Shockwave Medical Unveils First One-Year Results of Coronary Intravascular Lithotripsy

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New Data at TCT From the Disrupt CAD Clinical Program Demonstrate Consistency of Shockwave IVL Outcomes Over Time, Across Calcium Morphologies and Between Genders

SANTA CLARA, Calif., Nov. 05, 2021 (GLOBE NEWSWIRE) -- Shockwave Medical, Inc. (NASDAQ: SWAV), a pioneer in the development of Intravascular Lithotripsy (IVL) to treat severely calcified cardiovascular disease, today unveiled new data confirming the safety and effectiveness of coronary IVL out to one year, a new gender analysis that found similar outcomes between men and women, and an OCT analysis that found consistent acute performance in eccentric, concentric and nodular calcified lesions. The data from the Disrupt CAD clinical program were presented in several sessions at the 32nd Transcatheter Cardiovascular Therapeutics (TCT) annual scientific symposium of the Cardiovascular Research Foundation, in Orlando, Fla.

First One-Year Outcomes Find Durability of Excellent Procedural Results

The first one-year outcomes from the prospective, multicenter, single-arm, global investigational device exemption (IDE) Disrupt CAD III study demonstrated low rates of major adverse cardiovascular events (MACE, 13.8 percent) and target lesion failure (11.9 percent). The MACE results were primarily driven by the rate of non-Q wave myocardial infarction (9.2 percent), demonstrating durable safety and effectiveness following lesion preparation with IVL prior to stent deployment. The MACE rate included low rates of cardiac death (1.1 percent), myocardial infarction (10.5 percent), and target vessel revascularization (6.0 percent) one year after the index procedure. In addition, target lesion revascularization (TLR), occurred in only 4.3 percent of patients and definite or probable stent thrombosis occurred in 1.1 percent of patients at one year, with only one patient having a definite or probable stent thrombosis beyond 30 days, resulting a late stent thrombosis rate of at 0.3 percent.

“It is very significant that these data show sustained and persistent relative benefit of IVL for lesion preparation prior to coronary stenting, particularly since this is the first robust one-year report that has been presented on the technology," said Dean Kereiakes, M.D., FACC, FSCAI, Medical Director of The Christ Hospital Heart and Vascular Center and the Christ Hospital Research Institute; Professor of Clinical Medicine, The Ohio State University; Co-Principal Investigator of Disrupt CAD III. “The achievement of an average stent expansion of 102 percent and a minimum stent area (MSA) of 6.5mm^2 at the index procedure with IVL should have predicted excellent long-term results. We were optimistic that there should be a low rate of late target lesion revascularization and stent thrombosis to one year, and that is exactly what we found following IVL.”

OCT Analysis Finds Similar MSA and Stent expansion Across Calcium Morphologies

A pooled analysis of 262 patients enrolled in OCT sub-studies from Disrupt CAD I, II, III, & IV, the largest intravascular imaging analysis of any calcium modification tool to date, confirmed that coronary IVL achieved excellent MSA and stent expansion (SE) consistently in lesions with both eccentric and concentric calcium. MSA and SE at the maximum site of calcification were similar across the four calcium arc quartiles analyzed: ≤180° (6.1mm^2 & 104%), 181-270° (6.0mm^2 & 101%), 271-359° (6.1mm^2 & 98%) and 360° (6.2mm^2 & 105%), respectively.

In a separate analysis of calcific nodules, coronary IVL was found to have a notable acute effect on calcific nodules, which were identified in 22 percent of cases, either by flattening or fracturing the nodule, resulting in consistent MSA (6.3mm^2 vs 6.0mm^2) and SE (101% vs 103%) in lesions with calcified nodules (n=54) or those without (n=194), respectively. The analysis also found that calcific nodules, defined as an accumulation of nodular calcification, or small calcium deposits, with disruption of fibrous cap on the calcified plate, were more commonly associated with concentric calcium and greater overall calcium burden.

“The ability to modify calcium regardless of its morphology, whether eccentric, concentric or nodular, and have MSA and stent expansion still remain consistent shows the versatility of IVL to make a meaningful impact on clinical practice,” said Ziad Ali, M.D., DPhil, Director of the DeMatteis Cardiovascular Institute and Investigational Interventional Cardiology at St Francis Hospital & Heart Center, and presenter of the data at TCT. “To date all OCT analyses of IVL reveal that the greater the calcium burden, the greater the number of fractures. These data now show that evidence of visible fracture by OCT is not necessary to achieve large MSA or adequate stent expansion, particularly in these unique, but clinically relevant sub-groups of calcification. The take home message is that IVL liberates vascular compliance in all sub-groups including eccentric lesions and calcified nodules.”

Coronary IVL Found Equally Safe and Effective in Men and Women

A pooled analysis of the Disrupt CAD I, II, III, & IV studies showed IVL was equally safe and effective in men and women, unlike previous findings with atherectomy.[i] The analysis of 628 patients stratified outcomes by sex. Women in the analysis, who accounted for 23 percent of total patients, were older and more likely to have hyperlipidemia, renal insufficiency and prior myocardial infarction. Despite more frequent comorbidities and smaller vessel size in women, the primary safety endpoint of 30-day MACE for women and men was similar (8.3 percent vs 7.1 percent, p=0.61). The primary effectiveness endpoint of procedural success for women and men was also similar (91.7 percent vs 92.6 percent, p=0.72). Notably, there were also consistent post-IVL serious angiographic complications between women and men (1.6 percent vs 2.3 percent, p=0.75), which differs from previous atherectomy gender analyses.

“Given the strong safety profile of IVL and the known higher risks of women undergoing PCI, coronary IVL is an attractive option for optimizing outcomes in 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, CT. “While this is the first analysis of its kind for coronary IVL, it is highly suggestive that the technology could potentially serve as first-line therapy for women with calcified lesions, particularly if these findings can be confirmed in a larger patient cohort.”

Summarizing the totality of the data presented at TCT, Dr. Kereiakes commented, “Looking at these data holistically, it doesn’t matter whether you're in Europe, Japan or the U.S. It doesn’t matter if you're in a big center, or little center. It doesn’t matter which type of calcium or which type of patients you’re treating. The beauty of these data are the consistency of safety and effectiveness. We found no differences with IVL. For these reasons I call IVL the great equalizer.”

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 IA - 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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