

Shockwave Medical Introduces Enhanced Coronary IVL Catheter in the United States

October 20, 2023 at 8:30 AM EDT

Shockwave C2+ Debut Joins Packed Shockwave Agenda at Transcatheter Cardiovascular Therapeutics Conference in San Francisco

SANTA CLARA, Calif., Oct. 20, 2023 (GLOBE NEWSWIRE) -- Shockwave Medical, Inc. (NASDAQ: SWAV), a pioneer in the development and commercialization of transformational technologies for the treatment of cardiovascular disease, announced today the planned U.S. introduction of the Shockwave C²⁺ Coronary Intravascular Lithotripsy (IVL) catheter following approval by the U.S. Food and Drug Administration. The Shockwave C²⁺ catheter provides 50 percent more pulses per catheter than the Shockwave C² catheter that was approved in the U.S. in 2021. The enhanced C²⁺ catheter will make its U.S. debut at the 35th Transcatheter Cardiovascular Therapeutics (TCT) annual scientific symposium of the Cardiovascular Research Foundation, with the full commercial launch planned for the beginning of November.

"The enhancements of Shockwave C ²⁺ will be an added benefit of IVL for optimally treating complex calcium, including more diffuse disease, as well as nodular and thick, eccentric calcium," said Richard Shlofmitz, MD, Chairman, Department of Cardiology, St. Francis Hospital in Roslyn, New York, who performed the first U.S. commercial case with Shockwave C²⁺. "When additional pulses are added to the existing intuitive catheter design and simple-to-use system that are foundational to the success of Shockwave IVL, the result is an updated catheter that can enhance workflow and improve procedural efficiency."

TCT23 to Feature New Coronary IVL Data and Insights and Symposia on COSIRA-II

The following scientific sessions and symposia supporting Shockwave Medical's growing portfolio of technologies and clinical studies will be taking place at TCT:

Monday, October 23, 2023

TCT WorldLink Latin America Featured Clinical Science: Complex Coronary Intervention

Presentation Title: Shock India Registry: Multicenter Registry of Coronary IVL in Calcified Coronary Arteries in Real-World Indian Patient

Population

Time and Location: 10:30 AM – 10:41 AM; Presentation Theater 3, Room 215, Level 2, Moscone South Presenter: Prof. Ashok Seth. MBBS*, Fortis Escorts Heart Institute & Research Centre

Tuesday, October 24, 2023

Shockwave Medical Sponsored Symposia

Presentation Title: The COSIRA-II Trial: Designed To Demonstrate Refractory Angina Relief with the Coronary Sinus Reducer

Time and Location: 2:00 PM - 3:00 PM, Presentation Theater 1, Room 205, Level 2, Moscone South

Presenters: Gregg W. Stone, MD, Mount Sinai Heart Health System; Allen Jeremias, MD*, St. Francis Hospital; Timothy D. Henry,

MD, The Christ Hospital; Prof. Stefan Verheye*, ZNA Middelheim Hospital; Megha Prasad, MD, New York-Presbyterian

Columbia University Irving Medical Center

Wednesday, October 25, 2023

Shockwave Medical Sponsored Symposia

Presentation Title: TOPSHOCK: Vote for this Year's Best Coronary IVL Case

Time and Location: 11:00 AM - 12:00 PM, Presentation Theater 1, Room 205, Level 2, Moscone South

Presenters: Prof. James C. Spratt, MD*, St. George's University Hospitals NHS Trust; Ziad Ali, MD*, St. Francis Hospital; Kalaivani

Mahadevan, MD*, Portsmouth Hospitals University NHS Trust; Tim O'Connor, MD*, Beaumont Hospital; Sameh Sayfo,

MD*, Baylor Scott & White, The Heart Hospital

Thursday, October 26, 2023

Coronary Spotlight Session: Calcium - How Hard Should We Try?

Presentation Title: Coronary IVL in the US: Trends, Hospital Variation, & Predictors of Use: Insights From the ACC NCDR CathPCI Registry

Time and Location: 10:42 AM - 10:50 AM, Coronary Spotlight Theater, Hall E, Exhibition Level, Moscone North

Presenter: Neel Butala, MD*, UCHealth University of Colorado Hospital

Shockwave Medical Sponsored Symposia

Presentation Title: Coronary IVL: More Pulses, More Data, More Insights

Time and Location: 12:45 PM – 1:45 PM, Presentation Theater 2, Room 208, Level 2, Moscone South

Presenters: Yousif Ahmad, M.D.*, Yale Medicine; Neel Butala, MD*, UCHealth University of Colorado Hospital; Prof. Ashok Seth,

MBBS*, Fortis Escorts Heart Institute & Research Centre; Prof. Gennaro Sardella, MD*, Presso Policlinico Umberto; Ziad

Ali, MD*, St. Francis Hospital; Darshan Doshi, MD*, Massachusetts General Hospital

A detailed agenda for all Shockwave Medical symposia and featured presentations can be found here.

