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## **Shockwave Medical Unveils First Clinical Outcomes of New IVL Platform in Late-Breaking Presentation at VIVA 2024**

*Novel Intravascular Lithotripsy (IVL) catheter demonstrates ability to modify calcium safely, enabling treatment and crossing of tightly-stenosed lower limb lesions*

*Technology has received U.S. FDA clearance for patients with peripheral arterial disease*

**LAS VEGAS, November 4, 2024** – Shockwave Medical, Inc., part of Johnson & Johnson MedTech and a global leader in the field of circulatory restoration, announced today the first clinical outcomes associated with the Shockwave Javelin Peripheral IVL Catheter, a novel, non-balloon-based lithotripsy platform designed to modify calcium and cross extremely narrowed vessels in patients with peripheral artery disease (PAD). Despite the challenging nature of the calcified lesions studied, the 30-day results met both prespecified performance goals while showing a similar safety and effectiveness profile to balloon-based Shockwave IVL catheters. The results, which helped support U.S. Food and Drug Administration clearance of the technology last month, were presented as a late breaker today at the annual Vascular InterVentional Advances (VIVA) meeting.

“The outcomes were exactly what we have come to expect from IVL studies – a strong safety profile with the low final residual stenosis that physicians would hope to achieve,” said JD Corl, MD, FACC, FSCAI, Medical Director of the PAD/CLI Program at The Lindner Center for Research and Education at The Christ Hospital and Principal Investigator of FORWARD PAD Study.<sup>†</sup> “These new initial data are promising and pave the way for a new approach to the application of Shockwave IVL in our peripheral practices. With technologies now suited to safely address both crossable and uncrossable lesions, IVL has a unique opportunity to play an increasingly important role in optimizing outcomes for a wider set of patients with PAD.”

PAD affects more than eight million people aged 40 and older in the United States.<sup>1</sup> People suffering from PAD have not only impaired quality of life but also increased risk of heart attack or stroke.<sup>2</sup> Chronic limb-threatening ischemia (CLTI) is the most advanced and serious form of PAD, impacting nearly two million patients in the U.S. It is associated with 40% major amputations at one year, and a 50% mortality rate at five years,<sup>3</sup> worse than most forms of cancer.

The Shockwave Javelin Peripheral IVL Catheter is a novel, non-balloon-based device that features a single 120-pulse lithotripsy emitter at the distal tip of the catheter. It is designed for use in sub-total occlusions or extremely narrowed vessels in which a wire will cross but devices will not. With this new platform, the sonic pressure waves expand spherically from the forward-shifted emitter beyond the tip of the catheter, allowing modification of the obstructive calcification that facilitates device crossing.

The Shockwave Javelin Peripheral IVL Catheter met both prespecified safety and effectiveness endpoints, with a major adverse event rate of 1.1% at 30 days, and a technical acute procedural success rate of 99%. Additionally, at final angiography, angiographic complications were

restricted to a single case of dissection with no reported perforations, abrupt vessel closure, distal embolization or no-reflow.

The feasibility and IDE studies of the Shockwave Javelin IVL catheter, MINI S and FORWARD PAD, respectively, were prospective, multi-center, single-arm, angiographic core-lab adjudicated studies with similar inclusion and exclusion criteria. The studies enrolled 90 patients with 103 heavily calcified, stenotic peripheral arterial lesions. The average lesion length was 77mm, and just under half of the target lesions were located below the knee, and over a third were chronic total occlusions.

“Recognizing the risks that patients with difficult-to-cross lesions are exposed to with other treatment modalities, we’re extremely optimistic about the role that Shockwave Javelin could play in offering an effective alternative crossing and treatment tool with a strong safety profile,” said Nick West, MD, Chief Medical Officer at Shockwave Medical. “We look forward to learning more about the performance of the Shockwave Javelin IVL catheter as we add to the ongoing trial follow-up data with a limited market release of the device in the coming months.”

### **About Shockwave Medical**

Shockwave Medical, part of Johnson & Johnson MedTech, 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. Its Reducer technology, which is under clinical investigation in the United States and is CE Marked in the European Union and the United Kingdom, is designed to provide relief to the millions of patients worldwide suffering from refractory angina by redistributing blood flow within the heart. Learn more at [www.shockwavemedical.com](http://www.shockwavemedical.com).

### **Cardiovascular Solutions from Johnson & Johnson MedTech**

Across Johnson & Johnson, we are tackling the world’s most complex and pervasive health challenges. Through a cardiovascular portfolio that provides healthcare professionals with advanced mapping and navigation, miniaturized tech, and precise ablation we are addressing conditions with significant unmet needs such as heart failure, coronary artery disease, stroke, and atrial fibrillation. We are the global leaders in heart recovery, circulatory restoration and the treatment of heart rhythm disorders, as well as an emerging leader in neurovascular care, committed to taking on two of the leading causes of death worldwide in heart failure and stroke.

### **About Johnson & Johnson**

At Johnson & Johnson, we believe health is everything. Our strength in healthcare innovation empowers us to build a world where complex diseases are prevented, treated, and cured, where treatments are smarter and less invasive, and solutions are personal. Through our expertise in Innovative Medicine and MedTech, we are uniquely positioned to innovate across the full spectrum of healthcare solutions today to deliver the breakthroughs of tomorrow, and profoundly impact health for humanity. Learn more about our MedTech sector’s global scale and deep expertise in cardiovascular, orthopaedics, surgery and vision solutions at <https://thenext.jnjmedtech.com>. Follow us at [@JNJMedTech](https://twitter.com/JNJMedTech) and on [LinkedIn](https://www.linkedin.com/company/johnson-johnson-medtech). Shockwave Medical, Inc. is part of Johnson & Johnson MedTech.

### **Cautions Concerning Forward-Looking Statements**

This press release contains “forward-looking statements” as defined in the Private Securities Litigation Reform Act of 1995. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Shockwave Medical, Inc. and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: uncertainty of commercial success; challenges to patents; competition, including technological advances, new products and patents attained by competitors; manufacturing difficulties and delays; product efficacy or safety concerns resulting in product recalls or regulatory action; changes to applicable laws and regulations, including global health care reforms; changes in behavior and spending patterns of purchasers of health care products and services; and trends toward healthcare cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson’s Annual Report on Form 10-K for the fiscal year ended December 31, 2023, including in the sections captioned “Cautionary Note Regarding Forward-Looking Statements” and “Item 1A. Risk Factors,” and in Johnson & Johnson’s subsequent Quarterly Reports on Form 10-Q and other filings with the Securities and Exchange Commission. Copies of these filings are available online at [www.sec.gov](http://www.sec.gov), [www.jnj.com](http://www.jnj.com) or on request from Johnson & Johnson. Neither of Shockwave Medical, Inc. nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

*† Dr. Corl is a paid consultant for Shockwave Medical. He has not been compensated in connection with this press release.*

<sup>1</sup> <https://www.nhlbi.nih.gov/health/peripheral-artery-disease>

<sup>2</sup> <https://www.cdc.gov/heart-disease/about/peripheral-arterial-disease.html>

<sup>3</sup> <https://www.ahajournals.org/doi/full/10.1161/CIRCOUTCOMES.120.007539>