CMS Grants Transitional Pass-Through (TPT) Payment for Shockwave's Coronary IVL

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Provides Incremental Reimbursement in Hospital Outpatient Setting

SANTA CLARA, Calif., June 11, 2021 (GLOBE NEWSWIRE) -- Shockwave Medical, Inc. (NASDAQ: SWAV), a pioneer in the development of Intravascular Lithotripsy (IVL) to treat severely calcified cardiovascular disease, announced today that the Centers for Medicare & Medicaid Services (CMS) granted approval for a Transitional Pass-Through (TPT) payment for Shockwave C^2 Coronary IVL device, effective July 1, 2021. The TPT status provides incremental payment for Shockwave C^2 devices used in the hospital outpatient settings.

In the July 2021 Update of the Hospital Outpatient Prospective Payment System (OPPS), CMS issued a new device transitional pass-through code (C1761) for use by hospitals to bill for Shockwave C^2 Coronary IVL catheters. In addition, as part of the payment calculation, CMS announced that a customary deduction known as a device offset will not be applied to coronary stenting procedures involving coronary IVL. The Shockwave C^2 Coronary IVL device will be eligible for TPT payments for three years.

This announcement comes less than two months after CMS recommended Coronary IVL be eligible for incremental payment via a New Technology Add-on Payment (NTAP) as part of the Fiscal Year 2022 Hospital Inpatient Prospective Payment System (IPPS) Proposed Rule. The intent of both the TPT and NTAP programs are to facilitate Medicare beneficiary access to the benefits of new and innovative devices while cost data is collected for eventual incorporation into the respective payment systems.

The FDA granted the Shockwave C^2 Coronary IVL system Breakthrough Device Designation (BDD) in 2019 based on the device's potential to provide a more effective treatment for life-threatening or irreversibly debilitating conditions when compared to existing treatment options. Since 2020, CMS has provided an alternative pathway for innovative technologies that have received FDA marketing authorization and BDD to quality for device pass-through payment.

"We thank CMS for its work to expand access to innovative medical technologies such as Coronary IVL and for their commitment to ensuring that breakthrough treatments are rapidly accessible to Medicare beneficiaries," said Robert Fletcher, Vice President of Marketing and Market Access at Shockwave Medical. "Together with the proposed NTAP, the granting of the TPT payment means that incremental Medicare reimbursement for Coronary IVL would be available in all settings where coronary angioplasty procedures are performed, providing another important step in increasing access to our technology for patients suffering from complex, calcified coronary artery disease."

The Shockwave IVL System with the Shockwave C^2 Coronary IVL Catheter received PMA approval in February 2021 and is indicated for lithotripsy-enabled, low-pressure balloon dilatation of severely calcified, stenotic *de novo* coronary arteries prior to stenting in the United States. Every year almost 1 million percutaneous coronary interventions (PCI) are performed in the United States to treat patients with coronary artery disease. The company estimates that approximately one third of these interventions involve severe or moderate calcium.

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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