Shockwave C²⁺ is commercially available for the treatment of *de novo* coronary artery disease in the United States, Europe and select other geographies.

About Shockwave Medical, Inc.

Shockwave Medical is a leader in the development and commercialization of innovative products that are transforming the treatment of cardiovascular disease. Its first-of-its-kind Intravascular Lithotripsy (IVL) technology has transformed the treatment of atherosclerotic cardiovascular disease by safely using sonic pressure waves to disrupt challenging calcified plaque, resulting in significantly improved patient outcomes. Shockwave has also recently acquired the Neovasc Reducer, which is under clinical investigation in the United States and Canada, and is CE Marked in the Europe. By redistributing blood flow within the heart, the Reducer is designed to provide relief to the millions of patients worldwide suffering from refractory angina. Learn more at www.shockwavemedical.com and www.neovasc.com.

About Reducer

While under clinical investigation in the COSIRA-II trial (U.S. and Canada), the Reducer is CE-marked for the treatment of refractory angina, a painful and debilitating condition that occurs when the coronary arteries deliver an inadequate supply of blood to the heart muscle, despite treatment with standard revascularization or cardiac drug therapies. It affects millions of patients worldwide, who typically lead severely restricted lives as a result of their disabling symptoms, and its incidence is growing. The Reducer provides relief of angina symptoms by altering blood flow within the myocardium of the heart and increasing the perfusion of oxygenated blood to ischemic areas of the heart muscle. Placement of the Reducer is performed using a minimally invasive transvenous procedure.

Forward-Looking Statements

This press release contains statements relating to our expectations, projections, beliefs, and prospects, which are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. In some cases, you can identify these statements by forward-looking words such as "may," "might," "will," "should," "expects," "plans," "anticipates," "believes," "estimates," "predicts," "potential" or "continue," and similar expressions, and the negative of these terms. Forward-looking statements in this press release include, but are not limited to, statements regarding our ability to design, develop, manufacture and market innovative products to treat patients with challenging medical conditions, particularly in coronary artery disease; our ability to successfully execute our commercialization strategy for our approved or cleared products; our business strategy and plans, our objectives for future operations, and other matters. You are cautioned not to place undue reliance on these forward-looking statements. Forward-looking statements are only predictions based on our current expectations, estimates, and assumptions, valid only as of the date they are made, and subject to risks and uncertainties, some of which we are not currently aware.

Important factors that could cause our actual results and financial condition to differ materially from those indicated in the forward-looking statements include, among others: the impact of macroeconomic conditions, including inflation, rising interest rates, the federal budget, instability in the global banking system, and volatile market conditions, geopolitical factors, including the ongoing conflict between Russia and Ukraine and responses thereto, and supply chain disruptions, on our operations, financial results, liquidity, capital resources, expenses, supply chain, manufacturing, research and development activities, clinical trials, and employees; our ability to successfully execute our business and growth strategies; our ability to develop, manufacture, obtain and maintain regulatory approvals for, and market and sell, our products; our expected future growth, including the size and growth potential of the markets for our products; our ability to obtain coverage and reimbursement for procedures performed using our products; our ability to scale our organizational culture; the impact of the development, regulatory approval, efficacy and commercialization of competing products; the loss of key scientific or management personnel; our ability to develop and maintain our corporate infrastructure, including our internal controls; our financial performance and capital requirements; the success of any acquisitions that we make; and our ability to obtain and maintain intellectual property protection for our products, as well as our ability to operate our business without infringing the intellectual property rights of others. These factors, as well as others, are discussed in our filings with the Securities and Exchange Commission (SEC), including in the sections titled "Risk Factors" in our most recent Annual Report on Form 10-K and subsequently filed Quarterly Reports on Form 10-Q, and in our other reports filed with the SEC. Except to the extent required by law, we do not undertake to update any of these forw

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*Physicians are paid consultants of Shockwave Medical.



Source: Shockwave Medical, Inc.