

# Shockwave Medical Launches New Coronary IVL Catheter Internationally and Enrolls First Patient in All-Female Empower Study

May 15, 2023

Shockwave C<sup>2+</sup> Catheter Expands Utility of IVL in Calcified Coronary Arteries

SANTA CLARA, Calif., May 15, 2023 (GLOBE NEWSWIRE) -- Shockwave Medical, Inc. (NASDAQ: SWAV), a pioneer in the development and commercialization of transformational technologies for the treatment of cardiovascular disease, today announced the full commercial availability of the Shockwave C<sup>2+</sup> Coronary Intravascular Lithotripsy (IVL) Catheter to treat severely calcified coronary artery disease in select international markets. Shockwave C<sup>2+</sup> provides 50 percent more pulses per catheter than Shockwave C<sup>2</sup> and is optimally designed to treat longer calcified lesions and more challenging eccentric and nodular calcium.

"Shockwave C <sup>2+</sup> maintains the intuitive catheter design and ease of use that are foundational to the success of Shockwave IVL and incorporates improvements that will enhance procedural efficiency and optimize the treatment of the most challenging morphologies," said Jonathan Hill, MD, Consultant Cardiologist at the Royal Brompton Hospital in London. "The extra pulses are most advantageous in areas with the highest burden of calcium, including nodular, eccentric, diffuse and multivessel calcium."

### First Patient Enrolled in EMPOWER CAD

Shockwave Medical also announced enrollment of the first patient in EMPOWER CAD, the first prospective, all-female study of percutaneous coronary intervention, seeking to confirm the benefits of coronary IVL in female patients with calcified lesions, who historically have experienced less favorable clinical outcomes than male patients with traditional therapies. The first patient was enrolled by Richard A. Shlofmitz, MD, Chairman, Department of Cardiology, St. Francis Hospital in Roslyn, New York.

"We are excited to initiate enrollment of the EMPOWER CAD study, the first prospective clinical study in the interventional space that is completely dedicated to female patients," said Margaret McEntegart, MD, PhD, Director of Complex Percutaneous Coronary Intervention Program at Columbia University Medical Center/New York-Presbyterian Hospital and co-principal investigator of EMPOWER CAD, after she attended the first case performed by Dr. Shlofmitz. "This is a major step towards better understanding the optimal strategy for calcium modification in female patients, an under-represented patient population who frequently are more challenging to treat and often experience suboptimal outcomes."

The co-principal investigators for EMPOWER CAD are Margaret McEntegart, MD, PhD, and Alexandra Lansky, MD, Professor of Medicine, Section of Cardiovascular Medicine and Director, Heart and Vascular Clinical Research Program at Yale University School of Medicine. The study's European lead is Nieves Gonzalo, MD, PhD, Consultant Interventional Cardiologist at Hospital Clinico San Carlos in Madrid, Spain.

Shockwave C<sup>2+</sup> is commercially available for the treatment of *de novo* coronary artery disease in Europe and select other geographies.

## **About Shockwave Medical**

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 is CE Marked in the European Union and the United Kingdom. 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 <a href="https://www.shockwavemedical.com">www.shockwavemedical.com</a> and <a href="https://www.neovasc.com">www.neovasc.com</a>.

### **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 statements regarding: our business strategy, plans, and ability to successfully execute our commercialization strategy; our expectations around product design; and the progress of clinical trials regarding our products. You are cautioned not to place undue reliance on these forward-looking statements. Forward-looking statements are 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, instability in the global banking system, volatile market conditions, geopolitical factors, including the ongoing conflict between Russia and Ukraine and responses thereto, supply chain disruptions, and the remaining effects of the COVID-19 pandemic, 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, market and sell, 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 any 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 forward-looking statements after the date hereof to conform these statements to actual results or revised expectations.

### Media Contact:

Scott Shadiow +1.317.432.9210 sshadiow@shockwavemedical.com

### **Investor Contact:**

Debbie Kaster <a href="mailto:dkaster@shockwavemedical.com">dkaster@shockwavemedical.com</a>



Source: Shockwave Medical, Inc.