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Shockwave Launches Coronary Intravascular Lithotripsy in Europe

First-of-its-Kind Lesion Preparation Tool Fractures Calcium in CAD with Sonic Pressure Waves, Enabling Optimal Stent Delivery and Expansion While Minimizing Trauma

First Patient Enrolled in DISRUPT CAD II Post-Market Study

Fremont, Calif. — May 21, 2018 — Shockwave Medical, a pioneer in the treatment of calcified cardiovascular disease, today announced the European commercial availability of Intravascular Lithotripsy (IVL) for calcified coronary artery disease (CAD), as well as the enrollment of the first patient in the DISRUPT CAD II post-market study by Professor Jonathan Hill, MD, at King's College in London.

Coronary artery calcium physically impairs stent expansion,ⁱ and is perhaps the single most important predictor of early stent thrombosis and restenosis after stent procedures.^{ii iii iv} Current calcium modification treatments, which can be difficult to perform, only address the burden of intimal calcium with varying degrees of success and result in an increased risk for adverse events since they don't differentiate between the calcific lesion and soft intimal tissue.

IVL is a novel therapy designed to treat calcified artery blockages with sonic pressure waves historically used to treat patients with kidney stones. The technology minimizes trauma within the artery by delivering pulsatile sonic pressure waves locally to effectively fracture both intimal and medial calcium in the artery wall but pass through surrounding soft vascular tissue in a safe manner. Additionally, IVL requires no specialized training with its familiar technique, and it allows physicians to use their own guidewire of choice to seamlessly integrate into the existing workflow.

“For many years, addressing challenging calcium in patients with complex coronary artery disease has been a balancing act weighing the risk of certain therapies with their clinical benefit,” said Jean Fajadet, MD, co-principal investigator of the DISRUPT CAD II study and co-director of the Interventional Cardiovascular Group at Clinique Pasteur in Toulouse, France. “Now with the availability of IVL, we finally have an intuitive calcium modification tool that offers the maximum benefit in increasing vessel compliance prior to stent implantation with minimal safety risks.”

The technology previously obtained CE Mark on the strength of the safety and efficacy data in the DISRUPT CAD study, a pre-market, prospective multi-center single arm study conducted at seven centers in Europe and Australia that enrolled 60 patients with complex calcified CAD. The newly initiated DISRUPT CAD II study is a post-market study that will enroll an additional 120 patients at sites across the globe, including Italy, Germany, Netherlands, Denmark, France, UK, Spain, Sweden and Belgium.

“Having used Intravascular Lithotripsy in both a clinical trial setting as well as in our everyday clinical practice for complex patients, it’s clear that this is a game-changing technology for the treatment of calcified coronary artery disease,” said Prof. Hill. “A more widespread introduction of this technology will significantly augment our ability to modify calcific lesions. It is a highly accessible technology, which is simple to use and can be rapidly deployed in the cath lab.”

The Shockwave Coronary IVL System complements the existing large and small diameter peripheral IVL catheters, which have been available in Europe for the treatment of calcified peripheral disease from the iliac arteries down to the foot since 2015 and early 2018, respectively. The Shockwave Coronary IVL System, similar to the peripheral IVL systems, includes a compact, battery-powered generator, a simple and quick hand-held connector cable with a single therapy delivery button and an intuitive catheter, which houses an array of lithotripsy emitters enclosed in an integrated balloon. The catheter is delivered to a lesion similar to standard interventional techniques and on the physician’s choice of guidewire.

“The introduction of the Shockwave Coronary IVL System represents a significant advance not only for the treatment of calcified coronary artery disease, but also for the future growth of the company by diversifying our portfolio of IVL devices,” said Doug Godshall, CEO of Shockwave Medical. “Our initial experience with the technology over the last few months has bolstered our belief in what a meaningful impact this technology will have in the hands of operators across the globe.”

Shockwave IVL catheters are now commercially available for coronary artery disease in Europe; they are not available in the United States.

About Shockwave Medical’s Intravascular Lithotripsy System

Shockwave Medical’s IVL System leverages similar principles to urologic lithotripsy, which has been used as a safe and effective treatment for kidney stones for several decades. The generator produces energy that travels through the connector cable and catheter to an array of miniaturized lithotripsy emitters located near the calcified lesion. With the integrated balloon expanded to ultra-low pressure, a small electrical discharge at the emitters vaporizes the fluid within the balloon, creating a rapidly expanding bubble that collapses within microseconds. The bubble’s expansion and collapse generates a series of sonic pressure waves that travel through the fluid-filled balloon and pass through soft vascular tissue, selectively cracking any hardened calcified plaque inside the vessel wall. After the calcium has been fractured, the integrated balloon can be expanded, performing angioplasty safely at low pressures.

The presence of calcium can make coronary interventions more difficult and lead to complications during the procedure and escalating healthcare costs. Shockwave Medical’s IVL system was designed to minimize trauma to the artery, simplify the procedure, and optimize outcomes for CAD patients. To view an animation of the Intravascular Lithotripsy System visit <http://shockwavemedical.com>.

About Shockwave Medical

Shockwave Medical, based in Fremont, Calif., is developing and commercializing innovative intravascular lithotripsy technology for the treatment of calcified peripheral vascular, coronary vascular and heart valve disease. For more information, visit www.shockwavemedical.com.

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