. Philippe Généreux, interventional cardiologist at Morristown Medical Center, NJ, and director of the Angiographic Core Laboratory at the CRF Clinical Trials Center, presented the rationale for the study and trial design.

Said Dr. Généreux, “Coronary calcification has been shown to increase procedural complexity and adverse events following conventional percutaneous coronary intervention (PCI). Using a less invasive procedure, orbital atherectomy has the ability to significantly modify lesion morphology, enabling successful stent delivery to help optimize stent expansion and apposition. This valuable trial will inform physicians regarding the most effective treatment protocols and strategies for treating patients with calcific CAD, ultimately improving PCI outcomes.”

CSI’s Diamondback 360® Coronary OAS is the first and only atherectomy device approved to specifically treat severely calcified coronary arteries. Since FDA approval on October 21, 2013, over 20,000 devices have been used to treat patients with CAD.

Data shows that severe coronary calcium results in higher rates of major adverse coronary events and death. It is estimated that severe calcium is present in nearly 400,000 of U.S. coronary procedures performed annually.

About Coronary Artery Disease (CAD) CAD is a life-threatening condition and a leading cause of death in men and women in the United States. CAD occurs when a fatty material called plaque builds up on the walls of arteries that supply blood to the heart. The plaque buildup causes the arteries to harden and narrow (atherosclerosis), reducing blood flow. The risk of CAD increases if a person has one or more of the following: high blood pressure, abnormal cholesterol levels, diabetes, or family history of early heart disease. According to the American Heart Association, 16.3 million people in the United States have been diagnosed with CAD, the most common form of heart disease. Heart disease claims more than 600,000 lives in the United States each year. According to estimates, significant arterial calcium is present in nearly 40 percent of patients undergoing a PCI. Significant calcium contributes to poor outcomes and higher treatment costs in coronary interventions when traditional therapies are used, including a significantly higher occurrence of death and major adverse cardiac events (MACE).

About Cardiovascular Systems, Inc. Cardiovascular Systems, Inc., based in St. Paul, Minn., is a medical device company focused on developing and commercializing innovative solutions for treating vascular and coronary disease. The company’s Orbital Atherectomy Systems treat calcified and fibrotic plaque in arterial vessels throughout the leg and heart in a few minutes of treatment time, and address many of the limitations associated with existing surgical, catheter and pharmacological treatment alternatives. The U.S. FDA granted 510(k) clearance for the use of the Orbital Atherectomy System in peripheral arteries in August 2007. In October 2013, the company received FDA approval for the use of the Orbital Atherectomy System in coronary arteries. To date, over 260,000 of CSI’s devices have been sold to leading institutions across the United States.

Filing Data

Not available.

Contract

Not available.