CMS Proposes Additional Payment for Shockwave's Coronary IVL in Hospital Inpatient Cases

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New Technology Add-on Payment (NTAP) Included in Proposed Fiscal Year 2022 Rule

SANTA CLARA, CALIF., April 27, 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 and Medicaid Services (CMS) published the Fiscal Year 2022 Hospital Inpatient Prospective Payment System (IPPS) Proposed Rule, which recommended that coronary IVL cases be eligible for incremental payment via a New Technology Add-On Payment (NTAP) from CMS when performed in the hospital inpatient setting. The proposed annual rule is now open for public comment and is expected to be finalized and in effect by October 1, 2021.

NTAP is a program designed by CMS to provide payment for qualifying new technologies in order to facilitate patient access to the new technology while CMS collects cost data. The NTAP program is intended to cover the majority of excess costs related to the new technology, though payment varies on a case-by-case basis. In its proposed ruling, CMS noted that coronary IVL is an FDA-designated Breakthrough Device that has met all the requirements for an NTAP and proposed that the maximum amount of NTAP payment for a procedure involving coronary IVL is an additional $3,666 to the hospital's Medicare Severity Diagnosis Related Group (MS-DRG) payment.

"We applaud CMS for proposing an NTAP for Shockwave's coronary IVL and for their commitment to improving Medicare beneficiary access to breakthrough technologies," said Robert Fletcher, Vice President of Marketing and Market Access at Shockwave Medical. "This is another step forward in our early introduction of coronary IVL and in our mission to expand access to new technology that addresses a significant unmet need in the treatment of complex coronary artery disease."

The Shockwave IVL System with the Shockwave C^2 Coronary IVL Catheter is indicated for lithotripsy-enabled, low-pressure balloon dilatation of severely calcified, stenotic *de novo* coronary arteries prior to stenting in the United States. It received PMA approval earlier this year in February 2021.

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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