



Shockwave IVL Coronary Studies Demonstrate Excellent PCI Outcomes in Both Women and Men at One Year

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Findings Hold Promise for Female Patients with Calcified Coronary Artery Disease Who Previously Suffered Worse Safety Outcomes than Male Patients Undergoing Atherectomy

SANTA CLARA, Calif., May 19, 2022 (GLOBE NEWSWIRE) -- Shockwave Medical, Inc. (NASDAQ: SWAV), a pioneer in the development of Intravascular Lithotripsy (IVL) to treat severely calcified cardiovascular disease, announced today new data confirming excellent one-year outcomes with coronary IVL in both women and men. The one-year results from the Disrupt CAD clinical program were presented at the 2022 Scientific Sessions of the Society for Cardiovascular Angiography & Interventions (SCAI).

Unlike previous reports with atherectomy that have shown worse angiographic complications in women versus men,ⁱ a pooled analysis of the Disrupt CAD III & IV studies showed that IVL was equally safe and effective in men (n=342) and women (n=106). Despite the smaller vessel size in women (2.8mm vs 3.1mm, $p<0.001$), the primary effectiveness endpoint of procedural success for women and men was similar (90.6 percent vs 93.0 percent, $p=0.47$). The primary safety endpoint of 30-day MACE for women and men was also similar (9.4 percent vs 7.0 percent, $p=0.55$). Notably, there were also consistently low rates of post-IVL serious angiographic complications in women and men (2.2 percent vs 2.6 percent, $p=0.85$), which differs from similar analyses in an atherectomy population.

At one year, women and men had similar rates of MACE (12.7 percent vs 13.3 percent, $p=0.83$) and target lesion failure (10.4 percent vs 11.2 percent, $p=0.85$), respectively. The components of target lesion revascularization (TLF) were low in both women and men and numerically favored females, including target vessel-myocardial infarction (8.5 percent vs 9.7 percent), target lesion revascularization (2.9 percent vs 4.2 percent) and stent thrombosis (0 percent vs 1.2 percent).

"Given the established safety profile of IVL and the high rates of acute and long-term adverse events in women undergoing PCI, with or without atheroablation of calcified lesions, coronary IVL is an attractive treatment option for optimizing outcomes in our female patients," said Alexandra Lansky, MD, FACC, FAHA, FSCAI, FESC, Professor of Medicine (Cardiology); Director of Yale Cardiovascular Clinical Research Program, Yale University School of Medicine, New Haven, Conn. "While this is the first one-year analysis of its kind for coronary IVL, the sustained benefit in MACE at one year suggests that IVL should be considered first-line therapy for plaque modification in women with calcified lesions."

The presentation follows the recent publication of SCAI's "[Expert Consensus Statement on Sex-Specific Consideration in Myocardial Revascularization](#)" in *JSCAI*, which referenced the role of IVL in female patients. The SCAI statement concluded, "while additional evidence is needed, these results taken in the context of outcomes with atherectomy devices suggest that IVL may emerge as a first-line therapy for plaque modification of calcified lesions in women specifically."

"As someone who is dedicating her career to addressing the needs of the most complex patients, I find these results very encouraging," said Katherine Kunkel, MD, MEd, FSCAI, an interventional cardiologist at Piedmont Heart Institute in Atlanta, Ga., one of the sites that participated in Disrupt CAD III. "Thanks to an increasing focus on the challenges of female patients, which often include atypical symptoms, later presentation with smaller and more tortuous vessels, and possibly an unconscious bias that may be associated with under-treatment, I am confident that we are heading in the right direction to improve outcomes in female patients. Additionally, tools like IVL are helping level the playing field for safely and effectively treating all types of patients with calcified disease."

About Shockwave Medical, Inc.

Shockwave is focused on developing and commercializing products intended to transform the way calcified cardiovascular disease is treated. Shockwave aims to establish a new standard of care for the interventional treatment of atherosclerotic cardiovascular disease through differentiated and proprietary local delivery of sonic pressure waves for the treatment of calcified plaque, which the company refers to as Intravascular Lithotripsy (IVL). IVL is a minimally invasive, easy-to-use and safe way to significantly improve patient outcomes. To view an animation of the IVL procedure and for more information, visit www.shockwavemedical.com.

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. 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 the COVID-19 pandemic on our operations, financial results, and liquidity and capital resources, including the impact on our sales, expenses, supply chain, manufacturing, research and development activities, clinical trials, and employees; our ability to develop, manufacture, obtain and maintain regulatory approvals for, 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; 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 Part I, Item 1A - Risk Factors in our most recent Annual Report on Form 10-K filed with the SEC, and in our other periodic and 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

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ⁱ <https://onlinelibrary.wiley.com/doi/10.1002/ccd.28373>



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